LIFESTYLE INTERVENTIONS TO SUPPORT PEOPLE WITH CHRONIC NON-SPECIFIC LOW BACK PAIN

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A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

Faculty of Medicine and Health

The University of Sydney

April, 2022

LIFESTYLE INTERVENTIONS TO SUPPORT PEOPLE WITH CHRONIC NON-SPECIFIC LOW BACK PAIN

Emma Kwan-Yee Ho

CANDIDATE'S STATEMENT

This is to certify that to the best of my knowledge, the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.

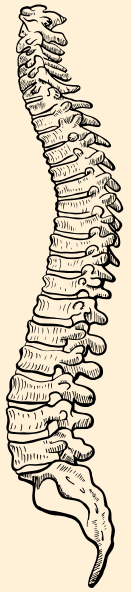
I certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

Emma Kwan-Yee Ho
16th April 2022

SUPERVISOR'S STATEMENT

This is to certify that the thesis entitled "Lifestyle interventions to support people with chronic non-specific low back pain" submitted by Emma Kwan-Yee Ho in fulfilment of the requirements for the degree of Doctor of Philosophy is in a form ready for examination.

Professor Paulo Henrique Ferreira
16th April 2022



This thesis is dedicated to the 577 million people who live with low back pain across the globe, and to the clinicians who dedicate their livelihoods to improve the health and wellbeing of patients living with low back pain.

I hope this thesis may benefit humankind, present and future, by contributing to scientific knowledge of musculoskeletal health.

ACKNOWLEDGMENTS

This thesis was not possible without all those who contributed and supported me throughout the journey. First and foremost, my family – Amy, David, Kevin, Bernice, and Martin. Without your love, sacrifice, and encouragement of faith, nothing would be possible.

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To those not mentioned, simply because there were too many to name. I consider you all a blessing.

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PUBLICATIONS, PRESENTATIONS, AND ACHIEVEMENTS

Parts of the work presented in this thesis have been published and/or presented in national and international journals and forums.

Publications in peer-reviewed journals

Chapter Two: Ho E, Ferreira M, De Barros Pinheiro M, Carvalho-E-Silva A, Madrid-Valero J, Zadro J, Ordoñana J, Ferreira P. Factors associated with seeking medical care for low back pain in a twin adult sample. *Eur J Pain,* 2021;00:1–16. doi: 10.1002/ejp.1731

Chapter Four: Ho E, Ferreira M, Chen L, Simic M, Ashton-James C, Comachio J, Wang D, Hayden J, Ferreira P. Psychological interventions for chronic non-specific low back pain: protocol of a systematic review with network meta-analysis. *BMJ Open,* 2020;10:e034996. doi: 10.1136/bmjopen-2019-034996.

Chapter Five: Ho EK-Y, Chen L, Simic M, Ashton-James CE, Comachio J, Wang DXM, Hayden JA, Ferreira ML, Ferreira PH. Psychological interventions for chronic non-specific low back pain: systematic review with network meta-analysis. *BMJ 2022;376:e067718. doi: 10.1136/bmj-2021-067718.*

Chapter Six: Ho EK, Ferreira ML, Bauman A, Hodges PW, Maher CG, Simic M, Morton RL, Lonsdale C, Li Q, Baysari MT, Amorim AB, Ceprnja D, Clavisi O, Halliday M, Jennings M, Kongsted A, Maka K, Reid K, Reynolds T, Ferreira PH. Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: Protocol for a randomised controlled trial. *BMC Musculoskelet Disord*, 2021;22(1):611. doi: 10.1186/s12891-021-04479-z.

Manuscripts submitted for publication

Chapter Three: Ho EK, Ferreira ML, Bauman A, Carvalho-e-silva AMC, Pinheiro MB, Calais-Ferreira L, Simic M, Ferreira PH. Beneficial and harmful effects of physical activity on care-seeking for low back pain. *Eur J Pain,* Under review.

Chapter Eight: Ho EK, Ferreira M, Hodges PW, Halliday M, Maka K, Ceprnja D, Jennings M, Amorim AB, Baysari MT, Ferreira PH. Developing resilient clinical trials: lessons learned from rolling out the Get Back to Healthy trial during a pandemic. *Health Res Policy Syst,* Under review.

Conference Presentations

Ho E, Ferreira M, De Barros Pinheiro M, Carvalho-E-Silva A, Madrid-Valero J, Zadro J, Ordoñana J, Ferreira P. Factors associated with seeking medical care for low back pain in a twin adult sample. Sydney Musculoskeletal, Bone and Joint Health Alliance 4th Annual Scientific Meeting, 2020, Sydney, Australia. Lightning talk presentation.

Ho E, Ferreira M, De Barros Pinheiro M, Carvalho-E-Silva A, Madrid-Valero J, Zadro J, Ordoñana J, Ferreira P. Factors associated with seeking medical care for low back pain in a twin adult sample. Charles Perkins Centre Early Mid-Career Researcher Symposium, 2021, Sydney, Australia. Poster Presentation.

- Awarded Best Poster Presentation.

Ho EK, Ferreira ML, Bauman A, Carvalho-e-silva AMC, Pinheiro MB, Calais-Ferreira L, Simic M, Ferreira PH. Beneficial and harmful effects of physical activity on care-seeking for low back pain. Back and Neck Forum, 2021, Virtual International Conference. Poster Presentation.

Ho EK-Y, Chen L, Simic M, Ashton-James CE, Comachio J, Wang DXM, Hayden JA, Ferreira ML, Ferreira PH. Psychological interventions for chronic non-specific low back pain: systematic review with network meta-analysis. Back and Neck Forum, 2021, Virtual International Conference. Oral Presentation.

Ho EK, Ferreira ML, Bauman A, Hodges PW, Maher CG, Simic M, Morton RL, Lonsdale C, Li Q, Baysari MT, Amorim AB, Ceprnja D, Clavisi O, Halliday M, Jennings M, Kongsted A, Maka K, Reid K, Reynolds T, Ferreira PH. Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: Protocol for a randomised

controlled trial. Back and Neck Forum, 2021, Virtual International Conference. Poster Presentation.

Ho EK, Ferreira ML, Bauman A, Hodges PW, Maher CG, Simic M, Morton RL, Lonsdale C, Li Q, Baysari MT, Amorim AB, Ceprnja D, Clavisi O, Halliday M, Jennings M, Kongsted A, Maka K, Reid K, Reynolds T, Ferreira PH. Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: Protocol for a randomised controlled trial. Implementation Science Health Conference Australia 2021, 2021, Sydney, Australia. Poster Presentation.

Ho EK, Ferreira ML, Bauman A, Hodges PW, Maher CG, Simic M, Morton RL, Lonsdale C, Li Q, Baysari MT, Amorim AB, Ceprnja D, Clavisi O, Halliday M, Jennings M, Kongsted A, Maka K, Reid K, Reynolds T, Ferreira PH. Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: Protocol for a randomised controlled trial. Charles Perkins Centre Early Mid-Career Researcher Symposium, 2021, Sydney, Australia. Poster Presentation.

Other invited presentations during candidature

2021: Sydney Neuromusculoskeletal Research Collaborative, invited panel member for virtual seminar on systematic review methods.

2019: University of Sydney Faculty of Medicine and Health Honours Information Session, invited panel member.

Grants related to this thesis

Ferreira P, Ferreira M, Bauman A, Hodges P, Maher C, Simic M, Morton R, Lonsdale C, Li Q, Baysari M, Amorim A, Ceprnja D, Clavisi O, Halliday M, Herbert R, Ho E, Jennings M, Kongsted A, Maka K, Reid K. NHMRC Partnership Grant 2020. The Get Healthy Coaching Service to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability. 2020. GNT1180474. AU$2,265,889.00

Ceprnja D, Maka K, Ferreira P, Halliday M, Ferreira M, Ho E. Western Sydney Local Health District Kickstarter Allied Health Research Grant. The Get Healthy Coaching Service® as a discharge pathway for people with chronic low back pain: effectiveness and acceptability. 2019. AU$5,000.00

Ho E. Australian Government Research Training Program Stipend Scholarship (2019 – 2022)

Other research grants

Puterflam J, Ho E, Marcelo A. University of Sydney Office of Student Life Student Co-Curricular Grant 2021. Students of USYD. AU$1,920.00

Ho E. Faculty of Medicine and Health Funding to collaborate with the Norwegian University of Science and Technology. AU$1,948.34

Research impact

2022: Ho EK-Y, Chen L, Simic M, Ashton-James CE, Comachio J, Wang DXM, Hayden JA, Ferreira ML, Ferreira PH. Psychological interventions for chronic non-specific low back pain: systematic review with network meta-analysis. BMJ 2022;376:e067718. doi: 10.1136/bmj-2021-067718.

- Altmetric attention score of 328, since publication on 30th March 2022
- Top 5% of all research outputs scored by Altmetric
- High Attention Score compared to outputs of the same age (99th percentile)
- Cited by 24 national and international news and radio outlets, including Sydney Morning Herald (Australia), Physician's Weekly (United States), The Epoch Times (United States), MedicalXpress (United Kingdom), Toronto Telegraph (Canada), Hindustan Times (India), and FranceTV Info (France)
- Tweeted by 220 Twitter users, reaching an upper bound of 1,035,216 followers across 34 countries
- Emma was invited to provide a news grab for 2SM radio

Awards

2021: Charles Perkins Centre Early Mid-Career Research Symposium 2021 – Awarded Best Poster Presentation for study "Factors associated with seeking medical care for low back pain in a twin adult sample."

2021: University of Sydney, Faculty of Medicine and Health - Q1 Makers and Shapers Award for Diversity and Inclusion.

2020: University of Sydney 3 Minute Thesis Finalist 2020 – Empowering independence in people with chronic low back pain.

Leadership

2019 – ongoing: Research coordinator of the Charles Perkins Centre Musculoskeletal Research Hub, led by Professor Paulo Ferreira.

2021: Working group member of the Digital Health and Informatics Network Early Career Research Community, a research group part of the Digital Health and Informatics Network (DHIN) at the University of Sydney.

2021: Peer Mentor, Faculty of Medicine and Health HDR Peer Mentoring Program.

2020: HDR Liaison Committee, student representative from the Faculty of Medicine and Health.

2020: Peer Mentor, Faculty of Medicine and Health HDR Peer Mentoring Program.

Research roles

2020 – ongoing: Clinical trial coordinator for the Get Back to Healthy trial, contributing to the design, project administration, and writing of manuscripts since April 2020.

2020 - ongoing: Project manager of the TANGO study, contributing to data collection, project administration, and writing of manuscripts since July 2020.

2020 – ongoing: Research assistant on the SUcceSS trial, contributing to data collection and project administration since January 2020.

Research supervision

2021 – 2022: Huo M. Honours student (University of Sydney – Physiotherapy)

2021 – 2022: Liu C. Charles Perkins Centre Summer Research Scholar (University of Sydney, Physiotherapy) – "The interaction between physical activity, sedentary behaviour, and sleep quality on low back pain"

Peer-review experience for scientific journals

2022: BMC Musculoskeletal Disorders

2022: Therapeutic Advances in Musculoskeletal Disease

2021: Therapeutic Advances in Musculoskeletal Disease

2020: Journal of Back and Musculoskeletal Rehabilitation

2020: BMC Musculoskeletal Disorders

Invited interviews

2022: Podcast interview for Health Coaching Australia and New Zealand Association Conference: Breaking Through Health and Wellness Coaching in a post-pandemic world. April 2022.

2022: Interviewed by Sydney Morning Herald, for study published in BMJ (Ho EK-Y et al. Psychological interventions for chronic non-specific low back pain: systematic review with network meta-analysis. BMJ 2022;376:e067718)

2022: Invited interview for Painrelief.com, for study published in BMJ (Ho EK-Y et al. Psychological interventions for chronic non-specific low back pain: systematic review with network meta-analysis. BMJ 2022;376:e067718)

2022: Invited interview for University of Sydney Staff Newsletter

2021: Invited interview for Digital Health and Informatics Network Newsletter

2020: Invited opinion piece on 'Research Student Experience' for Faculty of Medicine and Health Higher Degree Research Newsletter

PREFACE

This thesis is organised into nine chapters, written so that each chapter can be read independently. It includes an introduction (**Chapter One**), six submitted or published studies (**Chapters Two to Six**, and **Chapter Eight**), a traditional thesis chapter (**Chapter Seven**), and a discussion and conclusion (**Chapter Nine**)**.** The University of Sydney allows published studies that arise from the candidature to be included in the thesis.

Chapter One provides an overview of current literature related to the epidemiology and global patterns of health care utilisation for low back pain, as well as an introduction to the relevance of lifestyle interventions for improving health outcomes in people with chronic non-specific low back pain.

Chapter Two is a cross-sectional observational study that investigates the factors associated with seeking medical care for low back pain. This manuscript is presented as published in the *European Journal of Pain.*

Chapter Three is a longitudinal observational study exploring the association between physical activity, sedentary behaviour, and care-seeking behaviours for low back pain. This manuscript is presented in the format required for the *European Journal of Pain*, where it is currently under review.

Chapters Four and Five are a series of related chapters. **Chapter Four** presents the protocol of a systematic review with a network meta-analysis of psychological interventions for chronic non-specific low back pain. This manuscript is presented as published in *BMJ Open.* **Chapter Five** presents the results of the systematic review with network meta-analysis described in Chapter Four. This manuscript is presented as published in the *British Medical Journal.*

Chapters Six, Seven, and Eight are a series of related chapters. **Chapter Six** describes the protocol for a randomised controlled trial investigating the effect of introducing a support system at discharge from treatment for chronic non-specific low back pain, on patients' future use of hospital, medical, and health services for low back pain. The support system incorporates referral to a public health coaching program and is being compared with usual

care provided at discharge from physiotherapy treatment. This manuscript is presented as published in *BMC Musculoskeletal Disorders.* **Chapter Seven** describes the preliminary results and current progress of the randomised controlled trial presented in **Chapter Six**. To meet the requirements for a thesis submitted under emergency conditions, **Chapter Seven** also describes the proposed interim statistical analysis plan for a study which could not be completed due to the substantial impact of the COVID-19 pandemic on trial recruitment and data collection. This chapter is presented in the format of a traditional thesis chapter. **Chapter Eight** describes the lessons learned from the implementation of the randomised controlled trial presented in **Chapter Six**, during the COVID-19 pandemic. **Chapter Eight** provides practical recommendations to improve the design and implementation of resilient clinical trials, conducted in any context, in the future. This manuscript is presented in the format required for *Health Research Policy and Systems*, where it is currently under review.

Finally, **Chapter Nine** summarises the key findings and clinical implications of this thesis, discusses the strengths and limitations of the included studies, and provides recommendations for future research.

Each chapter contains its own reference list. Published and unpublished appendices are included at the end of the thesis. Ethical approval was gained from the University of Murcia Ethics Committee for the study reported in **Chapter Two,** Twin Research Australia and the University of Sydney Human Research Ethics Committee for the study reported in **Chapter Three**, and Western Sydney Local Health District Human Research Ethics Committee for the studies reported in **Chapters Six, Seven, and Eight**. The remaining chapters did not require ethical approval.

ABSTRACT

The broad aim of this thesis was to investigate the health and lifestyle factors influencing health care utilisation for low back pain, and to examine the role of psychological interventions (including lifestyle interventions) for improving health outcomes and/or reducing health service utilisation in people with chronic non-specific low back pain. To address the broad aim, the studies included in this thesis were conducted and organised according to three aims: (i) to identify health and lifestyle factors associated with patients seeking care for low back pain, (ii) to investigate the comparative effectiveness and safety of psychological interventions for improving health outcomes in patients with chronic low back pain, and (iii) to evaluate the effectiveness of introducing a lifestyle intervention, involving health coaching, into the discharge care pathway for patients with low back pain to reduce the use of health services for low back pain and improve health outcomes.

Chapter One provided an overview of current literature related to the epidemiology and global patterns of health care utilisation for low back pain, as well as an introduction to the relevance of lifestyle interventions for improving health outcomes in people with chronic non-specific low back pain. **Chapters Two and Three** addressed the first aim. **Chapter Two** investigated the relationship between various anthropometric, sociodemographic, health, and lifestyle factors, and the use of medical care for chronic non-specific low back pain. A co-twin case-control design was used to adjust for the potential confounding influence of aggregated familial factors (e.g., genetics and the early shared environment) on the relationship between these factors and the use of medical care for chronic non-specific low back pain. Poor sleep quality was identified as the only factor associated with seeking medical care for low back pain in the long term, with the relationship being independent of aggregated familial factors. **Chapter Three** examined the relationship between different intensities, volumes, and/or domains of physical activity and sedentary behaviour, on various care-seeking behaviours for low back pain. The study in **Chapter Three** discovered that different intensities, volumes, and/or domains of physical activity and sedentary behaviour, at baseline, have different effects on varying patterns of health care utilisation for low back pain. Specifically, engagement in medium-to-high volumes of household domain physical activity at baseline significantly increases the risk of the overall utilisation of care, and the utilisation of self-management strategies, for low back pain over one year. Further, people who engage in medium-to-high volumes of physically demanding tasks at work at baseline utilise more

overall care for low back pain, whilst people who engage in medium-to-high volumes of sedentary behaviour at baseline utilise more self-management strategies for low back pain, over a one-year period. In contrast, engagement in medium-to-high volumes of moderate-to-vigorous intensity physical activity appears to halve the risk of overall care utilisation for low back pain. No physical activity or sedentary behaviour variables demonstrated any significant associations with the utilisation of health services for low back pain.

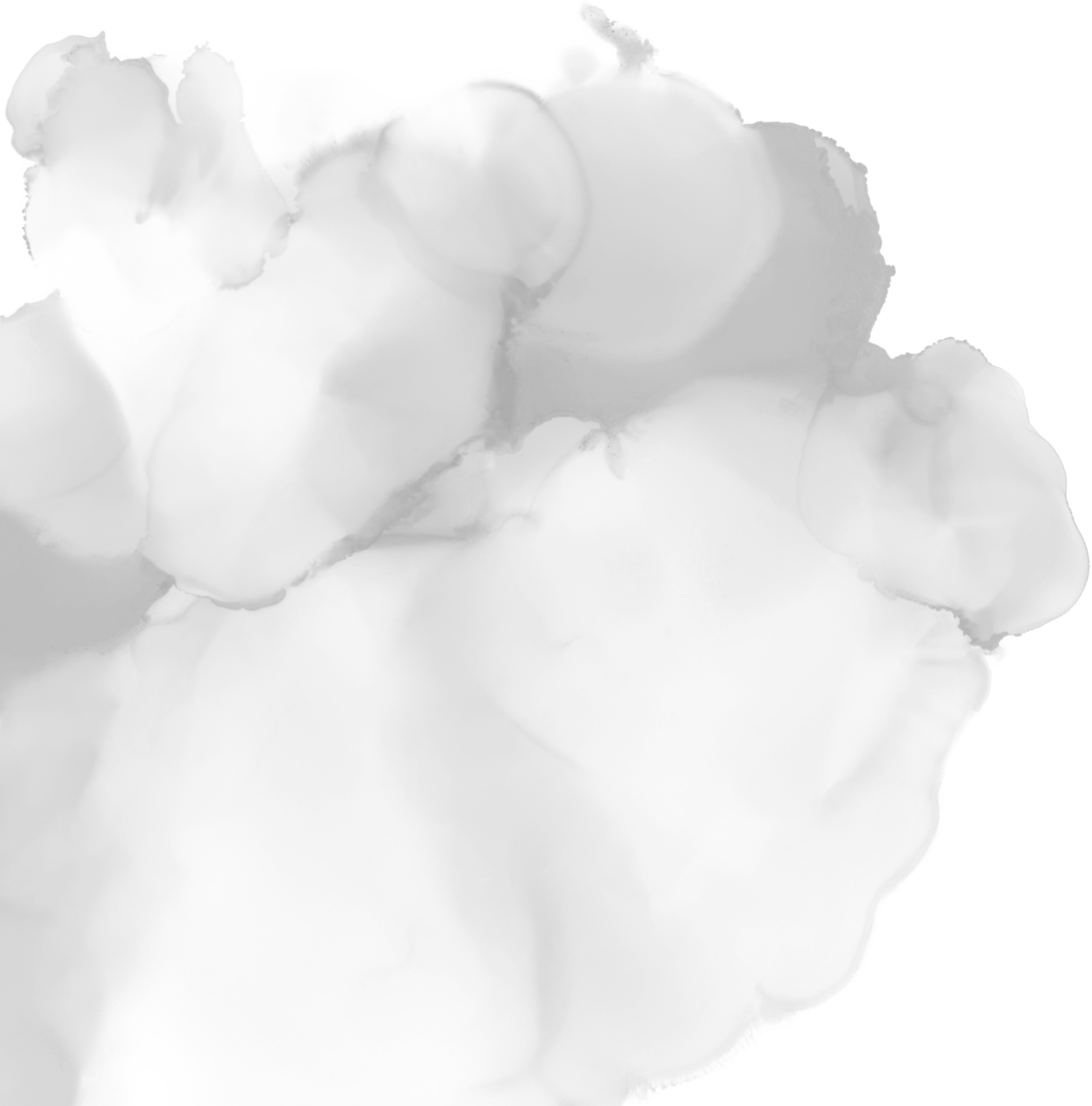
Chapters Four and Five addressed the second aim. **Chapter Four** described the protocol of a systematic review including a network meta-analysis of psychological interventions for chronic non-specific low back pain. The primary outcomes were patients' physical function and pain intensity, and the secondary outcomes were fear avoidance, health-related quality of life and intervention compliance, and safety. The results of the systematic review and meta-analysis are presented in **Chapter Five**. In total, 97 randomised controlled trials involving 13,136 participants and 17 treatment nodes were included. Results of the network meta-analysis demonstrated that compared with physiotherapy care alone (mainly structured exercise), pain education programs delivered with physiotherapy care (mainly structured exercise) offer the most sustainable effects of treatment for physical function and fear avoidance. Differently, behavioural therapy delivered with physiotherapy care (mainly structured exercise) results in the most sustainable effects of treatment for pain intensity. There is uncertainty surrounding their long-term effectiveness (≥12 months post-intervention) because of a lack of studies with long-term follow-up periods. However, limited but consistent evidence suggests psychological interventions are safe for people with chronic non-specific low back pain, given that the occurrence of adverse events related to the intervention is rare (i.e., only reported in three of 20 studies). Even when reported, the adverse events are not considered serious in nature. The review also confirmed a prevailing lack of high-quality randomised clinical trials investigating the effectiveness of mindfulness-based interventions (i.e., mindfulness-based stress reduction), and counselling-based interventions (i.e., lifestyle interventions) for this population.

Building on the evidence gaps identified in **Chapters Four and Five, Chapters Six, Seven, and Eight** addressed the final aim of this thesis. **Chapter Six** described the protocol of a randomised controlled trial designed to evaluate the effectiveness of introducing a support system, involving a lifestyle intervention (i.e., a health coaching program), into the discharge

care pathway for patients with chronic non-specific low back pain (Get Back to Healthy trial). The comparison intervention is usual care provided at discharge from treatment, and the primary outcome is the use of health services for low back pain, over one year. The trial will recruit 374 adults in Australia. However, the unprecedented COVID-19 pandemic has caused significant delays in the progress of the trial. Disruptions to recruitment and data collection have precluded the completion of an additional study, which was intended for inclusion in this thesis. The proposed study was designed to investigate the joint association between physical activity and sleep on various care-seeking behaviours for low back pain. In the absence of sufficient data to complete the proposed study, **Chapter Seven** reports on the progress made during the early implementation phase of the trial, summarises preliminary findings to date, and describes the intended interim statistical analysis plan. To conclude, **Chapter Eight** provides a narrative summary of the specific challenges and key lessons learned during the implementation of the Get Back to Healthy trial, described in **Chapter Six**. **Chapter Eight** aimed to bring greater awareness to the complexity of conducting a large, pragmatic, multi-site randomised clinical trial of a lifestyle intervention, delivered by an established public health service, during a global pandemic. Practical recommendations to improve the conduct and implementation of clinical trials, in any context in the future, are presented in this chapter.

Finally, **Chapter Nine** summarised the key findings, clinical implications, and strengths and limitations of this thesis, and also provided recommendations for future research.

CHAPTER ONE



Introduction

An introduction to low back pain

Low back pain is often described as discomfort located between the lower rib margins and the buttock creases.[1, 2] Most cases of low back pain are non-serious (i.e., symptoms are not attributable to serious pathologies such as cancer, infection, trauma, or inflammatory diseases), and specific causes or nociceptive sources cannot be accurately identified.[3] Low back pain of this nature is frequently termed *non-specific low back pain* and represents approximately 90 to 95% of cases.[4] Most people who experience an acute episode of low back pain will demonstrate improvements in pain and disability levels within six weeks from symptom onset,[5, 6] regardless of receiving treatment or not.[7] However, the recurrence and persistence of symptoms are common.[8] A systematic review of 28 observational studies and eight randomised controlled trials has demonstrated that on average, 62% (range: 42% to 75%) of people with low back pain continue to experience pain after 12 months.[9] When pain persists for more than 12 weeks duration, symptoms are described as *chronic*.

The global prevalence of low back pain

Low back pain is highly prevalent across the world. The global point prevalence of low back pain is 7.8%, equating to approximately 577 million people affected at any point in time,[10] and the lifetime prevalence of low back pain is estimated to be 84%.[11] Recent estimates from the 2017 Global Burden of Disease Study indicate that the prevalence of low back pain increases with age, peaking around the ages of 80 to 89 years before decreasing slightly.[10] It is also frequently reported that the prevalence of low back pain is higher in females compared with males;[10, 12] although sex-related patterns of low back pain prevalence seem to vary between low and middle-income countries to high-income countries, and even between low-income regions.[13] As an example, self-reported data from the Australian Bureau of Statistics National Health Survey (2017 to 2018) found that the age-adjusted prevalence of low back pain was similar between females (15%) and males (16%).[14] Similarly, the point prevalence of LBP has been shown to be comparable between females (40%) and males (39%) in Iran.[15] However, in Korea, the lifetime (approximately 60% *vs* 50%) and point prevalence (approximately 30% *vs* 17%) of low back pain are higher in females compared with males.[16] Genetic diversity, differences in sociocultural norms including work patterns (i.e., engagement in hard physical labour),[17] and gender

inequalities, may contribute to inconsistencies in sex-disaggregated estimates of the prevalence of low back pain across countries.

Furthermore, a systematic review of 165 observational studies has shown that the mean prevalence of low back pain is higher in high-income countries (32.9% [standard deviation 19.0%]), compared with middle (25.4% [25.4%]) and low-income countries (16.7% [16.7%]);[12] although differences may be influenced by the paucity of studies conducted in low and middle-income countries, as well as methodological differences between studies.[12] The same review did not identify any significant differences in the mean prevalence of low back pain between urban and rural areas globally.[12] These findings are echoed in a recent Australian report (2020) indicating that the prevalence of low back pain is 16%, 17%, and 15% across major cities, inner regional areas, and outer regional and remote areas in Australia, respectively.[14] Collectively, the prevalence of low back pain is clearly substantial across the world.

The global burden of low back pain

The global burden of low back pain on the individual

Low back pain is one of the leading causes of disability globally. Between 1990 and 2017, the number of years lived with disability due to low back pain increased from 42.5 million to 64.9 million (52.7%).[18] In 2019, low back pain was ranked the seventh leading global cause of years disability-adjusted life-years for adolescents and young adults aged between 10 to 24 years, fourth for adults aged between 25 to 49 years, and sixth for adults aged between 50 to 74 years, when compared with 369 diseases and injuries across 204 countries.[19] In Australia, one in six people (i.e., 4 million Australians) reported experiencing back-related problems between 2017 to 2018. Evidently, low back pain represents a substantial burden on both the individual and society.

The burden of low back pain on the individual is frequently expressed through the high levels of disability and activity limitation associated with the condition, which increases with age.[10] Disabling low back pain imposes serious consequences on the individual by impairing societal participation, reducing the quality of life, and impacting financial prosperity.[13] A systematic review, with a meta-synthesis of 42 qualitative studies from high-income countries, found that many people with low back pain struggle to meet social

expectations and obligations.[20] Loss of function (i.e., domestic chores, valued recreational activities), difficulty sleeping, damaged relationships (i.e., avoidance of family activities, absence of intimacy), modification of work-related activities, fear of job loss, and financial worries, emerged as some of the key concerns of this population.[20] A report from the Australian government published in 2020 confirms a similar pattern, indicating that back pain interferes at least "moderately" with daily activities for almost two in five (38%) Australians with back problems.[14] In addition, low back pain is the most common cause of medically certified sick leave in Europe[21] and accounts for more workdays lost compared with any other musculoskeletal condition in the United States.[22] In Australia, back pain is the most common health condition forcing older Australians to retire prematurely,[23] with significant economic (i.e., low income, savings, and assets) and living standards impact.[24] It was estimated that productivity loss due to chronic pain conditions (including low back pain) approximated AU$21,830 per person of working age in Australia, in 2018.[25] Evidently, the burden of low back pain on the individual spans across many facets of one's livelihood.

Comorbidities such as arthritis, cardiovascular disease, and mental health problems are common in people with low back pain,[26] and their presence can exacerbate the burden of the condition on the individual. For example, people with low back pain, who present with three or more comorbidities, are more likely to report poorer health status, compared with patients with low back pain only or those with fewer than three comorbidities.[27] People with low back pain, with three or more comorbidities, are also more likely to be prescribed medications (i.e., dexamethasone, oral steroids, colchicine, antidepressants) and not be advised against resting in bed, compared with patients with low back pain only or those with fewer than three comorbidities.[27] Further, it is estimated that between 20 to 25% of adults with low back pain experience depressive symptoms.[28] A study has shown that in patients with chronic low back pain, those with comorbid depressive symptoms experience more severe pain, worse health-related quality of life, presenteeism (i.e., impairment whilst at work), overall work and activity impairment, and utilise a greater number of health care visits, compared with those without depression.[29] People experiencing both conditions (low back pain and depression) are also likely to have higher numbers of compensation claims for low back pain, lower prevalence of returning to full work duties, and higher prevalence of sickness absence when compared with people with low back pain without

depressive symptoms.[30] In addition, in people with chronic low back pain, health service utilisation has been found to be predicted by more negative work-related fear-avoidance beliefs and higher back pain related social stresses (e.g., unemployment, financial difficulties).[31] Thus, the burden of low back pain on the individual appears to substantially increase in the presence of comorbidities. Overall, the global burden of low back pain on the individual is significant as it is common and pervades many aspects of one's life.

The global burden of low back pain on society

The global resource and economic burden of low back pain on society are also substantial, largely attributable to high direct costs associated with health care utilisation and indirect costs due to loss of work productivity and absenteeism. To contextualise the societal impact of low back pain, costs associated with low back pain are comparable to other highly prevalent conditions such as cardiovascular disease, cancer, mental health, and autoimmune diseases.[32]

In 2006, it was estimated that the total costs of health care for low back pain in the United States exceeded US$100 billion per year,[33] the highest amount of health care spending amongst 154 diseases studied.[34] In the United Kingdom and Australia, the direct costs of low back pain alone are estimated at £2.8 billion[35] and AU$4.7 billion per year, respectively.[36] A recent Australian study has reported that over five years (2014 to 2019), the total cost of inpatient and emergency department care for non-serious low back pain in three public metropolitan hospitals alone (out of approximately 693 public hospitals across Australia[37]) was AU$36.7 million.[38] It is likely that globally, the direct costs of low back pain are underestimated due to the use of informal care or care provided in private hospitals not being captured by public health care systems.

Regardless, whilst the cost of low back pain varies between countries, indirect costs consistently contribute disproportionally to the total costs of low back pain, with replacement wages accounting for 80 to 90% of total costs.[13] As an example, in Australia, full-time workers with low back pain earn an average of AU$7,124 less than colleagues without low back pain per annum, representing an economic loss of AU$10.5 billion in gross domestic product, with estimates projected to increase to AU$14.5 billion by

2030.[39] There remains a lack of studies investigating the costs associated with low back pain in low and middle-income countries;[13] however, the figures are likely substantial.

Nevertheless, despite increased research efforts and health expenditure related to low back pain over the years, patient outcomes have not improved substantially, and the adverse societal consequences of low back pain continue to escalate. Although indirect costs account for a larger proportion of the economic burden of low back pain, a better understanding of the overall patterns of health care utilisation for low back pain is crucial to assist with the development of more effective interventions for people with low back pain. Subsequently, improved patient care and outcomes may lead to sustainable reductions in the economic burden of low back pain over time.

Health care utilisation associated with low back pain

Importance of evaluating health care utilisation as an outcome

Health care utilisation is an outcome used to quantify the use of health treatments to prevent, cure, promote, or maintain one's health and well-being, or to obtain information about one's health status and prognosis.[40] In literature, the definition of health care utilisation varies widely depending on the specific health treatments, clinical populations, or research question of interest. In this thesis, health care utilisation broadly encompasses the use of health services (e.g., hospital, medical, and allied health services), self-management strategies (e.g., exercise, hot packs), or medications for low back pain (e.g., analgesics).

Health care utilisation is a useful outcome to assess in low back pain populations for several reasons. Broadly, examining overall patterns of health care utilisation for low back pain can contribute to quantification of the national and global public health impact of the condition. Health care utilisation is also a useful metric for monitoring changes in the usage of resources for low back pain (e.g., facilities, personnel, supplies), to assist with forecasting future health care needs and expenditures. Furthermore, evaluating utilisation patterns for different types of health care, for low back pain, can enable identification of patient subpopulations at risk of utilising ineffective or potentially harmful health treatments, as well as those underutilising effective self-management strategies. It can also enable identification of patient subpopulations at risk of overutilising health services and exacerbating the high burden of the condition on global health care systems. Knowledge

gained may guide development of more effective and targeted interventions to support individuals to better self-manage their condition, and potentially reduce their reliance and burden on chronically overwhelmed health services and systems. As such, health care utilisation has great utility as a health outcome and was selected as the main outcome explored in this thesis.

Global rates of health care utilisation for low back pain

To fully understand the global public health impact of low back pain, it is necessary to examine the care-seeking patterns for the condition across different populations. Rates of health care utilisation for low back pain vary across geographical regions. A systematic review with meta-analysis of 20 population-based observational studies has shown that the pooled prevalence rate (with 95% confidence interval) of health care utilisation due to an episode of low back pain is 67% (50% to 84%), 47% (39% to 56%), and 48% (33% to 63%), in the United States, United Kingdom, and Europe, respectively.[41] In Australia, low back pain is the sixth most commonly managed condition in primary care.[42] Variations may be attributable to differences in costs associated with health care use, sociocultural norms, public health approaches, or legislation between countries and continents. Regardless, the high rates of health care utilisation for low back pain across the world are concerning, particularly in the absence of population-level improvements in patient outcomes or disease burden. The types of care frequently utilised by people with low back pain, and the costs associated with health care utilisation, are described later.

Low back pain in primary care and emergency departments

Globally, low back pain is typically managed in primary care, with general practitioners, chiropractors, and physiotherapists being the most frequently consulted health care providers by patients with low back pain.[41] Patients with low back pain often consult with general practitioners as the first point of care,[43] although, the severity[44] or duration of pain[45], geographical location of the patient (e.g., rural or urban residence),[46] have been found to influence the choice or order of practitioner consulted . Potentially, the availability of health services and rebates, and treatment costs may also play a role.[47] Of the wide range of treatment approaches available for low back pain, exercise (78%), medications (61%), and passive therapies (i.e., massage therapy (67%), hot and cold therapies (61%), electrotherapies (24%), acupuncture (18%)) are the most prescribed treatments for low back

pain in Australia.[48] A systematic review of observational studies, conducted in the United States, United Kingdom, and Europe, investigating patterns of health care utilisation for low back pain, also reported similar findings.[41] Other studies have shown that imaging and invasive procedures are also commonly utilised.[49, 50] Worldwide and in Australia, low back pain is a leading reason for emergency departments presentations and admissions,[51, 52] despite few cases constituting medical emergencies.[53] As seen, patients with low back pain access many different types of health services across different settings and receive a wide array of treatment modalities to manage their symptoms.

Challenges towards overcoming the high rates of health care utilisation for low back pain

In order to reduce the significant costs associated with low back pain care the following barriers need to be overcome: (i) the gaps between evidence-based recommendations and clinical practice, (ii) general patterns of overutilisation of treatments and procedures for low back pain, (iii) the disproportional contribution of people with chronic low back pain, as opposed to acute or sub-acute low back pain, to the high burden of health care utilisation for the condition, (iv) the sub-optimal effects that current treatment approaches offer for patients to achieve sustained outcomes. These issues are explored further below.

At the forefront, the gaps between evidence-based recommendations and clinical patterns of health care utilisation for low back pain are highly concerning. For patients with chronic non-specific low back pain, clinical guidelines consistently recommend advice to remain active, education about the nature of low back pain and radicular pain, exercise, and cognitive behavioural therapy for those who have not responded to previous treatments, as first-line treatments.[54] The guidelines also typically recommend against or propose limited use of pharmacological therapies, invasive procedures, imaging, and passive therapies (e.g., acupuncture, spinal manipulation).[46, 55] For example, paracetamol is not recommended for low back pain due to its ineffectiveness and potential for harm.[56, 57] Although opioids offer small short-term analgesic benefits in people with low back pain, compared with placebo, their benefit might not be clinically relevant and the effect on function remains unclear.[58, 59] Subsequently, guidelines now recommend against their routine use due to the high risks of misuse, addiction, and even death,[60, 61] and indicate they should only be prescribed to carefully selected patients for short durations, in low doses, and with appropriate monitoring.[61] Furthermore, most guidelines recommend the

use of non-steroidal anti-inflammatory drugs (NSAIDs) as an adjunct treatment for patients with acute and chronic low back pain,[55] provided that the lowest effective dose is prescribed for the shortest possible time and the risks of gastrointestinal, liver, and cardiorenal toxicity are considered.[62]

However, clinical practice commonly does not reflect these recommendations. A systematic review of 26 studies investigating usual care for low back pain in primary care (United States, Australia, Europe) and emergency departments (United States only) has found that less than 20% of patients with low back pain receive evidence-based information and advice from their family practitioner, with up to 30% of patients being prescribed opioids in primary care and up to 60% in emergency departments.[50] Although opioid prescription rates are beginning to fall in the United States[63] and the United Kingdom[64], opioids continue to be prescribed or used inappropriately (i.e., high dosages, prolonged use), perpetuating worse patient outcomes and greater health care utilisation.[65, 66] Furthermore, whilst exercise prescription rates for low back pain in primary care are generally high (78%),[48] passive therapies continue to be commonly utilised (e.g., massage therapy, heat and cold therapies, electrotherapies, acupuncture),[41, 48] despite evidence suggesting they only offer short-term benefits for patients with low back pain.[46] One study found that a staggering 61% of patients receiving primary care treatment for low back pain in Australia were prescribed at least one form of analgesic medication.[48] Indisputably, there are clear and persistent gaps between evidence and practice for the management of low back pain.

Other observed patterns of health care utilisation for low back pain, which are blatantly inconsistent with guideline recommendations, are also worrying. Many guidelines clearly state that surgery is not recommended for people with non-specific low back pain,[46, 55] particularly considering the 20% failure rate (i.e., need for revision surgery, incomplete recovery).[67] Nevertheless, interventional invasive procedures are frequently performed to manage low back pain,[68] particularly in high-income countries with high disease burden. For example, in the United States, 488,000 spinal fusion surgeries were performed in 2011 alone, costing US$12.8 billion – the highest aggregate hospital costs of any surgical procedure.[49] Moreover, imaging (e.g., x-ray, magnetic resonance imaging (MRI)) is not recommended for low back pain unless serious causes of symptoms are suspected.[55]

However, the liberal use and availability of diagnostic imaging for low back pain persist, with studies from the United States, Australia, and Europe indicating that one in four people with low back pain receives imaging referrals in family practice, and one in three in emergency departments in the United States.[50] A systematic review of 14 studies found that compared with people who do not receive imaging for low back pain (i.e., x-ray, computerised tomography, MRI), people who receive imaging may experience higher medical costs, health care utilisation, and work absence.[69] Unsurprisingly, the economic burden owing to inappropriate use of imaging for low back pain is substantial. A study from the United States reported that 59% of outpatient lumbar spine scans were provided to people without indications for serious causes of low back pain in the 2012 fiscal year, equivalent to US$300 million per year.[70] Taken together, the incongruency between consistent clinical guideline recommendations against the use of surgery and imaging for low back pain, and the high rates of their inappropriate utilisation, remains a difficult challenge to overcome.

In Australia, there are currently no national primary health initiatives monitoring or regulating the provision of care for low back pain in emergency departments or primary care settings (e.g., general practice, physiotherapy, chiropractic care). However, several retrospective reviews of patient records or care provider surveys have been conducted in specific health settings to investigate the patterns of usual care provided for low back pain. For example, a retrospective review of low back pain-related presentations to three public hospital emergency departments in Sydney, Australia, between 2016 to 2018, found that among those diagnosed with a lumbar spine condition (6,393 presentations), 24% received lumbar imaging, 70% received opioids, and 18% were admitted.[71] Similar health care utilisation rates were found for low back pain-related emergency department presentations in a private hospital located in Melbourne, Australia: 39% of patients received lumbar spine imaging, 62% had pathology tests, and 87% received medications (opioids: 66%, paracetamol: 49%, NSAIDs: 36%, benzodiazepines: 26%, pregabalin: 6%).[72] Survey data collected from general practitioners providing care for patients with low back pain indicated that 25% of patients are referred for imaging and 65% were prescribed medications (opioids: 20%, paracetamol: 18%, NSAIDs: 38%).[73] Alarmingly, only 33% of patients who were prescribed paracetamol received the recommended dose of four grams per day,[73] despite strong evidence against its use for low back pain altogether.[56] An even greater cause for

concern is that only 21% of patients consulting general practitioners for new low back pain symptoms were provided with advice and education,[73] despite guidelines consistently recommending the provision of advice, education, and reassurance of a favourable prognosis as first-line care for low back pain.[13] Evidently, the gap between evidence and practice related to health care utilisation for low back pain is widespread across the world and in Australia. Taken together, there is a prevailing global pattern of overutilising low-value care (i.e., care which is ineffective or potentially harmful) and underutilising high-value care (i.e., care which is shown to be effective, beneficial, and cost-effective) for low back pain.

Compounding this issue, a general pattern of overutilising health services for low back pain has been observed. People with low back pain commonly seek treatment from multiple health care providers. This pattern has been demonstrated in the results of an Australia survey which identified that 79% of patients who sought primary care treatment for low back pain consulted two or more different types of health care practitioners.[48] The same survey also identified that a worrying 28% of patients consulted between four to eight different practitioners.[48] Considering that most cases of low back pain require little to no formal care, and the excessive use of care does not necessarily lead to improved patient outcomes,[3] overcoming the high rates of health care utilisation for low back pain will require innovative solutions.

Moreover, a large proportion of health care utilisation and expenditure for low back pain is attributable to a small sub-group of people with recurrent or persistent symptoms. To elaborate on this point, most episodes of low back pain resolve acutely, and only a small proportion of individuals will need care from a health care provider.[8, 74, 75] Of those who seek care, the majority of patients experience improvements in pain and disability within weeks of receiving treatment.[8] Nonetheless, one third will develop recurrent and persistent symptoms,[76] and it is this sub-group of patients who disproportionally contribute towards the high disability and costs associated with low back pain.[74, 77] The burden of this sub-group is demonstrated through a systematic review of eight longitudinal studies, which identified that the proportion of patients experiencing persistent and recurrent episodes of pain resulting in care-seeking ranged from 22 to 77%, depending on the follow-up time point assessed.[78] Extrapolating on these findings, a cohort study conducted in the

United States has demonstrated that in people claiming worker's compensation for non-specific low back pain, those with recurrent low back pain experienced higher total length of work disability and medical and indemnity costs, compared with those without recurrent pain.[77] Specifically, those with recurrent low back pain accounted for 69% of total lost time from work, 71% of associated indemnity costs, and 84% of total medical costs.[77] As shown, people with recurrent and chronic low back pain represent a sub-group of patients who magnify the global burden of low back pain on health care systems.

Finally, existing evidence suggests that current approaches for managing low back pain do not necessarily lead to sustained improvements in patient outcomes. It has been observed that 60 to 80% of people with low back pain who consult health services for treatment continue to experience symptoms after one year.[8] In the United Kingdom, 60 to 80% of people who consult a general practitioner for low back pain continue to experience pain and disability after one year,[9, 79] whilst in Portugal, 50% of people seeking care from general practitioners report persistent disability at six months after consultation.[80] In Australia, 28% of people with low back pain are not fully recovered at 12 months, after seeking treatment from primary care practitioners (e.g., general practitioners, physiotherapists, chiropractors).[81] Evidence clearly suggests that modern treatment approaches are suboptimal for achieving sustainable health outcomes in people with low back pain, and better solutions are urgently needed.

All in all, the existing patterns of health care utilisation suggest that the recurrence or persistence of pain and disability is common in people with low back pain, a wide gap between evidence and clinical practice remains, and current treatment approaches appear suboptimal for patients with low back pain. Evidence demonstrates that the overuse of low-value care and underuse of high-value care for low back pain continues to escalate. Therefore, understanding the factors driving different patterns of health care utilisation may assist with identifying people who are less likely to recover, and guiding the development of more effective, cost-effective, and sustainable health solutions for people with low back pain.

Factors associated with health care utilisation for low back pain

A large proportion of the existing research in the field of low back pain has been dedicated towards understanding the prognostic factors for low back pain. Many studies have identified a multitude of factors associated with poor outcomes for low back pain. For example, a review of 69 studies examining prognostic factors for low back pain has identified 221 distinct factors which have been investigated across previous studies.[82] Various symptom-related (i.e., higher levels of functional disability, presence of sciatica), individual (i.e., older age, poorer general health), and psychological characteristics (i.e., psychological stress, negative cognitive characteristics), and work (i.e., poor relationship with colleagues, heavy physical work demands) and social environmental factors (i.e., presence of compensation), have been consistently found to be associated with poorer outcomes for low back pain.[83]

However, despite rising rates of health care utilisation for low back pain and high associated expenditure, less attention has been paid towards understanding the individual drivers of care-seeking behaviours for the condition, and the breadth has been limited. To date, two systematic reviews of cohort studies have investigated the factors associated with health care utilisation for low back pain.[41, 75] Both reviews identified that women, high pain intensity, and high levels of disability are common factors associated with increased rates of health care utilisation for low back pain. A more recently published study (2022),[84] comprising data from two observational cohorts of older people seeking primary care for back pain, found similar findings – higher degree of pain severity and disability, as well as depression and lower physical health-related quality of life, are consistently associated with high costs related to healthcare utilisation for back pain. From the two aforementioned systematic reviews,[41, 75] some studies have also shown that a previous history of low back pain, longer duration of pain, and moderate/worse perceived general health status are also associated with increased health care utilisation for low back pain. There is inconsistent evidence for the influence of increasing age, marital status, employment status, and ethnicity on health care utilisation for low back pain.[41, 75] As demonstrated, existing studies have primarily focused on unravelling the relationship between symptom presentation or sociodemographic factors on care-seeking behaviours in people with low back pain.

Only a small number of studies have attempted to investigate the association between health (defined as physical or mental health conditions, e.g., cardiovascular disease, depression) or lifestyle factors (defined as modifiable behaviours or habits which have potential to impact health and/or wellbeing, e.g., physical activity levels, alcohol intake) and health care utilisation for low back pain.[41] Findings from these studies have been conflicting. For example, a 2019 systematic review of observational studies [41] identified three studies which have examined the influence of number of comorbidities,[85] depression and anxiety,[85, 86] smoking status,[85] drinking status,[85] or body mass index[85, 87] on health care utilisation for low back pain. In these studies, no significant associations were found between any of these health or lifestyle factors and health care utilisation for low back pain.[85-87] This is in stark contrast with a more recent population-based cross-sectional study conducted in Ethiopia (2020), which found that smoking habits, alcohol habits, depressive symptoms, and insomnia were significantly associated with health care utilisation for low back pain.[88] Specifically, the prevalence of health care utilisation was 26% lower in former smokers compared with current smokers (adjusted prevalence ratio [APR] 0.74, 95% confidence interval [CI] 0.55 to 0.99), 32% lower in former alcohol consumers compared with current alcohol consumers (APR 0.68, 95% CI 0.59 to 0.78), and 21% lower in individuals with borderline of depressive symptoms compared with those with no depressive symptoms (APR 0.79, 95% CI 0.66 to 0.93). This study also found that individuals with insomnia were 1.34 times more likely to utilise care compared with those with no insomnia (APR 1.34, 95% CI 1.15 to 1.54).[88] Evidently, few studies have examined the association between various health or lifestyle factors on the utilisation of care for low back pain, the selection of factors has been limited, and the findings have been conflicting between studies.

Identifying the specific health or lifestyle factors associated with health care utilisation for low back pain is clinically beneficial for several reasons. Firstly, it is well established that a wide variety of health (i.e., sleep,[89] cardiovascular disease,[90] diabetes,[91] obesity[92]) and lifestyle factors (i.e., physical activity,[93, 94] alcohol intake,[95] smoking[96]) are associated with the prevalence of chronic low back pain. Also, given that people with low back pain who report worser symptoms (i.e., higher pain and disability levels) are more likely to utilise health care for the condition,[75] identifying the specific health and lifestyle factors associated with health care utilisation for low back pain may

guide implementation of more comprehensive screening measures to facilitate early recognition of patients at risk of poorer prognosis (e.g., developing more intense or disabling low back pain). Expanding on this, lifestyle factors are modifiable in nature. Therefore, identifying the specific lifestyle factors which are associated with health care utilisation for low back pain may guide the development of holistic health interventions which focus on addressing these key lifestyle factors, but may also lead to cascading beneficial effects on low back pain-related outcomes (i.e., symptoms, prognosis, utilisation of care). Ultimately, studies investigating the relationship between a wider selection of health or lifestyle factors and health care utilisation for low back pain, particularly factors known to be associated with the prevalence of low back pain, are needed.

Further considerations should also be made. Heritability studies have demonstrated that genetic factors account for between 21% to 67% of the variance of low back pain, with the genetic component being higher for more chronic and disabling low back pain.[97] Shared familial factors (i.e., genetics, or the early shared environment such has socio-economic status, educational opportunities, neighbourhood) also play an important role in explaining population differences in the prevalence of common comorbidities associated with low back pain (i.e., diabetes,[98, 99] obesity,[100] depression and anxiety[101, 102]) and lifestyle choices (i.e., physical activity engagement[103]). It is plausible that shared familial factors may also confound the relationship between health or lifestyle factors, and the utilisation of health care for low back pain. However, previous studies investigating the determinants of health care utilisation for low back pain have not accounted for the potential confounding effects of shared familial factors, representing an additional gap in knowledge.

Chapters Two and Three of this thesis report the results of two observational cohort studies examining the relationship between various anthropometric, sociodemographic, health, and lifestyle factors, and the use of different types of care for low back pain. Chapter Two is a cohort study of 1605 adult twins from Spain which utilises a co-twin case-control design to investigate the influence of various anthropometric, sociodemographic, health, and lifestyle factors on the use of medical care for chronic non-specific low back pain, whilst adjusting for the confounding influence of shared familial factors such as genetics and the early shared environment.[104, 105] The use of a co-twin case-control analysis method allows for the control of a variety of measured (data derived) and unmeasured (aggregated familial

background) factors, to gain a clearer understanding of whether the relationship between given variables of interest can be considered direct and consistent with causality.[105] Chapter Three involves a cohort of 340 adult twins recruited across urban and rural Australia for the AUTBACK study,[106, 107] and examines the relationship between different amounts and domains of physical activity or sedentary behaviour, on various types of care-seeking behaviours for low back pain.

Influence of psychological factors on low back pain

Over the recent decades, the biopsychosocial model has been adopted as a framework to improve understanding of the complex nature of low back pain. The biopsychosocial model has facilitated increasing awareness of the multifactorial interaction between the genetic, biophysical, psychosocial, health, and lifestyle factors[13, 108] which may contribute towards the development of recurrent and disabling low back pain. In particular, the impact of psychosocial factors or mental health comorbidities on the prevalence and persistence of low back pain symptoms has been subject to clinical interest. As described earlier, depression is also common in people with low back pain,[26] and is associated with worse low back pain outcomes.[30] Further, although the mechanisms are not fully understood, numerous studies have shown that psychosocial factors, such as fear avoidance, catastrophising, poor illness perception, and poor self-efficacy, can lead to an increased risk of disability associated with low back pain[109] and form significant barriers towards recovery. Results from a systematic review have also shown that being fearful that low back pain could impair capacity to work, having externalised locus of control for pain management, and holding beliefs that low back pain is a lifelong problem can increase the odds of utilising health care for the condition.[41] It is clear that psychological factors play an important role in influencing recovery from low back pain, and should be considered when managing the condition.

Previous studies have attempted to identify the most important psychological factors that predict poor outcomes in people with low back pain. For example, Foster et al. conducted a cohort study of 1591 patients consulting general practice for low back pain-related care and investigated 20 potential psychological obstacles to recovery after treatment.[109] The authors found that weak beliefs and confidence to self-manage one's back problem, expectations that back problems last a long time, and the perception that other health

symptoms are related to one's back problem, were psychological obstacles which were more predictive of poorer clinical outcomes at six months after primary care consultation, compared with fear avoidance, catastrophising or depression.[109] These obstacles explained 57% of the variance in disability associated with the condition.[109] All in all, it is well-established that the comorbid presence of psychological factors can complicate the management of low back pain and increase the use of health care for the condition. Given that psychological factors are potentially modifiable through clinical interventions, incorporating psychological interventions or strategies into treatment for low back pain may improve low back pain outcomes and lead to reduced utilisation of health care for low back pain.

Psychological interventions for chronic low back pain

Psychological interventions for chronic pain conditions aim to reduce pain-related distress and disability by changing negative beliefs, behaviours, and attitudes through a combination of principles and strategies informed by psychological theories.[110] Psychological interventions commonly aim to target specific environmental contingencies and maladaptive cognitive and emotional processes which underpin pain to promote self-efficacy and increased function.[111, 112] Previous systematic reviews have shown promising evidence that psychological interventions can improve overall functioning, pain experience, depression, cognitive appraisal, and health-related quality of life in people with chronic low back pain.[111-113] It has also been shown that patients with low back pain of up to six months in duration, who have high fear-avoidance beliefs, are more likely to experience improvements in pain and disability when their fear-avoidance beliefs are addressed through treatments, compared to when their beliefs are ignored.[114] Importantly, there is evidence to suggest that psychological interventions (e.g., cognitive behavioural therapy, behavioural therapy) are effective for reducing health care utilisation in people with chronic pain.[115] Thus, the use of psychological interventions or strategies may have a beneficial role for improving outcomes in patients with low back pain as well as potentially decreasing care-seeking for the condition.

However, previous reviews of psychological interventions for low back pain have mainly focused on a small selection of approaches available for people with low back pain – namely cognitive behavioural therapy and behavioural approaches such as biofeedback.[111-113,

116-118] Emerging psychological interventions, such as cognitive functional therapy[108] and acceptance and commitment therapy,[119] have been neglected. Critically, previous reviews have only conducted multiple independent pairwise meta-analyses, and to our knowledge, no attempts have been made to synthesise the separate results. Ultimately, the comparative effectiveness and safety of the wider collection of psychological interventions available for managing chronic low back pain is unknown, which may contribute to patients and clinicians being uncertain regarding the most optimal choice of treatment. It also remains unclear whether psychological interventions are most effective when delivered alone, or in conjunction with non-psychological co-interventions (e.g., exercises), for improving health outcomes in this population, representing further important gaps in the evidence.

Network meta-analysis is a statistical method which allows for the comparison and ranking of numerous interventions simultaneously, to determine the most effective interventions for a health condition of interest.[120] Identifying the most effective and safe psychological intervention for improving key outcomes for patients with low back pain, such as physical function, pain intensity, fear-avoidance, and health-related quality of life, may support clinical decision-making about their use. Chapters Four and Five of this thesis describe the protocol and results of a systematic review of 97 randomised controlled trials, incorporating network meta-analysis, investigating the comparative effectiveness, sustainability of treatment effectiveness, and safety of psychological interventions for adults with chronic non-specific low back pain. Briefly, in this review, psychological interventions were classified into five main categories: behavioural therapy-based interventions, cognitive behavioural therapy-based interventions, mindfulness-based interventions, counselling-based interventions, and pain education-based interventions. Definitions of these categories are summarised in Chapter Four, and the main findings of the review are reported in Chapter Five. Guided by ongoing gaps in knowledge identified in Chapter Five – specifically, that there is a lack of high-quality randomised controlled trials investigating counselling-based interventions (i.e., lifestyle interventions) – subsequent chapters in this thesis aimed to examine the role of lifestyle interventions for improving health outcomes and/or reducing health service utilisation in people with chronic non-specific low back pain.

Lifestyle interventions for chronic health conditions

With abundant evidence confirming the detrimental impact of negative lifestyle behaviours (e.g., physical inactivity, adverse nutrition, smoking) on the development of chronic illnesses, lifestyle interventions have gained increasing attention for their role in health management.[121, 122] Lifestyle interventions typically incorporate a variety of psychological interventions or strategies with health education on disease physiology, wellness-promoting dietary intake, and physical activity.[122, 123] The goal of lifestyle interventions is to support, guide, and motivate patients to change health and lifestyle behaviours to improve quality of life and achieve health-promoting goals.[124] There is evidence supporting the effectiveness and/or cost-effectiveness of lifestyle interventions for improving a variety of weight, cardiometabolic, respiratory, dietary, or physical activity outcomes in children with obesity[125] and adults with a range of health conditions (e.g., diabetes, cardiovascular disease, obesity, stroke).[126-131] Lifestyle interventions targeting physical outcomes can also lead to benefits in mental health and wellbeing in healthy individuals and in people with physical or mental health conditions (e.g., depression, anxiety).[132] Given that the current approaches (e.g. pain medication, spinal surgeries) for managing low back pain are suboptimal for achieving sustainable health outcomes, lifestyle interventions may be a viable and cost-effective solution to reduce health service utilisation in people with chronic low back pain.

Lifestyle interventions for chronic low back pain

Current hospital-based treatment approaches for managing low back pain appear to fall short in relation to the lack of support available for patients after they are discharged from formal health care. There is consistent evidence demonstrating that patients with low back pain desire the availability or awareness of support services after the cessation of treatment.[133, 134] Beyond pain relief, patients also value support which addresses activity limitations, participation with usual social roles, and improvements in quality of life and mood.[48] However, consumers with low back pain from a major tertiary public hospital in metropolitan Sydney, Australia have indicated that the lack of a co-ordinated system supporting patients after the cessation of treatment is a strong factor driving the pattern of patients returning to the health care system for further treatment (unpublished New South Wales hospital consumer committee report). Expanding on this, a qualitative study conducted within the same public hospital has found that patients with low back pain desire

support and guidance to self-manage their condition safely, over the long term, which may include psychological support provided alongside physical treatments.[47] As described earlier, the focus of lifestyle interventions is to support, guide, and motivate patients to achieve sustainable behaviour change. Therefore, incorporating physical-activity focused lifestyle interventions into the discharge care pathway for patients with low back pain may support better self-management of the condition within the community. In turn, this may reduce patients' reliance on the health care system for further treatment.

Health coaching programs are an integral part of lifestyle interventions. Although the definition of health coaching varies, these programs typically involve the practice of health education and health promotion,[135] to support individuals to achieve positive health behaviour change.[136] Health coaching programs are patient-oriented and are delivered by qualified individuals called health coaches, who utilise motivational interviewing, stage-based motivational counselling, and facilitative counselling techniques and approaches to guide sustainable improvements in health.[137] These programs are strongly grounded in behaviour-change theories such as Social Influence Theory and the Transtheoretical Model of Behaviour Change.[138] Social Influence Theory describes the process by which an individual's thoughts, attitudes, or behaviours change as a result of interactions with another individual or group.[139] The Transtheoretical Model of Behaviour Change is commonly used to describe the phenomenon that health behaviour change occurs through six stages: pre-contemplation, contemplation, preparation, action, maintenance, and termination.[140] Health coaches aim to assist patients with identifying the factors which contribute towards their current health behaviours, and align their coaching strategies with the patient's current stage of change, to optimise successful health behaviour change.

There is evidence to suggest that health coaching is effective for improving outcomes for a variety of health conditions. A systematic review of 13 studies has shown that health coaching has positive effects of motivating lifestyle behaviour changes in people living with chronic diseases (e.g., chronic pain, rheumatoid arthritis, depression, mobility impairments, diabetes, obesity, coronary disease, cancer).[141] The benefits include improvements in physical health status and physical activity levels, as well as improving self-efficacy, mental health status, and social support.[141] Results from a study also supports a lower rate of outpatient and overall health service expenditure (i.e., across inpatient, outpatient, emergent,

and prescription drug services) in high-risk individuals (i.e., patients with diabetes or cardiovascular disease) participating in a health coaching program, compared with matched controls who did not.[142]

A previous systematic review conducted in 2014 aimed to investigate the effectiveness of health coaching interventions for patients with low back pain.[143] The review identified four relevant studies – three randomised controlled trials and one cluster randomised control trial –of which only one trial limited their inclusion criteria to patients with low back pain of chronic duration.[144] This study concluded that the addition of motivational enhancement treatment to conventional physiotherapy care resulted in greater improvements in motivation, exercise compliance, and physical function, in patients with chronic low back pain, compared with conventional physiotherapy care alone.[144] Whilst these findings are promising, health care utilisation was not assessed as an outcome in this study.[144] It is clear that further high quality randomised clinical trials investigating the effectiveness of health coaching interventions on patient outcomes, including health care utilisation, in people with chronic non-specific low back pain, are warranted.

Lifestyle interventions to reduce health service utilisation for low back pain

Lifestyle interventions such as health coaching programs have the potential to positively affect health care utilisation in people with chronic non-specific low back pain. There is preliminary evidence available from the IMPACT study (2019), a pilot randomised controlled trial investigating the effectiveness of a mobile-health supported physical activity intervention introduced at discharge from treatment for chronic non-specific low back pain.[145] The IMPACT pilot study found that telephone-based health coaching programs are acceptable to people with low back pain, can improve physical activity levels, and may reduce the rate of care-seeking (i.e., use of health services and self-management strategies) for low back pain by 38% [95% confidence interval 0.32 to 1.18], compared with usual care.[145] Thus, health coaching programs may be a viable solution to support people with low back pain to remain physically active, improve self-management of their symptoms, and specifically, reduce the overutilisation of health services for low back pain.

In Australia, the Get Healthy Information and Coaching Service® (Get Healthy Service) delivers a variety of telephone-based health coaching programs for adults with a range of

health conditions in the Australian states of New South Wales and South Australia (https://www.gethealthynsw.com.au).[146] Introduced in 2009, the Get Healthy Service® is a well-established and fully operational service which is funded by state governments and is available at no charge for state residents. The goal of the Get Healthy Service® is to improve and support an individual's capacity to self-manage their own health and wellbeing. The service currently offers a *Standard (health) Coaching* module which supports participants with goal setting, motivation, confidence to overcome barriers, and achievement of sustainable lifestyle changes (i.e., increased physical activity levels, reduced sedentary behaviour). Participants receive up to 10 individually tailored health coaching calls, delivered according to participant preference, over six months. The Get Healthy Service® is a readily implementable public health coaching service which has strong potential to bridge the gap in the clinical care pathway for patients with low back pain – namely, the patients' perceived lack of support available in the community after discharge from formal treatment.

Previous studies have shown that the Get Healthy Service® is effective in improving moderate and vigorous physical activity levels and reducing behavioural risk factors for chronic diseases (i.e., weight, waist circumference, body mass index, nutrition-related behaviours) in the general population.[23, 24] To date, it appears there are two randomised controlled trials investigating the effectiveness of the Get Healthy Service® for improving health outcomes in people with chronic non-specific low back pain. The results of one study has not yet been published;[147] although, the protocol paper does not indicate that an assessment of intervention effect on the use of medical or health services for low back pain will be performed. The completed study investigated the effectiveness of a healthy lifestyle intervention, incorporating the Get Healthy Service®, in people with chronic low back pain, and reported no effect on pain intensity, disability, physical activity, or health care use (assessed as health care utilisation over the past 6 weeks preceding assessment).[148] However, adherence to treatment was poor in this study, and the study population was selected from a waiting list for consultation with an orthopaedic specialist.[148] There are currently no published randomised clinical trials investigating the effectiveness and cost-effectiveness of systematically integrating the Get Healthy Service® at discharge from formal treatment for chronic non-specific low back pain, to support patients with self-

managing their symptoms in the community and potentially reduce their future utilisation of medical, hospital, or health services for the condition.

Chapters Six, Seven and Eight of this thesis aimed to address this gap in evidence and knowledge. In Chapter Six, the protocol of a randomised controlled trial (Get Back to Healthy trial) investigating the effectiveness and cost-effectiveness of introducing a coordinated support system at discharge from low back pain treatment, on the future use of hospital, medical, and health services for low back pain, compared with usual care provided at discharge, is presented. The unprecedented COVID-19 pandemic has caused significant delays in the progress of the trial, disrupting recruitment and data collection, and precluding completion of a planned interim statistical analysis intended for inclusion in this thesis. In lieu of the results for the interim statistical analysis, Chapter Seven provides a preliminary report on the progress made during the early implementation phase of the trial, as well as preliminary findings from the trial. In accordance with the University of Sydney requirements of a thesis submitted under emergency conditions, Chapter Seven also outlines the proposal of the planned interim statistical analysis, which will be completed once sufficient data are available. Chapter Eight provides a commentary of the lessons learned from the early implementation phase of the Get Back to Healthy trial, to bring awareness to the complexity of conducting a large multi-site clinical trial, involving multi-sector stakeholders and a lifestyle intervention delivered by an established public health service, during a global pandemic.

OBJECTIVES OF THE THESIS

The broad aim of this thesis was to investigate the health and lifestyle factors influencing health care utilisation for low back pain, and to examine the role of psychological interventions (including lifestyle interventions) for improving health outcomes and/or reducing health service utilisation in people with chronic non-specific low back pain. This thesis reports on a series of studies which were conducted to address this aim.

The specific aims were to:

1. To identify health and lifestyle factors associated with patients seeking care for low back pain **(Chapters Two and Three)**
2. To investigate the comparative effectiveness and safety of psychological interventions for improving health outcomes in patients with chronic low back pain **(Chapters Four and Five)**
3. To evaluate the effectiveness of introducing a lifestyle intervention, involving health coaching, into the discharge care pathway for patients with low back pain to reduce the use of health services for low back pain and improve health outcomes **(Chapters Six, Seven, and Eight)**

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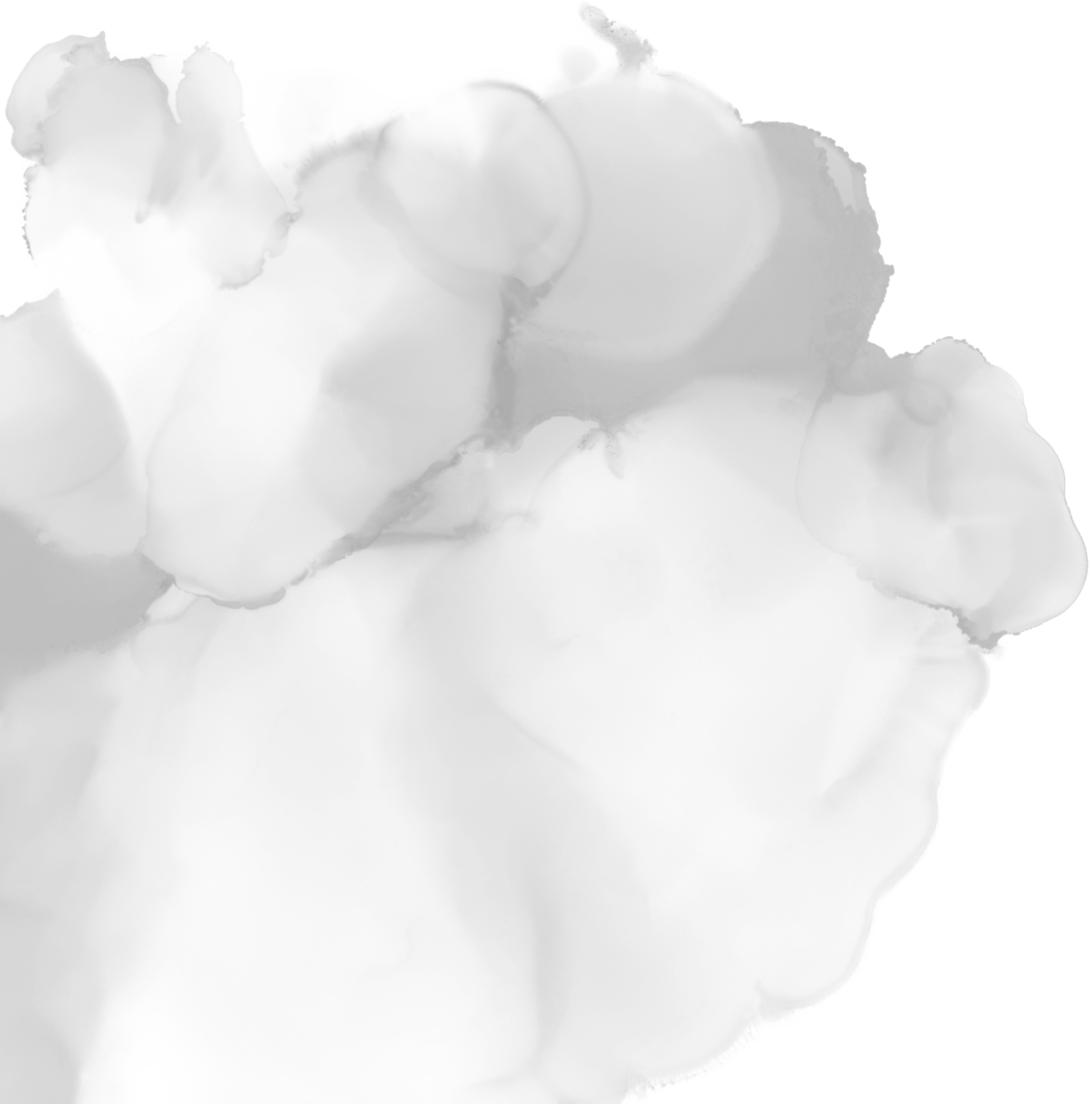
CHAPTER TWO



Factors associated with seeking medical care for low back pain in a twin adult sample

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AUTHORSHIP STATEMENT

The co-authors of the paper "Ho E, Ferreira M, De Barros Pinheiro M, Carvalho-E-Silva A, Madrid-Valero J, Zadro J, Ordoñana J, Ferreira P. Factors associated with seeking medical care for low back pain in a twin adult sample. *European Journal of Pain,* 2021;00:1–16. doi: 10.1002/ejp.1731" confirm that Emma Kwan-Yee Ho has provided the following contributions to the study:

- conception and design of the research
- data analysis and interpretation of findings
- writing of the manuscript and critical appraisal of the content

As the primary supervisor for the candidate upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

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Factors associated with seeking medical care for low back pain in a twin adult sample

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Abstract

Background: Previous studies have only investigated how symptom presentation and socio-demographic factors influence care-seeking for low back pain (LBP). However, the influence of health and lifestyle factors remains unclear, and the potential confounding effects of aggregated familial factors (including genetics and the early shared environment) has not been considered extensively.

Methods: A cross-sectional analysis was performed on 1605 twins enrolled in the Murcia Twin Registry (Spain). The outcome was seeking medical care for LBP and various self-reported demographic, health and lifestyle factors were considered predictors. All variables except sleep quality and diabetes were collected in 2013, which were cross-referenced from 2009 to 2010. A multivariate logistic regression model was performed on the total sample, followed by a co-twin case–control analysis.

Results: The only significant factor found to increase the odds of seeking medical care for LBP without being affected by familial factors was poor sleep quality (total sample OR = 1.58, 95%CI 1.24–2.01; case–control OR = 1.75, 95%CI 1.14–2.69). The factors that were associated with reduced odds of seeking medical care for LBP and not confounded by familial factors were male sex (case–control OR = 0.55, 95%CI 0.33–0.93), alcohol intake (case–control OR = 0.90, 95%CI 0.82–0.99) and a history of diabetes (case–control OR = 0.50, 95%CI 0.25–0.97). No other factors significantly influenced medical care-seeking for LBP.

Conclusions: People reporting poor sleep quality are more likely to seek medical care for LBP in the long term, with this relationship being independent from aggregated familial factors. Conversely, males, people reporting higher alcohol intake, and people with a history of diabetes are less likely to seek medical care for LBP.

Significance: This is the first study investigating the factors that influence seeking medical care for LBP, while adjusting for the influence of familial factors using a co-twin control design. Poor sleep quality is associated with seeking medical care for LBP in the long term and does not appear to be confounded by familial factors. Early screening for indicators of poor sleep quality and appropriate referral to interventions for improving sleep quality or reducing pain in sleep may improve LBP management.

1 | INTRODUCTION

Low back pain (LBP) is a highly common condition, prevailing as the leading global cause of years lived with disability (James et al., 2018). Total cost estimates for LBP vary depending on the approach employed for synthesizing available cost data. For example, it is estimated that the total cost for LBP in the United States may range between US$19.6 and $118.8 billion, or between US$84.1 and $624.8 billion (Dagenais et al., 2008). Nevertheless, it is clear the economic burden of LBP is substantial in the United States and globally (Dagenais et al., 2008).

While most episodes of LBP resolve acutely, one-third of sufferers will experience recurrent and chronic pain (Machado et al., 2017). Surprisingly, less than half of chronic LBP sufferers will seek care for the condition (Ferreira et al., 2010; Walker et al., 2004). Nevertheless, those who choose to seek care account for a dominant proportion of the high costs associated with LBP (Walker et al., 2004). This may be due to an overdiagnosis of LBP (Stewart et al., 2015) and overprescription of medical management (e.g., diagnostic imaging, analgesics, spinal surgery) for the condition, despite evidence suggesting medical care does not necessarily lead to better patient outcomes (Chaparro et al., 2013; Flynn et al., 2011; Machado et al., 2017; Machado et al., 2015; Rosenblum et al., 2008; Shaheed et al., 2016). Therefore, recognizing the factors that influence seeking medical care in people with LBP is crucial to ensure that patients receive appropriate high-quality care and reduce unnecessary expenses associated with the excessive use of medical services.

Previous studies have only investigated how symptom presentation (i.e., disability levels, pain intensity, previous history of LBP) and socio-demographic factors can influence seeking care in people with LBP (Ferreira et al., 2010). However, the influence of health and lifestyle factors linked to LBP remains underinvestigated and unclear. Furthermore, the potential confounding effects of aggregated familial factors (including genetics and the early shared environment) have also not been considered extensively. Heritability studies have demonstrated that genetic factors account for between 21% and 67% of the variance of LBP, with the effect of genetic influence seemingly higher in more chronic and disabling LBP compared to acute and less disabling presentations of LBP (Ferreira et al., 2013; Zorina-Lichtenwalter et al., 2016). The wide range of the heritability estimates for LBP is likely a consequence of variations in the heritability analyses employed, methods used to assess LBP and populations investigated (i.e., estimates vary depending on country and age group examined) across these studies (Ferreira et al., 2013). Furthermore, familial factors play an important role in explaining population differences in the prevalence of health conditions and symptoms associated with LBP, such as diabetes (Carlsson et al., 2007; Willemsen et al., 2015), obesity (Nielsen et al., 2015), depression and anxiety (Boomsma et al., 2005; Khan et al., 2020) and sleep quality (Madrid-Valero et al., 2019). There is also a moderate influence of early shared environmental factors on lifestyle choices such as smoking (Avenevoli et al., 2003; Unger et al., 2004) and physical activity engagement (Horn et al., 2007). Evidently, familial factors influence LBP and various demographic, health and lifestyle factors associated with the condition. As such, to gain a more accurate estimation of the influence of various demographic, health and lifestyle factors on seeking medical care for LBP, the potential confounding effects of aggregated familial factors must be considered.

Therefore, the aim of this study was to investigate the extent to which demographic, health and lifestyle factors are associated with seeking medical care for LBP, while adjusting for the influence of aggregated familial factors (including genetics and the early shared environment) using a co-twin case–control design.

2 | METHODS

2.1 | Design and study population

The sample for this observational cross-sectional study included twins enrolled in the Murcia Twin Registry (MTR), which is a population-based register of people born in multiple births from 1940 to 1976, and resident in the region of Murcia (Southeast of Spain). Twins included in the MTR are periodically invited to answer a compilation of self-reported questionnaires on demographic, health and lifestyle factors, collected together with additional information (e.g., biological samples, anthropometrical measures). Waves and procedures of twin identification, contact and data collection have been described elsewhere (Ordoñana et al., 2019; Ordonana et al., 2018). All variables included in this study were collected in 2013 except for information on sleep quality and diabetes, which was cross-referenced from 2009 to 2010 as no equivalent data was available in 2013. A total of 1605 individual twins provided data for this study. All procedures involved in this study were approved by the University of Murcia Ethics Committee.

2.2 | Zygosity ascertainment

To categorize whether twin pairs were monozygotic (MZ) or dizygotic (DZ), a zygosity assessment was performed using a purposefully designed 12-item questionnaire which focuses on the degree of resemblance and mistaken identity between twin pairs. DNA testing in 338 pairs confirms that this questionnaire corresponds well with zygosity in nearly 96% of cases (Ordoñana et al., 2013).

2.3 | Assessment of seeking medical care for LBP

The outcome of this study was seeking medical care for LBP, which was dichotomous (yes or no). We defined seeking medical care for LBP as the development of LBP to the extent where medical care was sought for the condition. To collect information on seeking medical care for LBP, first, we established the lifetime prevalence of LBP with the question: 'Have you ever suffered from chronic LBP?' This question originated from the Spanish National Health Survey (Spanish Statistical Office, 2012). Chronic LBP was defined as seasonal or recurrent episodes of pain in the lower back, lasting for at least 6 months. From the 1,609 individual twins who provided a response to the question, 1,016 twins reported 'no' and 593 twins reported 'yes' to having experienced chronic LBP. Twins who reported having experienced chronic LBP ($n = 593$) were asked a follow-up question: 'Did you seek medical help because of this pain?' Out of 593 twins, 589 twins provided a response to the follow-up question, with 55 twins responding 'no' and 534 twins responding 'yes.' Those who responded 'yes' to the follow-up question were considered as cases for seeking medical care for LBP (cases: total $n = 534$). We considered those who did not have a history of chronic LBP ($n = 1,016$), and those who reported having experienced chronic LBP but had never sought medical care for the pain ($n = 55$) to be controls (controls: total $n = 1,071$).

2.4 | Predictor variables

Age, sex, body mass index (BMI), smoking history, depression and anxiety, alcohol intake, history of heart disease, physical activity, diabetes, sleep quality and antidepressant use were variables which were regarded as having a potential effect on seeking medical care for LBP (predictor variables). Except for age and BMI, which were considered continuous variables, and alcohol intake, which was considered a polytomous variable, all other variables were entered into the analysis as dichotomous variables.

2.5 | BMI

It has been proposed that higher BMI (i.e., obesity) can increase the mechanical load and forces exerted on the lumbar spine during activity, which may predispose obese people to injury (i.e., LBP) (Shiri et al., 2010a). Interestingly, a longitudinal twin study has found that BMI is not associated with developing chronic LBP nor seeking care for the condition, even after adjusting for familial factors (Dario et al., 2017). Nonetheless, a meta-analysis of 33 studies has found that people with high BMI (i.e., overweight or obese populations) are more likely to seek care for LBP compared to people with normal BMI (Shiri et al., 2010a); therefore, we considered BMI as a possible predictor for seeking medical care for LBP to examine the relationship further. Thirty-eight percent of the sample provided self-reported measures of their height and weight. For the remaining sample (62%), standardized anthropometric measurements on weight, height, waist circumference and percentage body fat were collected by a blinded research assistant. BMI was calculated by dividing an individual's body weight in kilograms by the square of their height in metres.

2.6 | Smoking

Smoking is associated with the development of non-specific LBP (Goldberg et al., 2000; Shiri et al., 2010b) and is associated with seeking care for the condition (Shiri et al., 2010b). Goldberg et al. (2000) has summarized several plausible biological mechanisms to explain the relationship between smoking and LBP: for example, (i) smoking increases coughing activity, which increases intradiscal and intra-abdominal pressure and may potentially promote disc bulge and herniation; (ii) smoking diminishes bone mineral content, which is linked to the development of osteoporosis and back pain; (iii) smoking promotes fibrin deposition and scar formation, which may lead to chronic inflammation and back pain; and (iv) smoking reduces blood flow to vertebral bodies, which may adversely affect metabolic balances of intervertebral discs, accelerate degeneration and consequently increase spinal susceptibility to mechanical deformity and injuries. However, evidence supporting these proposed mechanisms remains conflicting and unclear. Nonetheless, given that smoking is related to developing and seeking care for LBP (Shiri et al., 2010b), and it is a well-established risk factor for comorbid conditions associated with chronic LBP (e.g., cardiovascular disease (Banks et al., 2019), diabetes (Willi et al., 2007)), we considered smoking history as a possible predictor for seeking medical care for LBP. Participants were questioned regarding their smoking history, with answers being recorded as: (1) Never smoker; (2) Occasional smoker; and (3) Current smoker. For occasional and current smokers, follow-up questions were asked: (i) 'Do you smoke now?' and (ii) 'Specifically in the last 3 months, how often have you smoked?' Answers were dichotomized as either ex-smoker/never smoked or current smoker.

2.7 | Depression and anxiety

Psychological factors have been shown to influence health consultation behaviours in patients with chronic musculoskeletal conditions (Uhlig et al., 2002). Furthermore,

psychosocial characteristics such as depression may contribute to the mechanisms of central sensitization in people with chronic LBP (Roussel et al., 2013); therefore, we considered depression and anxiety as a possible predictor for seeking medical care for LBP. The 'Depression and Anxiety' domain of the EuroQol-5dimension (EQ-5D) questionnaire was used to determine symptoms of depression and anxiety (Szende et al., 2014). Three options were provided to best describe the participant at the time of data collection: (1) 'I am not anxious or depressed'; (2) 'I am moderately anxious or depressed'; and (3) 'I am extremely anxious or depressed'. Responses were dichotomized as either having symptoms of depression and anxiety (i.e., those who responded with [2] or [3]), or not having symptoms of depression and anxiety (i.e., those who responded with [1]). The EQ-5D questionnaire has been validated in people with chronic pain (Obradovic et al., 2013).

2.8 | Alcohol intake

Alcohol consumption is associated with chronic and complex presentations of LBP (i.e., higher levels of comorbidities, worse symptoms) (Ferreira et al., 2013). Expanding on this, it has been found that individuals with chronic pain report high levels of alcohol use to manage acute pain symptoms (Alford et al., 2016), particularly in those experiencing more severe pain levels (Brennan et al., 2005). Given that people with LBP who experience higher pain and disability levels are more likely to seek care for LBP compared to those with lower pain and disability levels, it is plausible that alcohol intake may influence care-seeking for LBP. Therefore, we considered alcohol intake a possible predictor for seeking medical care for LBP. Alcohol intake was assessed according to the frequency of consumption. Answers were recorded as: (1) Nothing; (2) Once a year or less; (3) Sometimes/year; (4) Once a month (approximately); (5) Sometimes/Month; (6) Once a week; (7) Sometimes/week; or (8) Daily.

2.9 | History of heart disease

Chronic LBP is associated with a higher lifetime prevalence of coronary heart disease and myocardial infarction (Fernandez et al., 2016). Fernandez et al. (2016) has proposed several mechanisms to explain this relationship: for example, (i) disability and inactivity associated with LBP may contribute to the development of comorbidities, including heart disease; (ii) pain can affect mental health and trigger symptoms of depression and anxiety, which are psychological factors known to drive the chronicity of LBP; (iii) the presence of atherosclerosis in the abdominal aorta, which is common in people with LBP (Kauppila, 2009), may limit blood supply and nutritional exchange in lumbar intervertebral discs, promoting increased disc degeneration (Kurunlahti et al., 1999). Extending on this, with advancements in the medical innovations for heart disease (i.e., drug treatments, interventions, diagnostic technologies), it is plausible that people with comorbid heart disease and chronic LBP are more frequent users for medical services for both conditions. Therefore, we considered a history of heart disease as a possible predictor for seeking medical care for LBP. Participants were asked: 'Has your doctor ever told you that you have heart disease?' Responses were dichotomized as yes or no.

2.10 | Physical activity

Previous related studies have found that engagement in physical activity is associated with seeking care for LBP (Ferreira et al., 2010; Mortimer et al., 2003); therefore we considered physical activity as a possible predictor for seeking medical care for LBP. Participants provided self-reported responses to questions adapted from the Active Australia Survey (Brown et al., 2005) regarding engagement in vigorous and moderate physical activity. These questions have been described elsewhere (Zadro et al., 2017). In accordance with the World Health Organization guidelines on recommended physical activity (World Health Organization, 2010), participants who engaged in at least 150-min moderate-intensity or 75-min vigorous-intensity physical activity per week, accumulated in multiple bouts, were considered as meeting the physical activity guidelines.

2.11 | Diabetes

Type 2 diabetes is associated with severe chronic LBP (Dario et al., 2017). Although a direct causal pathway between the two health conditions remains unclear (Pozzobon et al., 2019), it has been suggested that typical physiological type 2 diabetes characteristics (i.e., premature accumulation of advanced glycation end-products and low-grade systemic inflammation) may lead to structural changes in intervertebral discs (Carvalho-E-Silva et al., 2020). Furthermore, poor glycaemic control, which is common in people with type 2 diabetes, has been found to impair tissue healing (Cho et al., 2015). Consequently, it is plausible that people with type 2 diabetes may experience accelerated onset of mechanical LBP and poorer recovery, which may predispose them to seek health care. Therefore, we considered diabetes as a possible predictor for seeking medical care for LBP. In 2009, participants were asked: 'Have you ever suffered diabetes?' If the answer was affirmative, two follow-up questions were asked: (i) 'Has it been diagnosed by a doctor?' and (ii) 'Did

you take medication for diabetes in the previous month?' Those who responded 'yes' to any of these questions were considered as having diabetes.

2.12 | Sleep quality

Sleep disturbances can adversely affect an individual's psychosocial and physical functioning, for example, impairing one's ability to manage stress (Kashani et al., 2012). The significant impact of poor sleep on an individual's life may consequently predispose them to seek health-care treatment. In fact, it has been found that sleep disturbances are highly prevalent in people who seek care for LBP (Alsaadi et al., 2011). Therefore, we considered sleep quality as a possible predictor for seeking medical care for LBP. In 2009, data on sleep quality was collected using the Spanish version of the Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989; Royuela A, 1997), an 18-item self-reported questionnaire assessing sleep disturbances in the last month. The total score is composed of a sum of scores in 7 different domains and ranges from 0 to 21, where a higher score indicates poorer sleep quality. Participants' responses were dichotomized based on a total PSQI score cut-off point of > 5, which has been shown to demonstrate high diagnostic sensitivity (89.6%) and specificity (86.5%) in distinguishing good and poor sleepers (Buysse et al., 1989).

2.13 | Antidepressant use

Antidepressants are commonly prescribed for patients who suffer from symptoms of depression and anxiety. Extending on the rationale described previously regarding depression and anxiety as a possible predictor for seeking medical care for LBP, we therefore also considered antidepressant use as a possible predictor. Participants were questioned regarding their antidepressant or stimulant use in the past month, with responses dichotomized (yes or no). Participants who answered 'yes' were asked follow-up questions to elucidate their reason for use, dosage, and whether the antidepressant or stimulant was medically prescribed.

2.14 | Data analysis

Descriptive statistics were conducted for all variables. A multivariate logistic regression, where the outcome variable (seeking medical care for LBP) and all predictive variables were simultaneously entered into the model, was conducted in two stages: total sample analysis and co-twin case–control analysis (Figure 1). Odds ratios (OR) and 95% confidence intervals (CI) were used to examine the strength of association between each predictor and seeking medical care for LBP, when adjusted for the effects of the other predictors in the model. Statistical analyses were conducted using Stata (version 14). A robust estimator was used to control for non-independence of data in the total sample.

2.15 | Stage one: Total sample analysis

A total sample analysis was conducted to investigate the association between all predictive variables and seeking medical care for LBP, with no adjustment for aggregated familial factors. Both complete and incomplete twin pairs were included in this analysis, regardless of whether they sought medical care for LBP (i.e., twins were analysed as individuals, rather than as pairs). Results from the total sample analysis were interpreted based on statistical significance, defined as $p < .05$.

2.16 | Stage two: Co-twin case–control analysis

A subsequent co-twin case–control analysis, which only included twin pairs who were discordant for seeking medical care for LBP, was conducted (Figure 1). The use of a co-twin case–control analysis allowed us to control for a variety of unmeasured aggregated familial background factors, for example, genetics and early shared environmental factors (e.g., socio-economic status, educational opportunities, neighbourhood) (Kendler et al., 1993; Vitaro et al., 2009). In theory, if the strength of association (i.e., magnitude of the OR) between a given predictor and outcome increased or remained significant from the total sample to the co-twin case–control

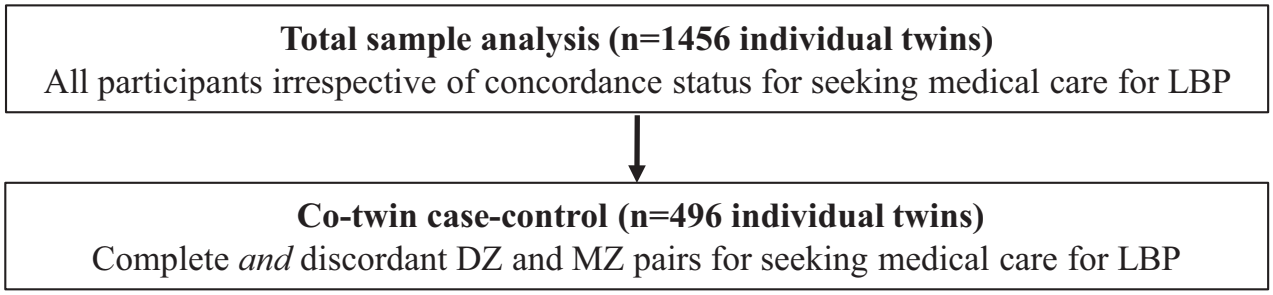

FIGURE 1 Statistical analysis schema. *LBP* = low back pain; *DZ* = dizygotic; *MZ* = monozygotic

analysis, this would suggest that the association between the two variables was not confounded by measured (data derived) and unmeasured (aggregated familial background) factors. In this case, the relationship between the two variables could be considered more direct (Vitaro et al., 2009). To avoid loss of power, we combined the samples of DZ and MZ twin pairs for the co-twin case–control analysis.

3 | RESULTS

3.1 | Sample Characteristics

A total of 1605 individual twins were included in this study. The characteristics of the total sample, including sex-stratified data, can be found in Table 1. Sample characteristics stratified by seeking medical care for LBP are reported in Table 2. Briefly, the total sample largely comprised of females (55%) and DZ twins (69.8%), and the mean age was 56.7 years (standard deviation (*SD*) 7.1) (Table 1).

Overall, the lifetime prevalence of chronic LBP in the total sample was 36.7%, and 90.7% of them (33.3% of the total sample) reported having sought medical care for the condition (Table 1). The lifetime prevalence of chronic LBP was slightly higher in females (38.8%) compared to males (34.1%); similarly, the proportions seeking medical care among those reporting LBP was higher in females (94.2%) compared to males (85.8%) (Table 1).

When the total sample was stratified by seeking medical care for LBP, the mean age (± *SD*) was similar across those who sought (56.8 ± 6.9 years) or had not sought medical care for their LBP (56.7 ± 7.3 years). Those who sought medical

TABLE 1 Characteristics of the total study sample (all and sex-stratified), including anthropometric data and lifestyle factors

	Total sample		Stratified by sex			
	All		Male		Female	
Variables	**Mean (*SD*)**	***n*/*n*(total)**	**Mean (*SD*)**	***n*/*n*(total)**	**Mean (*SD*)**	***n*/*n*(total)**
Lifetime prevalence of chronic LBP	36.7%	589/1605	34.1%	246/722	38.8%	343/883
Sought medical care for LBP	33.3%	534/1605	29.2%	211/722	36.6%	323/883
Proportion who reported a lifetime prevalence of chronic LBP and sought medical care for LBP	90.7%	534/589	85.8%	211/246	94.2%	323/343
Sex (male)	45.0%	722/1605	-	722	-	883
Age (years)	56.7 (7.1)	1605	56.4 (6.9)	722	57.0 (7.3)	883
Height (m)	1.6 (0.9)	1498	1.7 (0/7)	707	1.6 (0.7)	791
Weight (kg)	73.2 (13.8)	1569	80.7 (12.8)	712	66.9 (11.2)	857
BMI (kg/m^2)	27.3 (4.3)	1487	27.8 (3.9)	704	26.8 (4.6)	783
Zygosity						
MZ twins	30.2%	484/1605	31.2%	225/722	38.3%	338/883
DZ twins	69.8%	1121/1605	68.8%	497/722	61.7%	545/883
Smoking[a]	36.1%	579/1603	39.2%	283/722	33.6%	296/881
Depression and anxiety[b]	25.9%	415/1605	17.6%	127/722	32.6%	288/883
Alcohol intake[c]	60.6%	1598/1598	78.5%	565/720	45.9%	403/878
History of heart disease	8.4%	134/1601	9.7%	70/721	7.3%	64/880
Physical activity[d]	60.5%	962/1589	67.6%	480/710	54.8%	482/879
Diabetes	13.8%	220/1595	14.9%	107/718	12.9%	113/877
Poor sleep quality[e]	44.4%	713/1605	38.0%	274/722	49.7%	439/883
Taking antidepressants	8.7%	139/1605	4.0%	29/722	12.5%	110/883

Abbreviations: LBP, low back pain; MZ, monozygotic; DZ, dizygotic; *n*, number of individual twins; BMI, body mass index.

Values are reported as mean (SD), unless stated otherwise.

[a]Indicates current smokers

[b]Indicates being moderately/extremely depressed or anxious

[c]Indicates consuming alcohol at least once per week

[d]Indicates meeting the physical activity guidelines

[e]Indicates reporting poor sleep quality in the past month.

TABLE 2 Characteristics of the total study sample, including anthropometric data and lifestyle factors, stratified by seeking medical care for LBP

	Stratified by seeking medical care for LBP			
	Did not seek medical care		Sought medical care	
Variables	**Mean (*SD*)**	***n*/*n*(total)**	**Mean (*SD*)**	***n*/*n*(total)**
Lifetime prevalence of chronic LBP	5.2%	55/1071	100%	534/534
Sex (male)	47.7%	511/1071	39.5%	211/534
Age (years)	56.7 (7.3)	1071	56.8 (6.9)	534
Height (m)	1.6 (0.9)	1071	1.6 (1.1)	486
Weight (kg)	73.0 (13.5)	1049	73.4 (14.3)	520
BMI (kg/m^2)	27.1 (4.2)	1003	27.5 (4.5)	484
Zygosity				
MZ twins	36.7%	393/1071	31.8%	170/534
DZ twins	63.3%	678/1071	68.2%	364/534
Smoking[a]	36.7%	393/1070	34.9%	186/533
Depression and anxiety[b]	22.7%	243/1071	32.2%	172/534
Alcohol intake[c]	63.4%	677/1067	55.0%	292/531
History of heart disease	7.2%	77/1070	10.7%	57/531
Physical activity[d]	62.7%	664/1059	56.2%	298/530
Diabetes	13.5%	144/1065	14.3%	76/530
Poor sleep quality[e]	39.7%	425/1071	53.9%	288/534
Taking antidepressants	6.8%	73/1071	12.4%	66/534

Abbreviations: LBP, low back pain; MZ, monozygotic; DZ, dizygotic; *n*, number of individual twins; BMI, body mass index.

[a]Indicates current smokers

[b]Indicates being moderately/extremely depressed or anxious

[c]Indicates consuming alcohol at least once per week

[d]Indicates meeting the physical activity guidelines

[e]Indicates reporting poor sleep quality in the past month. Values are reported as mean (*SD*), unless stated otherwise.

care for their LBP had greater symptoms of depression and anxiety, lower alcohol intake, poorer sleep quality, and higher antidepressant intake compared to those who had not sought medical care for their LBP (Table 2).

From the total sample, complete data on all the predictive variables of interest were available for 1456 individual twins, which were entered into a multivariate logistic regression model (Table 3). From these 1456 individual twins, 496 individual twins (i.e., 248 twin pairs) were discordant for seeking medical care for LBP, of which 140 individual twins (i.e., 70 twin pairs) were MZ (28.2%) (Table 3).

3.2 | Sleep Quality

In the total sample analysis, the only variable that significantly increased the odds of seeking medical care for LBP was poor sleep quality (Table 3). Those who previously reported experiencing poor sleep quality in the last month were 58% more likely to seek medical care for LBP compared to those reporting better sleep quality (OR = 1.58, 95%CI 1.24–2.01, $p < .001$, $n = 1{,}456$). After controlling for aggregated familial factors in the co-twin case–control analysis, the odds of seeking medical care for LBP increased to 75% and the association remained statistically significant (OR = 1.75, 95%CI 1.14–2.69, $p = .01$, $n = 496$) (Table 3).

3.3 | Sex

In the total sample analysis, male sex was not significantly associated with reduced odds of seeking medical care for LBP (OR = 0.88, 95%CI 0.68–1.14, $p > .05$, $n = 1{,}456$). However, in the co-twin case–control analysis, male sex was significantly associated with 45% reduced odds of seeking medical care for LBP, after controlling for aggregated familial factors (OR = 0.55, 95%CI 0.33–0.93, $p = .03$, $n = 496$).

TABLE 3 Total sample and co-twin case–control analyses for seeking medical care for LBP

	All	
Variables	**OR (95% CI)**	***p***
Total sample analysis	($n = 1456$)	
Age (years)	0.99 (0.97–1.00)	0.17
Sex (male)	0.88 (0.68–1.14)	0.32
Body mass index	1.02 (0.99–1.05)	0.21
Smoking	0.94 (0.73–1.20)	0.61
Depression and anxiety	1.21 (0.92–1.60)	0.17
Alcohol intake	0.97 (0.93–1.01)	0.11
Heart disease	1.46 (0.97–2.21)	0.07
Physical activity	0.90 (0.71–1.14)	0.38
Diabetes	0.91 (0.64–1.27)	0.57
Poor sleep quality	1.58 (1.24–2.01)	**<0.001**
Taking antidepressants	1.42 (0.94–2.15)	0.10
Within-pair (DZ and MZ) case–control analysis	($n = 496$)[a]	
Sex (male)	0.55 (0.33–0.93)	**0.03**
Body mass index	1.03 (0.97–1.09)	0.29
Smoking	0.72 (0.45–1.15)	0.17
Depression and anxiety	0.86 (0.53–1.40)	0.53
Alcohol intake	0.90 (0.82–0.99)	**0.03**
Heart disease	0.82 (0.42–1.57)	0.54
Physical activity	0.83 (0.54–1.30)	0.41
Diabetes	0.50 (0.25–0.97)	**0.04**
Poor sleep quality	1.75 (1.14–2.69)	**0.01**
Taking antidepressants	1.86 (0.87–3.96)	0.11

Note: Abbreviations: LBP, low back pain; OR, odds ratio; CI, confidence interval; DZ, dizygotic; MZ, monozygotic; n, number of individual twins entered into the analysis.

Age and BMI are continuous variables; Sex, smoking, depression and anxiety, heart disease, physical activity, diabetes, poor sleep quality and taking antidepressants are dichotomous variables; Alcohol intake is a polytomous variable.

Estimates in bold denote significance at the 0.05 level.

[a]248 twin pairs were discordant for seeking medical care for LBP (70 MZ twins pairs, 178 DZ twins pairs).

3.4 | Alcohol Intake

In the total sample analysis, higher alcohol intake was not significantly associated with seeking medical care for LBP (OR = 1.46, 95%CI 0.97–2.21, $p > .05$, $n = 1{,}456$). However, after controlling for confounding by aggregated familial factors in the co-twin case–control analysis, we found that higher alcohol intake was significantly associated with 10% reduced odds of seeking medical care for LBP (OR = 0.90, 95%CI 0.82–0.99, $p = .03$, $n = 496$) (Table 3).

3.5 | Diabetes

In the total sample analysis, a previous history of diabetes was not significantly associated with seeking medical care for LBP (OR = 0.91, 95%CI 0.64–1.27, $p > .05$, $n = 1{,}456$). However, after controlling for confounding by aggregated familial factors in the co-twin case–control analysis, we found that a history of diabetes was significantly associated with 50% reduced odds of seeking medical care for LBP (OR = 0.50, 95%CI 0.25–0.97, $p = .04$, $n = 496$) (Table 3).

3.6 | Other predictive variables

No other variables were found to significantly influence seeking medical care for LBP in the total sample or co-twin case–control analyses (Table 3).

4 | DISCUSSION

4.1 | Summary of Results

This study found that even after controlling for aggregated familial factors (including genetics and the early shared environment), there was a persistent relationship between poor sleep quality and seeking medical care for LBP. We also found that after controlling for aggregated familial factors, male sex, higher alcohol intake and a history of diabetes were associated with reduced odds of seeking medical care for LBP. The other predictive variables examined did not significantly affect the odds of seeking medical care in people with LBP in the co-twin case–control analysis.

4.2 | Comparison to literature

It is difficult to compare our findings due to the limited availability of existing studies investigating the determinants of seeking medical care for LBP, coupled with the heterogeneity of lifestyle and health factors that have been investigated. In addition, our care-seeking variable only considered medical-related care and excluded care sought from other types of care providers (e.g., massage or acupuncture), which may have further contributed to difficulties in comparing our study findings (Mannion et al., 2013).

Nevertheless, our study demonstrated consistencies with the limited existing studies. Our study found that poor sleep quality was associated with seeking medical care for LBP. Similarly, Rhon et al. (2019) demonstrated that the comorbid presence of sleep disorders in people with LBP was significantly associated with increased health-care visits and costs associated with LBP. Furthermore, Alsaadi

et al. (2011) found that patients with LBP reporting sleep disturbances (e.g., poor sleep quality, non-restorative sleep, early awakenings and difficulty initiating and maintaining sleep) were twice more likely to be hospitalized compared to those who did not. These findings are echoed by Kaila-Kangas et al. (2006), who followed a cohort of Finnish industrial employees over 28 years and found that complaints of at least one sleep disturbance (i.e., difficulty falling asleep or waking at night, experiencing nightmares) was predictive of a 2.1-fold risk of back-related hospitalization compared to those with no sleep disturbances. Even in children and adolescents, a similar pattern is observed, with those visiting general practitioners for sleep problems more likely to seek medical consultations for musculoskeletal conditions in the future (Andreucci et al., 2020).

The association between poor sleep quality and an increased likelihood for seeking care for LBP is unsurprising, considering that sleep disturbances are highly prevalent (59%) in people who seek care for the condition (Alsaadi et al., 2011). We propose several explanations for the relationship identified between sleep quality and seeking medical care for LBP. First, it is well-established that sleep disturbances can adversely affect an individual's psychosocial and physical functioning. For example, sleep disturbances are associated with severely reduced quality of life (Kyle et al., 2010), impaired cognitive and emotional functioning such as reduced problem solving capacity (Fortier-Brochu et al., 2012) and ability to manage stress (Kashani et al., 2012), and poorer general mental health (Spiegelhalder et al., 2013). Sleep disturbances are also significantly associated with higher disability levels (Chien et al., 2015; Salo et al., 2010), a factor strongly associated with seeking care for LBP (Ferreira et al., 2010).

Given the significant adverse effects resulting from sleep disturbances, poor sleep quality may be independently associated with seeking medical care for LBP. Second, the robust bidirectional relationship between sleep disturbances and pain should be considered (Gerhart et al., 2016; Koffel et al., 2016; Wei et al., 2018), particularly as higher pain intensity is associated with an increased likelihood of care-seeking for LBP in adults (Beyera et al., 2019; Ferreira et al., 2010) and also for general musculoskeletal conditions in adolescents (Rathleff et al., 2013). In chronic pain populations, the relationship between sleep disturbances and pain has been shown to be both reciprocal and acutely reactive, for instance, a night of poor sleep quality is perceived to correspond with worse pain intensity experienced on the subsequent day, and vice versa (Wei et al., 2018). In addition, the reactive nature of this relationship appears to be stronger in people suffering from longer durations and more severe levels of sleep disturbances and pain (Wei et al., 2018). In the context of chronic musculoskeletal pain, the bidirectional relationship described between sleep and pain persists, such that changes in sleep complaints predict future changes in musculoskeletal pain, and to a lesser extent, changes in musculoskeletal pain predict future changes in sleep complaints (Koffel et al., 2016). Finan et al. (2013) echoes similar findings, emphasizing that sleep disturbances can worsen the long-term prognosis of existing musculoskeletal pain. Consequently, it seems plausible that sustained poor sleep quality may cause frequent and persistent fluctuations in pain and poorer overall recovery, leading to help seeking for LBP. The converse direction of effect may also be possible, such that worsening pain may cause poorer sleep quality and subsequently lead to care-seeking for the condition. This alternative is also explored in detail by Wei et al. (2018), however it appears that the effect of pain on sleep is not as responsive compared to the effect of sleep on pain. Third, it is also perceivable that latent factors may affect sleep quality, which may in turn increase the odds of seeking medical care for LBP. For example, higher BMI is associated with poorer sleep quality in men and women, even after controlling for genetic factors (Madrid-Valero et al., 2017). In addition, higher BMI is also associated with other sleep dimensions, such as shorter sleep duration, less sleep efficacy and shorter periods of deep sleep in women (Theorell-Haglöw et al., 2010). Furthermore, type 1 diabetes is associated with poorer sleep quality and higher prevalence of obstructive sleep apnoea in adults (Reutrakul et al., 2016), although we did not explore the possibility of latent factors in our present study. All in all, poor sleep quality is common in people who seek care for LBP and is associated with important symptom-related factors which may increase care-seeking for LBP. Consequently, the presence of persistent poor sleep quality may complicate the management of LBP. Interestingly, a twin study has found that although genetics plays a contributing role, the majority of covariance (57.5%) between sleep quality and LBP is largely attributable to unique environmental factors (Pinheiro et al., 2018). Therefore, considering the modifiable nature of sleep quality, earlier and frequent screening for indicators of poor sleep quality with appropriate referral to sleep interventions (i.e., interventions targeting improved sleep quality and reduced pain in sleep) may improve LBP management (Ho et al., 2019) and potentially reduce health-care utilization by people with chronic LBP.

Furthermore, similar to existing studies, we did not find an association between seeking care for LBP and various lifestyle and health factors. Consistent with Ferreira et al. (2010) and Mortimer et al. (2003), smoking history was not associated with seeking care for LBP in our study. Likewise, no statistically significant associations were found between BMI and seeking care for LBP (Dario et al., 2017; Ferreira et al., 2010; Mortimer et al., 2003). Although, our findings contrast with Shiri et al. (2010a), who found that

being overweight or obese is strongly associated with seeking care for chronic low back pain. Several reasons may explain why our findings differ from Shiri et al. (2010a). First, Shiri et al. (2010a) compared people with normal BMI against overweight or obese people. Notably, the BMI of our study population was considerably high, and the distribution was similar across those who did and did not seek medical care for LBP (27.5 ± 4.5kg/m^2 and 27.1 ± 4.2kg/m^2, respectively). Furthermore, given that aggregated familial factors (including genetics and the early shared environment) play an important role in explaining population differences in the prevalence of obesity (Nielsen et al., 2015), familial factors may confound the relationship between higher BMI and seeking care for LBP. This is confirmed by Dario et al. (2017), who found that obesity-related measures, including BMI, are not associated with developing chronic LBP nor seeking care for LBP, with or without adjustment for familial factors. This may also explain why we did not find any significant associations between these two variables in our study. Moreover, previous studies have also shown that the presence of comorbidities reduces the odds of care-seeking for LBP (Ferreira et al., 2010; Idowu et al., 2015). This may be partially explained by the iceberg phenomenon in disease epidemiology (Last et al., 2013), which describes the concept that many controllable health conditions often remain undetected by medical practitioners or are underreported by patients. For example, it is possible that medical practitioners are more likely to focus on the detection or management of more serious pathologies (i.e., cancer). Alternatively, patients may adopt a self-perception that LBP is less threatening to one's health or is more self-manageable compared to comorbid health conditions, and are therefore more likely to seek care for the comorbid condition instead (Hurwitz et al., 1999; Idowu et al., 2015). It has also been found that LBP patients with comorbidities are less likely to receive appropriate care for their LBP, compared to LBP patients who do not have comorbidities (Ramanathan et al., 2018). For example, LBP patients with one comorbid condition are less likely to be examined for the presence of red flags (e.g., fractures, cancer, infection), whereas those suffering from three or more comorbidities are at higher risk of being prescribed unnecessary medications and failing to receive appropriate advice for managing their LBP (Ramanathan et al., 2018). This pattern was mirrored by the significant inverse association we found between a history of diabetes and seeking medical care for LBP, highlighting the complexity of managing LBP in the presence of multimorbidities.

Moreover, associations observed between various demographic factors and seeking care for LBP in our study were also similar to existing literature. For example, consistent with previous studies (Campbell et al., 1996; Chenot et al., 2008), a greater proportion of females sought medical care for the LBP compared to men. This may be partially explained by the association that exists between female sex, and higher disability levels and more days of sick leave due to LBP (Chenot et al., 2008), or the trend of women generally consulting doctors more frequently compared to men (Campbell et al., 1996). Expanding further on sex-related observations, our study mirrored findings from Ferreira et al. (2010) which showed that males are less likely to seek care for LBP compared to females. Also similar to Ferreira et al. (2010), we did not identify any significant associations between age and seeking medical care for LBP in our study. This is in contrast with Campbell et al. (1996), who proposed a U-shaped distribution between age and doctor consultations for general health conditions, with children and elderly populations consulting doctors more frequently. The difference in findings may be due to Campbell et al. (1996) exploring overall health-related consultations, whereas our study and Ferreira et al. (2010) specifically focused on LBP populations. Even so, Rekola et al. (1993) investigated doctor consultations related to musculoskeletal conditions and found that visitation rates were highest between ages 45–54 years in men, and 55–64 years in women, with LBP being the most common reason for consultation in men aged 25–54 years. It is possible that these trends were not identified in our study due to our sample largely comprising of females and older people.

Some findings in our study differed also from results observed in previous literature. This discrepancy may be attributable to the fact that previous studies included a broader definition of care-seeking behaviour (i.e., not limited to medical care only). Furthermore, the epidemiology of LBP may also have influenced our findings, as the prevalence of LBP peaks at middle-age for males (age 40–49) (Hartvigsen et al., 2018), while our sample was mostly aged between 50 and 60 years old. In addition, it has been reported that those who engage in physical activity are more likely to seek medical care for LBP in adults (Ferreira et al., 2010; Mortimer et al., 2003). Even in adolescents who suffer from musculoskeletal conditions, it appears that higher physical activity levels are associated with seeking more health care (Paananen et al., 2011). However, the relationship between physical activity and seeking medical care for LBP was not observed in our study. This disparity may be due to differences in how physical activity has been assessed across our study and previous published literature. For example, Mortimer et al. (2003) assessed physical activity based on 'performing in sport activities' (yes or no) (Mortimer et al., 2003), and Paananen et al. (2011) assessed physical activity as a polytomous variable (i.e., hours spent participating in moderate-to-vigorous physical activity, defined categorically), while our study assessed physical activity with respect to meeting the World Health Organization guidelines (dichotomized as yes or no). Furthermore, we found that higher alcohol intake was associated with reduced odds of seeking medical care for

LBP, after controlling for aggregated familial factors. In the absence of recent studies investigating the relationship between alcohol intake and LBP care-seeking patterns, it is difficult to compare our findings. However, the inverse relationship between these two factors seems plausible. Literature suggests that alcohol intake is associated with LBP in LBP populations who exhibit alcohol consumption dependence, or have chronic and complex LBP presentations (i.e., suffer from comorbidities, worse symptoms) (Ferreira et al., 2013). Alcohol self-medication, which describes the practice of using alcohol to self-manage disorders or symptoms, is common in people with chronic pain as a means of managing acute pain symptoms (Alford et al., 2016), particularly in those suffering from more severe pain levels (Brennan et al., 2005). Alcohol self-medication is also common in people suffering from mood and anxiety disorders (Turner et al., 2018), and even in elderly populations (Aira et al., 2008). It is therefore conceivable that people with LBP who habitually consume alcohol, potentially as a form of self-management for LBP itself or other comorbid health conditions, are less likely to then seek medical assistance to manage their LBP. Although, given that moderate alcohol intake is associated with beneficial health effects, including lower chronic disease burden (Beulens et al., 2017) and reduced cardiovascular mortality (Zhao et al., 2017), the relationship between alcohol intake and care-seeking for LBP may only be important in populations who exhibit excessive alcohol consumption rates or suffer from comorbidities (Conner et al., 2009; Lai et al., 2015). Overall, the limited comparisons we have drawn highlight the need for more robust studies with large sample sizes, clearer definitions of care-seeking behaviour, and the inclusion of less-investigated lifestyle factors, to gain a better understanding of the factors associated with seeking care for LBP.

4.3 | Strengths and limitations

There were considerable strengths in this study. First, given that LBP is associated with common comorbidities such as heart disease (Fernandez et al., 2016) and diabetes (Dario et al., 2017), our study has extended on previous studies to include a wider variety of demographic, health and lifestyle factors which could potentially influence seeking medical care for LBP. Second, the use of a co-twin design involving discordant twin-pairs allowed us to approximate causal relationships, as this method naturally controls for a wide range of confounding aggregated familial factors (including genetics and the early shared environment) (Vitaro et al., 2009), which has been a limitation of previous related studies. We achieved this by conducting a two-stage analysis approach: a total sample analysis, followed by a co-twin case–control analysis. The staged approach was advantageous as it allowed us to first examine general associations within the study population without adjustment for aggregated familial factors. Out of the 11 predictors entered into the total sample analysis, only one factor (sleep quality) was significantly associated with seeking medical care for LBP. After controlling for familial factors using a co-twin case–control analysis, three additional factors became significantly associated with seeking medical care for LBP. Overall, the co-twin analysis identified one demographic (male sex), one lifestyle (alcohol intake) and two health (diabetes, sleep quality) factors related to seeking medical care for LBP. A possible explanation for the increase in statistically significant findings in the co-twin analysis, compared to the total sample analysis, relates to the different sex distribution in both samples and the overrepresentation of opposite-sex DZ pairs in the co-twin analysis. Given the higher prevalence of LBP in women, this may have caused some predictors to increase the strength of their initially non-significant association. Hence, assuming that genetic factors account for between 21% and 67% of the variance of LBP (Ferreira et al., 2013; Zorina-Lichtenwalter et al., 2016), and shared environmental factors play an important role in explaining population differences in the prevalence of health conditions and symptoms associated with LBP (Boomsma et al., 2005; Carlsson et al., 2007; Khan et al., 2020; Madrid-Valero et al., 2019; Nielsen et al., 2015; Repetti et al., 2002; Willemsen et al., 2015), the pattern of additional factors emerging as statistically significant findings in the co-twin case–control analysis is unsurprising. Importantly, our study highlights the importance of accounting for potential confounding by aggregated family factors when investigating factors associated with care-seeking behaviours for any health condition and elevates a twin approach as a useful tool to achieve this. In addition, there is evidence suggesting that familial context can influence an individual's help-seeking behaviour, through various mechanisms related to socialization (i.e., smaller family size, high educational level of both parents, families with children all under the age of 12) and shared circumstances (i.e., conjoint visits to general practitioners) (Cardol et al., 2006). By design, the co-twin case control analysis allows us to control for unmeasured early shared environmental factors. All in all, these strengths have provided us with a clearer understanding of the extent to which various factors influence seeking medical care for LBP.

The results of this study should be considered in the light of some limitations. Firstly, our measure of seeking care for LBP was relatively simplistic and only considered medical care. No data were available on the type or frequency of medical care utilized, or whether other care was sought (e.g., physiotherapist). Second, data included in this study was mostly self-reported, which relies on the

subjective interpretation of what constitutes as 'medical' care and other questions, and introduces the undesirable effects of recall bias. We also did not have data available on health beliefs, which has been reported as an important determinant for health care use in previous studies (Beyera et al., 2019; Szpalski et al., 1995). Furthermore, studies comparing subjective (i.e., self-reported) and objective measures (i.e., actigraphy) of sleep have shown that subjective measures are poor predictors of objective measures of sleep, particularly in older adults (Landry et al., 2015; Matthews et al., 2018). Although, it is important to note that subjective and objective measures of sleep appear to target different aspects of sleep quality, therefore self-reported measures seem to capture different dimensions of sleep (Buysse et al., 2008; Landry et al., 2015). Nonetheless, we utilized the Pittsburgh Sleep Quality Index to measure sleep quality, which has been shown to have good psychometric properties (i.e., internal consistency, reliability, construct validity) (Carpenter et al., 1998; Raniti et al., 2018) and is highly correlated with objective measures (i.e., actigraphy) (Boudebesse et al., 2014). Another limitation is that our sample size did not allow for stratified co-twin case–control analyses of discordant twin pairs by zygosity group (MZ, DZ). Consequently, we were unable to obtain additional information about the influence of genetic and early shared environmental factors. Lastly, data on sleep quality and diabetes were cross-referenced from 2009. However, Kaila-Kangas et al. (2006) argue that based on the prevailing association found between sleep disturbances and hospitalization for back-disorders over a 28-year follow-up period, there is a considerable degree of stability in poor sleep quality which may persevere over time. Therefore, it is reasonable to conclude that previous complaints of poor sleep quality may be related to seeking medical care for LBP in the long term.

Despite these limitations, this study is the first to comprehensively consider the influence of various health and lifestyle factors on seeking medical care for LBP, while adjusting for the confounding effects of aggregated familial factors (including genetics and the early shared environment) using a co-twin control design.

5 | CONCLUSION

Poor sleep quality is associated with seeking medical care for LBP in the long term, and the relationship is not confounded by aggregated familial factors. Males, people reporting higher alcohol intake, and people with a history of diabetes are less likely to seek medical care for LBP. These relationships are not confounded by aggregated familial factors. Interventions should aim to address these factors to reduce the high costs associated with seeking care for LBP and improve patient outcomes.

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CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

EKH drafted the manuscript. EKH, APC, JRO and PHF were involved in the conception and design of this study. JJMV and JRO were involved in acquisition of data. All authors were involved in the analysis and interpretation of data, discussed the results and critically commented on the manuscript, and approved the final version of the manuscript for publication.

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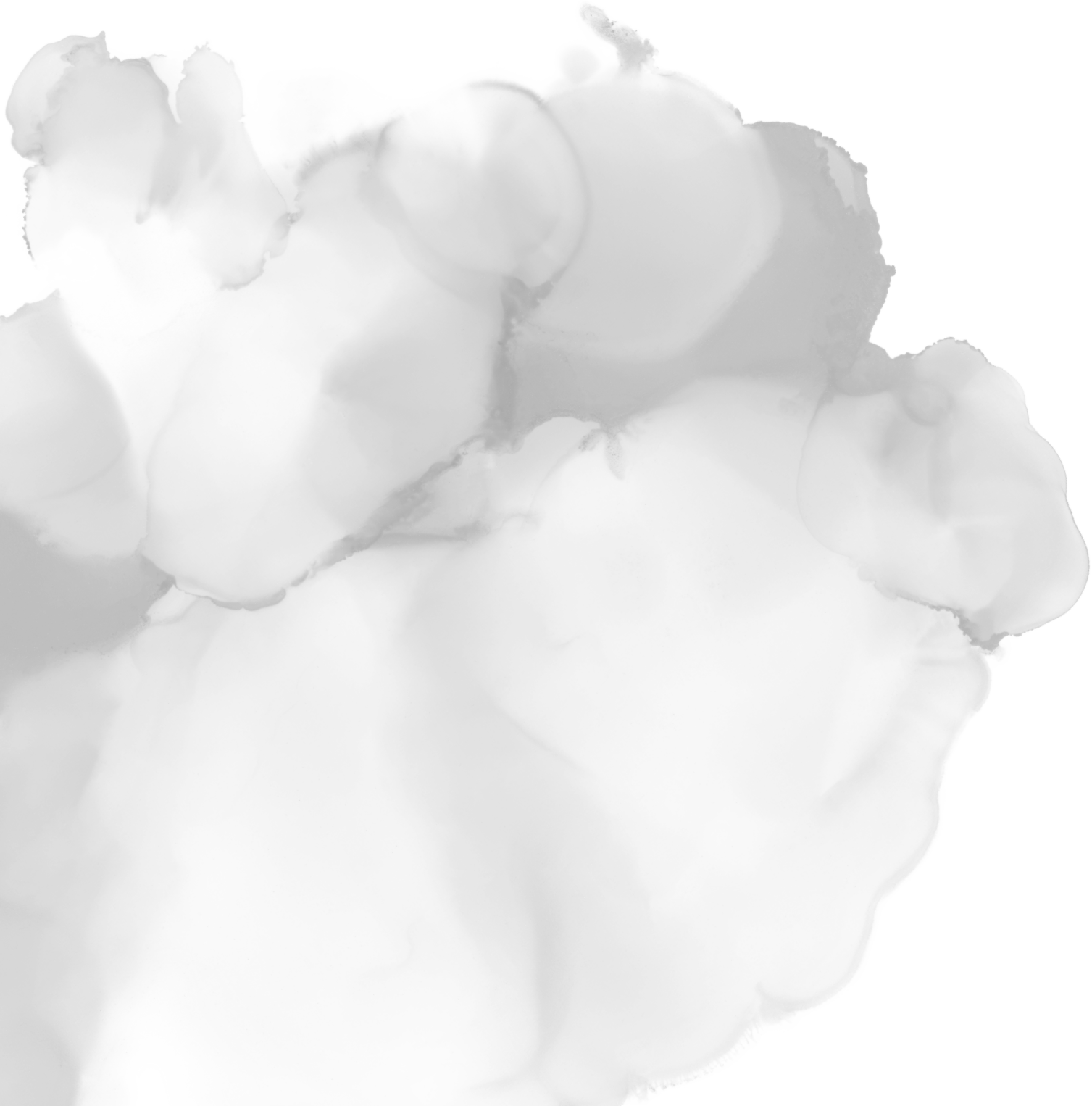
CHAPTER THREE



Beneficial and harmful effects of physical activity on care-seeking for low back pain

This study was submitted to the European Journal of Pain on 21st February 2022 and is currently under review.

AUTHORSHIP STATEMENT

The co-authors of the paper "Ho EK, Ferreira ML, Bauman A, Carvalho-e-silva A, Pinheiro MB, Hübscher M, Calais-Ferreira L, Simic M, Ferreira PH. Beneficial and harmful effects of physical activity on care-seeking for low back pain. *European Journal of Pain.* Under review" confirm that Emma Kwan-Yee Ho has provided the following contributions to the study:

- conception and design of the research
- data acquisition
- data analysis and interpretation of findings
- writing of the manuscript and critical appraisal of the content

As the primary supervisor for the candidate upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Paulo Ferreira
date: 16th April 2022

Beneficial and harmful effects of physical activity on care-seeking for low back pain

Physical activity and healthcare use for back pain

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Conflicts of interest

None declared.

Significance

Different intensities, volumes, and domains of physical activity have different effects on healthcare utilisation for LBP. Patients and clinicians should strategise ways to reduce harmful volumes of household physical activity or physical demanding work and increase engagement in moderate-to-vigorous intensity physical activity.

What's already known about this topic?

- Compared with those engaged in low volumes, people who engage in medium-to-high volumes of household domain physical activity or sedentary behaviour are at double the risk of utilising more care for low back pain (LBP), whilst people who engage in medium-to-high volumes of occupation-related physical workload are at approximately triple the risk of utilising more care for LBP.
- In contrast, the risk of utilising care for LBP appears to be approximately halved in people who engage in medium-to-high volumes of moderate-to-vigorous intensity physical activity.

What does this study add?

- Clinical guidelines are not clear regarding the specific amounts, intensities and domains of physical activity, or sedentary behaviour, that are harmful or beneficial for people with LBP.
- Patients and clinicians should collaborate to screen and develop strategies for modifying engagement in harmful volumes of domestic labour, physically demanding tasks at work, or sedentary behaviour, as these factors are indicators of poorer and potentially more complicated recovery from LBP (i.e., requiring greater use of care).
- Given the well-established health benefits of engagement in moderate-to-vigorous intensity physical activity, we recommend that patients and clinicians consider strategising ways to increase physical activity levels across these intensities, to improve clinical outcomes and reduce the use of care in people with LBP.

ABSTRACT

Objective: To investigate the relationship between different intensities, volumes, and domains of physical activity and care-seeking behaviours, in people with a history of low back pain (LBP).

Methods: Longitudinal data from adult twins were drawn from the AUstralian Twin BACK study. The primary outcome was the total self-reported frequency (counts) of overall utilisation of care for LBP, over one year. Explanatory variables were device-based sedentary behaviour and moderate-to-vigorous intensity physical activity, and self-reported physical workload, and work, transport, household, and leisure domain physical activity, at baseline.

Results: Data from 340 individuals were included. Medium-to-high baseline volumes of household domain physical activity (risk ratio 2.09, 95% confidence interval 1.27 to 3.43) and physical workload (2.67, 1.20 to 5.94) were significantly associated with greater counts of overall care utilisation over one year. In contrast, medium-to-high baseline volumes of moderate-to-vigorous intensity physical activity appeared to be associated with fewer counts of overall care utilisation over one year (0.56, 0.32 to 1.01). No other explanatory variables were associated with the primary outcome.

Conclusion: People who engage in medium-to-high volumes of household domain physical activity or physically demanding tasks at work are more likely to utilise care for LBP, whilst engagement in medium-to-high volumes of moderate-to-vigorous intensity physical activity appears to halve the risk.

INTRODUCTION

Low back pain (LBP) is the highest contributor to disability in the world (James et al., 2018; Sebbag et al., 2019), imposing substantial economic burden on health systems. Low back pain is a leading reason for emergency departments presentations and admissions globally (Edwards et al., 2017), even though few cases constitute medical emergencies (Machado et al., 2018). For example, in 2019 to 2020, LBP was the principal diagnosis for 130,222 presentations to emergency departments in Australia, placing it in the top ten reasons for visits nationally (Australian Institute of Health and Welfare, 2020). Furthermore, despite their limited role in managing LBP, up to 30% of patients with LBP in family practice are prescribed opioids (Kao et al., 2014; Deyo et al., 2015; Kamper et al., 2020), and one in four receive imaging referrals (Rosenberg et al., 2015; Rizzardo et al., 2016; Downie et al., 2020; Kamper et al., 2020). Similarly, even without clear evidence for their effectiveness, interventional procedures are frequently performed to manage LBP (Machado et al., 2017) (i.e., in the United States, 488,000 spinal fusion surgeries were performed in one year alone (Weiss et al., 2014)). Understanding the factors associated with various care-seeking behaviours for LBP is important to reduce the burden of the condition on global health systems and society.

Previous studies have examined the impact of demographic, symptom-related, health, and lifestyle factors, on the use of care for LBP (Ferreira et al., 2010; Beyera et al., 2019). However, the relationship between physical activity or sedentary behaviour and the use of care for LBP remains unclear. To our knowledge, only two studies have investigated the relationship between physical activity and care-seeking for LBP. These studies have not confirmed an association between physical activity and care-seeking for LBP (e.g., the studies found no (Ho et al., 2021) or small and non-statistically significant associations (Mortimer et al., 2003) between physical activity and care-seeking for LBP). It is possible that this is a result of methodological limitations of previous studies, including the use of self-reported measures of physical activity only (Mortimer et al., 2003; Ho et al., 2021), single-domain measures of physical activity (i.e., sport participation) (Mortimer et al., 2003), and single-time measures of care-seeking behaviour (Mortimer et al., 2003; Ho et al., 2021). No studies have examined sedentary behaviour as a potential risk factor for care-seeking for LBP. Evidently, the available evidence for the relationship between sedentary behaviour or physical activity, and care-seeking for LBP, is limited and inconsistent.

World Health Organisation guidelines recommend that all adults should engage in 150 to 300 minutes of moderate-intensity, or 75 to 150 minutes of vigorous-intensity physical activity, or equivalent combinations of moderate and vigorous-intensity aerobic physical activity, per week (World Health Organization, 2020). A reduction of sedentary behaviours across all age groups and abilities is also recommended (World Health Organization, 2020). However, clinical guidelines are not clear regarding the specific amounts and domains of physical activity that are harmful or beneficial for people with LBP. Given that physical activity and sedentary behaviour are modifiable lifestyle factors, improving understanding of the relationship between physical activity or sedentary behaviour and care-seeking associated with LBP will support the development of specific recommendations regarding these lifestyle factors for people with LBP. The aim of this study was to investigate the relationship between different amounts (i.e., intensities and volumes), and/or domains of physical activity or sedentary behaviour, and future care-seeking behaviours for LBP in people with a history of LBP.

PATIENTS AND METHODS

Design and study population

Data for this study were drawn from the AUstralian Twin BACK (AUTBACK) study, a longitudinal, observational cohort study which aimed to establish the relationship between physical activity and LBP outcomes (Carvalho-e-Silva et al., 2020). A detailed description of the design, variables, and procedures for recruitment and data collection have been described elsewhere (Pinheiro et al., 2016; Carvalho-e-Silva et al., 2020). Briefly, between 2015 to 2020, 401 participants were recruited from Twins Research Australia (Hopper et al., 2006). Participants were recruited from across urban, remote, or rural regions of Australia. Eligible participants were twins aged over 18, with internet access via computer or smartphone, and an active email account. Those with self-reported serious spinal pathology (e.g., inflammatory, metastatic, or infectious disease of the spine), recent history of spinal surgery (≤ 12 months), or pregnant women were excluded. Participants in the AUTBACK study were followed up for one year. At baseline and at 6-month follow-up, participants provided self-reported information on anthropometric measures (e.g., body mass index, height, hip and waist circumference), as well as health (e.g., smoking status, mental health, sleep quality), low back pain (e.g., prevalence, activity limitation, duration,

intensity, disability due to low back pain) and physical activity outcomes. At these timepoints, participants also provided device-based measures of physical activity, assessed with an Actigraph accelerometer. Furthermore, participants provided weekly self-reported data related to symptom presentation (e.g., severity of low back pain) and use of care (e.g., type and frequency of health care or self-management strategies utilised), for low back pain. Self-reported data on physical activity was also assessed monthly. Characteristics of the entire AUTBACK study cohort have been described elsewhere (Carvalho-e-Silva et al., 2020).

The current study examines the longitudinal relationship between different volumes of sedentary behaviour or physical activity at baseline, and various care-seeking behaviours for low back pain assessed over one year. Only participants who reported a lifetime prevalence of LBP, and also provided both baseline and weekly data, were included in the current study (n = 340).

Ethical approval

All study procedures were approved by Twins Research Australia and the University of Sydney Human Research Ethics Committee (Project No: 2015/407). All participants provided informed consent prior to data collection.

Assessment of lifetime prevalence of LBP

Out of 401 participants, baseline and weekly data were available for 398 participants. Out of these, 340 participants (86%) reported a lifetime prevalence of LBP, which was assessed via the question: “in your lifetime, have you ever had pain in your low back?” (yes/no).

Assessment of care-seeking behaviours for LBP (outcomes)

Data on care-seeking behaviours for LBP were collected on a weekly-basis over one year, via electronic questionnaires. Firstly, participants were asked if they experienced LBP in the past week (yes/no). Those who responded ‘yes’ were asked follow-up questions about their use of care for the current episode of LBP, including the specific categories and types of care utilised. Broadly, the different categories of care included health services, self-management strategies, and medications. The different types of health services of interest were general practitioners, physiotherapists, chiropractors, emergency departments,

surgical procedures, as well as 'other' health services. The different types of self-management strategies of interest were hot packs, bed rest, light exercise (e.g., walking), hot showers, or seeking information on internet and books, as well as 'other' self-management strategies. The different types of medications of interest were non-opioid medications, weak opioids, strong opioids, antidepressants, natural remedies, as well as 'other' medications. For each type of care utilised, participants were asked to indicate the frequency (number of days) of utilising each specific type of care (e.g., visitations to a general practitioner, use of hot packs, use of non-opioid analgesics) over the past seven days (Supplementary A).

The primary outcome of the study was the overall utilisation of care for LBP, defined as the total frequency (counts) of utilising any type of health services, self-management strategies, or medications, for a current episode of LBP, over one year.

The secondary outcomes were:

(i) Utilisation of health services for LBP: the total frequency (counts) of utilising any type of health services for a current episode of LBP, over one year.

(ii) Utilisation of self-management strategies for LBP: the total frequency (counts) of utilising any type of self-management strategies, for a current episode of LBP, over one year. This outcome excluded data on medication use.

Assessment of physical activity and sedentary behaviour (explanatory variables)

A detailed description of methods for assessing physical activity and sedentary behaviour in the AUTBACK study have been described elsewhere (Carvalho-e-Silva et al., 2020). For this study, we considered sedentary behaviour, moderate-to-vigorous intensity physical activity, physical workload, and work, transport, household, and leisure domain physical activity, at baseline, as our explanatory variables. The methods used to assess these variables are summarised in Supplementary A.

Assessment of covariates

The following variables were considered as possible covariates due to their potential to influence the prevalence or use of care for LBP (Ferreira et al., 2010; Shiri et al., 2010; Shiri et al., 2010; Beyera et al., 2019; Ho et al., 2021): sex, age, body mass index, smoking

history, recent episode of LBP at baseline (i.e., ≤ 4 weeks prior to baseline assessment), disability, sleep quality, depression, anxiety, and stress. Data on all covariates were collected via self-reported questionnaires administered electronically at baseline. The methods used to assess these variables are summarised in Supplementary A.

Statistical analysis

Descriptive statistics were conducted for all variables and presented as medians and interquartile ranges (IQR) due to non-normal distribution of the data. Firstly, we assessed univariable associations between covariates and each of the study outcomes. Except for sex (dichotomous), recent episode of LBP (dichotomous), and smoking history (categorical), covariates were analysed as continuous variables. To maintain statistical power, study outcomes were retained as count data. Only covariates which demonstrated a p-value < 0.10 in the univariable models were included in the final regression models (Supplementary B) (Bursac et al., 2008). We then performed negative binomial regression models to determine the association between physical activity or sedentary behaviour, and the study outcomes. Study outcomes were analysed as count data in separate models, for each of the seven explanatory variables. All 340 participants were included in all univariate and multivariate models, except for analyses of physical workload or work domain physical activity. For analyses of physical workload or work domain physical activity, we excluded participants who did not have a job (paid or unpaid) at baseline.

To contrast different volumes of physical activity or sedentary behaviour, each explanatory variable was categorised into tertiles (low, medium, and high volumes), then dichotomised as low or medium-to-high volumes (Supplementary C). Low volumes were considered as the reference group.

Adjusted incident risk ratios (IRR) and 95% confidence intervals (CIs) were used to describe the strength of association between the study outcomes and explanatory variables. To control for non-independence of data from complete twin pairs, a robust estimator of standard errors was used in all analyses. Mixed models were used to make efficient use of all available data points. Statistical significance was set at $p < 0.05$. All analyses were performed using Stata (version 14) (StataCorp, 2015).

RESULTS

Overall, 16,690 weekly questionnaires assessing LBP status and the use of care for LBP were completed across all participants included in this study, corresponding to a response rate of 94%. On average, participants completed 42 weekly questionnaires over a one-year period.

The baseline characteristics of the total study sample are presented in Table 1. The baseline characteristics of the total study sample, stratified by recent episode of LBP at baseline, are presented in Table 2. The total sample consisted of 340 twins, of which the majority were female (73%), monozygotic twins (65%), and non-smokers (82%). Median body mass index was 24.6 kg/m2 (IQR 22.1 to 28.2 kg/m2). Baseline levels of disability were low (Roland Morris Disability Questionnaire: median 0, IQR 0 to 2), despite 48% reporting a recent episode of LBP at baseline. Median total time engaged in sedentary behaviour and moderate-to-vigorous intensity physical activity at baseline was 3316 minutes/week (IQR 2852 to 3772 minutes/week), and 180 minutes/week (IQR 96 to 289 minutes/week) respectively.

Out of 340 participants included in the study, 160 reported a recent episode of LBP at baseline, with a median pain intensity of 3 (IQR 2 to 4) assessed on a Numeric Pain Rating Scale (where 0 indicates no pain, and 10 indicates worst possible pain). In terms of physical activity, moderate-to-vigorous intensity physical activity, leisure domain physical activity, and sedentary behaviour were slightly higher in participants who did not report a recent episode of LBP at baseline, compared with participants who did (Table 2). Conversely, work and household domain physical activity levels were higher in participants who reported a recent episode of LBP at baseline, compared with participants who did not (Table 2).

Overall utilisation of care for LBP

No statistically significant associations were found between sedentary behaviour and the overall utilisation of care for LBP over one year (see Table 3). Compared with low volumes, medium-to-high volumes of household domain physical activity at baseline were significantly associated with greater counts of overall care utilisation for LBP over one year (IRR 2.09, 95% CI 1.27 to 3.43, p = 0.004). Further, compared with low volumes, medium-to-high volumes of physical workload at baseline were significantly associated with greater

counts of overall care utilisation for LBP over one year (IRR 2.67, 95% CI 1.20 to 5.94, p = 0.016).

In contrast, compared with low volumes, medium-to-high volumes of moderate-to-vigorous intensity physical activity appeared to be associated with fewer counts of overall care utilisation for LBP over one year, with results approaching statistical significance (IRR 0.56, 95% CI 0.32 to 1.01, p = 0.054). No other explanatory variables demonstrated any statistically significant associations with overall utilisation of care for LBP over one year (see Table 3).

Utilisation of health services for LBP

No statistically significant associations were found between sedentary behaviour, or different intensities or domains of physical activity, and the utilisation of health services for LBP, over one year (see Table 4).

Utilisation of self-management strategies for LBP

Compared with low volumes, medium-to-high volumes of sedentary behaviour were significantly associated with greater counts of utilising self-management strategies for LBP over one year (IRR 1.60, 95% CI 1.02 to 2.50, p = 0.040). Compared with low volumes, medium-to-high volumes of household domain physical activity at baseline were significantly associated with greater counts of utilising self-management strategies for LBP over one year (IRR 1.62, 95% CI 1.04 to 2.53, p = 0.032). No other explanatory variables demonstrated any statistically significant associations with the utilisation of self-management strategies for LBP over one year (see Table 4).

DISCUSSION

Summary of findings

This is the first study to examine the relationship between different amounts (i.e., intensities and volumes), and/or domains of physical activity or sedentary behaviour, and various care-seeking behaviours for LBP. Our study demonstrated that people who engage in medium-to-high volumes of household domain physical activity (e.g., housework, gardening, yard work, general maintenance, caring for family members) at baseline utilise more overall care and self-management strategies, for LBP, over a one-year period. Further, people who

engage in medium-to-high volumes of physical workload at baseline utilise more overall care for LBP, whilst people who engage in medium-to-high volumes of sedentary behaviour at baseline utilise more self-management strategies for LBP, over a one-year period. On the contrary, people who engage in medium-to-high volumes of moderate-to-vigorous intensity physical activity at baseline may utilise less overall care for LBP, over a one-year period. There were no statistically significant associations between sedentary behaviour or physical activity, and the utilisation of health services for LBP.

Comparison with previous studies

In the absence of clear evidence for the relationship between physical activity or sedentary behaviour, and care-seeking behaviours for LBP, we compared our results to studies examining associations between physical activity or sedentary behaviour and the prevalence or risk of LBP. It has been consistently shown that higher engagement in strenuous work (Heuch et al., 2017), excessive occupational standing (Coenen et al., 2018), and awkward postures (i.e., bending, twisting, squatting, kneeling) (Amorim et al., 2019), lead to increased risk or prevalence of LBP. In our study, we found that medium-to-high volumes of physical workload resulted in greater utilisation of overall care for LBP over one year. We postulate that people who engage in higher volumes of physically demanding work are likely to experience greater role limitations due to LBP (i.e., diminished capacity to engage in work), which may precipitate greater utilisation of overall care for the condition. Interestingly, whilst work domain physical activity paralleled the positive relationship found between physical workload and care-seeking behaviours for LBP for overall care utilisation, findings were not statistically significant. This may suggest that, as opposed to the overall volume of any physical activity performed at work, it is the intensity and/or frequency of engaging in specific tasks or postures at work (e.g., heavy lifting, prolonged awkward body positions) which contribute to worse role limitations and precipitate greater utilisation of overall care for LBP.

Moreover, previous studies have demonstrated a positive association between heavy household physical activity and risk of LBP (Hübscher et al., 2014; Osinuga et al., 2021), with a recent systematic review with meta-analysis also showing that performing domestic labour in non-neutral postures increases the odds of LBP in women (Osinuga et al., 2021). In our study, we identified a positive relationship between household domain physical

activity and the use of care for LBP. Considering that people with LBP commonly report difficulties with performing household duties (i.e., disability in performing home chores or gardening) (Chou et al., 2018) and fulfilling social roles (Ahern et al., 2019), our hypothesis – worse role limitations (i.e., diminished capacity to fulfil domestic roles) precipitate greater utilisation of care – is plausible.

Furthermore, our findings mirror previous patterns observed in studies of moderate-to-vigorous intensity physical activity and leisure domain physical activity in people with LBP. Existing studies have identified an inverse relationship between moderate-to-vigorous intensity physical activity and the prevalence of LBP (Alzahrani et al., 2019). An inverse relationship has also been found between leisure domain physical activity and the prevalence of recurrent LBP (Alzahrani et al., 2019; Amorim et al., 2019), as well as pain and disability (Pinto et al., 2014). Whilst our findings were not statistically significant, we found a similar pattern: medium-to-high volumes of moderate-to-vigorous intensity physical activity appeared to be associated with less use of overall care and self-management strategies, for LBP, and leisure domain physical activity appeared to be associated with less use of overall care for LBP.

Despite evidence suggesting there is only a weak association between sedentary behaviour and LBP, which only appears to exist in females (Amorim et al., 2017; Balling et al., 2019), we found that people who were engaged in medium-to-high levels of sedentary behaviour utilised more self-management for LBP over one year. An overrepresentation of females in our study (73%) may have influenced these results. A lack of existing studies investigating the relationship between transport-related physical activity and LBP precluded comparison of our study findings (Alzahrani et al., 2019).

All in all, our findings are consistent with the occupational physical activity paradox which advocates that high work-related physical activity impairs health, whilst high leisure-related physical activity promotes health (Gupta et al., 2020). Interestingly, we found that the amount of physically demanding work, as opposed to overall volume of physical activity performed at work, was associated with greater utilisation of overall care for LBP. We also identified a consistent pattern between engagement in medium-to-high levels of household domain physical activity and the utilisation of more care for LBP. We propose that the

mechanism driving greater care utilisation for LBP, particularly self-management strategies, is the occurrence of worse role limitations (i.e., diminished capacity to fulfil occupational or household roles) due to engagement in higher volumes of physically demanding work or domestic labour.

Clinical Implications

Provision of advice to remain physically active and the prescription of exercise are the most commonly endorsed approaches for managing chronic LBP (Oliveira et al., 2018). However, clinical guidelines remain silent on the specific amounts, intensities, or domains of physical activity, or sedentary behaviour, which should be recommended or prescribed to patients. Our findings provide initial information to support clinical and occupational decision-making. Given that physical activity is a modifiable risk factor, patients and clinicians should collaborate to screen and develop strategies for modifying engagement in harmful volumes of physically demanding tasks at work, domestic labour, or sedentary behaviour, as these factors are indicators of poorer and potentially more complicated recovery from LBP (i.e., requiring greater use of care). Finally, our study identified a likely beneficial relationship between engaging in higher levels of moderate-to-vigorous intensity physical activity and leisure domain physical activity in people with a history of LBP. Given the extensive health benefits conferred by engaging in appropriate levels of moderate-to-vigorous intensity physical activity and leisure domain physical activity across the lifespan (Cheng et al., 2018; Dale et al., 2019; Lopez et al., 2019; Cunningham et al., 2020), patients and clinicians should consider ways to meet adequate physical activity levels across these intensities and domains, as they may be associated with better outcomes for LBP (i.e., requiring less use of care, potentially less role limitations due to LBP) (Gugusheff et al., 2020).

Strengths and limitations

This study has several strengths. Firstly, the AUTBACK study utilised device-based measures of moderate-to-vigorous intensity physical activity and sedentary behaviour. This is advantageous, since self-reported physical activity data may be prone to bias or misclassification (Øverås et al., 2020) (e.g., people with or without LBP tend to overestimate self-reported moderate-to-vigorous intensity physical activity and underestimate self-reported sedentary time) (Schaller et al., 2016; Gupta et al., 2018).

Although we encountered missing data, a common issue in longitudinal studies involving frequent repeated measures, the response rate in our study was high (94%) and the use of mixed models accounted for differences in response rates between participants. This allowed us to minimise the potential impact of recall bias. We also assessed a diverse range of commonly utilised health services or strategies for managing LBP, allowing us to perform disaggregated analyses based on the overall utilisation of care, the utilisation of health services only, and the utilisation of self-management strategies only, for LBP.

This study has some limitations. Firstly, we utilised self-reported measures of domain-specific physical activity in the absence of reliable device-based methods to separately assess these domains. Further, it has been shown that regional areas have fewer health services available per capita when compared with urban areas (Pain Australia, 2019). Whilst the AUTBACK study recruited participants from Australia-wide, analyses were not adjusted for geographical location of participants. This could be examined in a further study. Finally, sex and/or gender differences in the prevalence (Wu et al., 2020), severity (Chenot et al., 2008), and utilisation of care for LBP (Ferreira et al., 2010; Beyera et al., 2019) are well-established. Sex and/or gender differences also contribute to disparities in exposures to physical workload and domestic labour (Osinuga et al., 2021), and engagement in physical activity (van Uffelen et al., 2017). Whilst we adjusted our analyses for sex, we lacked statistical power to perform sex-disaggregated analyses.

CONCLUSION

Compared to those engaged in low volumes, people who engage in medium-to-high volumes of household domain physical activity or sedentary behaviour are at double the risk of utilising more care for LBP over one year, whilst people engaged in medium-to-high volumes of occupation-related physical workload are at approximately triple the risk of utilising more care for LBP over one year. In contrast, the risk of utilising care for LBP appears to be approximately halved in people who engage in medium-to-high volumes of moderate-to-vigorous intensity physical activity. Findings may improve clinical practice and guidelines regarding the harmful and potentially beneficial effects of different amounts, intensities, and domains of physical activity, or sedentary behaviour, on the use of care for LBP.

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AUTHOR CONTRIBUTIONS

EKH drafted the manuscript. PHF, MLF, MBP, and MH designed the study. PHF, MBP, LC, and APC supported implementation of the study. PHF, MLF, AB, and MH attracted funding for the study. EKH, PHF, and AB performed data analysis. All authors (EKH, MLF, AB, APC, MBP, MH, LC, MS, PHF) discussed, edited, and approved the final manuscript.

Table 1. Baseline characteristics of the total study population

Characteristic	Total sample Median (IQR)	n
Age (years)	56.4 (44.9 - 62.3)	340
Sex (male)	27% (n = 92)	340
Body Mass Index (kg/m^2)	24.6 (22.1 - 28.2)	335
Zygosity		340
Monozygotic	65% (n = 221)	
Dizygotic	35% (n = 119)	
Recent episode of LBP[a]	48% (n = 160)	334
Disability (0-24)	0 (0 - 2)	340
Depression (0 - 42)	2 (0 - 4)	340
Anxiety (0 - 42)	2 (0 - 4)	340
Stress (0 - 42)	6 (2 - 12)	340
Sleep quality (0 - 21)	6 (4 - 8)	187
Smoking history		337
Non-smoker	82% (n = 275)	
Ex-smoker	14% (n = 49)	
Occasional or current smoker	4% (n = 13)	
Sedentary behaviour (min/week)[b]	3316 (2852 - 3772)	313
Moderate-to-vigorous intensity physical activity (min/week)[b]	180 (96 - 289)	313
Physical Workload (0 - 62)[c]	9 (4 -15)	236
Work domain physical activity (MET-min/week)[c]	240 (0 - 2346)	251
Transport domain physical activity (MET-min/week)[c]	330 (33 - 809)	340
Household domain physical activity (MET-min/week)[c]	968 (300 - 2490)	340
Leisure domain physical activity (MET-min/week)[c]	729 (198 - 1755)	340

IQR: interquartile range; LBP: low back pain; MET: metabolic equivalent of task; min: minutes, n = total number of participants who provided data for each variable.

[a]Recent episode of LBP is defined as experiencing LBP ≤ 4 weeks prior to completion of baseline assessment.

[b]Device-based measures (assessed with an accelerometer).

[c]Self-reported measures (assessed with the long-form version of the International Physical Activity Questionnaire).

Table 2. Baseline characteristics, stratified by recent episode of LBP at baseline

	LBP at baseline[a]		No LBP at baseline	
Characteristic	**Median (IQR)**	**n**	**Median (IQR)**	**n**
Age (years)	56.9 (45.1 - 62.3)	160	56.1 (44.9 - 62.5)	174
Sex (male)	27% (n = 43)	160	28% (n = 48)	174
Body Mass Index (kg/m^2)	24.4 (21.8 - 27.5)	159	24.7 (22.5 - 28.4)	170
Zygosity		160		174
Monozygotic	70% (n = 111)		61% (n = 106)	
Dizygotic	30% (n = 49)		39% (n = 68)	
Disability (0-24)	2 (0 - 5)	160	0 (0 - 0)	174
Depression (0 - 42)	0 (0 - 4)	160	2 (0 - 4)	174
Anxiety (0 - 42)	2 (0 - 6)	160	2 (0 - 4)	174
Stress (0 - 42)	6 (2 - 14)	160	6 (2 - 10)	174
Sleep quality (0 - 21)	7 (5 - 9)	87	6 (4 - 8)	99
Smoking history		158		173
Non-smoker	82% (n = 129)		82% (n = 142)	
Ex-smoker	14% (n = 23)		14% (n = 25)	
Occasional or current smoker	4% (n = 6)		4% (n = 6)	
Sedentary behaviour (min/week)[b]	3300 (2799 - 3774)	148	3402 (2909 - 3743)	159
Moderate-to-vigorous intensity physical activity (min/week)[b]	166 (98 - 275)	148	185 (96 - 311)	59
Physical Workload (0 - 62)[c]	10 (4 -16)	114	9 (4 - 16)	159
Work domain physical activity (MET-min/week)[c]	594 (0 - 3900)	119	0 (0 - 579)	174
Transport domain physical activity (MET-min/week)[c]	321 (33 - 725)	160	330 (40 - 813)	174
Household domain physical activity (MET-min/week)[c]	1113 (340 - 2750)	160	748 (270 - 2445)	174
Leisure domain physical activity (MET-min/week)[c]	743 (212 - 1920)	160	767 (198 - 1680)	174

IQR: interquartile range; LBP: low back pain; MET: metabolic equivalent of task; min: minutes, n = total number of participants who provided data for each variable.

[a]Recent episode of LBP, defined as experiencing LBP ≤ 4 weeks prior to completion of baseline assessment.

[b]Device-based measures (assessed with an accelerometer).

[c]Self-reported measures (assessed with the long-form version of the International Physical Activity Questionnaire).

Table 3. The relationship between physical activity, sedentary behaviour, and overall care utilisation for LBP

		Overall care utilisation for LBP[a]		
Explanatory variable	**Volume**	**IRR (95% CI)**	***p***	**n**
Sedentary behaviour	Low	*reference*		169
	Medium-to-high	1.37 (0.77 - 2.46)	0.287	
By intensity of physical activity:				
Moderate-to-vigorous physical activity	Low	*reference*		169
	Medium-to-high	0.56 (0.32 - 1.01)	0.054	
Physical workload	Low	*reference*		120
	Medium-to-high	2.67 (1.20 - 5.94)	**0.016**	
By domain of physical activity:				
Work	Low	*reference*		131
	Medium-to-high	1.44 (0.79 - 2.64)	0.234	
Transport	Low	*reference*		186
	Medium-to-high	1.02 (0.59 - 1.76)	0.959	
Household	Low	*reference*		186
	Medium-to-high	2.09 (1.27 - 3.43)	**0.004**	
Leisure	Low	*reference*		186
	Medium-to-high	0.78 (0.44 - 1.38)	0.397	

CI: confidence interval; IRR: incident risk ratio; LBP: low back pain; n: number of participants. Estimates in bold are significant at $p < 0.05$. Each explanatory variable was analysed in separate models.

[a]Analysed as count data and adjusted for sex, recent episode of LBP, disability, sleep quality, and stress.

Table 4. The relationship between physical activity, sedentary behaviour, and the utilisation of health services or self-management strategies for LBP

		Use of health services[a]			Use of self-management[b]		
Explanatory variable	**Volume**	**IRR (95% CI)**	***p***	**n**	**IRR (95% CI)**	***p***	**n**
Sedentary behaviour	Low	*reference*		307	*reference*		307
	Medium-to-high	0.76 (0.37 - 1.58)	0.468		1.60 (1.02 - 2.50)	**0.040**	
By intensity of physical activity:							
Moderate-to-vigorous	Low	*reference*		307	*reference*		307
physical activity	Medium-to-high	1.55 (0.70 - 3.42)	0.277		0.70 (0.46 - 1.08)	0.106	
Physical workload	Low	*reference*		231	*reference*		231
	Medium-to-high	0.94 (0.40 - 2.22)	0.885		1.44 (0.82 - 2.53)	0.203	
By domain of physical activity:							
Work	Low	*reference*		246	*reference*		246
	Medium-to-high	1.22 (0.58 - 2.60)	0.602		0.91 (0.58 - 1.41)	0.668	
Transport	Low	*reference*		334	*reference*		334
	Medium-to-high	1.27 (0.64 - 2.53)	0.503		0.77 (0.52 - 1.13)	0.182	
Household	Low	*reference*		334	*reference*		334
	Medium-to-high	0.64 (0.28 - 1.48)	0.297		1.62 (1.04 - 2.53)	**0.032**	
Leisure	Low	*reference*		334	*reference*		334
	Medium-to-high	0.63 (0.30 - 1.34)	0.234		1.16 (0.75 - 1.80)	0.505	

CI: confidence interval; IRR: incident risk ratio; LBP: low back pain; n: number of participants. Estimates in bold are significant at $p < 0.05$. Each explanatory variable was analysed in separate models.

[a]Utilisation of health services for LBP, analysed as count data and adjusted for sex, recent episode of LBP, and disability.

[b]Utilisation of self-management strategies for LBP, analysed as count data and adjusted for sex, recent episode of LBP, disability, and stress.

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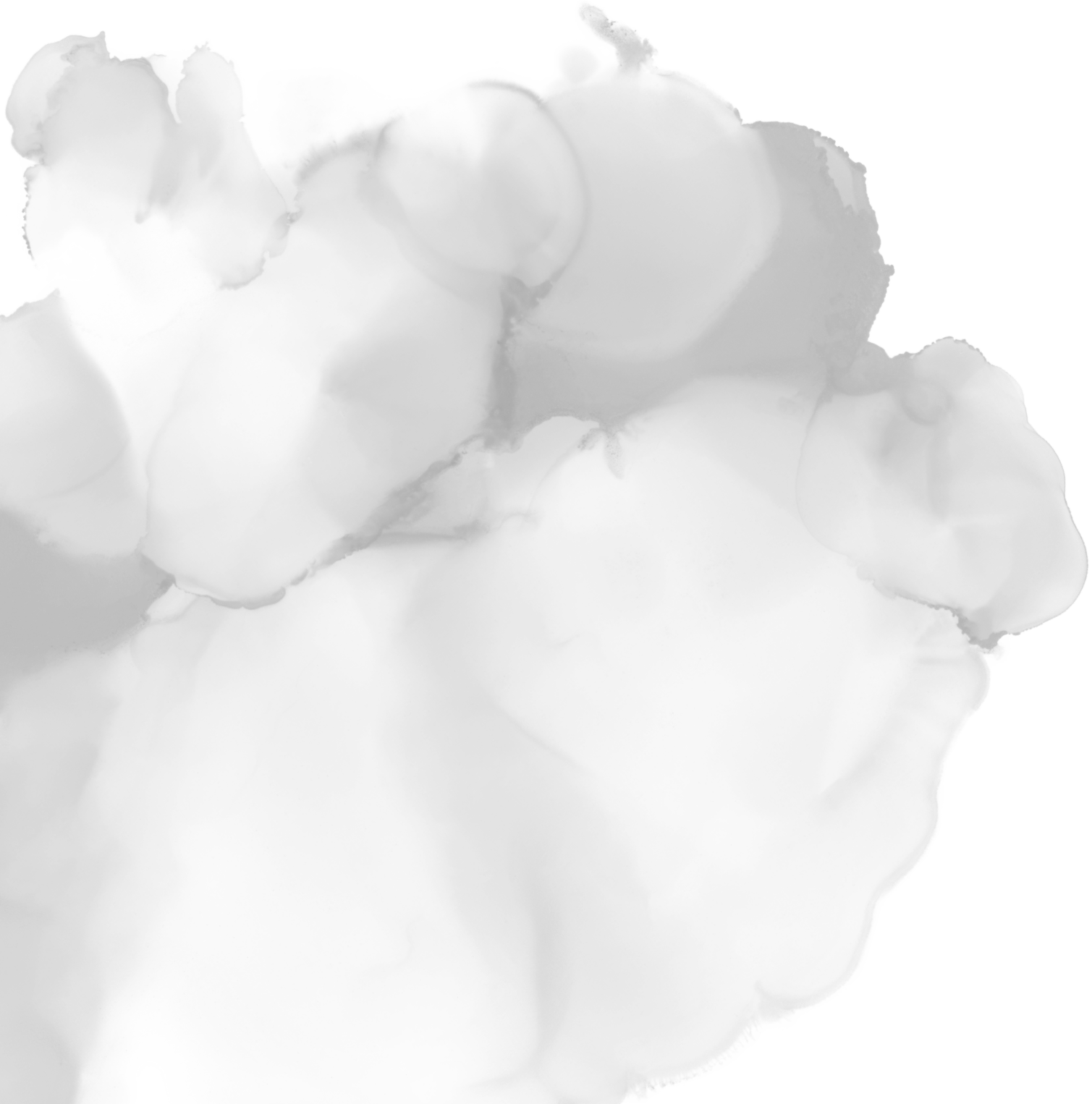
CHAPTER FOUR



Psychological interventions for chronic non-specific low back pain: protocol of a systematic review with network meta-analysis

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AUTHORSHIP STATEMENT

The co-authors of the paper "Ho E, Ferreira M, Chen L, Simic M, Ashton-James C, Comachio J, Wang D, Hayden J, Ferreira P. Psychological interventions for chronic non-specific low back pain: protocol of a systematic review with network meta-analysis. *BMJ Open* 2020;10:e034996. doi: 10.1136/bmjopen-2019-034996" confirm that Emma Kwan-Yee Ho has provided the following contributions to the study:

- conception and design of the research
- writing of the manuscript and critical appraisal of the content

As the primary supervisor for the candidate upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Paulo Ferreira
date: 16th April 2022

BMJ Open

Psychological interventions for chronic non-specific low back pain: protocol of a systematic review with network meta-analysis

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ABSTRACT

Introduction Psychological factors such as fear avoidance beliefs, depression, anxiety, catastrophic thinking and familial and social stress, have been associated with high disability levels in people with chronic low back pain (LBP). Guidelines endorse the integration of psychological interventions in the management of chronic LBP. However, uncertainty surrounds the comparative effectiveness of different psychological approaches. Network meta-analysis (NMA) allows comparison and ranking of numerous competing interventions for a given outcome of interest. Therefore, we will perform a systematic review with a NMA to determine which type of psychological intervention is most effective for adults with chronic non-specific LBP.

Methods and analysis We will search electronic databases (MEDLINE, Embase, PsycINFO, Cochrane Central Register of Controlled Trials, Web of Science, SCOPUS and CINAHL) from inception until 22 August 2019 for randomised controlled trials comparing psychological interventions to any comparison interventions in adults with chronic non-specific LBP. There will be no restriction on language. The primary outcomes will include physical function and pain intensity, and secondary outcomes will include health-related quality of life, fear avoidance, intervention compliance and safety. Risk of bias will be assessed using the Revised Cochrane risk-of-bias tool for randomised trials (RoB 2) tool and confidence in the evidence will be assessed using the Confidence in NMA (CINeMA) framework. We will conduct a random-effects NMA using a frequentist approach to estimate relative effects for all comparisons between treatments and rank treatments according to the mean rank and surface under the cumulative ranking curve values. All analyses will be performed in Stata.

Ethics and dissemination No ethical approval is required. The research will be published in a peer-reviewed journal.

PROSPERO registration number CRD42019138074.

Strengths and limitations of this study

- This is the first systematic review using an network meta-analysis (NMA) design to simultaneously compare different types of psychological interventions for improving physical function, pain intensity, health-related quality of life, fear avoidance and intervention compliance and assess their safety, in people with chronic non-specific low back pain.
- The main strength is the NMA design will allow for the comprehensive comparison and ranking of multiple psychological interventions simultaneously, which was not possible with previous systematic reviews that only conducted pairwise meta-analyses.
- An additional strength is that in comparison to previous pairwise systematic reviews, the NMA design will allow for the inclusion and synthesis of a larger number of studies investigating a wider range of psychological interventions.
- The main limitation is that we anticipate numerous studies involving different combinations of psychological approaches (eg, cognitive behavioural therapy plus pain education, counselling-based interventions plus pain education), but small number of eligible studies per combination, hence we will lump combination interventions into one treatment node for practical reasons.

Low back pain (LBP) is one of the largest contributors to disability worldwide[1 2] and is associated with substantial health and economic burden relating to increased healthcare utilisation costs, work absenteeism and productivity loss.[3] The challenge associated with treating chronic non-specific LBP lies in the complex multifactorial interaction between genetic, biophysical, psychosocial, health and lifestyle factors which are largely individualistic.[4 5] Particularly, psychological factors such as fear avoidance beliefs, depression, anxiety, catastrophic thinking and familial and social stress[4] are often poorly identified and inadequately addressed,[6] and have been shown to alter pain processing pathways, perceptions and coping responses.[5 7] The influence of these factors in chronic non-specific LBP have been found to increase the risk of disability,[8 9] which commonly manifests

as reduced functional capacity, avoidance of usual activities including work and impaired societal and recreational participation.[5 10]

Psychological interventions in chronic pain conditions aim to reduce pain-related distress and disability by changing negative beliefs, behaviours and attitudes through a combination of principles and strategies informed by psychological theories. Psychological interventions commonly focus on targeting the specific environmental contingencies and maladaptive cognitive and emotional processes underpinning pain in order to promote self-efficacy and increased function.[11 12] In clinical trials of psychological interventions for chronic LBP, psychological interventions are delivered either in isolation[12 13] or as part of an integrated treatment programme that may involve non-psychological co-interventions such as exercise, passive treatment or physiotherapy.[14–16] For the purposes of this review, we have defined five main categories of psychological interventions relevant to LBP: behavioural therapy-based interventions, cognitive behavioural therapy-based interventions, mindfulness-based interventions, counselling-based interventions and pain education-based interventions. These categories reflect the three 'waves' of how psychological interventions have evolved over time.[17] Behavioural interventions are typically considered 'first wave' approaches,[17] and include interventions focussed on altering maladaptive behaviours, and dysfunctional sensations or movements.[18] Cognitive behavioural interventions are considered 'second wave' approaches,[17] and include interventions that aim to modify harmful cognitions (eg, thoughts, beliefs) which may proliferate pain and disability.[18] Mindfulness-based interventions, counselling-based interventions and pain education-based interventions represent different types of 'third wave' approaches.[17] Unlike behavioural and cognitive behavioural interventions which focus on targeting psychological and emotional symptoms, 'third wave' interventions adopt a more holistic approach to promoting health and wellness.[17] Key characteristics and examples of the psychological intervention categories that will be included in our review are summarised below in table 1.

Previous systematic reviews have shown promising evidence that psychological interventions can improve overall functioning, pain experience, depression, cognitive appraisal, health-related quality of life and decreased healthcare utilisation in people with chronic LBP.[11 12 15] Psychological interventions can also reduce fear avoidance beliefs and behaviours (eg, kinesiophobia),[19] which are associated with increased disability and pain in people with chronic LBP.[20 21] Based on the evidence and LBP research experts, international clinical guidelines consistently endorse the integration of psychological interventions with exercise in the management of chronic LBP.[22–27]

However, LBP guideline recommendations remain vague regarding the specific types of psychological approaches that clinicians should consider incorporating

Table 1 Categories of psychological interventions for low back pain

	Category	Characteristics	Examples
First wave	Behavioural therapy-based interventions	Behavioural interventions focus on the removal of positive reinforcement of pain behaviours and teach patients to overcome stressful situations through relaxation skills.[17]	Biofeedback(17 18)
Second wave	Cognitive behavioural therapy-based interventions	Cognitive behavioural interventions aim to restructure negative cognitions (eg, thoughts, beliefs) and behaviours and promote emotion regulation and problem-solving capacity.[17]	Graded activity(17) Graded exposure(17)
Third wave	Mindfulness-based interventions	Mindfulness-based interventions focus on promoting self-awareness, attention control and pain acceptance.[13 52]	Mindfulness-based stress reduction(17 52) Acceptance and commitment therapy(17)
	Counselling-based interventions	Counselling-based interventions focus on using supportive communication and active listening techniques to build interpersonal clinician-patient relationships.	Health coaching(54 55) Motivational interviewing(54 55)
	Pain education-based interventions	Pain education-based interventions target a patient's understanding and knowledge of pain to reduce fear associated with low back pain. Pain education interventions move away from the traditional biomechanical explanation of pathology and pain, and instead focus on the reconceptualisation of the pain experience. Some pain education interventions specifically aim to desensitise the nervous system.	Pain neuroscience education(82)

into treatment.[22–27] This may be due to the fact that previous systematic reviews, which have informed these guidelines, have mainly focussed on a small selection of available approaches—namely cognitive behavioural therapy and behavioural approaches such as biofeedback.[11 12 15 18 28 29] Emerging psychological interventions such as cognitive functional therapy (a combination of psychological approaches involving cognitive behavioural strategies, pain education and exercise)[5] and acceptance and commitment therapy have been neglected from these reviews, despite recent evidence for their effectiveness in reducing LBP-related disability.[30 31] Importantly, previous reviews have only conducted multiple independent pairwise meta-analyses, and to our knowledge, no attempts have been made to synthesise the separate results. Ultimately, the comparative effectiveness of the wider collection of psychological interventions available for managing chronic LBP is unknown and clinical guidelines remain unclear. This represents an important gap in the evidence. Subsequently, there is an increased reliance on a clinician's expertise to select the most appropriate psychological approach for people with chronic LBP. Given that clinicians such as physiotherapists report a perceived lack of training and confidence in addressing psychological factors,[32–34] and tend to be biassed towards a biomedical approach despite increasing efforts to adopt a biopsychosocial, person-centred approach,[34 35] the gap in evidence must be addressed. A network meta-analysis (NMA) design will allow us to determine the comparative effectiveness of psychological interventions for managing chronic LBP, while addressing the limitations identified from previous reviews.

A NMA is an extension of a traditional pairwise meta-analysis and involves the synthesis of direct and indirect evidence to simultaneously compare numerous competing interventions within a single, coherent treatment network.[36] Direct evidence refers to data obtained from studies directly comparing competing interventions in head-to-head trials. Direct evidence can be used to indirectly estimate the effect of interventions that have not been previously compared in head-to-head trials but have been compared with a common comparator (indirect evidence). Integrating direct and indirect evidence increases the precision of treatment effect estimates, provided that the assumptions of transitivity (balanced distribution of potential effect modifiers across all comparisons within a network)[37–39] and consistency (statistical agreement between direct and indirect evidence for each comparison)[39 40] are satisfied. Treatment effect estimates are used to generate relative treatment rankings to rank all the competing interventions for a particular outcome measure. As such, the current research aims to perform a NMA to investigate the comparative effectiveness and safety of psychological interventions for chronic LBP and determine which specific type is most effective for improving physical function, pain intensity, health-related quality of life, fear avoidance and intervention compliance in chronic non-specific LBP.

METHODS AND ANALYSIS

Study design

This protocol was written in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for systematic reviews[41] and the PRISMA extension for developing review protocols (PRISMA-P)[42] and for NMA (PRISMA-NMA).[43] The systematic review protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO): CRD42019138074.

Eligibility criteria

Types of studies

We will include published parallel and cluster randomised controlled trials (RCT). We will also include the first phase of cross-over RCTs. There will be no restriction on length of follow-up. Observational studies, non-randomised trials, short reports, research letters, conferences abstracts or studies that have not been published as full-length articles in peer-reviewed scientific journals will be excluded. In accordance with the Cochrane handbook,[44] we will only include data from cluster RCTs which account for the cluster design (eg, data analysed at the level of allocation). If cluster-level data is not reported for a given cluster RCT study, we will attempt to use the approximate approaches described in the Cochrane handbook to adjust the results,[44] otherwise the study will be excluded.

Types of participants

Eligible studies will include adults experiencing chronic non-specific LBP, with or without the presence of leg pain. Chronic non-specific LBP will be defined according to the National Institute for Health and Care Excellence (NICE) UK guidelines as pain in the back between the bottom of the rib cage and buttocks crease with no known pathoanatomical cause, for greater than 12 weeks in duration.[22 45] Studies including participants with serious pathologies (eg, spinal stenosis, malignancy, trauma, vertebral fracture, infection, inflammatory disorders) will be excluded. We will include studies involving a combination of acute, subacute or chronic LBP populations, provided that >50% of participants have chronic LBP and the results are reported separately for chronic LBP populations. We will also include studies of chronic LBP participants combined with other chronic pain conditions, provided that >50% of participants have a single diagnosis of chronic LBP and the results are reported separately for chronic LBP populations. If it is unclear, study eligibility will be determined by consensus among reviewers.

Types of interventions

We will include studies of psychological interventions. Expanding on the definition provided by Hoffman *et al*,[12] we will consider an intervention as 'psychological' if it is conceived by the authors of the study as a psychological intervention, or if it is clearly based on any of

the following approaches: cognitive behavioural therapeutic strategies (relaxation, graded exposure (desensitisation), imagery (distraction), goal setting, operant conditioning), mindfulness-based stress reduction, acceptance and commitment therapy, cognitive functional therapy, health-coaching, biofeedback (delivered with a therapeutic intent to promote muscle relaxation), pain education and counselling directly employing principles of psychological theory. Interventions such as cognitive behavioural therapeutic strategies and biofeedback were purposely included based on their inclusion across a variety of previous relevant systematic reviews.[12 15 17 18] Additional approaches such as cognitive functional therapy, health coaching and acceptance and commitment therapy were included as they have been neglected in previous reviews. If our search identifies other psychological interventions which are not explicitly listed above but meet our definition for a psychological intervention, we will consider including them in our review. Disagreements regarding their eligibility for inclusion will be resolved by consensus.

We will include studies of combinations of psychological interventions, defined as interventions that contain two or more psychological approaches delivered together, with or without additional non-psychological co-interventions. There will be no restriction on the non-psychological co-interventions or comparison interventions identified by our search strategy.

Types of outcome measures

The primary outcomes of interest are physical function and pain intensity:

1. Physical function, defined as lower back specific physical function, measured at the end of treatment. Physical function is commonly measured by continuous, self-report scales (eg, Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire (RMDQ), Core Outcome Measures Index (COMI), Quebec Back Pain Disability Index (QBPDI)) or rating scales within a composite measure (eg, 12-Item or 36-Item Short Form (SF-12, SF-36)). We will not exclude studies that use other measurement tools.
2. Pain intensity, measured at the time point closest to the end of treatment. Pain intensity is commonly measured by continuous, self-report scales (eg, Numeric Rating Scale (NRS), Visual Analogue Scale (VAS)) or a rating scale within a composite rating scale (eg, McGill Pain Questionnaire). We will not exclude studies that use other measurement tools.

Secondary outcomes of interest include:

1. Health-related quality of life, measured at the end of treatment. It is commonly measured by the SF-12, SF-36, EuroQol five-dimension (EQ-5D), Nottingham Health Profile (NHP) and 10-Item Patient-Reported Outcomes Measurement Information System Global Health Short Form (PROMIS-GH-10). We will not exclude studies that use other measurement tools.
2. Fear avoidance, defined as fear of pain and consequent avoidance of movement, measured at the end of treatment. Fear avoidance is commonly measured by the Fear-Avoidance Beliefs Questionnaire (FABQ), Pain Catastrophizing Scale (PCS), Tampa Scale for Kinesiophobia (TSK) and Fear of Pain Questionnaire (FPQ). We will not exclude studies that use other measurement tools.
3. Intervention compliance, measured as the proportion of participants who complete their assigned intervention (psychological or comparison) during the intervention period.
4. Safety, defined as the proportion of participants who experience at least one adverse effect during the intervention period. Adverse effects will be broadly defined as any 'adverse event,' 'side effect,' 'complication' or event resulting in discontinuation of treatment, associated with the intervention (psychological or comparison) under investigation.

Study selection

Electronic searches

The following databases will be searched for eligible studies via Ovid from inception until 22 August 2019: MEDLINE, Embase, PsycINFO, Cochrane Central Register of Controlled Trials, Web of Science, SCOPUS and CINAHL. Search concepts will include language and keywords for: randomised controlled trial, low back pain and terms relating to psychological interventions, according to the eligibility criteria defined earlier in the protocol. A full MEDLINE search strategy can be found in online supplementary appendix A of this protocol. There will be no restriction on language.

Additional search strategies

We will search reference lists and perform citation tracking of included studies and relevant systematic reviews[11 12 15 17 18 28 29] and clinical guidelines[22–24] to identify additional eligible studies.

Identification and selection of studies

Citations identified by our search strategy will be managed using EndNote X9[46] and screened using Covidence.[47] Eligibility screening will be conducted independently by two reviewers in two independent stages: (1) citation titles and abstracts and (2) full text. Disagreements will be resolved by consensus or a third reviewer. A PRISMA flow-diagram will be presented to map the number of records included and excluded during the study selection process, with reasons for exclusions reported.

Data extraction

Two reviewers will independently extract data from the included studies using a pre-designed Microsoft Excel data extraction form. We will pilot-test the form on a small number of articles. Disagreements will be resolved by consensus or a third reviewer.

Publication characteristics

We will extract data on the following publication characteristics: first author, publication year, journal, funding and location.

Study design characteristics

We will extract data related to the study design, including number of participants randomised and durations of follow-up.

Participant characteristics

We will extract data on the individual study sample, including age, male/female, body mass index, baseline pain intensity, socioeconomic status and comorbidities.

Interventions and comparators

We will extract data on the interventions of interest and any comparation interventions. We will extract the key components of the psychological intervention (eg, details of the specific psychological principles or approaches used, qualifications of the personnel delivering the intervention, co-interventions involved) and comparison intervention. We will extract all available data on intervention dosage and frequency, and intervention duration including duration of any washout.

Outcomes

We will extract the definitions provided for our primary and secondary outcomes of interest. We will also extract the type and dimensions of the measurement tools used to assess our primary and secondary outcomes of interest.

RESULTS

For intervention compliance, we will extract the number of participants randomised to each intervention group (psychological or comparison), as well as the number of participants who complete their assigned intervention (ie, provide data at the time point closest to the end of treatment). If this data is not available, we will extract the number of participants in each group who discontinued treatment for any reason (ie, all-cause discontinuation) within the intervention period, to calculate the number of participants who completed their assigned intervention. We will express this data as a proportion of the total number of participants randomised to each group respectively. For studies comparing a psychological intervention to a non-intervention comparison (ie, waitlist control, no intervention), we will assume that the intervention compliance for the non-intervention comparison is 100%.

For safety, we will extract all available data on adverse effects, broadly encompassing adverse and serious adverse events, side effects, complications and all-cause discontinuation. We will extract authors' definitions and reasons for any adverse effects. We will also extract all available data, including authors' definitions, on alternative measures of safety reported in the included studies. We will extract the number of participants who experience at least one adverse effect related to the psychological or comparison intervention under investigation and express this as a proportion of the total number of participants randomised to each group respectively. We will also extract data on adherence if reported.

For all other outcome measures, we will be preference extracting the mean baseline and outcome scores (at the time point closest to end of treatment) for each group, and the accompanying measures of variance or statistics to impute these values. Otherwise, we will extract the change in outcome from baseline and the accompanying measures of variance for each group. If neither are available, we will extract between-group differences in scores and the accompanying measures of variance. For the following outcomes, we will extract all available data in the order which the measurement tools are listed, in accordance with the proposed hierarchy for analysis. If a given outcome is measured by several measurement tools not explicitly listed, the hierarchy for analysis will be decided by consensus from the reviewers.

For studies measuring physical function: ODI; RMDQ; COMI; QBPQI; rating scale for disability from a composite measure of physical function (eg, SF-12, SF-36); other measurement tools.[48 49] For studies measuring pain intensity: NRS; 100 mm VAS; 10 cm VAS; rating scale for pain intensity from a composite measure of pain intensity; other measurement tools.[48 49] We will extract data on pain intensity at the time point closest to randomisation and end of treatment, in the order of average pain intensity (preferred); worst pain intensity, alternative measures of pain intensity. If several alternative measures of pain intensity are reported, we will calculate an average score. For studies measuring health-related quality of life: PROMIS-GH-10; EQ-5D; SF-36 or SF-12 (physical component summary subscore); SF-36 or SF-12 (mental component summary subscore); SF-36 (overall score); NHP;[48 49] rating scale from a composite measure of health-related quality of life; other measurement tools. If only an overall score for the SF-36 is provided, we will contact authors for the physical and mental component summary subscores. For studies measuring fear avoidance: FABQ (physical activity scale); FABQ (work scale); FABQ (overall score); PCS, TSK; FPQ; rating scales of fear avoidance from a composite measure of fear avoidance; other measurement tools.[50] If only an overall score for the FABQ is provided, we will contact authors for the physical activity and work subscores. Authors will be contacted for additional information where necessary.

Data will be classified and assessed at the following time points: (1) pre-intervention; (2) post-intervention (ie, time point closest to end of treatment); (3) short-term treatment sustainability (≥2 months but <6 months post-intervention); (4) mid-term treatment sustainability (≥6 months but <12 months post-intervention); (5) long-term treatment sustainability (≥12 months post-intervention), and NMA will be performed at each time point separately.

Network treatment nodes

Using the framework proposed by Caldwell *et al*,[51] we will use a splitting approach to classify the psychological interventions. A splitting approach was chosen because psychological interventions are typically complex and heterogeneous in nature. For example, two separate trials involving cognitive behavioural therapy may focus on using different psychological principles or strategies and incorporate different additional co-interventions (eg, exercise, passive therapies). Failing to adequately account for the variability, as best as possible, may potentially result in inaccurate estimates of treatment effects. In attempts to account for heterogeneity, we will first scrutinise intervention descriptions to classify the psychological interventions into five treatment nodes based on five key approaches (behavioural, cognitive behavioural, mindfulness-based, counselling-based and pain education). We will also form a separate treatment node using a lumping method to account for combination approaches (eg, two or more psychological approaches delivered together). Then, we will further differentiate whether additional non-psychological co-interventions are involved, which will be subclassified as exercise, passive treatments or physiotherapy. If present, the combination of the psychological approach with a non-psychological co-intervention will form a separate treatment node (eg, cognitive behavioural therapy plus exercise).

The following treatment nodes will be formed for the psychological interventions:

- Behavioural therapy-based interventions (eg, relaxation-based interventions, biofeedback, operant conditioning), which we will consider as psychological approaches focussed on facilitating the removal of positive reinforcement of pain behaviours and promoting health behaviours, in the absence of cognitive strategies;[17 18]
- Cognitive behavioural therapy-based interventions, which we will consider as the combination of behavioural therapies with an additional focus of changing unhelpful cognitions (ie, thoughts, beliefs and attitudes), and/or promoting emotion regulation and problem-solving;[17]
- Mindfulness-based interventions, which we will consider as psychological approaches focussed on practicing techniques such as meditation, non-judgemental attention control and awareness (eg, mindfulness-based stress reduction, acceptance and commitment therapy);[52 53]
- Counselling-based interventions, which we will consider as psychological approaches focussed on using supportive communication and active listening techniques to facilitate healthy behaviour change (eg, health coaching, motivational interviewing);[54 55]
- Pain education-based interventions, which we will consider as psychological approaches focussed on improving understanding and knowledge about pain. These interventions may involve a biomechanical explanation of LBP, but are clearly focussed on the reconceptualisation of beliefs about the pain experience;[56]
- Combinations of psychological interventions (eg, pain education combined with behavioural therapy), which we will consider as the delivery of two or more psychological approaches together, in the absence of a non-psychological co-intervention.

Non-psychological co-interventions will be classified into the following treatment nodes:

- Exercise, which we will define as interventions that formally prescribe a structured exercise programme (eg, consisting of aerobic, strengthening, stretching, stabilisation, motor control exercises) and/or direct instructions to increase physical activity levels;
- Passive treatment, including but not limited to spinal manipulative therapy, massage and electrotherapies;
- Physiotherapy, which we will define as interventions delivered by a physiotherapist, which may involve a combination of exercise and passive treatments.

Comparison interventions will be classified into the following treatment nodes:

- Exercise, defined above;
- Passive treatment, defined above;
- Physiotherapy, defined above;
- General practitioner care, which we will define as interventions considered as standard care provided by general practitioners;
- Advice, which we will consider as interventions providing general advice that is not psychologically-informed;
- No intervention (eg, waitlist control, no intervention).

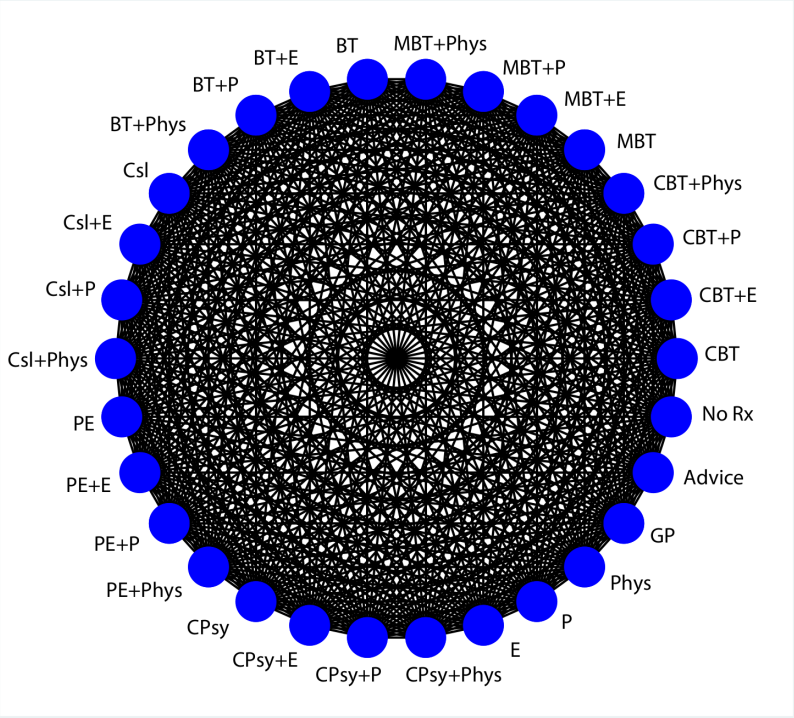
For comparison interventions described as 'usual care' by study authors, we will scrutinise the authors' descriptions of the intervention to classify them into the above treatment nodes.

Figure 1 represents all possible combinations of treatment nodes. Consensus will be sought regarding accurate classification of interventions prior to conducting statistical analyses.

Prior to data analysis, we will consult clinical experts from the review team to establish the appropriateness of further lumping treatment nodes together if there are inadequate number of studies are available for a given treatment node (eg, less than two studies available). Any post-hoc alternative network geometrics formed using this approach will be clearly identified and justified in the final review. A decision set and supplementary set will be formulated for the final review.

Risk of bias in the included studies

Two reviewers will independently assess risk of bias in the included studies using the Revised Cochrane risk-of-bias tool for randomised trials (RoB 2).[57 58] We will use the licensed Microsoft Excel tool to implement the RoB 2. We will pilot-test the risk of bias assessment procedure on a small number of articles. Authors will be contacted for additional information where necessary. The RoB 2 assesses five domains: (1) bias arising from the



BT: behavioural therapies; CBT: cognitive behavioural therapies; MBT: mindfulness-based therapies; Csl: counselling-based therapies; PE: pain education; CPsy: combination of psychological interventions; E: exercise; P: passive treatment; Phys: physiotherapy; GP: general practioner care, No Rx: no intervention.

Figure 1 Network plot of all theoretically possible network comparisons.

randomisation process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in measurement of the outcome; and (5) bias in selection of the reported result. Each domain will be graded as low risk of bias, some concerns or high risk of bias, and the results will be summarised in a table. For cluster RCTs, we will use the Cochrane cluster RCT variant of the RoB 2 tool, which assesses an additional domain: bias arising from identification or recruitment of individual participants within clusters.[59] An overall risk of bias judgement (low risk of bias, some concerns, or high risk of bias) will be made based on the five (or six) domain-level judgements, as described in Sterne *et al*.[57] Generally, the overall risk of bias judgement corresponds to the worst risk of bias in any of the five (or six) domains, however studies with multiple domains graded as 'some concerns' may be judged as high risk of overall bias.[57] Disagreements will be resolved through consensus or a third reviewer.

Data analysis

Characteristics of the publications, study designs, study populations, interventions and comparators and outcome measures will be summarised descriptively and presented in a table. Pairwise meta-analysis and NMA will be performed in Stata[60] using the metan command (with Knapp-Hartung adjustment applied), and the network package[61–63] and network graphs package,[64 65] respectively.

Measures of treatment effect

For continuous outcomes that use the same rating scale across all studies, we will use mean differences (MD) and 95% CIs. If different rating scales are used for comparable outcomes, all continuous data for the given outcome will be converted to a common standardised 0 to 100 scale. If data is reported as dichotomous, we will use ORs and 95% CI.

Dealing with missing outcome data and missing statistics

For continuous outcomes, we will impute missing data by converting standard errors, p values or CI into SD.[44] If a study only reports the median or IQR, SD will be calculated by dividing the IQR by 1.35, and we will consider the median to be equivalent to the mean. If relevant information is provided in figures, we will extract data from the graphs. If data cannot be obtained, we will attempt to contact authors.

Geometry of the network

The network diagram will be used to graphically depict the available evidence. Nodes will be used to represent the different interventions and comparators, and the weight

of the edges will be used to visually represent the proportional number of studies comparing two connected nodes within the network.

Pairwise meta-analysis

We will perform traditional pairwise meta-analyses of all direct comparisons for which there are at least two studies available. We will apply the khartung command to adjust for the Hartung-Knapp-Sidik-Jonkman random-effects method, which has less error rates compared with the DerSimonian and Laird approach in particular across comparisons with greater heterogeneity and when the number of studies is small.[66] We will assume the heterogeneity variance for each pairwise comparison is different. We will use the Q statistic to test for statistical heterogeneity in pairwise comparisons. We will use alpha <0.10 as we anticipate a few studies per comparison. We will calculate Higgins I^2 statistic to indicate the proportion of variability in effect estimates due to heterogeneity and interpret I^2 >50% as suggesting substantial heterogeneity.[44] Forest plots will be created to graphically depict individual and pooled effect sizes. Narrative analysis will be performed if we are unable to impute missing data or cannot contact authors for data, inadequate number of studies are available for a given comparison (eg, <2 studies), or there is substantial heterogeneity.

Assessment of transitivity assumption

Transitivity implies the assumption that distribution of clinical and methodological variables that could potentially act as effect modifiers across available treatment comparisons is balanced within a network.[37–39 67] Given the lack of conclusive evidence on treatment effect modifiers for LBP[68] or psychological interventions,[12 69 70] we will consider the following factors to be potential effect modifiers: age,[68] gender,[71] sample size,[72] baseline physical function, baseline pain intensity, baseline fear avoidance,[73] sciatica (leg pain with nerve root compromise). We anticipate that we will have difficulty assessing the distribution of effect modifiers, due to insufficient reporting the potential effect modifiers within individual studies and few studies available per pairwise comparison to make reasonable judgements.[74] To assess transitivity, we will use Stata to adjust the weight of the edges within the network plot, proportional to the baseline distribution of the pre-specified effect modifier and visually inspect comparability within the network.[67] If minor intransitivity is suspected (ie, minor or negligible dissimilarities in the distribution of a given effect modifier across comparisons based on clinical judgement), we will proceed with the NMA and perform network meta-regressions or subgroup analyses (or both) to explore the influence of suspected factors on the results. If the distribution of a given effect modifier is clearly dissimilar across comparisons, we will exclude network nodes. If intransitivity persists, we will consider not proceeding with NMA.

Network meta-analysis

A NMA will be performed using a frequentist approach to simultaneously compare direct and indirect evidence. We will assume the heterogeneity variance across different comparisons within the NMA model will be the same.[75] We will use heterogeneity variances from the NMA model as an index of global network heterogeneity. Mean rank and relative treatment rankings will be estimated for each intervention node according to the surface under the cumulative ranking curve (SUCRA) values.

Assessment of inconsistency

Valid NMA results rely on the assumption of consistency, which describes statistical agreement between direct and indirect evidence for each comparison within a network.[39 40] Global inconsistency of the entire network will be assessed using the design-by-treatment interaction model,[76] which is a goodness-of-fit test. The presence of inconsistency will be inferred based on p<0.10. Local inconsistencies within closed loops will be assessed with the loop specific approach (Bucher method),[77] and by fitting side-splitting models.[61] The loop specific approach (Bucher method) will be implemented in Stata using the ifplot command. We will infer the presence of local inconsistencies using a threshold of p<0.10 for either approach. If inconsistencies are identified, we will first check for errors in data extraction. Then, we will examine the potential influence of the pre-specified effect modifiers within inconsistent loops using network meta-regression models or subgroup analyses, and conduct sensitivity analyses excluding studies that may be the source of inconsistency (eg, high risk of bias, studies measuring physical function using the SF-12 or SF-36). If substantial inconsistency remains and the origin remains unexplained, we will consider not proceeding with NMA.

Sensitivity and subgroup analysis

To examine robustness of results, we will conduct a sensitivity analysis by excluding studies with high risk of bias, provided that the original network structure remains the same. We will also perform a sensitivity analysis by excluding studies measuring physical function using the SF-12 or SF-36, which may be a potential source of heterogeneity, provided that sufficient data for physical function is available and the original network structure remains the same. We will also perform network meta-regressions or subgroup analyses on the following covariates, if sufficient data is available: age, gender, sample size, baseline physical function levels, baseline pain levels, baseline fear avoidance, sciatica (leg pain with nerve root compromise). We will assume that for each network meta-regression model, the regression co-efficient for each covariate will be the same across all comparisons in the network. We specify the following assumptions about the direction of effect for each covariate:

- Age (continuous): Increasing magnitudes of the covariate reduces the differences in effect sizes between the

intervention and comparator (compared with trials in which the covariate is less).
- Gender (continuous): Gender will be summarised as the proportion (percentage) of males. Increasing magnitudes of the covariate reduces the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).
- Sample size (continuous): Increasing magnitudes of the covariate reduces the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).
- Baseline physical function (continuous): Increasing magnitudes of the covariate increases the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).
- Baseline pain intensity (continuous): Increasing magnitudes of the covariate reduces the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).
- Baseline fear avoidance (continuous): Increasing magnitudes of the covariate reduces the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).
- Sciatica (leg pain with nerve root compromise) (continuous): Presence of sciatica will be summarised as the proportion (percentage) of participants reporting sciatica at baseline. Increasing magnitudes of the covariate reduces the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).

Further, subject to the availability of data, we will attempt to perform meta-regressions to explore the effects of intervention parameters relating to dosage and/or frequency (eg, total length (in weeks) of the intervention, total intended hours of the intervention during the intervention period). We make the following assumption about the direction of effect for intervention dosage and/or frequency (continuous): Increasing magnitudes of the covariate increases the differences in effect sizes between the intervention and comparator (compared with trials in which the covariate is less).

We will also perform the following subgroup analyses, provided that sufficient data is available and the original network structure remains the same:

1. Delivery format of psychological intervention (eg, face-to-face, telephone-administered, web-based, self-help booklets), the hypothesis is that face-to-face delivery format will result in greater improvements in disability and pain intensity.
2. Individual versus group-based intervention delivery, the hypothesis is that group-based interventions will result in greater improvements in disability and pain intensity.

Publication bias

Publication bias in the NMA will be evaluated by visual inspection of comparison-adjusted funnel plots for asymmetry. As described above, meta-regression using sample size and effect estimates will be performed to detected small study effect.[78]

Confidence in cumulative evidence

Judgements of the confidence in cumulative evidence will be evaluated using the Confidence in Network Meta-Analysis (CINeMA) framework,[79–81] a web application of the Grading of Recommendations Assessment, Development and Evaluation ratings approach. The framework assesses six domains: within-study bias, across-studies bias, indirectness, imprecision, heterogeneity and incoherence.

Patient and public involvement

Patients will not be involved.

CONTRIBUTIONS TO LITERATURE

To date, there is no conclusive consensus regarding the most effective psychological approach for managing chronic non-specific LBP. Previous studies have only investigated a small portion of available psychological interventions and have only conducted multiple independent pairwise meta-analyses which have not been synthesised. As such, clinical guidelines for chronic LBP, which are based on these reviews, remain vague regarding the specific type of psychological intervention which should be incorporated into treatment for the condition. This systematic review with NMA will synthesise direct and indirect evidence for a comprehensive variety of psychological interventions with respect to improving physical function, pain intensity, health-related quality of life and fear avoidance in people with chronic non-specific LBP. The review will also assess the proportion of compliance to different psychological interventions in this population, as well as the safety of such interventions. The NMA will compare the competing interventions within the network and produce treatment effect estimates. Effect estimates will be used to generate relative treatment rankings, allowing us to rank the different types of psychological approaches for each outcome. Findings from this review will provide pragmatic support for clinical guideline recommendations regarding the use of psychological interventions for adults with chronic non-specific LBP.

ETHICS AND DISSEMINATION

Ethical review will not be required as the systematic review will only involve the use of previously published data for analysis. Our intention is to publish the completed research in a peer-review journal and present our findings at national and international conferences.

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Contributors All authors (EKH, MF, LC, MS, CA-J, JC, JAH, PF) conceived the study. EKH drafted the manuscript. EKH, LC and JC participated in the search strategy development. PF assisted in the initial protocol design, and all authors (EKH, MF, LC, MS, CA-J, JC, JAH, PF) assisted in the protocol revision. LC provided statistical expertise. CA provided expertise on psychological interventions. All authors (EKH, MF, LC, MS, CA-J, JC, JAH, PF) read and approved the final manuscript as submitted.

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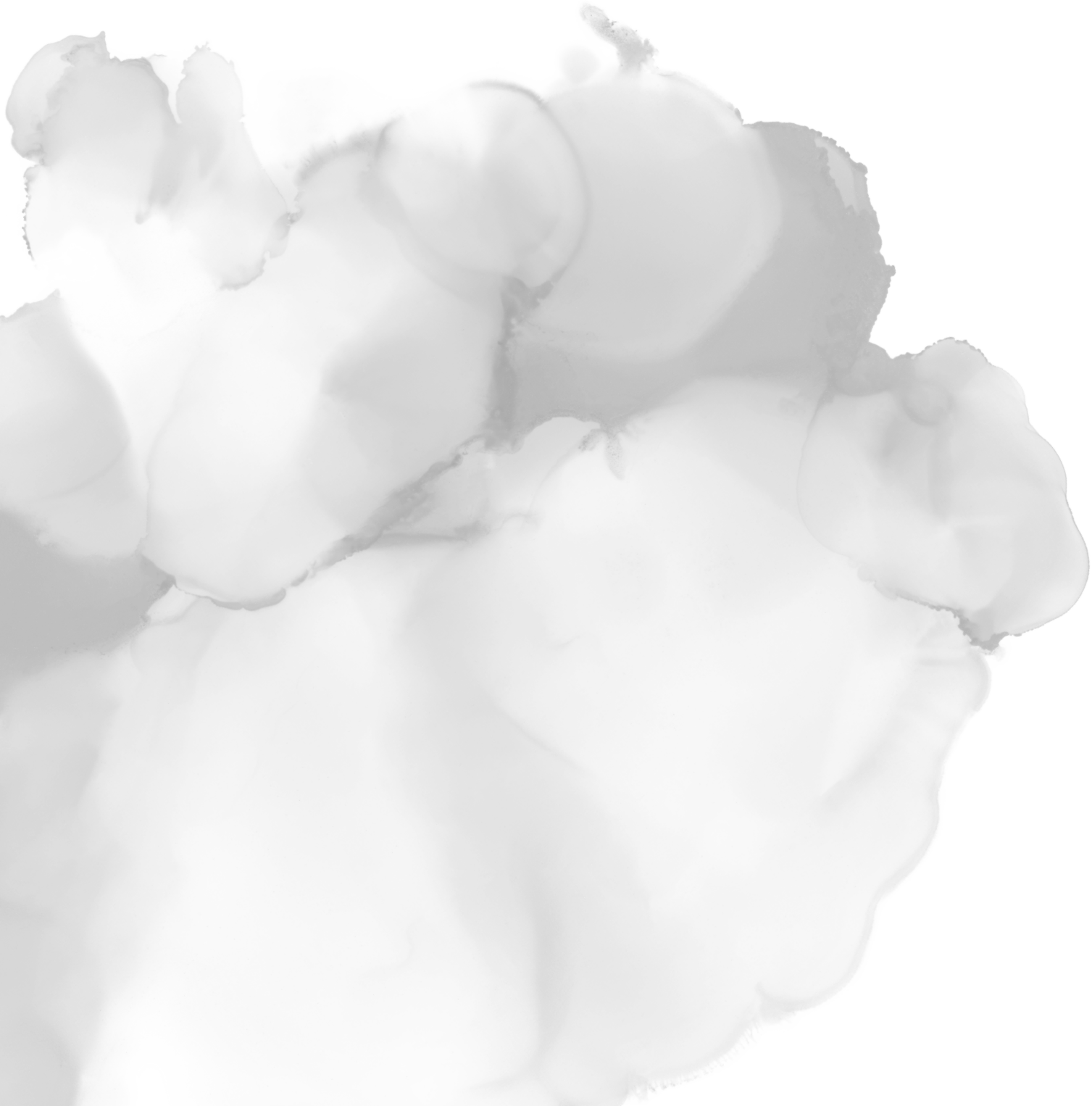
CHAPTER FIVE



Psychological interventions for chronic non-specific low back pain: a systematic review with network meta-analysis

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AUTHORSHIP STATEMENT

The co-authors of the paper "Ho EK-Y, Chen L, Simic M, Ashton-James CE, Comachio J, Wang DXM, Hayden JA, Ferreira ML, Ferreira PH. Psychological interventions for chronic non-specific low back pain: systematic review with network meta-analysis. *BMJ* 2022;376:e067718. doi: 10.1136/bmj-2021-067718" confirm that Emma Kwan-Yee Ho has provided the following contributions to the study:

- conception and design of the research
- data acquisition
- data analysis and interpretation of findings
- writing of the manuscript and critical appraisal of the content

As the primary supervisor for the candidate upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Paulo Ferreira
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Psychological interventions for chronic, non-specific low back pain: systematic review with network meta-analysis

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ABSTRACT

OBJECTIVE

To determine the comparative effectiveness and safety of psychological interventions for chronic low back pain.

DESIGN

Systematic review with network meta-analysis.

DATA SOURCES

Medline, Embase, PsycINFO, Cochrane Central Register of Controlled Trials, Web of Science, SCOPUS, and CINAHL from database inception to 31 January 2021.

ELIGIBILITY CRITERIA FOR STUDY SELECTION

Randomised controlled trials comparing psychological interventions with any comparison intervention in adults with chronic, non-specific low back pain. Two reviewers independently screened studies, extracted data, and assessed risk of bias and confidence in the evidence. Primary outcomes were physical function and pain intensity. A random effects network meta-analysis using a frequentist approach was performed at post-intervention (from the end of treatment to <2 months post-intervention); and at short term (≥2 to <6 months post-intervention), mid-term (≥6 to <12 months post-intervention), and long term follow-up (≥12 months post-intervention). Physiotherapy care was the reference comparison intervention. The design-by-treatment interaction model was used to assess global inconsistency and the Bucher method was used to assess local inconsistency.

RESULTS

97 randomised controlled trials involving 13 136 participants and 17 treatment nodes were included. Inconsistency was detected at short term and mid-term follow-up for physical function, and short term follow-up for pain intensity, and were resolved through sensitivity analyses. For physical function, cognitive behavioural therapy (standardised mean difference 1.01, 95% confidence interval 0.58 to 1.44), and pain education (0.62, 0.08 to 1.17), delivered with physiotherapy care, resulted in clinically important improvements at post-intervention (moderate quality evidence). The most sustainable effects of treatment for improving physical function were reported with pain education delivered with physiotherapy care, at least until mid-term follow-up (0.63, 0.25 to 1.00; low quality evidence). No studies investigated the long term effectiveness of pain education delivered with physiotherapy care. For pain intensity, behavioural therapy (1.08, 0.22 to 1.94), cognitive behavioural therapy (0.92, 0.43 to 1.42), and pain education (0.91, 0.37 to 1.45), delivered with physiotherapy care, resulted in clinically important effects at post-intervention (low to moderate quality evidence). Only behavioural therapy delivered with physiotherapy care maintained clinically important effects on reducing pain intensity until mid-term follow-up (1.01, 0.41 to 1.60; high quality evidence).

CONCLUSIONS

For people with chronic, non-specific low back pain, psychological interventions are most effective when delivered in conjunction with physiotherapy care (mainly structured exercise). Pain education programmes (low to moderate quality evidence) and behavioural therapy (low to high quality evidence) result in the most sustainable effects of treatment; however, uncertainty remains as to their long term effectiveness. Although inconsistency was detected, potential sources were identified and resolved.

SYSTEMATIC REVIEW REGISTRATION

PROSPERO CRD42019138074.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Existing clinical guidelines consistently endorse multimodal treatment approaches, involving exercise and psychosocial therapies, for managing chronic low back pain

Current guidelines provide limited information regarding the specific types of psychological interventions that should be recommended for different clinical outcomes, as well as the comparative longevity of intervention outcomes

The comparative effectiveness of psychological interventions available for managing chronic low back pain is unknown, potentially contributing to patients and clinicians being uncertain regarding the most optimal choice of treatment

WHAT THIS STUDY ADDS

This systematic review with network meta-analysis, a statistical method that enables simultaneous comparison of multiple interventions, investigates the effectiveness of psychological interventions for chronic low back pain

Compared with physiotherapy management, the most sustainable effects for physical function and fear avoidance were achieved with pain education programs delivered with physiotherapy care, and for pain intensity was behavioural therapy delivered with physiotherapy care

Findings can help to improve the clarity of guideline recommendations regarding the most effective psychological interventions for this population, to better support patients and clinicians in treatment decision making

Introduction

Low back pain (LBP) describes pain, muscle tension, or stiffness localised below the costal margin and above the inferior gluteal folds, with or without leg pain. LBP is defined as chronic when it persists for more than 12 weeks. Psychological factors have an important role in an individual's experience of LBP and its impact on

their functioning and quality of life. Fear avoidance beliefs, depression, anxiety, catastrophic thinking, and familial and social stress are highly prevalent in adults with chronic LBP[1] and can increase the risk of physical disability,[2 3] manifesting as reduced functional capacity, avoidance of usual activities including work, and impaired societal and recreational participation.[4] Fear avoidance beliefs can also mediate the relation between pain and disability in individuals with LBP,[5 6] and have an important influence on physical health related quality of life and health service usage in this population.[7] Consequently, consideration of psychological factors might be important in the management of LBP.[8]

Psychological interventions for chronic pain conditions commonly aim to reduce pain related distress and disability by changing patients' negative beliefs, behaviours, and attitudes through a combination of principles and strategies informed by psychological theories. Several systematic reviews have examined the effectiveness of psychological interventions for chronic, non-specific LBP.[9-15] Yet, previous reviews have mainly focused on a small selection of psychological approaches for chronic LBP (that is, cognitive behavioural therapy and behavioural therapies), neglecting more recently developed psychological interventions (that is, cognitive functional therapy and acceptance and commitment therapy). Importantly, previous reviews have conducted only independent pairwise meta-analyses, and to our knowledge, no attempts have been made to synthesise the results cohesively. Ultimately, the comparative effectiveness and safety of the wider collection of psychological interventions available for managing chronic LBP is unknown, representing an important gap in the evidence.

Most clinical practice guidelines endorse the use of psychological treatments for chronic LBP.[16] However, existing guidelines typically provide generic or incomplete recommendations. Cognitive behavioural therapy is the most frequently recommended psychological approach,[16] often without mention of evidence for other forms of psychological interventions.[17-19] Some guidelines list a range of psychological interventions that might be beneficial for chronic LBP.[19-22] However, making decisions about psychological interventions for LBP is fraught with difficulty owing to lack of information about which psychological interventions are most effective to obtain a specific clinical outcome of interest and a paucity of evidence for the comparative longevity of intervention outcomes. Examining the comparative effectiveness and safety of the wide range of available psychological interventions for chronic LBP might help to improve the clarity of guideline recommendations and better support clinicians and patients in treatment decision making.

In this systematic review, we used a network meta-analysis design (NMA) to investigate the comparative effectiveness of different types of psychological interventions for improving physical function, pain intensity, fear avoidance, health related quality of life, and intervention compliance in people with chronic, non-specific LBP. We also investigated the comparative safety of psychological interventions for this population. In contrast to traditional pairwise meta-analysis, NMA involves the synthesis of direct and indirect evidence to enable simultaneous comparison and ranking of numerous competing interventions within one coherent treatment network.

Methods

Study design

This systematic review with NMA was reported in accordance with the PRISMA statement for systematic reviews[23] and the PRISMA extension for NMA (PRISMA-NMA).[24] The protocol was registered on PROSPERO (registration No CRD42019138074) and the protocol paper was peer reviewed and published in *BMJ Open*.[25] The systematic review team consisted of physiotherapists (EK-YH, JC, DXMW, MS, MLF, and PHF), a medical doctor (LC), a psychologist (CEA-J), and a chiropractor (JAH). These reviewers are experienced in the design and conduct of systematic reviews.

Data sources

We searched Medline, Embase, PsycINFO, Cochrane Central Register of Controlled Trials, Web of Science, SCOPUS, and CINAHL via OVID from database inception until 31 August 2020, and updated our search on 31 January 2021. Our search combined an exhaustive list of concepts, language, and keywords for randomised controlled trial, LBP, and psychological interventions (supplementary A). We also searched reference lists of relevant systematic reviews and clinical guidelines.

Study selection

Types of studies

We included parallel and cluster randomised controlled trials, and the first phase of crossover randomised controlled trials, which had been published in peer reviewed journals. We did not restrict our studies by length of follow-up. The search excluded observational studies, non-randomised trials, short reports, research letters, conferences abstracts, or studies that had not been published as full length articles in peer reviewed scientific journals. In accordance with the Cochrane Handbook,[26] cluster randomised controlled trials were included only when study results accounted for the cluster design (eg, data analysed at the level of allocation).

Types of participants

We included studies of people aged 18 years and older, experiencing chronic, non-specific LBP, with or without the presence of leg pain. We defined chronic, non-specific LBP according to guidelines from the UK National Institute for Health and Care Excellence as pain in the back between the bottom of the rib cage and buttocks crease with no known pathoanatomical cause, for more than 12 weeks in duration.[17 27] The analysis excluded studies of

participants with serious pathologies (eg, spinal stenosis, malignancy, trauma, vertebral fracture, infection, and inflammatory disorders). We included studies involving a combination of populations with acute, subacute, or chronic LBP, provided that more than 50% of participants had chronic LBP and that the results were reported separately for the chronic LBP subgroup. The analysis also included studies of participants who had chronic LBP combined with other chronic pain conditions, provided that more than 50% of participants reported a diagnosis of chronic LBP and that the results were reported separately for the chronic LBP subgroup. Disagreements were resolved by consensus among systematic reviewers (EK-YH, JC, DXMW, PHF).

Types of interventions

We included studies comparing psychological interventions (independently or combined with another treatment) with any comparison interventions. We replicated the definition provided by Hoffman et al[10] by defining psychological interventions as interventions conceived by the authors of the study as being a psychological intervention. Our analysis expanded on this definition by further including interventions clearly based on any of the following approaches: cognitive behavioural therapeutic strategies, mindfulness based stress reduction, acceptance and commitment therapy, cognitive functional therapy, health coaching, biofeedback (delivered with a therapeutic intent to promote muscle relaxation), pain education, and counselling directly using principles of psychological theory. Examples of cognitive behavioural strategies were relaxation, graded exposure (desensitisation), imagery (distraction), goal setting, and operant conditioning. We also included studies of combined psychological approaches, defined as interventions containing two or more psychological approaches delivered together, with or without additional non-psychological co-interventions. The non-psychological co-interventions or comparison interventions identified by our search strategy had no restrictions, provided that the psychological, non-psychological co-intervention (if present), and comparison interventions could be classified into our initial prespecified treatment nodes (supplementary B). Citations identified by our search strategy were managed using Endnote X9[28] and screened using Covidence.[29] Two pairs of reviewers (EK-YH and JC, JC and DXMW) independently screened eligibility in two stages: citation titles and abstracts, and full text. Disagreements were resolved by consensus among systematic reviewers (involving physiotherapists (EK-YH, JC, DXMW, and PHF) and the psychologist (CEA-J)).

Outcome measures

The primary outcomes were physical function and pain intensity of the lower back, which were continuous outcomes. The secondary outcomes were fear avoidance, health related quality of life, intervention compliance, and safety. We defined fear avoidance as fear of pain and consequent avoidance of movement. Intervention compliance was assessed as the proportion of participants who completed their assigned intervention (psychological or comparison) during the intervention period. We defined safety as the proportion of participants who had at least one adverse effect during the intervention period. Adverse effects were broadly defined as any adverse event, side effect, complication, or event resulting in discontinuation of treatment, which was associated with the intervention (psychological or comparison) under investigation. Safety was assessed in studies that were included in the NMA for either of the primary outcomes of this systematic review.

Existing outcome data for all available follow-up time points were extracted for all outcomes of interest. We classified data according to the following intervals: pre-intervention (that is, baseline); post-intervention (that is, at the end of treatment or <2 months post-intervention); short term treatment sustainability (from ≥2 to <6 months post-intervention); mid-term treatment sustainability (from ≥6 to <12 months post-intervention); and long term treatment sustainability (≥12 months post-intervention). An NMA was conducted at each time point separately. If two or more follow-up assessments occurred within a given time point, we analysed data that were assessed at the time point closest to the lower limit of the respective category.

The primary endpoint for all analyses was post-intervention.

Data extraction

Two reviewers (JC and DXMW) independently extracted all available data for publication (eg, publication year and funding), study design (eg, number of participants randomised and duration of follow-up), participants (eg, age, sex, body mass index, race or ethnic minority, comorbidities, and socioeconomic status (that is, education and income levels)), and intervention characteristics (eg, key components of the psychological and comparison interventions, intervention dosage and frequency, and intervention duration), as well as relevant outcome data. Disagreements were resolved by consensus among systematic reviewers (JC, DXMW, EK-YH, PHF). We contacted 21 authors of studies that might have met our inclusion criteria to request information or data to determine suitability for inclusion in our systematic review (eg, availability of data for chronic, non-specific LBP subgroup only, data for sample characteristics, and missing outcome data). In total, 12 (57%) of 21 authors provided the necessary information or data.

For studies reporting two or more measures of physical function at a given time point, we used the following hierarchy for extraction: Oswestry Disability Index, Roland Morris Disability Questionnaire, Core Outcome Measures Index, Quebec Back Pain Disability Index, rating scales for disability within a composite measure of physical function (eg, 12

or 36 item short form (SF-12 or SF-36)), and other measurement tools.[30 31] For studies reporting two or more measures for pain intensity at a given time point, we used the following hierarchy for extraction: Numeric Rating Scale, Visual Analogue Scale, rating scale for pain intensity from a composite measure of pain intensity (eg, McGill Pain Questionnaire), and other measurement tools.[30 31] For studies reporting two or more measures for pain intensity at a given time point, we extracted data according to the following order: average pain intensity (preferred), worst pain intensity, and alternative measures of pain intensity. For studies reporting two or more measures of fear avoidance at a given time point, we used the following hierarchy for extraction: Fear Avoidance Beliefs Questionnaire; Pain Catastrophising Scale; Tampa Scale of Kinesiophobia; Fear of Pain Questionnaire; rating scales of fear avoidance from a composite measure of fear avoidance; and other measurement tools.[32] If authors reported Fear Avoidance Belief Questionnaire scores, we extracted data according to the following hierarchy: physical activity scale, work scale, overall score. If authors only provided an overall score for the Fear Avoidance Beliefs Questionnaire, we contacted them for the physical activity (preferred) or work subscores. For studies measuring health related quality of life at a given time point, we used the following hierarchy for extraction: Patient-Reported Outcomes Measurement Information System-Global Health-10; EuroQoL-5D; SF-12 or SF-36 (physical component summary subscore); SF-12 or SF-36 (mental component summary subscore); SF-36 (overall score); Nottingham Health Profile [30 31]; rating scale from a composite measure of health related quality of life; and other measurement tools.

To assess intervention compliance, we extracted the number of participants who completed their assigned intervention, as reported by the study authors. If this information was not available, we subtracted the sum of the reported number of participants who did not commence their assigned intervention and those who commenced but discontinued their assigned intervention, from the total number of participants allocated to the respective intervention group. Studies that did not report any of the previously mentioned information clearly were not included in the NMA for intervention compliance. In accordance with the protocol, we initially assumed intervention compliance for no intervention was 100%.[25] However, we decided that this assumption was not clinically meaningful and would bias effect estimates. Therefore, we excluded the no intervention treatment node from our NMA for intervention compliance.

Risk of bias in individual studies and confidence in the evidence

After pilot testing, two reviewers (JC and DXMW) independently assessed risk of bias for the relevant outcomes, only in studies included in the NMA, using the licensed Excel tool to implement the revised Cochrane risk-of-bias 2 tool for randomised trials.[33 34] An overall risk of bias judgment (low risk of bias, some concerns, or high risk of bias) was made based on five domain level judgments, as described in Sterne et al.[35] Disagreements were resolved through a third reviewer (EK-YH). Confidence in the cumulative evidence was evaluated using the Confidence in NMA (CINeMA) framework,[35] a web application of the Grading of Recommendations Assessment, Development, and Evaluation ratings approach. A description of the reasons for downgrading confidence ratings has been provided in supplementary K.

Treatment node classification

The final network consisted of 17 treatment nodes (table 1, supplementary B). Examples of interventions or approaches that were classified into the respective treatment nodes have been described in the published protocol paper.[25] Psychological interventions were clustered into six nodes: behavioural interventions, cognitive behavioural therapies, mindfulness, counselling, pain education, and combined psychological approaches (that is, the delivery of two or more psychological approaches together, in the absence of a non-psychological co-intervention). Comparison interventions were classified as: physiotherapy care, general practitioner care, advice, no intervention, and usual care. Each psychological intervention node, delivered with physiotherapy care as a co-intervention, formed a separate treatment node.

Physiotherapy care was the reference comparison intervention. Physiotherapy care was selected because exercise and passive therapies, which are frequently prescribed or used by physiotherapists, were the most frequently investigated comparison interventions in the included studies and because exercise is the most commonly endorsed treatment approach for managing chronic LBP.[8 16] To explore potential heterogeneity within the physiotherapy care node, we identified all studies included in the review that involved physiotherapy care (as a non-psychological co-intervention or a comparison intervention) in at least one of the intervention arms. Then, we delineated between the number of studies in which the physiotherapy care node consisted of exercise alone, passive therapy alone, or exercise delivered with passive therapy.

Statistical analysis

We conducted quantitative analysis for physical function, pain intensity, fear avoidance, and intervention compliance. For both traditional pairwise meta-analyses and NMA, we estimated random effects using the restricted maximum likelihood method, and derived 95% confidence intervals using the Hartung-Knapp-Sidik-Jonkman approach.[41] We performed traditional pairwise meta-analyses for all direct comparisons with at least two studies available, and random effects NMA with a frequentist approach to simultaneously combine direct and indirect evidence. We assumed that the

Table 1 | Final treatment nodes included in network meta-analysis

Treatment node	Description
Psychological interventions	
Behavioural therapy	Psychological approaches focused on facilitating the removal of positive reinforcement of pain behaviours and promoting health behaviours, in the absence of cognitive strategies[14 15]
Cognitive behavioural therapy	Combination of behavioural therapies with an additional focus of changing unhelpful cognitions (thoughts, beliefs, and attitudes), or promoting emotion regulation and problem solving[15]
Mindfulness	Psychological approaches focused on practicing techniques such as meditation, non-judgmental attention control, and awareness (eg, mindfulness based stress reduction, and acceptance and commitment therapy)[36 37]
Counselling	Psychological approaches focused on using supportive communication and active listening techniques to facilitate healthy behaviour change (eg, health coaching and motivational interviewing)[38 39]
Pain education	Psychological approaches focused on improving understanding and knowledge about pain (eg, a biomechanical explanation of LBP), but are clearly focused on the reconceptualisation of beliefs about the pain experience[40]
Combined psychological approaches	The delivery of two or more psychological approaches together, in the absence of a non-psychological co-intervention (eg, pain education delivered with behavioural therapy)
Psychological interventions delivered with non-psychological co-interventions	Behavioural therapy with physiotherapy care; cognitive behavioural therapy with physiotherapy care; mindfulness with physiotherapy care; counselling with physiotherapy care; pain education with physiotherapy care; combined psychological approaches with physiotherapy care
Comparison interventions	
Physiotherapy care	Interventions that include any combination of care typically delivered by a physiotherapist, for example: formally prescribed and structured exercise programmes (eg, consisting of aerobic, strengthening, stretching, stabilisation, and motor control exercises); passive treatment, including but not limited to spinal manipulative therapy, massage, and electrotherapies; general advice delivered in combination with structured exercise or passive treatment
General practitioner care	Interventions considered as standard care provided by general practitioners (eg, medications)
Advice	Interventions involving the provision of general advice that is not psychologically informed. Eg, direct instructions to increase physical activity levels, in the absence of a formally prescribed, structured exercise programme
No intervention	Eg, waitlist control or no intervention
Usual care	Interventions that could not be classified into the other treatment nodes

heterogeneity variance across different comparisons within the NMA model were the same. We estimated the mean rank and relative treatment rankings for each intervention node according to the surface under the cumulative ranking curve (SUCRA) values. We produced rankograms for the primary outcomes at each time point of analysis.

Many studies only reported change from baseline scores and did not provide outcome scores at post-intervention or follow-up time points. Consequently, to maximise the number of studies included in the NMA, we converted mean baseline and outcome scores for each intervention group, at each relevant time point, into scores of change from baseline with the accompanying measures of variance. Change scores were calculated in accordance with formulas provided in the Cochrane Handbook.[26] We calculated change from baseline means by subtracting outcome means from baseline means, and calculated change from baseline standard deviations by using the formula provided in the handbook, assuming a correlation coefficient (r) of 0.50.[26] We selected r=0.50 as a conservative approximation of estimates presented by Suzuki et al,[42] who examined the correlation between changes in pain intensity in people with chronic LBP relative to changes in various clinical outcomes after treatment. Continuous outcomes (that is, physical function, pain intensity, fear avoidance) were measured using different rating scales; therefore, we converted outcomes to standardised mean differences (SMD) and 95% confidence intervals. We assessed intervention compliance as odds ratios with corresponding 95% confidence intervals.

For studies involving two or more interventions classified as the same treatment node, with at least one other comparison intervention available (eg, a study involving three arms, in which two arms were classified as physiotherapy care, and the third arm was classified as pain education), data from the duplicated treatment nodes were pooled and the study was included in the meta-analyses. However, studies that compared only the same type of psychological intervention, without any other comparison interventions (eg, a study involving two arms, where both arms were classified as cognitive behavioural therapy), were excluded from the meta-analyses.

We classified magnitudes of effect according to the following criteria: small or slight (SMD ≥0.20 to <0.50), moderate (SMD ≥0.50 to <0.80), or large or substantial (SMD ≥0.80).[43 44] We also selected SMD values of 0.50 as the cut-off point for clinical effectiveness, which was equivalent to a mean difference of the following values between groups:

- 2.3 points on the Roland Morris Disability Questionnaire (0 to 24) scale for physical function (that is, 9.7 points difference on a 0 to 100 scale);
- 12.7 points on the Modified Von Korff (0 to 100) scale for pain intensity; and
- 3.3 points on a Fear Avoidance Beliefs Questionnaire (0 to 24) scale for fear avoidance (that is, 13.4 points difference on a 0 to 100 scale).

To transform SMD to mean difference values, based on a methodological paper,[45] we multiplied the SMD by the pooled standard deviation obtained from the largest trial assessing each outcome: physical function,[46] pain intensity,[46] and fear avoidance.[46] We used Stata (version 14) for all analyses.[47] We used the metan command (with Hartung-Knapp-Sidik-Jonkman adjustment applied) for the pairwise meta-analyses, and the network package and network graphs package for the NMA.[47]

We attempted but were unable to perform a meta-analysis for health related quality of life and safety, owing to heterogeneity of assessment or reporting or both. The results of studies assessing health related quality of life were summarised descriptively. For safety, we dichotomised studies into two groups. The first consisted of studies that provided clear information about adverse effects occurring during the intervention period, including information about relatedness to the intervention or interventions under investigation (which were summarised descriptively). The second group included studies that did not provide clear information about any adverse effects occurring during the intervention period, including information about relatedness to the intervention or interventions under investigation. Only results of studies from the first group for safety were summarised descriptively.

Dealing with missing outcome data and missing statistics

For continuous outcomes, we imputed missing data by converting standard errors, P values, or confidence intervals into standard deviations.[26] If a study reported only the median or interquartile range, the standard deviation was calculated by dividing the interquartile range by 1.35, and we considered the median to be equivalent to the mean. If relevant information was provided in figures, we extracted data from the graphs. Authors were contacted when data could not be obtained. We performed sensitivity analyses excluding data imputed from median and interquartile range values, which was only relevant to the primary outcomes, to examine the robustness of our primary analyses. Effect estimates were highly similar to our primary analysis in terms of the magnitude and certainty of the effect, and clinical significance (supplementary N).

Assumptions of transitivity and consistency

We assessed transitivity by visual inspection of a table containing categorised study characteristics: mode study setting (inpatient, outpatient, outpatient online only); intervention duration (weeks); mode of study-level mean participant age, dichotomised as younger than 50 years or 50 years and older; mode of study-level sex distribution, dichotomised as a population of less than 50% of male individuals or 50% or more of male individuals; and outcome scales reported. Global inconsistency of the entire network was assessed by the design-by-treatment interaction model.[48] Local inconsistencies were assessed by the Bucher method.[49] If global inconsistency was detected, we explored possible causes of inconsistency through sensitivity analyses.

Evaluation of small-study effects

Small-study effects were evaluated by visual inspection of comparison-adjusted funnel plots, including only comparisons with at least one study available, for asymmetry.[48] We performed meta-regression using the total sample size to detect small-study effects.[50] We attempted to perform a sensitivity analysis by excluding studies with a sample size of less than 100; however, this process resulted in the exclusion of 53 (55%) of 97 studies from our systematic review, leading to large changes in our network structure. Therefore, this additional analysis was not performed.

Sensitivity and subgroup analyses

To examine the robustness of our results and to examine sources of potential inconsistency, we performed the following sensitivity analyses at post-intervention: firstly, excluding studies with high risk of bias; secondly, including only studies using intention-to-treat analysis; thirdly, excluding studies published before the year 2000; and finally, excluding studies of patients with leg pain. To examine whether older studies resulted in remarkable changes in effect estimates, we also performed two additional sensitivity analyses for each of the primary outcomes, excluding studies published before year 1995 and before year 2005. For outcomes analysed quantitatively, we did meta-regression at each time point based on mean age, percentage of male individuals, and sample size.

For physical function, pain intensity, and fear avoidance, we performed meta-regression at each time point based on baseline values of the respective outcome. Because study authors used different measurement scales, we converted baseline data to standardised 0 to 100 (maximum) scales before performing meta-regressions. Subgroup analyses based on meta-regression results were only performed when both of the following criteria were met: P value of the regression coefficient was less than 0.05 and 10 or more studies were available for the relevant comparison.[51] If inconsistency continued to persist in the network, we then sought to remove it by performing sensitivity analyses excluding portions of evidence in the network,[48] based on visual inspection of possible sources of intransitivity across relevant studies. For these analyses, which were only relevant to the primary outcomes, we presented the justifications for exclusion, the resulting effect estimates, and the corresponding global tests of inconsistency (showing no detected inconsistency) in supplementary N. Owing to heterogeneity of reporting, we were unable to perform meta-regression based on intervention dosage or frequency. We attempted but were unable to perform subgroup analyses based on intervention delivery format (that is, face-to-face, telephone administered, web based, self-help booklets, and hybrid; dichotomised as face-to-face or other delivery format) or setting (that is, individual, group based, and hybrid; dichotomised as group based or other delivery setting). After dichotomising interventions according to delivery format and setting, we observed large changes in the network structure (that is, many treatment nodes became disconnected, resulting in networks that were dissimilar to the primary network plots). Therefore, we did not proceed with subgroup analyses.

Patient and public involvement

This study is an NMA of previously published studies. No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for the design and conduct of the study. No patients were asked to advise on interpretation or writing up of results.

Results

Overall, 7983 records were identified from electronic database (6919 records) and registry searches (1064 records). After removing duplicates, 4728 records were screened for titles and abstracts, and 235 full text articles were screened for eligibility (see supplementary C). From electronic database and registry searching, we identified 70 eligible articles. An additional 27 records which were identified from other sources (that is, reference lists of relevant systematic reviews[9-15] and clinical guidelines,[17 22 52] citation alerts, and contacting authors of included studies) were also included in the review. No cluster randomised controlled trials were eligible for inclusion in our review. In total, 97 articles involving 97 unique studies and 13 136 people with chronic, non-specific LBP were included in the systematic review (fig 1). Figure 2 and figure 3 depict the network plots for the primary outcomes (supplementary Q).

Overview of studies

Table 2 presents general characteristics of the 97 included studies, separated by study outcomes (supplementary D and E). Post-intervention was the

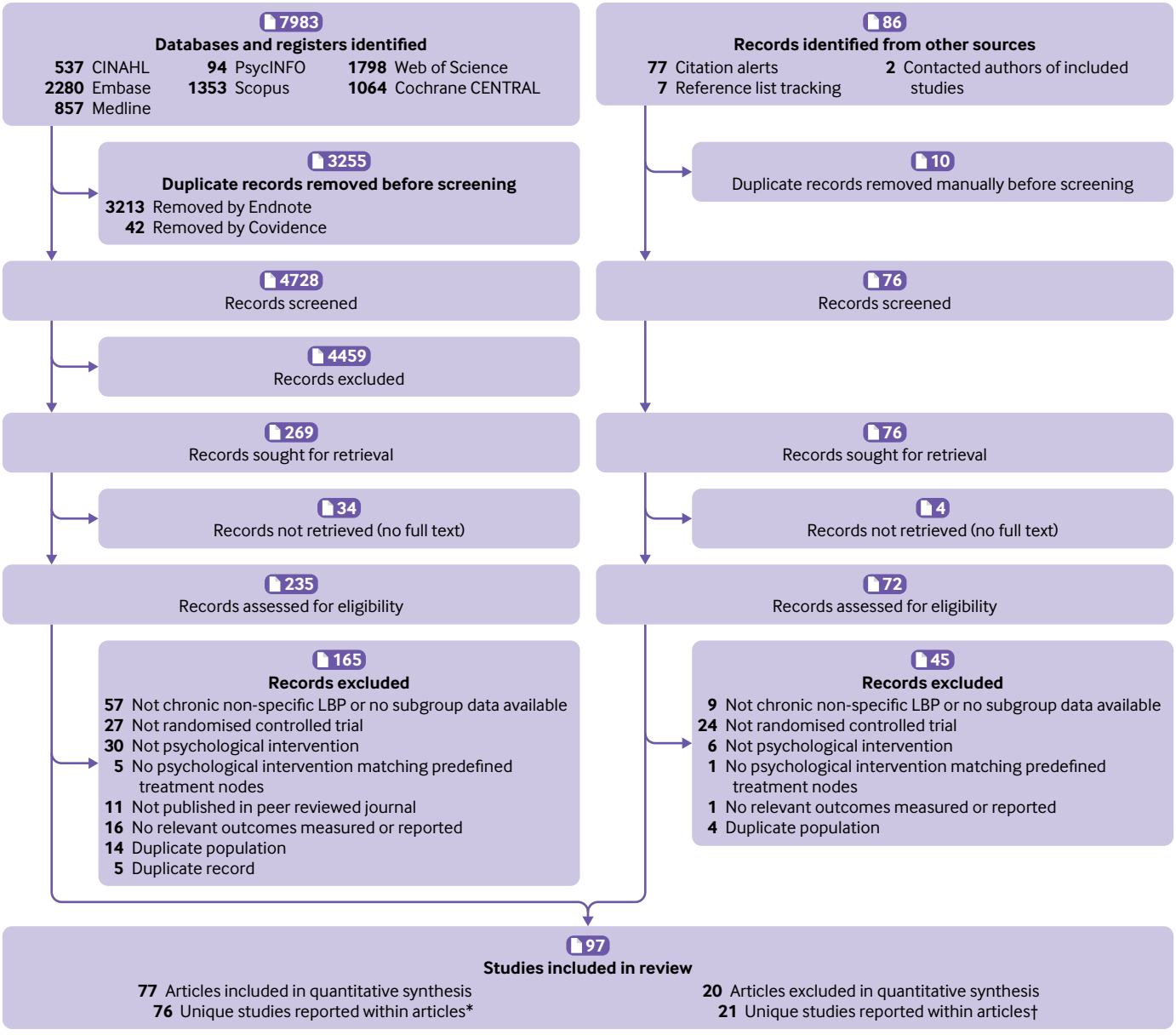

Fig 1 | Study selection flowchart. *One article reported data on two unique studies, one article reported long term follow-up data, and one article provided additional baseline data that were not available in a related, included article reporting the same study. †One article reported long term follow-up data for two unique studies. LBP=lower back pain

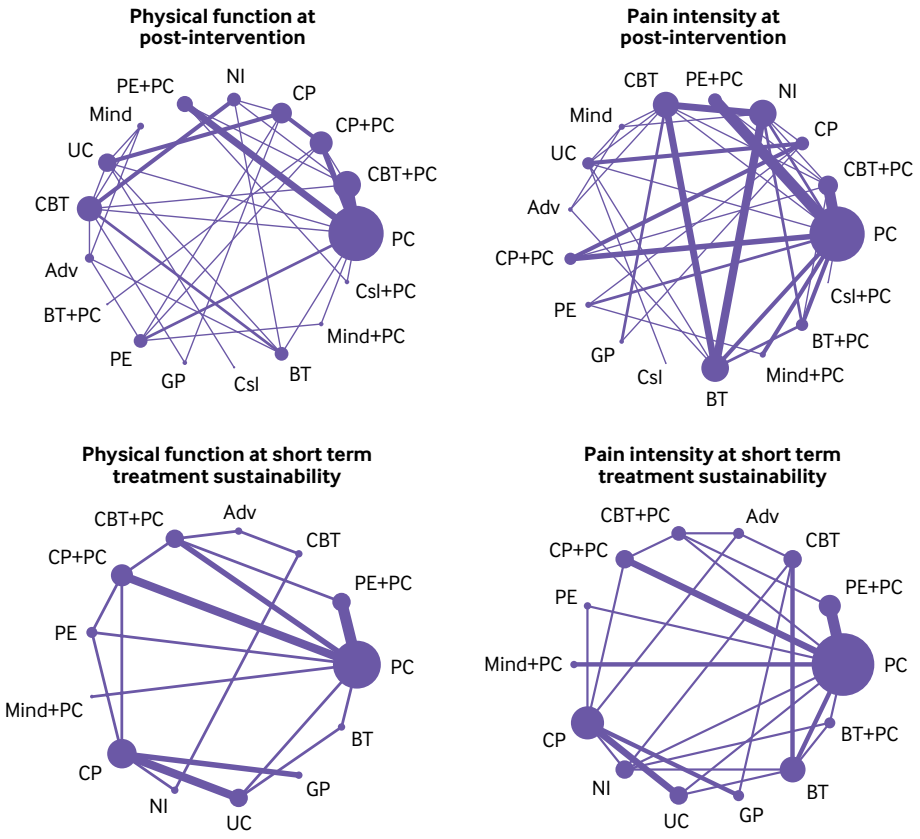

Fig 2 | Network plots of physical function and pain intensity at post-intervention and short term follow-up. Adv=advice; BT=behavioural therapy; BT+PC=behavioural therapy delivered with physiotherapy care; CBT=cognitive behavioural therapy; CBT+PC=cognitive behavioural therapy delivered with physiotherapy care; CP=combined psychological approaches; CP+PC=combined psychological approaches delivered with physiotherapy care; Csl=counselling; Csl+PC=counselling delivered with physiotherapy care; GP=general practitioner care; Mind=mindfulness; Mind+PC=mindfulness delivered with physiotherapy care; NI=no intervention; PE=pain education; PE+PC=pain education delivered with physiotherapy care; PC=physiotherapy care; UC=usual care

most frequently assessed time point across all outcomes. Most studies were published between 2011 and 2021 and were conducted in Europe (table 2). Physiotherapy care was the most frequently investigated comparison intervention for all outcomes. Mean body mass index and study sample size were similar across studies assessing physical function and pain intensity (table 2). However, mean age and percentage of males differed slightly across studies assessing physical function and pain intensity (table 2).

Overall, the reporting of socioeconomic information (eg, occupational status, educational levels, income, race, or ethnic minority) was poor and inconsistent across the included studies. For example, 32 (33%) of 97 included studies reported information on occupational status, of which only 14 reported study level data. Of 97 included studies, 32 (33%) reported information on educational levels, of which only 10 studies reported study level data. To explore whether these factors were potential effect modifiers, we attempted but were unable to impute arm level data from the remaining studies, owing to heterogeneity of reporting by study authors, precluding subgroup analyses or meta-regression.

Twenty one unique studies were not included in the NMA for physical function and pain intensity, and eight unique studies were not included in the NMA for fear avoidance (see supplementary G).

Exploring potential heterogeneity of the physiotherapy care node

To explore potential heterogeneity in the physiotherapy care reference node, we summarised all studies that investigated physiotherapy care, delivered as a non-psychological co-intervention or comparison intervention (supplementary F). In total, 44 unique studies included at least one intervention arm of physiotherapy care as a non-psychological co-intervention. From these 44 studies, 36 (82%) investigated exercise alone, six (14%) investigated exercise with passive therapy, and two (5%) investigated passive therapy alone, as non-psychological co-interventions. In total, 33 unique studies included at least one intervention arm involving physiotherapy care as a comparison intervention. From these 33 studies, 19 (58%) investigated exercise alone, nine (27%) investigated exercise with passive therapy, and four (12%) investigated passive therapy alone, as comparison interventions. Additionally, one study (3%) had two comparison arms classified as physiotherapy care (one arm involving the combined delivery of exercise

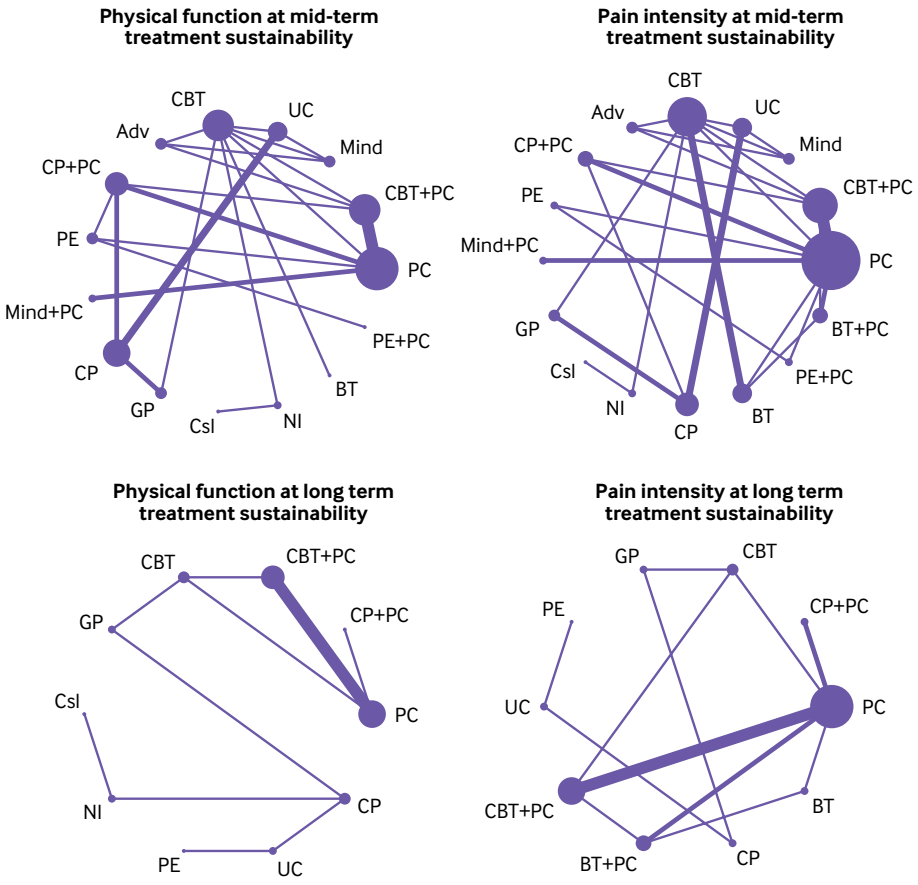

Fig 3 | Network plots of physical function and pain intensity at mid-term and long term follow-up. Adv=advice; BT=behavioural therapy; BT+PC=behavioural therapy delivered with physiotherapy care; CBT=cognitive behavioural therapy; CBT+PC=cognitive behavioural therapy delivered with physiotherapy care; CP=combined psychological approaches; CP+PC=combined psychological approaches delivered with physiotherapy care; Csl=counselling; GP=general practitioner care; Mind=mindfulness; Mind+PC=mindfulness delivered with physiotherapy care; NI=no intervention; PC=physiotherapy care; PE=pain education; PE+PC=pain education delivered with physiotherapy care; UC=usual care

with passive therapy and the other arm involving passive therapy delivered alone), which were pooled in the NMA. Overall, the physiotherapy care node mainly consisted of exercise interventions only, followed by a smaller number of studies investigating exercise delivered with passive therapy. Passive therapy was infrequently delivered alone, either as a co-intervention or a comparison intervention. Therefore, despite potential limitations of combining interventions considered effective (that is, exercise), ineffective (that is, passive therapies alone), and possibly effective (that is, exercise delivered with passive therapy) for chronic LBP,[17] we assumed that heterogeneity was unlikely to significantly affect the study results because most relevant studies involved exercise or exercise with passive therapy.

Transitivity

We summarised the study characteristics across direct comparisons within the network for physical function, pain intensity, fear avoidance, and intervention compliance (supplementary H). The mode study setting was balanced across all comparisons (conducted in outpatient settings) except in five (13%) of 38 comparisons for physical function, four (10%) of 40 comparisons for pain intensity, four (22%) of 18 comparisons for fear avoidance, and one (8%) of 13 comparisons for intervention compliance. Across dissimilar comparisons, online outpatient setting was the mode study setting across three (60%) of five comparisons for physical function, two (50%) of four comparisons for pain intensity, two (50%) of four comparisons for fear avoidance, and one (100%) of one comparisons for intervention compliance.

For physical function and pain intensity, the mode study level mean participant age appeared to be similar across most comparisons (<50 years), except in four (11%) of 38 comparisons for physical function, eight (20%) of 40 comparisons for pain intensity, four (22%) of 18 comparisons for fear avoidance, and three (23%) of 13 comparisons for intervention compliance. On further inspection, the mean age in four (67%) of six individual studies comprising the dissimilar comparisons for physical function was younger than 51.6 years,[53-56] and the mean age in nine (64%) of 14 studies comprising the dissimilar comparisons for pain intensity was younger than 53.4 years.[53-55 57-62] The mean age was younger than 53.3 years in four (67%) of six individual studies comprising dissimilar comparisons

Table 2 | General characteristics of all included studies

Characteristics	Primary outcomes		Secondary outcomes			
	Physical function (n=80)	Pain intensity (n=86)	Fear avoidance (n=37)	HR-QoL (n=45)	Intervention compliance (n=29)	Safety* (n=21)
Publication characteristics						
Total number of unique studies included	80	86	37	44	30	20
Publication year:						
1981-91	1	4	0	3	1	0
1991-2001	11	10	1	5	3	0
2001-11	26	24	11	10	7	7
2011-21	42	48	25	26	20	13
Funding:						
None	36	42	17	17	17	7
Non-commercial	41	37	18	25	10	12
Commercial	2	4	2	0	2	1
Unclear	1	1	0	2	1	0
Study design characteristics						
Range of study sample size	24-701	24-701	41-701	36-701	36-580	27-701
No of intervention arms included:						
2	70	68	33	36	24	19
3	10	13	4	5	5	1
4	0	4	0	3	1	0
5	0	0	0	0	0	0
6	0	1	0	0	0	0
No of studies containing the following treatment nodes:						
Behavioural therapy	5	11	2	6	4	1
Cognitive behavioural therapy	11	15	5	7	4	4
Mindfulness	2	3	1	2	0	1
Counselling	2	2	2	1	0	0
Pain education	9	6	4	6	3	2
Combined psychological approaches	16	16	8	7	6	3
Behavioural therapy + physiotherapy care	2	4	2	2	1	0
Cognitive behavioural therapy + physiotherapy care	17	16	7	6	6	3
Mindfulness + physiotherapy care	3	5	0	5	0	2
Counselling + physiotherapy care	2	1	0	1	1	2
Pain education + physiotherapy care	12	14	6	7	7	6
Combined psychological approaches + physiotherapy care	16	13	11	8	9	2
Physiotherapy care	27	33	16	18	18	10
General practitioner care	5	6	1	3	2	0
Advice	5	5	3	1	0	1
No intervention	9	14	5	8	3	3
Usual care	7	7	2	6	0	1
Other†	2	3	1	1	0	0
Studies with durations of follow-up:						
Post-intervention	64	72	35	34	27	18
Short term	28	34	15	20	13	11
Mid-term	41	44	17	25	12	11
Long term	16	16	6	11	3	1
Continent:						
Africa	1	1	1	0	1	0
Antarctica	0	0	0	0	0	0
Asia	10	13	5	6		3
Australia	7	6	4	3	5	2
Europe	41	40	17	22	7	10
North America	18	23	8	12	8	3
South America	3	3	2	1	2	2
Patient characteristics						
Range of mean age (years); No of studies	28.3-77.2; 76	35.4-77.2; 83	28.3-74.5; 36	35.4-77.2; 43	28.3-62.4; 30	39.0-74.5; 19
Range of males (%); No of studies	0-88; 76	8-100; 83	0-88; 36	8-69; 43	0-100; 30	20-58; 19
Range of mean body mass index; No of studies	23.5-31.2; 21	23.5-31.2; 18	24.4-31.1; 11	23.5-31.2; 10	24.1-27.3; 9	24.05-30.0; 7

HR-QoL=health related quality of life.
*Only studies providing clear information about adverse effects occurring during the intervention period have been presented.
†For physical function, two studies compared cognitive behavioural therapy delivered with physiotherapy care to lumbar fusion. For pain intensity, two studies compared cognitive behavioural therapy delivered with physiotherapy care to lumbar fusion, and another study compared behavioural therapy with three intervention arms involving variations of hypnosis therapy. For fear avoidance, one study compared cognitive behavioural therapy delivered with physiotherapy care, with lumbar fusion.

for fear avoidance,[54 55 58 63] and three (60%) of five studies comprising the dissimilar comparisons for intervention compliance.[54 58 59]

Although mode study level distribution of sex was similar across most comparisons for the primary outcomes (<50% males), 10 (26%) of 38 comparisons

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for physical function and 14 (35%) of 40 comparisons for pain intensity either had a mode of 50% or more males, or a bimodal distribution of sex. However, for physical function, the distribution of sex in six (67%) of nine unique studies comprising the dissimilar comparisons was less than 55% males,[64-69] while for pain intensity, the distribution of sex in 10 (59%) of 17 unique studies comprising the dissimilar comparisons was less than 54% males.[59 64 65 67 69 70-74] For the secondary outcomes, the mode study-level distribution of sex was similar across most comparisons except in three (17%) of 18 comparisons for fear avoidance and four (31%) of 13 comparisons for intervention compliance. For fear avoidance, the distribution of sex in three (50%) of six individual studies comprising the three dissimilar comparisons was less than 52% males.[63 64 68] For intervention compliance, the distribution of sex in two (33%) of six individual studies comprising the four dissimilar comparisons was less than 58% males,[59 75] while the distribution of sex in the remaining studies ranged from 62% to 88% males.[58 76 77] Nonetheless, meta-regression did not suggest that either mean age or proportion of males were effect modifiers (supplementary Y).

In addition, meta-regression based on mean baseline levels of physical function, pain intensity, or fear avoidance did not suggest these factors were effect modifiers (supplementary Y). The duration of intervention was also similar, mostly between two weeks and 12 weeks in length, across different comparisons involving the same types of psychological interventions. Overall, we considered the assumption of transitivity was valid.

Risk of bias within included studies

The domain level and overall risk of bias judgments for physical function, pain intensity, and fear avoidance are presented in supplementary J. A risk-of-bias assessment was not applicable to intervention compliance. For physical function, of 61 unique studies included in the NMA, 58 were judged as having some concerns and three were judged as having high risk of bias. For pain intensity, of 66 unique studies, 62 were judged as having some concerns and four were judged as having high risk of bias. For fear avoidance, of 30 unique studies included, 29 studies were judged as having some concerns and one study was judged as having high risk of bias. For all relevant outcomes, the main concerns related to risk of bias were pertaining to measurement of the outcome (domain four) and selection of the reported result (domain five). Sensitivity analyses excluding studies with high risk of bias did not substantially affect the results of the global or local inconsistency tests, suggesting studies with high risk of bias were not an important source of inconsistency.

Psychological interventions for physical function

Of 80 articles assessing physical function, 62 articles that reported data for 61 unique studies and involved 9397 people with chronic, non-specific LBP, were included in the NMA. The median time point for assessment for post-intervention was at the end of treatment (range 0-2 months post-intervention). The other median follow-up time points were 3 months (2-5 months) post-intervention for short term follow-up, 9 months (6-11 months) post-intervention for mid-term follow-up, and 12 months (12-33 months) post-intervention for long term follow-up. Physical function was assessed with the Oswestry Disability Index (English and Italian versions), Roland Morris Disability Questionnaire (23 item, 18 item, 16 item, and Spanish versions), Quebec Back Pain Disability Scale (English and Portuguese versions), Low Back Outcome Scale, modified Von Korff Scale, Hannover Activities of Daily Living Questionnaire, Activities of Daily Living Questionnaire, and Pain Disability Index and Pain and Disability Index (Million). Results of the NMA and CINeMA assessment (domain level judgments and overall confidence ratings) for physical function are presented in supplementary I and K.

We did not detect any inconsistency at post-intervention or long term follow-up for physical function (supplementary O). However, we detected global inconsistency at short term and mid-term follow-up (supplementary O). At these time points, local inconsistency was detected in four (22%) of 18 pairwise comparisons at short term follow-up, and five (24%) of 21 pairwise comparisons at mid-term follow-up (supplementary P). Sensitivity analyses were conducted at short term and mid-term follow-up for physical function, which resolved the presence of inconsistency at these time points. We resolved inconsistency at short term follow-up by removing three studies contributing to intransience related to the measurement tools for assessing physical function, for pairwise comparisons showing inconsistency.[67 78-80] Inconsistency at mid-term follow-up was resolved by removal of the same three studies contributing to intransience related to the measurement tools for assessing physical function at short term follow-up.[67 78-80] Additionally, one study contributing direct evidence to the pairwise comparison between cognitive behavioural therapy delivered with physiotherapy care and physiotherapy care alone, which showed inconsistency, and was removed (supplementary N).[81]

The NMA results showed that at post-intervention, cognitive behavioural therapy delivered with physiotherapy care (SMD 1.01, 95% confidence interval 0.58 to 1.44; moderate quality evidence; equivalent to 19.6 points mean difference in improvement on a scale of 0 to 100), and pain education delivered with physiotherapy care (0.62, 0.08 to 1.17; moderate quality evidence; equivalent to 12.0 points mean difference in improvement on a scale of 0 to 100) had large and moderate clinically important effects, respectively, for improving physical function in comparison with physiotherapy care alone (fig 4). Sensitivity analysis excluding two studies with high risk of bias produced similar effect estimates (1.09, 0.62 to 1.57 for cognitive behavioural therapy with physiotherapy care; and 0.63, 0.07 to 1.20 for pain education with physiotherapy care; supplementary N).

Results from all other sensitivity analyses conducted for physical function at post-intervention were similar to those of the primary analysis (supplementary N).

From the primary analysis, the effects of cognitive behavioural therapy delivered with physiotherapy care were maintained at short term follow-up (SMD 0.60, 95% confidence interval 0.20 to 1.00; moderate quality evidence; moderate and clinically important effect), and at mid-term follow-up (0.34, 0.13 to 0.56; moderate quality evidence; small and not clinically important effect). In contrast, results from the sensitivity analyses (resolving inconsistency) found that at short term follow-up, the effect of treatment was small and not clinically important (0.31, 0.01 to 0.61); results at mid-term follow-up were similar to effect estimates obtained in the primary analysis (0.25, 0.09 to 0.41; supplementary N). At long term follow-up, cognitive behavioural therapy delivered with physiotherapy care was not statistically significant compared with physiotherapy care alone (1.56, −0.10 to 3.21, supplementary I).

The primary analysis showed that compared with physiotherapy care alone, pain education delivered with physiotherapy care maintained a moderate and clinically significant effect at short term follow-up (SMD 0.63, 95% confidence interval 0.25 to 1.00; low quality evidence). Sensitivity analysis (resolving inconsistency) indicated that the effects of treatment were large and clinically important (0.85, 0.56 to 1.15; equivalent to 16.5 points mean difference in improvement on a scale of 0 to 100; low to moderate quality evidence). Nonetheless, at mid-term follow-up, results from both the primary analysis (0.67, −0.03 to 1.37; low quality evidence) and sensitivity analysis (resolving inconsistency) (0.39, −0.17 to 0.95; low quality evidence) found that treatment effects were no longer significant. No studies investigated the effect of pain education delivered with physiotherapy care in the long term.

Compared with physiotherapy care, only small or no treatment effects on physical function were observed for other types of psychological interventions, delivered with or without physiotherapy care, at post-intervention or follow-up time points (supplementary I and supplementary N).

Based on the SUCRA values and mean rank (supplementary L), the most highly ranked intervention at post-intervention was cognitive behavioural therapy delivered with physiotherapy care (SUCRA 92.3% and mean rank 2.2). At short term and mid-term follow-up, pain education delivered with physiotherapy care ranked first (for short term, 85.6% and 2.7; for mid-term, 90.7% and 2.3). At long term follow-up, cognitive behavioural therapy delivered with physiotherapy care ranked first (62.7% and 4.4). Rankograms for physical function are presented in supplementary L. In the sensitivity analysis (resolving inconsistency) at short term follow-up, pain education delivered with physiotherapy care remained the most highly ranked intervention (SUCRA 99.9%). In the sensitivity analysis (resolving inconsistency) at mid-term follow-up, combined psychological approaches delivered with physiotherapy care was ranked first (94.6%), followed by pain education delivered with

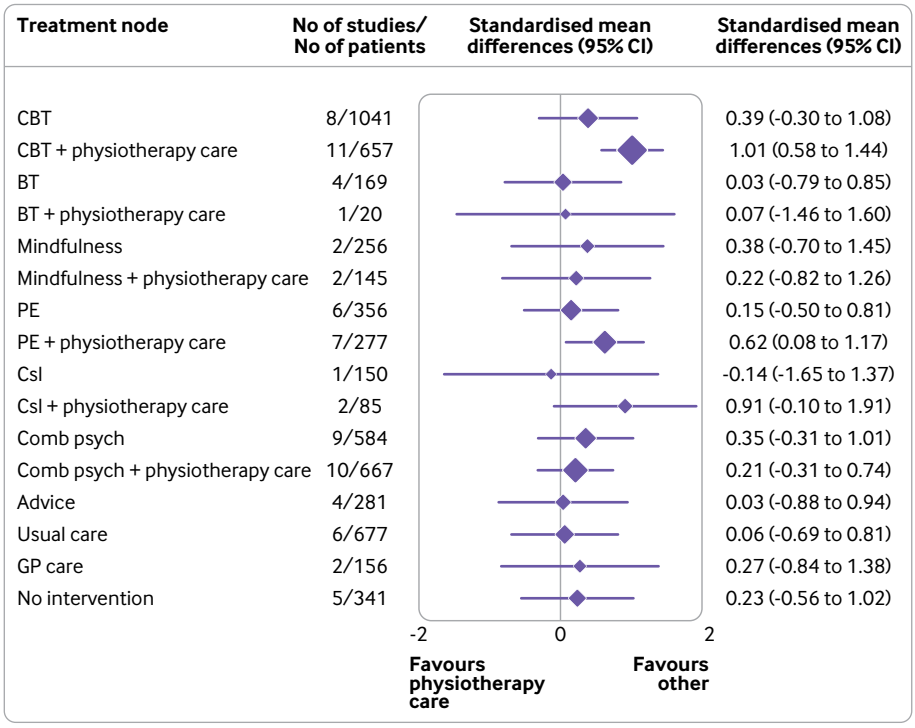

Fig 4 | Forest plot of network meta-analysis results for physical function at post-intervention. *Denotes significance at p<0.05. BT=behavioural therapy; CBT=cognitive behavioural therapy; Comb psych=combined psychological approaches; CsI=counselling; GP care=general practitioner care; PE=pain education; SMD=standardised mean difference. Physiotherapy care was the reference comparison group

physiotherapy care (84.5%). The comparison-adjusted funnel plots (supplementary M), and meta-regression based on sample size (supplementary Y), did not suggest small-study effects for physical function at any time points. We did not find any evidence suggesting that mean age, proportion of males, or mean baseline levels of physical function were effect modifiers (supplementary Y).

Psychological interventions for pain intensity

Of 86 articles assessing pain intensity, 67 articles reported data for 66 unique studies and involved 9462 people with chronic, non-specific LBP and were included in the NMA. For post-intervention, the median time point for assessment was at the end of treatment (range 0-2 months post-intervention). Median follow-up time points were 3 months (range 2-5 months), 9 months (6-11 months), and 12 months (12-60 months) post-intervention for short term, mid-term, and long term follow-up, respectively. Pain intensity was assessed with the Numeric Rating Scale (using scale ranges of 0-100, 0-10, and 0-20), Visual Analogue Scale (100 mm and 10 mm versions), bodily pain subscale of the SF-36, Pain Rating Chart, pain intensity subscale of the Low Back Outcome Score, Brief Pain Inventory, Box Scale, Pain Intensity Questionnaire, modified Von Korff pain scale, McGill Pain Questionnaire (short form version and Pain Rating Index subscale; English and Turkish versions), Graded Chronic Pain Scale, Chronic Pain Grade Questionnaire, Functional Rating Index Test, and Descriptor Differential Scale. We present the results of the NMA and CINeMA assessment (domain level judgments and overall confidence ratings) for pain intensity in supplementary I and K. We did not detect global inconsistency at post-intervention, mid-term, or long term follow-up for pain intensity (supplementary O). However, global inconsistency was detected at short term follow-up (supplementary O), with five (20%) of 25 pairwise comparisons indicating local inconsistency at this time point (supplementary P). Inconsistency for pain intensity at short term follow-up was resolved by removing one study that contributed to intransience related to intervention duration,[82] and one study that contributed direct evidence to all pairwise comparisons showing inconsistency (supplementary N).[83]

The NMA results showed that at post-intervention, behavioural therapy delivered with physiotherapy care (SMD 1.08, 95% confidence interval 0.22 to 1.94; low quality evidence; equivalent to 27.3 points mean difference in improvement on a scale of 0 to 100), cognitive behavioural therapy delivered with physiotherapy care (0.92, 0.43 to 1.42; moderate quality evidence), and pain education delivered with physiotherapy care (0.91, 0.37 to 1.45; moderate quality evidence) have a large and clinically important effect on reducing pain intensity, compared with physiotherapy care alone (supplementary I; fig 5). Sensitivity analysis, excluding three studies with high risk of bias, produced similar effect estimates (1.14, 0.04 to 2.24 for behavioural therapy with physiotherapy care; 0.91, 0.37 to 1.46 for cognitive behavioural therapy with physiotherapy care; and 0.91, 0.35 to 1.48 for pain education with physiotherapy care; supplementary N). Results from all other sensitivity analyses conducted for pain intensity at post-intervention were similar, except for cognitive behavioural therapy delivered with physiotherapy care, which was not significant in the sensitivity analysis excluding studies of patients with leg pain (0.56, −0.01 to 1.12; supplementary N).

From the primary analysis, behavioural therapy delivered with physiotherapy care maintained a large and clinically important effect on reducing pain intensity at short term follow-up (SMD 2.15, 95% confidence interval 0.27 to 4.03; moderate quality evidence). However, when we performed sensitivity analysis to resolve inconsistency at this time point, behavioural therapy delivered with physiotherapy care became disconnected from the network, precluding our ability to examine the robustness of these findings at short term follow-up (supplementary N). Nonetheless, we did not detect inconsistency at mid-term follow-up, and our results showed that behavioural therapy delivered with physiotherapy had a large and clinically important effect for reducing pain intensity, compared with physiotherapy care (1.01, 0.41 to 1.60; high quality evidence; equivalent to 25.6 points mean difference in improvement on a scale of 0 to 100). Effect estimates at long term follow-up suggested a large effect of treatment; however, the results were not significant (0.86, −1.12 to 2.84; moderate quality evidence).

The primary analysis showed that compared with physiotherapy care, cognitive behavioural therapy delivered with physiotherapy care was not significant for reducing pain intensity at short term follow-up (SMD 0.47, 95% confidence interval −0.66 to 1.61; moderate quality evidence). However, after sensitivity analysis (resolving inconsistency), we identified a moderate and clinically important effect at this time point (0.67, 0.01 to 1.33; moderate quality evidence; supplementary N). Nonetheless, significance was attenuated at mid-term (0.28, −0.01 to 0.57; moderate quality evidence) and long term follow-up (1.19, −0.10 to 2.48; moderate quality evidence).

Both the primary analysis (SMD 1.04, 95% confidence interval 0.19 to 1.88; moderate quality evidence; supplementary I) and sensitivity analysis (1.06, 0.56 to 1.55; supplementary N) found that pain education delivered with physiotherapy care maintained a large and clinically important effect at short term follow-up. The effect of treatment remained significant at mid-term follow-up, although the effect was small and not clinically important (0.41, 0.13 to 0.95; moderate quality evidence). No studies investigated the effect of pain education delivered with physiotherapy care on pain intensity in the long term.

We noted a large and clinically important difference between no intervention and physiotherapy care alone in reducing pain intensity at short term follow-up, favouring physiotherapy care (SMD −2.06, 95%

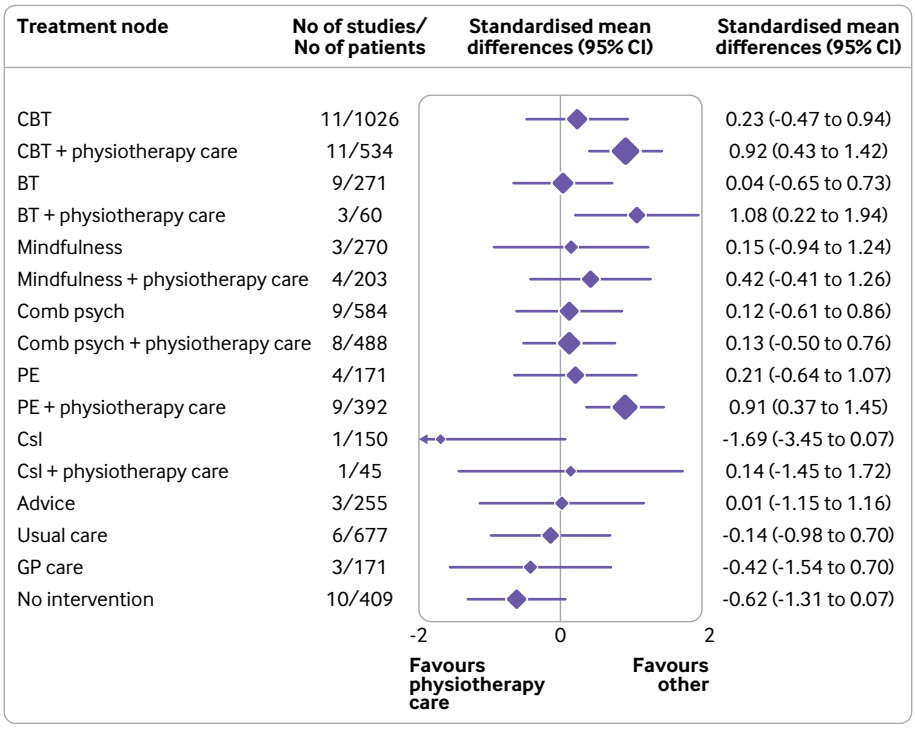

Fig 5 | Forest plot of network meta-analysis results for pain intensity at post-intervention. *Denotes significance at p<0.05. BT=behavioural therapy; CBT=cognitive behavioural therapy; Comb psych=combined psychological approaches; CsI=counselling; GP care=general practitioner care; PE=pain education. SMD=standardised mean difference. Physiotherapy care was the reference comparison group

confidence interval −3.51 to −0.60; moderate quality evidence). However, the effect did not remain after the sensitivity analysis (resolving inconsistency) (0.21, −0.86 to 1.28; supplementary N). The only other psychological intervention that had a significant effect on reducing pain intensity, compared with physiotherapy care, was pain education at mid-term follow-up (0.75, 0.16 to 1.35; low quality evidence).

Based on the SUCRA values and mean rank (supplementary L), the most highly ranked intervention at post-intervention (SUCRA 91.2%, mean rank 2.4), short term (96.7%, 1.4), and mid-term (96.6%, 1.5) follow-up was behavioural therapy delivered with physiotherapy care. At long term follow-up, cognitive behavioural therapy delivered with physiotherapy care was the highest ranked intervention (69.2%, 3.8). Rankograms for pain intensity are presented in supplementary L. In sensitivity analysis (removing inconsistency) at short term follow-up, behavioural therapy delivered with physiotherapy care became disconnected from the network, therefore, no SUCRA results were available. Instead, pain education delivered with physiotherapy care was the most highly ranked intervention (SUCRA 92.3%) at this time point. The comparison-adjusted funnel plots (supplementary M), and meta-regression based on sample size (supplementary Y), did not suggest small-study effects for pain intensity at any time points. We did not find any evidence suggesting that mean age, percentage of males, or mean baseline levels of pain intensity were effect modifiers (supplementary Y).

Psychological interventions for fear avoidance

Of 37 articles assessing fear avoidance, 29 articles that reported data for 29 unique studies and involved 4288 people with chronic, non-specific LBP, were included in the NMA. The network became disconnected at long term follow-up. For post-intervention, the median time point for assessment was at the end of treatment (range 0-2 months post-intervention). The median follow-up time points were 3 months (range 2-5 months) and 9 months (6-11 months) post-intervention for short term and mid-term follow-up, respectively. Fear avoidance was assessed using the Fear Avoidance Beliefs Questionnaire, Pain Catastrophising Scale, Tampa Scale of Kinesiophobia (English, Italian, Portuguese, and shortened versions), Pain Coping and Cognition List (Catastrophising subscale), and Coping Strategies Questionnaire (Catastrophising scale). Results of the NMA, risk-of-bias assessment for each study (domain level judgments and overall risk of bias), and CINeMA assessment (domain level judgments and overall confidence rating) for fear avoidance are presented in supplementary Q and R. We did not detect any global or local inconsistency for fear avoidance at any time (supplementary W and X). We did not find any evidence suggesting that mean age, proportion of males, or mean baseline levels of fear avoidance were effect modifiers.

The NMA results showed that at post-intervention, cognitive behavioural therapy delivered with physiotherapy care had a large and clinically important effect on reducing fear avoidance, compared with physiotherapy care alone (SMD 1.77, 95%

confidence interval 0.65 to 2.90; moderate quality evidence; equivalent to 47.4 points mean difference in improvement on a scale of 0 to 100). No other psychological interventions showed any significant differences compared with physiotherapy care alone. Sensitivity analysis excluding one study with high risk of bias resulted in similar effect estimates (1.79, 0.58 to 2.99; supplementary V). However, significance and clinical effectiveness were attenuated in the results from the sensitivity analysis that excluded studies of patients with leg pain (0.39, −0.04 to 0.82). In contrast, pain education delivered either alone (0.92, 0.25 to 1.60) or with physiotherapy care (1.03, 0.61 to 1.45) showed a large and clinically important effect on reducing fear avoidance (supplementary V).

At short term (SMD 0.01, 95% confidence interval −0.73 to 0.74; moderate quality evidence) and mid-term follow-up (0.50, −0.08 to 1.07; low quality evidence), cognitive behavioural therapy delivered with physiotherapy care had no significant effect on reducing fear avoidance, compared with physiotherapy care. Owing to disconnection of the network at long term follow-up, we performed only a pairwise meta-analysis of cognitive behavioural therapy delivered with physiotherapy care and physiotherapy care alone. The results were not significant; however, the 95% confidence interval suggested that results might favour cognitive behavioural therapy delivered with physiotherapy care (3.21, 0.00 to 6.41).

In contrast, pain education delivered alone (SMD 1.34, 95% confidence interval 0.38 to 2.30; moderate quality evidence) or with physiotherapy care (0.92, 0.50to 1.34; moderate quality evidence) had large and clinically important effects on reducing fear avoidance at short term follow-up. However, based on low quality evidence, treatment effects did not remain at mid-term follow-up (0.76, -0.11 to 1.62 for pain education delivered alone; 0.41, -0.36 to 1.19 for pain education delivered with physiotherapy care), with no network evidence available at long term follow-up.

The only other psychological intervention to show any significant effects on reducing fear avoidance, compared with physiotherapy care, was combined psychological approaches alone. The effects of treatment were observed only at short term follow-up (SMD 1.70, 95% confidence interval 0.38 to 3.02; moderate quality evidence), with no network evidence available at long term follow-up.

Based on the SUCRA values and mean rank (supplementary S), the most highly ranked intervention at post-intervention was cognitive behavioural therapy delivered with physiotherapy care (SUCRA 71.3%, mean rank 4.2). At short term follow-up, combined psychological approaches was ranked first (90.4%, 1.7), whereas pain education alone was ranked first at mid-term follow-up (80.5%, 3.3). SUCRA and mean rank were not assessed at long term follow-up because the network became disconnected. The comparison-adjusted funnel plots (supplementary T) and meta-regression based on sample size (supplementary Y) did not indicate small-study effects for fear avoidance at any time points. We did not find any evidence suggesting that mean age, percentage of males, or mean baseline levels of fear avoidance were effect modifiers (supplementary Y).

Psychological interventions for intervention compliance

Of 38 articles reporting enough data to assess intervention compliance, we included 25 articles that reported data for 26 unique studies and involved 2877 people with chronic, non-specific LBP in the NMA done at post-intervention (supplementary Q). We did not detect any global or local inconsistency for intervention compliance (supplementary W and X).

Compared with physiotherapy care, only combined psychological approaches significantly increased the odds of intervention compliance (odds ratio 0.28, 95% confidence interval 0.09 to 0.86; moderate quality evidence). The sensitivity analysis that excluded one study with high risk of bias produced similar effect estimates for combined psychological approaches (0.30, 0.10 to 0.94; supplementary V). However, significance was lost for combined psychological approaches, compared with physiotherapy care, in all other sensitivity analyses (supplementary V). No interventions showed a significant effect on reducing the odds of intervention compliance, compared with physiotherapy care, in the primary or sensitivity analyses.

Based on the SUCRA values and mean rank (supplementary S), the most highly ranked intervention for improving intervention compliance was combined psychological approaches (SUCRA 78.7%, mean rank 2.9). The comparison-adjusted funnel plots (supplementary T) and meta-regression based on sample size did not indicate small-study effects for intervention compliance at post-intervention. We did not find any evidence suggesting that mean age or percentage of males were effect modifiers (supplementary Y).

Psychological interventions for health related quality of life

Of 44 unique studies assessing health related quality of life, 18 studies involving 2079 people with chronic, non-specific LBP involved a physiotherapy care comparison group (supplementary U). In these studies, health related quality of life was assessed using the SF-12 (physical component summary score), SF-36 (physical component summary score, overall score, individual scores of all or some subscales), Sickness Impact Profile, Quality of Life Scale, and a question initiated by investigators about the overall assessment of quality of life.

The available evidence suggests that pain education delivered alone[67 69] or in conjunction with physiotherapy care,[84 85] cognitive behavioural therapy delivered with physiotherapy care,[86 87] and counselling delivered with physiotherapy care[88] are more effective than physiotherapy care alone for improving health related quality of life. Evidence is conflicting for the

effectiveness of combined psychological approaches delivered with physiotherapy care for improving health related quality of life, compared with physiotherapy care alone (ranging from no effect[89] to a significant effect at short term[90] or long term follow-up[91 92]). Similarly, evidence is mixed regarding the effect of mindfulness delivered with physiotherapy care on health related quality of life, compared with physiotherapy care (no effect[61 62] to short term effects only[60 93]). Behavioural therapy, delivered alone or in conjunction with physiotherapy care, did not appear to be more effective than physiotherapy care alone for improving health related quality of life.[71 73 83]

Safety of different types of psychological interventions

In total, 20 unique studies provided enough information about the number and relatedness of adverse effects occurring during the intervention period. Of these studies, 12 (60%) clearly reported that no adverse events occurred in any intervention group.[54 66 75 81 84 88 89 94-98] One study comparing cognitive behavioural therapy with no intervention reported that no serious adverse effects (defined as death or admission to hospital, events attributable to the intervention, or events that caused unwarranted distress to a participant) occurred in either group, during the intervention period.[46] Four studies reported on the occurrence of adverse events during the intervention period[53 60 99 100]; however, none was related to the psychological interventions under investigation. Three studies reported that adverse effects occurred in the psychological intervention group.[61 65 68] The adverse effects included: increased back pain (three (5%) of 61 participants allocated to cognitive behavioural therapy delivered with physiotherapy care)[65]; worsening of symptoms during treatment (one (2%) of 43 participants allocated to behavioural therapy alone)[68]; and emergence of painful emotional memories (one (6%) of 16 participants allocated to mindfulness delivered with physiotherapy care).[61] No event was considered as a serious adverse effect by the study authors.

Discussion

Principal findings

Compared with physiotherapy care alone (mainly structured exercise), physiotherapy delivered with psychological interventions are more effective for improving physical function and pain intensity in people with chronic, non-specific LBP. Based on moderate quality evidence, cognitive behavioural therapy delivered with physiotherapy care was the most effective intervention for improving physical function at post-intervention, compared with physiotherapy care (equivalent to 19.6 points mean difference in improvement on a scale of 0 to 100. However, the clinical effectiveness of treatment diminished at short term follow-up. In contrast, pain education delivered with physiotherapy care resulted in moderate effects at post-intervention (equivalent to 12.0 points mean difference in improvement on a scale of 0 to 100); although, the clinical benefits of treatment were more sustainable, at least until short term follow-up (equivalent of to 16.5 points mean difference in improvement on a scale of 0 to 100; low to moderate quality evidence).

Based on low to high quality evidence, behavioural therapy delivered with physiotherapy care was the most effective psychological intervention for reducing pain intensity at post-intervention, compared with physiotherapy care (equivalent to 27.3 points mean difference in improvement on a scale of 0 to 100). The clinically important effects of treatment were sustained at least until mid-term follow-up (equivalent to 25.6 points mean difference in improvement on a scale of 0 to 100). However, we emphasise caution with interpreting results at short term follow-up for behavioural therapy delivered with physiotherapy care because of the presence of inconsistency.

Based on moderate quality evidence, cognitive behavioural therapy delivered with physiotherapy was the most effective intervention for reducing fear avoidance at post-intervention (equivalent to a mean difference of 47.4 points mean difference in improvement on a scale of 0 to 100). Current evidence suggests that the effects of cognitive behavioural therapy delivered with physiotherapy can be sustained until mid-term and long term follow-up (low to moderate quality evidence). However, in people with chronic, non-specific LBP who do not report concurrent leg pain, at short term follow-up, pain education delivered alone or with physiotherapy care is the most effective intervention for reducing fear avoidance (moderate quality evidence).

Our systematic review identified that combined psychological approaches resulted in greater odds of intervention compliance, compared with physiotherapy care alone, although these findings should be interpreted with some caution. We were unable to determine the comparative effectiveness of psychological intervention for improving health related quality of life owing to heterogeneity of reporting across included studies. However, current evidence suggests that pain education, cognitive behavioural therapy, or counselling, delivered with physiotherapy care, can be more effective than physiotherapy care alone for improving health related quality of life.

Overall, our review has identified that pain education, behavioural therapy, and cognitive behavioural therapy are the most effective psychological interventions for people with chronic, non-specific LBP at post-intervention, when delivered with physiotherapy care. The most sustainable effects of treatment for physical function and fear avoidance are achieved with pain education programmes, and for pain intensity they are achieved with behavioural therapy. Although their clinical effectiveness diminishes over time, particularly in the long term (≥12 months post-intervention), evidence supports the clinical benefits of combining physiotherapy care with these specific types of psychological interventions

at the onset of treatment. The small total sample size at long term follow-up (eg, for physical function, n=6986 at post-intervention *v* n=2469 for long term follow-up; for pain intensity, n=6963 *v* n=2272) have resulted in wide confidence intervals at this time point; however, the magnitude and direction of the pooled effects seemed to consistently favour the psychological interventions delivered with physiotherapy care, compared with physiotherapy care alone. Future studies with longer follow-up periods are needed to further examine the long term effect of psychological interventions for people with chronic, non-specific LBP. Nonetheless, the limited but consistent available data suggest that psychological interventions are likely to be safe for people with chronic, non-specific LBP. Therefore, clinicians should consider incorporating psychological interventions with physiotherapy care (mainly structured exercise) to maximise improvements in health outcomes.

Strengths and limitations of this study

Our review had several strengths. Firstly, we used an NMA design to synthesise direct and indirect evidence on a wide range of psychological interventions available for managing chronic, non-specific LBP. This synthesis allowed us to simultaneously compare and rank many competing interventions within one coherent treatment network to determine the comparative effectiveness of psychological interventions for improving various outcomes important to patients with LBP. Importantly, we used a meticulous method to classify the psychological interventions, which has been described in the protocol paper[25] and in supplementary B. In summary, we used the splitting approach proposed by Caldwell et al[101] to separate different types of psychological interventions into distinct categories, and further, we delineated between psychological interventions delivered with or without co-interventions. This method is an important strength of our study because previous reviews have commonly grouped different types of psychological interventions together or grouped psychological interventions with or without co-interventions together, in a single comparison, potentially leading to heterogenous comparisons and inaccurate treatment effect estimates.

Further, we used a careful selection of search terms, extracted from many existing studies of psychological interventions for chronic pain conditions, to capture a broad range of psychological interventions. Importantly, we assessed core clinical outcomes for evaluating the efficacy or effectiveness of health interventions in people with non-specific LBP (eg, physical function, pain intensity, and health related quality of life).[102] These clinical outcomes are also consistent with the consensus based treatment targets of exercise for people with chronic, non-specific LBP: to improve function, improve quality of life, reduce pain, meet patient specific goals, and reduce fear of movement.[103] By investigating outcomes that are meaningful to patients and clinicians, our findings can help to support decision making about the use of psychological interventions for this population. In addition, we investigated the comparative safety of psychological interventions for chronic, non-specific LBP, which to our knowledge, has not been assessed comprehensively in previous reviews and is an important consideration when evaluating the risk-benefit ratio of health interventions.

This systematic review also had some limitations. Although we separated different types of psychological interventions into five broad but distinct categories to minimise heterogeneity, we made a pragmatic decision to combine interventions involving two or more types of psychological approaches into one treatment node. This decision could have resulted in heterogeneity of combinations of psychological interventions included within this treatment node. However, this pragmatic decision allowed us to gain statistical power and provide a simpler framework from which our findings could be translated more easily into clinical practice. Furthermore, our search strategy aimed to include the most common psychological interventions for patients with chronic, non-specific LBP. However, we identified one type of psychological intervention (hypnosis) that matched our inclusion criteria but did not match our predefined decision set for treatment nodes.[104] Consensus within the review team resulted in the inclusion of the study in our review, but exclusion from the NMA because of an inadequate number of studies available for pooling.

We also acknowledge that inconsistency was detected at various time points of analysis for our primary outcomes. If unresolved, the presence of inconsistency can threaten the validity of the NMA results. However, we performed a thorough examination of potential sources within the network (eg, visually inspecting study and patient characteristics to assess transitivity, exploring potential heterogeneity within the physiotherapy care node, and conducting numerous sensitivity analyses and meta-regressions), and we were able to sufficiently identify and resolve the main sources of inconsistency. Interpretation of study findings were made with consideration of the results of both the primary and sensitivity analyses.

The poor and inconsistent reporting of patient involvement in the design or development of the interventions described in the included studies limited our ability to ascertain whether the psychological interventions are considered acceptable to patients in clinical practice. In parallel, the absence of patient advocates involved in the planning and interpretation of the analyses could be considered a limitation of this review. The inherent inability to blind participants in clinical trials involving psychological interventions should also be considered as a potential source of bias (eg, study results could favour psychological interventions, delivered with or without physiotherapy care, over comparison interventions such as usual care, no interventions, or even physiotherapy care alone). In addition, poor and inconsistent reporting of data for socioeconomic factors and comorbidities precluded examination of these factors as potential

effect modifiers. Furthermore, although the decision to combine exercise, passive therapy, and physiotherapy into one node was pragmatic (that is, reflecting clinical practice), heterogeneity within the node was a potential limitation. However, we concluded that this potential heterogeneity was unlikely to significantly affect study results because most affected studies involved exercise only (36 (82%) of 44 studies with physiotherapy care as a co-intervention and 19 (58%) of 33 with physiotherapy care as a comparison intervention), or exercise delivered with passive therapy (six (14%) of 44 studies and nine (27%) of 33 studies, respectively).

Comparison with other studies

No previous studies have used NMA to synthesise evidence on psychological interventions for chronic, non-specific LBP. Although several non-Cochrane systematic and narrative reviews have explored this topic, with and without pairwise meta-analysis, many have included non-randomised trials (eg, pilot or feasibility studies), which are prone to bias. Therefore, we compared our findings with the most recent Cochrane review of behavioural interventions for chronic LBP conducted by Henschke et al in 2010,[14] which was an update of the Cochrane review conducted by van Tulder et al in 2000.[9]

The Cochrane review by Henschke et al[14] included 30 randomised controlled trials and evaluated three types of behavioural therapies for chronic LBP: operant, cognitive, and respondent therapies. The review found that behavioural therapy delivered with physiotherapy and back education was not more effective than was physiotherapy care and back education alone for pain relief and physical function over the short to intermediate term. The review also found low to moderate quality evidence that behavioural therapy and group exercise did not differ significantly in reducing pain intensity. However, several methodological differences between our reviews made comparisons of findings difficult. Firstly, Henschke et al[14] grouped psychological interventions, delivered alone or with non-psychological co-interventions, together within one comparison. For example, Henschke et al[14] combined studies of cognitive behavioural therapy alone with studies of cognitive behavioural therapy with a structured exercise programme or as part of a multidisciplinary rehabilitation programme.[14] In contrast, we delineated between cognitive behavioural therapy alone, and cognitive behavioural therapy with physiotherapy care co-interventions (mainly structured exercise), given that physiotherapy care and psychological interventions are traditionally delivered by distinct professions with different registration and training requirements. These professions are also governed by different hierarchical and interprofessional relationships. We sought to evaluate whether integration of these distinct therapies together, compared with delivery of these therapies in isolation, would result in differences in effect estimates.

Secondly, Henschke et al[14] performed separate pairwise meta-analyses of behavioural therapies, cognitive therapy, and cognitive behavioural therapy, compared with waiting list controls. However, these authors also grouped behavioural therapies (that is, operant and respondent therapy) together with cognitive behavioural therapy into one comparison (called behavioural treatment) in separate meta-analyses comparing psychological interventions with either usual care, group exercise, or physiotherapy care.[14] This grouping precluded examination of the differences between behavioural therapies and cognitive behavioural therapies, compared with exercise or physiotherapy care. In our review, we considered the distinction between behavioural therapy and interventions based on cognitive behavioural therapy to be important in our review, because we aimed to contrast traditional behavioural approaches (eg, biofeedback and progressive muscle relaxation) against contemporary behavioural approaches (eg, cognitive behavioural therapy), when compared with physiotherapy care. Furthermore, the clinical goal of physiotherapy care is typically grounded in changing behaviour, mainly through the promotion of exercise or physical activity. Although physiotherapists have been shown to partially recognise the presence of cognitive, psychological, and social factors in people with LBP, many do not have the confidence to deal with them.[105] By delineating between behavioural therapy and interventions based on cognitive behavioural therapy, we sought to provide clinicians with important insights regarding the additional benefit of incorporating cognitive strategies into treatment, to maximise health outcomes for patients with chronic LBP.

Methodological differences probably reflect the paucity of studies available at the time of publication (that is, year 2010) for Henschke et al's review.[14] As reported in table 2, most studies included in our review were published between 2011 and 2021. Fear avoidance, health related quality of life, intervention compliance, and safety were not analysed statistically in the previous Cochrane review.[14] We are not aware of any published high quality reviews directly comparing physiotherapy care with interventions based on pain education or counselling (that is, health coaching), delivered with or without a co-intervention, for people with chronic, non-specific LBP.

Implications for practice

Chronic pain conditions such as LBP require multimodal treatment approaches that address biopsychosocial dimensions.[8] Our study fills an important gap in research by use of an NMA design to determine the comparative effectiveness, relative rankings, and safety of a wide collection of psychological interventions available for managing chronic, non-specific LBP. Firstly, our review has identified the specific types of psychological interventions that are most effective for physical function, pain intensity, and fear avoidance, in people with chronic, non-specific LBP, when

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combined with physiotherapy care (mainly structured exercise). We have also identified the specific types of psychological interventions that show no significant effect for these outcomes. We have shown that different types of psychological interventions are not equal in treatment effectiveness, and that the effect of treatment can differ between psychological interventions delivered alone compared with psychological interventions delivered with co-interventions (that is, mainly structured exercise). Importantly, we investigated the comparative safety of psychological interventions for this population to facilitate improved evaluation of the risk-benefit ratio of psychological interventions for chronic, non-specific LBP. Crucially, we also evaluated the comparative sustainability of treatment effectiveness for different psychological interventions. Findings from our study can be used to inform clearer guideline recommendations regarding the use of specific psychological interventions for managing chronic, non-specific LBP and support decision making for patients and clinicians.

For adults with chronic, non-specific LBP

Existing guidelines consistently endorse that exercise and psychosocial therapies should be prescribed for management of chronic LBP.[16] However, guidelines are vague regarding the comparative effectiveness, and longevity of treatment effectiveness, of different types of psychological intervention that should be recommended to patients. Furthermore, guidelines scarcely provide supporting information to help clinicians and patients decide which psychological approach should be preferentially selected (eg, the particular psychological intervention that is most beneficial for a specific health outcome).[19-22] This systematic review provides evidence that the integrated delivery of psychological interventions with physiotherapy care is better than physiotherapy care alone, at least from post-intervention until the short term to mid-term. Available evidence suggests that psychological interventions are safe for this population. Ultimately, the choice of psychological intervention should be selected based on the patient's primary complaint, concurrent symptoms, and their treatment goals, and should be made in conjunction with the treating clinician. An exploration of the mechanisms by which these interventions improve clinical outcomes for people with chronic LBP is beyond the scope of our review. However, co-delivery of structured exercise and psychological strategies has strong potential to help patients with building resilience and psychological flexibility to better cope (that is, self-manage) with the physical and psychosocial challenges of living with chronic pain.[106 107]

For clinicians

Findings from our review are based on low to high quality evidence. Consistent with psychologically informed practice, an approach described more than a decade ago,[108 109] our results reinforce the clinical advantages of integrating physiotherapy care with psychological strategies or interventions. Specifically, in conjunction with physiotherapy care, pain education provides the most sustainable effects for improving physical function and behavioural therapy has the most sustainable effects for reducing pain intensity. For fear avoidance, cognitive behavioural therapy with physiotherapy care might result in the most sustainable effects over time; however, pain education delivered with physiotherapy care also results in clinically important benefits of treatment that persist until short term follow-up. Based on a small number of studies, evidence is inconclusive for the effect of mindfulness or counselling based interventions, with or without physiotherapy care, on physical function, pain intensity, and fear avoidance, compared with physiotherapy care. These recommendations are made with consideration of the limited but consistent evidence regarding the safety profile of psychological interventions for people with chronic, non-specific LBP. Given that the largest effects of treatment were found at post-intervention, early screening for the presence of psychological factors in patients with chronic LBP, and integration of both therapies together at the outset of treatment, might help to maximise improvements in patient outcomes.

However, existing patterns in patient access to exercise and psychological therapies for LBP suggest that early integration of both therapies at the outset of treatment might be difficult to implement. Across global healthcare systems, direct access (that is, self-referral) to exercise providers (eg, physiotherapists, exercise physiologists, and chiropractors) or psychological services is not the routine mechanism for patients accessing these types of care.[110 111] In contrast, patients typically access these services as secondary or tertiary care, via referral from general practitioners.[110 111] However, a systematic review of usual care for LBP has shown that the rate of referral to physiotherapy after consultation with a family practitioner is as low as 14% to 27%,[112] and in the absence of data, we postulate that the rate of referral to psychological services for LBP is even lower. Overcoming the low referral rates to exercise and psychological services, despite evidence for their effectiveness, is a challenge on its own. Furthermore, the current multidisciplinary approach towards health service delivery can impose further barriers towards early integration of both therapies. Results from an Australian survey of patients who had sought primary care treatment for LBP in the preceding year found that 28% of patients consulted between four to eight different practitioners for their LBP.[113] Although these findings are alarming, they are not surprising given that exercise providers and psychologists traditionally operate in siloed settings, which can lead to disjointed care. Considering that poor cross disciplinary collaboration can proliferate negative perceptions from the patient about illness, delay recovery, and reduce quality of life in patients with LBP,[114] the current multidisciplinary model of care for LBP could be insufficient in meeting patient needs and is likely to be inadequate for supporting effective integration of care.

To optimise co-delivery of exercise and psychological therapies at the onset of treatment, interdisciplinary or intradisciplinary approaches to treatment delivery can be feasible alternatives. In health, interdisciplinary approaches describe the co-ordination of different health disciplines working together to optimise care delivery, whereas intradisciplinary approaches describes single health disciplines blending skills within their own scope of practice, with concepts, methods, or techniques borrowed from other disciplines. The amount of evidence is growing suggesting that, in line with psychologically-informed practice, exercise providers (mainly physiotherapists) have the capacity to successfully incorporate psychological strategies into treatment for patients with musculoskeletal pain conditions.[60 115 116] In clinical psychology, promotion of physical activity and movement are established as inherent components of cognitive behavioural therapy interventions for chronic pain, such as graded activity or graded exposure. A recent systematic review with an NMA of 217 randomised controlled trials has shown that patients with LBP benefit from being encouraged to perform exercises that they enjoy.[117] Consequently, psychologists are well situated to potentially incorporate structured exercise programmes, guided by a patient's preference, into treatment. Overall, we remind exercise providers that incorporating psychological strategies into treatment is crucial for maximising physical function or reducing pain intensity and fear avoidance. We also remind psychologists that exercise is an important component of behavioural therapy or cognitive behavioural therapy, and adjunct to pain education programs. Incorporating exercise into treatment is crucial for optimising clinical improvements in people with LBP. Finally, we remind primary care practitioners that patient referrals should include recommendations for the early co-delivery of exercise and psychological therapies, ideally via an intradisciplinary approach; although, interdisciplinary care involving a coherent and coordinated effort between different disciplines might also be appropriate.

Nonetheless, we recognise that interdisciplinary or intradisciplinary approaches to treatment delivery come with their own challenges. Patients still perceive cross disciplinary care to be fragmented, and organisational support and collaboration between different health professionals is insufficient.[118 119] Clinician perceived barriers exist regarding the incorporation of psychological strategies into clinical practice, such as insufficient knowledge, concerns with reimbursement, time constraints, and reluctance of patients to engage in these types of treatment.[115 120] The establishment of integrated cross disciplinary clinical networks or coordinated care pathways, or the provision of sufficient training (eg, multiday workshops co-designed with multidisciplinary input), resources,[115 120] mentoring, feedback,[121] or subsidies for clinicians,[122] are potential strategies to overcome these challenges. However, further research involving key stakeholders is needed to better support clinicians, health systems, and ultimately, patients with LBP.

Implications for research

This review has identified a need for higher quality clinical trials investigating the effectiveness of interventions based on behavioural therapy, mindfulness, and counselling for people with chronic, non-specific LBP, as the quality of existing trials is highly variable (eg, small sample sizes). Furthermore, clinical trials with longer follow-up periods, particularly beyond 12 months post-intervention, are necessary to improve evaluation of the comparative long term effectiveness of psychological interventions. In addition, the assessment and reporting of data for health related quality of life and safety across studies of psychological interventions for chronic, non-specific LBP is highly heterogenous and generally absent, which prevented us from performing NMA for both outcomes. For health related quality of life, greater consistency in the measurement instruments used and a better understanding of the recommended administration and scoring procedures for validated instruments could improve our ability to compare findings across future studies. Nevertheless, we recognise that current tools specific for back pain or musculoskeletal conditions are scarce for assessing health related quality of life.[30 123]

We also raise some concerns about the poor quality of safety data reporting. Most studies did not have sufficient information regarding adverse events, for relatedness (that is, whether the adverse event was a direct result of participating in the study intervention), temporality (that is, whether the adverse event occurred during the intervention period or during the follow-up period), severity (that is, mild, moderate, or severe), and independence (that is, most studies reported a total count of adverse events across the entire study population and did not report whether multiple adverse events were experienced by the same participants). A previous review of 82 National Institute for Health Research funded clinical trials investigating psychological interventions has found that adverse events are often assessed according to inappropriate criteria that are not therapy specific.[124] Therefore, the development and implementation of standardised reporting guidelines for adverse events that are tailored for psychological interventions might improve accuracy of reporting and synthesising data[125] and strengthen the risk-benefit assessment of their clinical value.

Conclusions

This systematic review with NMA investigated the comparative effectiveness and safety of psychological interventions for managing chronic, non-specific LBP. Compared with physiotherapy care alone (mainly structured exercise), psychological interventions are most effective for people with chronic, non-specific LBP when they are delivered in conjunction with physiotherapy care. Although the clinical effectiveness

of psychological interventions diminish over time, the most sustainable effects of treatment for physical function and fear avoidance are achieved with pain education programmes. The most sustainable effects of treatment for pain intensity are noted with behavioural therapy. Limited but consistent evidence suggests that psychological interventions are safe for people with chronic, non-specific LBP, and the effects of treatment are maintained at least in the short term to mid-term after treatment. The comparative effectiveness of psychological intervention for improving health related quality of life is unclear owing to heterogeneity of reporting. Ultimately, to optimise improvement in patient outcomes, clinicians should consider strategies to promote early and cohesive co-delivery of structured exercise and psychological strategies or interventions together.

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The lead authors (EK-YH and LC) affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

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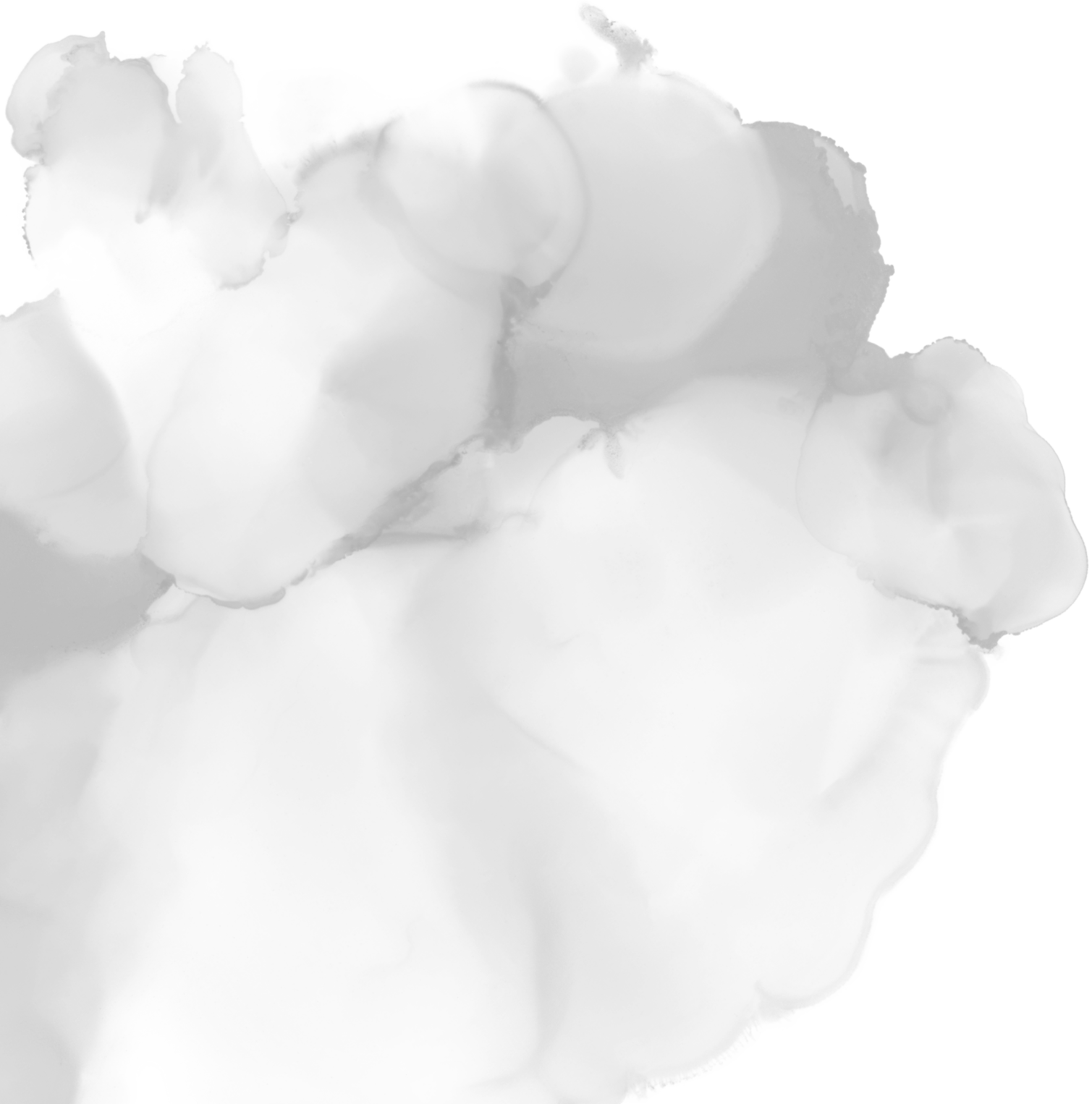
Web appendix: Supplementary material

CHAPTER SIX



Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: protocol for a randomised controlled trial

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AUTHORSHIP STATEMENT

The co-authors of the paper "**Ho EK**, Ferreira ML, Bauman A, Hodges PW, Maher CG, Simic M, Morton RL, Lonsdale C, Li Q, Baysari MT, Amorim AB, Ceprnja D, Clavisi O, Halliday M, Jennings M, Kongsted A, Maka K, Reid K, Reynolds T, Ferreira PH. Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: Protocol for a randomised controlled trial. *BMC Musculoskeletal Disorders*, 2021;22(1):611. doi: 10.1186/s12891-021-04479-z" confirm that Emma Kwan-Yee Ho has provided the following contributions to the study:

- conception and design of the research
- writing of the manuscript and critical appraisal of the content

As the primary supervisor for the candidate upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Paulo Ferreira
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STUDY PROTOCOL Open Access

Effectiveness of a coordinated support system linking public hospitals to a health coaching service compared with usual care at discharge for patients with chronic low back pain: protocol for a randomised controlled trial

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Abstract

Background: Although many people with chronic low back pain (LBP) improve following conservative treatment, one in five will experience worsening symptoms after discharge from treatment and seek health care again. The current LBP clinical care pathway in many health services lacks a well-integrated, systematic approach to support patients to remain physically active and self-manage their symptoms following discharge from treatment. Health coaching can support people to improve physical activity levels and may potentially reduce health care utilisation for LBP. The primary aim of this study is to evaluate the effect of introducing a coordinated support system (linking hospital outpatient physiotherapy services to a public health coaching service) at discharge from LBP treatment, on the future use of hospital, medical, and health services for LBP, compared with usual care provided at discharge.

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Methods: Three hundred and seventy-four adults with chronic non-specific LBP will be recruited from the outpatient physiotherapy departments of public hospitals in New South Wales, Australia. Participants will be individually randomised to a support system ($n = 187$) or usual care group ($n = 187$). All participants will receive usual care provided at discharge from treatment. Participants allocated to the support system will also receive up to 10 telephone-based health coaching sessions, delivered by the Get Healthy Service®, over a 6-month period. Health coaches will monitor and support participants to improve physical activity levels and achieve personal health-related goals. The primary outcome is the total number of encounters with hospital, medical, and health services for LBP, at 12 months from baseline. A within-trial economic evaluation will quantify the incremental costs and benefits of the support system from a health system perspective, to support reimbursement decision making.

Discussion: This study will establish the effect of a coordinated support system, introduced at discharge from treatment, on the future use of hospital, medical, and health services for LBP and various health outcomes.

Conclusion: Innovative community-driven solutions to support people with chronic LBP after discharge from treatment are urgently needed. Study findings will help inform health care policy and clinical practice in Australia.

Trial Registration: Prospectively registered on the Australian New Zealand Clinical Trials Registry (ACTRN12620000889954) on 10/09/2020.

Keywords: Chronic low back pain, Randomised controlled trial, Health coaching

Background

Low back pain (LBP) is the leading contributor to disability in Australia and globally [1, 2]. In Australia, nearly 4 million individuals report LBP at any one time [3] and the total cost of treatment exceeds $9 billion annually [4]. Within the current model of care for LBP in most countries, patients are commonly referred to primary care for treatment, including physiotherapy services (private clinics and hospital outpatient departments) [5, 6]. Although many people with LBP continue to improve following discharge from treatment, with approximately one third of individuals recovering within the first 9 months [7], one in five people experience recurrence of pain [8, 9] and resort to seeking further care within 12 months [10, 11]. For patients discharged after receiving treatment for LBP from hospital outpatient physiotherapy departments, this extra care may include additional pain medication intake, re-entry to the hospital system for further outpatient physiotherapy treatment, presentation to the emergency department, or surgical intervention.

In Australia, local hospital networks are responsible for managing and linking public hospitals, health institutions, and health services across defined geographical areas [12]. This includes the provision of hospital-based outpatient physiotherapy services for people with LBP. In the Australian state of New South Wales, 15 local hospital networks (called local health districts) service a total population of 8.2 million people, across eight metropolitan and seven rural and regional locations. In the Western Sydney Local Health District, an ethnically and culturally diverse metropolitan region, the rate of re-presentation to hospital services (i.e., physiotherapy clinics, emergency departments, pain clinics, neurosurgical clinics) within 1 year after discharge from outpatient physiotherapy treatment for LBP is 21% (unpublished New South Wales hospital data). The high rate of re-presentation constitutes a financial burden of $AUD744,000 yearly in direct costs in this local health district alone. Extrapolating these estimates across all local health districts within New South Wales, the cumulative financial and resource burden of re-presentations following discharge from hospital outpatient physiotherapy treatment is undoubtedly substantial.

The decline in clinical outcomes and the additional use of care (i.e., hospital, medical, and health services) for this subset of the LBP population is likely to be amplified by the lack of an integrated, systematic, local health district-driven approach to support patients to self-manage their condition once physiotherapy treatment ceases. After a series of consultations with senior musculoskeletal clinicians and consumer groups representing patients with LBP in Sydney, Australia, we identified that the lack of a coordinated support system at discharge is considered a strong factor driving the pattern of patients returning to hospital for further treatment (unpublished New South Wales hospital consumer committee report). Patients who participated in focus groups expressed concerns regarding the overload of information delivered abruptly prior to discharge from treatment, as well as the lack of ongoing support available. As a result, patients reported poor confidence for self-management of symptoms and maintenance of positive health behaviours (i.e., adherence to exercise). The integration of a simple, low-cost but well-structured post-discharge support system into the care pathway of chronic LBP is likely to improve outcomes.

Health coaching is a behavioural approach that aims to support individuals living with chronic conditions to adopt sustainable health-promoting behaviours and improve their quality of life [13]. The approach is strongly grounded in evidence-based behaviour-change theories such as Social Influence Theory and the Transtheoretical Model [14], and typically involves a qualified health coach using motivational interviewing techniques to support patients in achieving collaborative goals and empowering self-management of symptoms [15–17]. Evidence supports that telephone-based health coaching can result in clinically important improvements in physical activity in patients with chronic LBP [18]. This is important because people with chronic LBP who engage in moderate to high-intensity leisure-time physical activity have better outcomes in terms of pain, disability, and quality of life, than those who fail to maintain adequate levels of physical activity [11, 19–21]. Our pilot study of a health coaching intervention for LBP has provided evidence that a telephone-based health coaching intervention is acceptable to LBP patients, can improve physical activity levels, and crucially, may reduce the rate of care-seeking for LBP by 38% [95% confidence interval 0.32 to 1.18] compared with usual care [11]. Thus, health coaching appears to have potential to support people with LBP to remain physically active and reduce their future use of health services for LBP.

The Get Healthy Information and Coaching Service® (Get Healthy Service) delivers a variety of telephone-based health coaching programs for adults with a range of health behavioural risk factors and health complaints in the Australian states of New South Wales, South Australia, and Queensland [22]. Introduced in 2009, this is a well-established and fully operational service, funded by state governments, which provides health coaching programs at no charge for state residents. The goal of the Get Healthy Service® is to improve and support an individual's capacity to self-manage their own health and wellbeing. The service currently offers a Standard (health) Coaching module which aims to support participants with goal setting, motivation, confidence to overcome barriers, and achievement of sustainable lifestyle changes (i.e., increased physical activity levels, reduced sedentary behaviour). Previous studies have shown that the Get Healthy Service® is effective in improving moderate and vigorous physical activity levels and reducing behavioural risk factors for chronic diseases (i.e., weight, waist circumference, body mass index, nutrition-related behaviours) in the general population [23, 24]. Participants receive up to 10 individually tailored health coaching calls, delivered according to participant preference, over 6 months. The health coaching sessions are led by coaches with university-qualifications in allied health care (i.e., dietetics, exercise physiology), who monitor participants closely throughout the program to ensure they meet their goals safely. The sessions aim to compliment clinical care and offer accountability for treatment plans provided to patients by their clinicians prior to enrolment into the service. The service also has strong clinical governance and appropriate escalation pathways. The Get Healthy Service® is a viable and readily implementable solution that could be systematically integrated in the LBP clinical care pathway, potentially addressing the lack of support available after discharge from treatment across many regions in Australia.

There is only one published randomised controlled trial (RCT) which has evaluated the Get Healthy Service® in people with chronic LBP. The study investigated the effectiveness of a healthy lifestyle intervention (incorporating the Get Healthy Service®) in people with chronic LBP [25], and found no effect on pain intensity, disability, physical activity, or health care use (assessed as health care utilisation over the past 6 weeks preceding assessment) [25]. However, the lack of effect in the study was likely due to poor adherence with treatment, and importantly, the study only recruited overweight or obese patients identified from a waiting list for consultation with an orthopaedic specialist [25]. A protocol paper for a new study has been published for a RCT investigating a healthy lifestyle program involving consultations with a physiotherapist and dietician, provision of educational resources, and referral to the Get Healthy Service and a smoking cessation program [26]. The results of the trial have not been published; however, the protocol describes that study participants will be recruited from a mixed population of patients identified from primary and secondary care, and the general community. Further, the protocol does not describe any measurement of intervention effect on the use of medical or health services for LBP. No studies have investigated the effect of systematically integrating the Get Healthy Service® as a solution to support patients with chronic LBP immediately after discharge from hospital-based care.

This manuscript presents the protocol for a RCT and embedded qualitative study of a coordinated support system introduced after discharge from hospital-based physiotherapy treatment for chronic LBP. The support system will involve a structured referral pathway linking hospital-based outpatient physiotherapy services to a health coaching program, delivered by Get Healthy Service®, which has been tailored for chronic LBP. The primary aim of this study is to evaluate the effect of introducing a coordinated support system at discharge from LBP treatment, on the future use of hospital, medical, and health services for LBP, compared with usual care provided at discharge. The secondary aims of the study are: (i) to investigate the effectiveness and cost-

effectiveness of the support system on improving pain, disability, physical activity levels, and quality of life in people with chronic LBP and (ii) to identify factors related to the intervention, context, individual, and implementation process which may contribute to intervention outcomes and to use these findings to inform development of an implementation plan for scalability.

Methods

Study design

This is a randomised, single-blind, parallel, superiority clinical trial with 1:1 allocation ratio to either a coordinated support system introduced at discharge from treatment for chronic LBP (involving a structured referral pathway linking hospital-based outpatient physiotherapy services to the Get Healthy Service®), or usual care group (usual care provided at discharge from treatment). We will conduct an embedded qualitative study with key stakeholders, involving a series of in-depth interviews with clinicians and trial participants, and one or more focus groups with health coaches and agents from Get Healthy Service®. The trial protocol has been designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (see Additional file 1) [27]. The study intervention has been reported using the template for intervention description and replication (TIDieR) checklist (see Additional file 2) [28]. The results of the trial will be reported according to the CONsolidated Standards Of Reporting Trials (CONSORT) statement [29]. The trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000889954).

Participant timeline

Table 1 shows the assessments at each timepoint following the SPIRIT statement [27]. Figure 1 demonstrates the flow chart of the study.

Participants

We will recruit 374 participants with chronic non-specific LBP from outpatient physiotherapy departments of public hospitals in New South Wales, Australia. Consenting participants will be randomly allocated to either the support system ($n = 187$) or usual care group ($n = 187$).

Inclusion criteria

Potential participants will need to meet all the following inclusion criteria:

i) 18 years of age or older;
ii) presentation of non-specific LBP of at least 12-week duration, with or without leg pain but without radicular (e.g., reflex changes, motor loss) symptoms. Non-specific LBP will be defined as LBP without diagnosis of a specific cause, and the absence of serious spinal pathology or indicators of potentially serious conditions using 'red' flags;
iii) recently discharged (< 4 weeks post-treatment) from outpatient physiotherapy treatment from a participating hospital site. This includes discharge from one-to-one physiotherapy care directly into the community, or from supervised group exercise programs offered by the outpatient physiotherapy department;
iv) have adequate hearing and eyesight to participate safely in physical activity;
v) independent ambulatory status, with or without a gait aid.

Exclusion criteria

Potential participants will be excluded if they have any of the following:

i) known or suspected serious spinal pathology (e.g., fracture, inflammatory disorder); diagnosis of specific LBP (e.g., sciatica, spinal stenosis grade 3 to 4);
ii) co-morbid health condition(s) diagnosed by a medical practitioner that would prevent participation in physical activity or exercise programs;
iii) fibromyalgia or systemic/inflammatory condition; currently pregnant or planning to become pregnant over the study duration;
iv) inadequate English to complete outcome measures or participate in the health coaching intervention;
v) spinal surgery in the past 12 months;
vi) LBP caused by involvement in a road traffic crash in the last 12 months or ongoing compensation.

Outcomes

Primary outcome

The primary outcome will be the total number of encounters with hospital, medical, and health services for LBP (composite measure) [30] over 12 months from baseline assessment. The number of encounters of using hospital, medical, and health services for LBP could be related to a new or ongoing episode of LBP. Data will be collected at baseline, 6- and 12-months from baseline assessment, as well as fortnightly during the 12-month follow-up period, via online (electronic) self-reported questionnaires specifically designed for this study (see Additional file 3, Additional file 4, Additional file 5). Data will also be collected via linkage to participants' Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data. Encounters with

Table 1 Study assessments at specific time points

	STUDY PERIOD					
	Enrolment	**Baseline Assessment**	**Allocation**	**Follow-up Data Collection[a]**		
TIMEPOINT*	*Week – 4 to – 1*	*Week 0*	*Week 0*	*Fortnightly**	*6 months*	*12 months*
ENROLMENT:						
Informed consent	X					
Eligibility screen	X					
Allocation			X			
INTERVENTIONS:						
Support system			X	X	X	
Usual care only			X			
ASSESSMENTS:						
Use of hospital, medical, and health services for LBP		X		X	X	X
Self-reported physical activity levels		X			X	X
Objective physical activity levels		X			X	
Physical Function		X			X	X
Pain intensity		X		X	X	X
Disability		X			X	X
Quality of life		X			X	X
Self-management behaviours		X		X	X	X
Medication use		X		X	X	X
Sleep quality		X			X	X
Attitudes regarding use of pain medications		X			X	X
Beliefs about back pain		X			X	X

[a] From baseline assessment (week 0)

hospital, medical, and health services for LBP will be defined as: (1) a visit to any hospital service due to LBP (e.g., emergency department presentations, inpatient admissions/hospitalisations, outpatient services (e.g., outpatient physiotherapy, pain clinics), surgical procedures due to LBP); (2) a visit to a community-based medical or health practitioner due to LBP (e.g., general practitioner, specialist clinician, physiotherapist); (3) any diagnostic test for LBP (e.g., imaging); (4) a visit to any hospital, medical and health services to receive or fulfill a script for prescription medications, or a visit to any non-hospital Medicare services for LBP. Data on item 4 will be obtained through linkage to participants' Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data. Each encounter described above will be counted as an individual visit (e.g., a participant receiving 8 sessions of physiotherapy treatment will be considered as having 8 encounters). To account for data dependency, multiple encounters which occur within a 24-h period will be counted as one encounter.

Secondary outcomes

The secondary outcomes of this study are described in Table 2. Self-reported data on all secondary outcomes will be collected at baseline, and at 6- and 12-months from baseline assessment, via online (electronic) questionnaires (see Additional file 3, Additional file 4). In addition, self-reported data on pain intensity, self-management behaviours, and medication use will be assessed on a fortnightly basis during the 12-month follow-up period, collected via a repeating online (electronic) questionnaire specifically designed for this study (see Additional file 5).

Recruitment

Participant identification

Physiotherapists from the outpatient musculoskeletal physiotherapy departments of participating hospital sites will identify (all) patients who are within 1–2 weeks of their anticipated discharge from physiotherapy treatment for chronic LBP. The physiotherapist will introduce the study to all candidate patients. For patients indicating interest in participation, their contact details will be provided to the research team. The research team will phone the potential participant to provide them with further information about the study, including the study documents. Those who confirm their interest in the trial will be invited to take part in the consent procedures

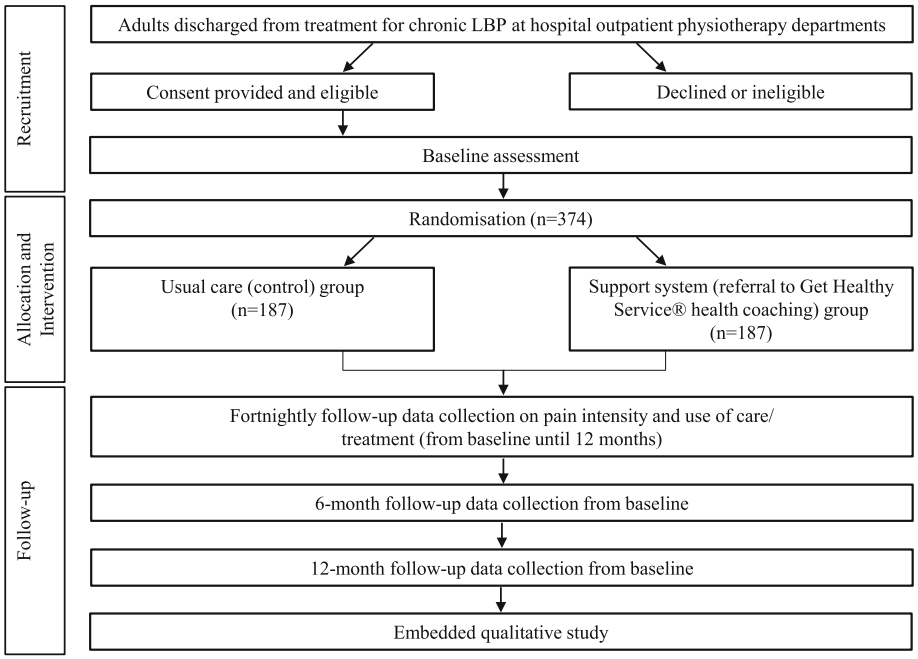

Fig. 1 Flow chart of the study

with a research team member, which will ideally occur within 1–2 weeks prior to discharge from treatment. De-identified demographic data (age, sex) and LBP pain scores at discharge from treatment (assessed with the NRS) will be collected from all candidate patients, irrespective of their interest or provision of consent. Data will be used to assess selection bias and target population reach.

Consent and screening

Depending on participant preference, consent procedures will occur face-to-face at the hospital site or remotely via an online consent form. For participants choosing to consent remotely, a research team member will provide support via phone call or video-conferencing software. During consent procedures, a research team member will discuss the study Participant Information Sheet and Consent Form with the participant (see Additional file 6). Potential participants who agree to take part in the study will be asked to sign a paper or online version of the study consent form. After signing the study consent form, the participant will be enrolled into the study and immediately assigned a unique participant code, which will be used on all study documents to protect their privacy. In addition, the research team will request written consent from participants to access their Medicare Benefits Schedule and Pharmaceutical Benefits Scheme claims data.

After consent procedures are completed, participants will be formally screened for eligibility and medical safety. For participants who meet the study eligibility criteria and are considered medically safe to participate in the trial, a research team member will phone the participant to invite them to take part in the baseline assessment. In accordance with standard Get Healthy Service® registration requirements [22], participants who are identified as requiring additional medical clearance will be referred to seek written recommendations from their medical doctor prior to randomisation.

Baseline assessment

Depending on participant preference, baseline assessment will occur face-to-face at the hospital site with a research assistant, or remotely. For participants completing baseline assessment remotely, a research team member will be available to provide support via phone call or video-conferencing software. Participants will be required to complete an online (electronic) baseline questionnaire to record demographic and anthropometric data (age, height, weight), and the study outcomes (see Additional file 3). In addition, participants will be given a tri-axial accelerometer (Axivity) to wear for 7 consecutive days on their right thigh. During the 7-day period, participants will be asked to document any physical activities or exercises completed in a paper-based logbook (see Additional file 7). After 7 days, participants will return the accelerometer and logbook to the research team

Table 2 Secondary outcomes

Secondary outcome	Measurement tool	Description
Self-reported physical activity levels	Global Physical Activity Questionnaire (GPAQ) [31]	The GPAQ assesses intensity-specific physical activity participation in 3 domains (activity at work, travel to and from places, recreational activities), and sedentary behaviour [31].
Objective physical activity levels	Axivity tri-axial accelerometer [32], assessed over a 7-day period	The device accurately estimates how physically active a person has been throughout the day using an accelerometer. The outcomes are overall physical activity, categorised according to intensity (sedentary, light, moderate, vigorous) and quantified as the average counts per minute of acceleration during the time the accelerometer is worn.
Function	Patient Specific Functional Scale (PSFS) [33]	At baseline, participants will be asked to self-select three activities they have difficulty performing due to their LBP. Each activity will be scored on an 11-point scale at each timepoint, with 0 representing 'unable to perform activity' and 10 representing 'able to perform activity at the same level as before injury or problem.' The scores for the three activities will be summed, giving a total score ranging from 3 to 30.
Pain intensity (i.e., mean intensity of LBP over the past fortnight)	Numerical Rating Scale (NRS) [34]	The NRS is an 11-point scale, scored on a scale of 0 to 10, with 0 representing 'no pain' and 10 representing 'worst possible pain.'
Disability	Roland–Morris Disability Questionnaire (RMDQ) [35]	The RMDQ consists of 24 items and total scores range from 0 to 24, with higher scores indicating higher disability levels.
Quality of life	Assessment of Quality of Life questionnaire (AQoL-8D) [36, 37]	The AQoL-8D consists of 35 items across 8 dimensions, with higher scores within each dimension corresponding to poorer quality of life. Utility weighted AQoL-8D scores will be used to estimate quality-adjusted life years (QALYs) for the cost-effectiveness analysis [38].
Self-management behaviours	Questionnaire specifically designed for this study	Examples of self-management behaviours will include, but are not limited to, the use of heat packs or hot showers for LBP, massage (not delivered by a professional), brace or support strapping/tape, topical creams/gels, physical activity and exercise, relaxation, meditation, mindfulness techniques, and walking aids specifically used to manage LBP.
Medication use	Questionnaire specifically designed for this study	Data on the use of medications for managing LBP, including type (i.e., paracetamol, non-steroidal anti-inflammatory drugs, opioids), dosage, and whether the medication was prescribed by a medical or health professional, will be collected on a fortnightly basis.
Sleep quality	Pittsburgh Sleep Quality Index (PSQI) [39]	The PSQI is an 18-item self-reported questionnaire assessing sleep disturbances in the last month. The total score is composed of a sum of scores in 7 different domains and ranges from 0 to 21, with higher scores indicating poorer sleep quality.
Attitudes regarding use of pain medications	Short-form Pain Medication Attitudes Questionnaire (PMAQ-14) [40]	The PMAQ-14 consists of 14 items across 7 areas of concern for users of pain medications (addiction, need, scrutiny, side effect, tolerance, mistrust of doctors, withdrawal). Each item is scored on a 6-point scale with 0 representing never true and 5 representing always true.
Beliefs about back pain	Back Beliefs Questionnaire (BBQ) [41]	The BBQ consists of 14 items and total scores range from 9 to 45, with lower scores indicating more negative beliefs about back pain.

via a pre-paid reply envelope. At baseline assessment, all participants will also receive a paper-based weekly diary (see Additional file 8) to document any adverse events which may occur during the intervention period (6 months) - see below. For participants who complete the baseline assessment at the hospitals, the online baseline questionnaire will be completed on-site and the research team member will directly attach the accelerometer onto the participant's thigh. For participants who complete the baseline assessment remotely, they will receive a link to the online baseline questionnaire via SMS or email, and any relevant study documents and equipment will be posted to them. The participant will receive a detailed sheet with labelled images and instructions on how to self-attach the accelerometer device (see Additional file 7). As required, a research team member will be available to provide support for any baseline assessment procedures, via phone call or video-conferencing software.

Randomisation

After baseline assessment has been completed and the participant has been discharged from treatment, participants will be randomised with 1:1 allocation ratio to either the support system or usual care group. Treatment allocation will be performed using a computer-generated random allocation schedule operated by a remote unblinded researcher to ensure concealment. As participants will be randomised after discharge from treatment,

with minimal potential for treatment contamination, randomisation will be at participant level. Randomisation will be by random permuted blocks of 4 and 6. Participants will be notified of their allocation via phone call from an unblinded research assistant. Select members of the research team will be unblinded to treatment allocation (i.e., main trial co-ordinator, the designated investigator managing referrals to the Get Healthy Service®, unblinded statistician monitoring trial safety, health coaches and agents from the Get Healthy Service®). Otherwise, all other research team members will remain blinded to treatment allocation. Participants will not be blinded to group allocation.

Usual care group

Participants in the usual care group will only receive the standard care delivered by their physiotherapist at discharge from outpatient treatment from participating hospitals. Usual care commonly involves the provision of advice, education, and a home-based exercise program, with no further intentional follow-up appointments arranged. Standard usual care at discharge may also involve referral to local community exercise providers, although the availability of these programs is highly variable across hospital sites and community regions. Participants in the usual care group will be able to continue seeking other forms of health care and treatments as desired.

Intervention group (support system involving referral to the Get Healthy Service®)

Similar to the usual care group, participants in the intervention group will receive the standard care delivered by their physiotherapist at discharge from outpatient treatment and will be able to seek other forms of health care and treatments as desired. In addition, participants in the intervention group will be referred for enrolment into the Get Healthy Service® *Standard Coaching* module (health coaching program) with a physical activity goal.

Referral to the Get Healthy Service®

All participants who are randomised to the support system will be referred to the Get Healthy Service® via the same structured referral pathway. A designated investigator (clinician) at each hospital will manage the referral process for the site. The designated investigator will enter the contact information of participants randomised to the support system group into a digital referral channel on the Get Healthy Service® website, via an online form specifically designed for the study. Evidence of medical clearance will be provided to the Get Healthy Service® via a secure file transfer program, when required. Upon receipt of the referral, a staff member (intake specialist) from the Get Healthy Service® will phone trial participants to complete the registration call. During the registration phone call, the intake specialist will enrol the participant into the *Standard Coaching* module. After successful enrolment, an assigned health coach will phone the participant to commence the health coaching program.

Structure of the Get Healthy Service®

The Standard Coaching module will be delivered in accordance with its current features and specifications, but with some adaptation to align the content of the module with best practice for management of LBP. Participants will be offered up to 10 individually tailored phone-based health coaching sessions over a 6-month period. Sessions will be approximately 17 minutes in duration and will be led by health coaches with university-qualifications in allied health (i.e., dietetics and/or exercise physiology). All health coaches are required to complete training in health coaching, predominately acquired through HealthChange® Australia (2-day Core Training program) [42], as well as internal training by clinical specialists as required. The sessions will be delivered to participants by their personal health coach, selected to match their goals and personal preference (i.e., male or female coach). The frequency of sessions will be tapered over the 6-month period according to each participant's preference and progress through the program. The initial health coaching session will focus on mutually establishing the participant's physical activity goals, as well as other health-related goals (i.e., reducing weight, achieving a healthy diet, reducing alcohol consumption) that are meaningful to the participant.

Contents of the health coaching program

Overall, the health coaching sessions will focus on utilising principles of behaviour change and self-regulation to assist participants with:

1. Increasing physical activity: Health coaches will assist participants to develop a tailored physical activity plan suitable to their individual lifestyle preferences;
2. Decreasing sedentary behaviour: Participants will be encouraged to increase daily incidental physical activity and decrease sitting time;
3. Achieving their health-related goals: The health coach will provide ongoing support and motivation to help participants achieve their personal physical activity and health-related goals. Health coaches will continually review participant progress with achieving their goals and assist with adjusting goals if necessary or as desired by the participant.

The contents of the *Standard Coaching* module will be individually tailored to meet the needs for people with chronic LBP. The tailored content will be informed by evidence-based recommendations for managing chronic LBP (see Table 3).

After completing the *Standard Coaching* module, participants will be given the option to discontinue the program (i.e., graduation), re-enrol for further health coaching sessions, or opt into a free SMS maintenance support program *(Get Healthy Stay Healthy)* for an additional 6 months. The option selected by the participant will be recorded. For participants who opt into the *Get Healthy Stay Healthy* maintenance support program, they will receive automated, standardised (pre-scripted) motivational SMS reminders tailored towards 3 distinct goal categories: (1) physical activity, (2) diet, (3) weight maintenance. Participants will be asked to select one-to-two goal categories of interest and indicate their preferences for the SMS reminders (i.e., frequency of receiving reminders, number of reminders received per goal category). Their personal health coach will establish specific behaviour goals (e.g., walk for 30 min daily), personal barriers (e.g., distracted and often miss walking time), and enablers (e.g., set phone alarm for 6 pm daily), which will be embedded into the SMS messages. At 3 months into the *Get Healthy Stay Healthy* program, the health coach will phone the participant to monitor their progress and adjust the goal/s or reminder preferences as needed. At 6 months, the health coach will phone the participant to confirm completion from the SMS program (i.e., graduation) and encourage ongoing self-maintenance of positive health behaviours.

Training

A series of training workshops will be implemented. Physiotherapists from the outpatient musculoskeletal physiotherapy departments of participating hospital sites will receive training from the research team to upskill on the process of identification of interested patients to the research team. The research team will undergo training to upskill on recruitment procedures (i.e., consent, eligibility screening). The designated investigator responsible for coordinating referral of participants to the Get Healthy Service® at each hospital site will receive training for managing the process (i.e., use of the digital referral form, provision of evidence of medical clearance). Health coaches delivering the study intervention will undergo a training workshop to familiarise themselves with the health coaching content which has been tailored to match the needs of chronic LBP (see Table 3). Health coaches will also receive training regarding indicators and procedures for clinical escalation (see Additional file 9).

Assessment of intervention fidelity and engagement

Fidelity of the referral process

We will assess fidelity of the referral process by recording the total number of participants who are randomised to the support system and successfully enrolled into the Get Healthy Service® (i.e., completion of registration call) and expressing this as a percentage of the total number of participants are randomised to the support system group.

Fidelity of the health coaching program

The Get Healthy Service® conducts internal health coaching call audits for 1% of all calls per month carried out by the service. The audits are based on the following key criteria: security and privacy, clinical best practice, health coaching (i.e., effective utilisation of health coaching skills and techniques), call etiquette, documentation. Further, in the initial period of study implementation, the Get Healthy Service® will perform targeted auditing of health coaching calls delivered for participants specifically referred from the trial. The purpose will be to ensure that appropriate clinical best practice and high quality referral processing are achieved.

The research team will assess fidelity of the health coaching program by evaluating the following: (i) number of participants randomised to the support system who successfully establish a physical activity goal at commencement of the health coaching program; (ii) total number of health coaching sessions received per participant; (iii) number of participants who complete the Get Healthy Service® *Standard Coaching* module, where completion will be defined as receiving the 10 allocated health coaching sessions or achievement of participant goals. Data will be collected by the Get Healthy Service® and provided to the research team.

Participant engagement

We will assess participant engagement with the study intervention by recording the total number of participants who successfully complete the *Standard Coaching* module and expressing this as a proportion of the total number of participants who are successfully enrolled into the *Standard Coaching* module (tailored for chronic LBP).

Monitoring adverse events

The research team has designed this study to minimise or prevent potential risks. Expected adverse events include: i) flare-ups of LBP, ii) muscle soreness, swelling, or muscle cramps related to commencement of unaccustomed exercise; iii) unexpected trip/fall. During the intervention period, participants will complete a paper-based weekly diary to capture any adverse events which may occur during the 6-month intervention period (see

Table 3 Tailored health coaching content for chronic LBP

Tailored health coaching content for chronic LBP
Goal-setting:
• Mutually establish a physical activity goal with the participant at commencement of the health coaching program. Where relevant, this will include ongoing adherence to the exercise program prescribed by their hospital physiotherapist prior to discharge from treatment.
• Establish other health-related goals that are meaningful to the participant (i.e., reducing weight, achieving a healthy diet, reducing alcohol consumption).
Promotion of exercise and physical activity:
• Explore barriers to exercise and physical activity participation (e.g., time, access, financial resources, social comfort).
• Promote participant-led problem-solving skills to encourage overcoming perceived and real barriers to exercise or physical activity participation.
Support:
• Empower patients to foster self-efficacy and take charge of their own health, including monitoring their own symptoms and capacity to adhere to goals.
• Encourage involvement of family members, partners, or friends for social support with achieving goals.
• Provide continual motivation, encouragement, and support for the use of positive self-management strategies (e.g., physical activity, exercise).
Interpersonal skills:
• Build report, trust, and commonality with the participant.
• Directly involve the participant in the problem-solving and decision-making processes.
• *Educate and advise participants that the presence of pain does not always equal to harm.*
Education:
• *Educate and advise participants that many findings on imaging are common and do not necessarily identify the exact cause of pain. Further, imaging should only be carried out when consideration of serious pathology is clinically indicated.*
• Identify and address unhelpful beliefs about their condition or progress.
• *Educate and advise participants on the benefits of exercise and the consequences of inactivity such as prolonged bed rest (*i.e.*, muscle weakness).*
• *Assist participants in navigating decision-making processes surrounding whether additional care from hospital, medical, or health services for LBP is necessary.*
Pacing and activity modification:
• *Encourage participants to maintain engagement in usual activities (*e.g.*, occupational, leisure).*
• *Promote activity modification when required (*i.e.*, regress the difficulty of an exercise or activity, perform alternative exercises or tasks that do not elicit painful symptoms, minimise sustained repetitive postures and activities, minimise excessive loads when sitting, bending, or twisting).*
• Educate and advise participants on incidental opportunities to increase physical activity levels when exercise may not be feasible (e.g., use public transportation, walk to the shops, stand at work, spend less time sitting at home).
• *Encourage activity pacing when required, according to the participant's physical capacity and goals.*
Identifying and addressing psychological factors:
• *Screen and address common psychological factors in chronic LBP populations (*e.g.*, fear avoidance, catastrophising, familial and social stress, work pressures, financial pressures).*
• De-escalate potential perceived threats.
• Ask simple and unambiguous questions.
• *Avoid using catastrophising terms when discussing pain (*e.g.*, bulging disc, crumbling discs, degenerated discs).*
• Use positive, supportive, and empathetic language.
Reframing:
• Focus problem-solving on the participant's functional ability (i.e., improved ability to complete certain tasks or activities), instead of drawing attention to their pain.
• Focus on activities that the participant can perform and what they are willing to try.
• *Encourage participants to continue safe participation in exercise, even in the presence of acute symptoms (*i.e.*, flare-ups of LBP).*
• Focus on activities that the participant has been able to perform successfully and provide ongoing encouragement for future success.

Items in italics indicate content which has been tailored specifically for chronic LBP

Additional file 8). Participants will be required to document any adverse events by answering the question: 'Did you experience any of the following this week?'. Possible responses will include increased back pain, pain elsewhere, muscle soreness, swelling, muscle cramp, trip/fall, emotional distress, serious event, and other symptoms. If relevant, participants will be asked whether the event persisted more than 24 h (yes or no) and whether medical attention was sought (yes or no). If the participant perceives that the adverse event is directly related to participation in the study or they have ongoing unresolved concerns about the event, the diary contains written instructions directing them to contact the research team as soon as possible. The research team will monitor the adverse event until resolution. If participants are harmed from taking part in the study, there will be no special compensation arrangements.

Follow-up data collection

At 6 and 12-months from baseline assessment, participants will complete a follow-up online (electronic) questionnaire to record the study outcomes (see Additional file 4). At each timepoint, participants will receive the link to complete the respective online questionnaire via SMS or email, depending on their preference. At the 6-month follow-up, the participant will also repeat the procedure of wearing the accelerometer device and completing the physical activity logbook for 7 consecutive days. Participants will receive the accelerometer, an instruction sheet for self-mounting the device, the logbook, and a pre-paid reply envelope via post.

All participants will complete a brief questionnaire every fortnight during the 12-month assessment period (see Additional file 5). Participants will receive a link to complete the online fortnightly questionnaire via SMS or email. The questionnaire will collect self-reported data related the primary outcome (i.e., use of hospital, medical, and health services for LBP), and select secondary outcomes (i.e., pain intensity, self-management behaviours). Participants will be asked whether they experienced LBP (yes or no) and whether they sought any care or treatment for LBP (yes or no), in the past fortnight. Where relevant, follow-up questions will be asked regarding the mean pain intensity and number of days experiencing LBP, the type of care or treatment sought, and any costs or travel time associated with managing their LBP.

In addition, an unblinded member of the research team will briefly contact all participants at 3, 6 and 9 months to identify any concerns of the participant regarding participation in the study, such as potential barriers towards ongoing engagement with responding to fortnightly and follow-up questionnaires. The research team will use this information to develop strategies to promote ongoing study engagement (e.g., explain to participants the importance of obtaining a complete data set for the study). To maintain engagement with participants in the usual care group, participants in the usual care group will be offered the opportunity to enrol into any of Get Healthy Service's® programs at the completion of their 12-month follow-up assessment.

Monitoring contamination

The Get Healthy Service® is well-established and free to use for state residents. It is possible that participants in the usual care group may self-refer to the Get Healthy Service® and enrol in any of the health coaching programs offered. To minimise the risk of contamination, participants will be informed prior to study enrolment that those randomised to the usual care group will be asked to not participate in the health coaching intervention. Participants will also be informed that at the end of their participation in the trial (i.e., after completing their 12-month follow-up assessment), they will be offered the opportunity to enrol into the Get Healthy Service® and any of its programs. During the trial, participants will still be allowed to seek other forms of care or continue with the standard usual care provided to them by their physiotherapist at discharge from treatment.

If a participant in the usual care group self-enrols into any of the Get Healthy Service's® programs during the study period, we will not ask them to discontinue the program and will continue collecting data from them unless they choose to withdraw from the study entirely. At the conclusion of the study (i.e., after completion of the 12-month follow-up), a research team member will phone all participants in the usual care group to confirm whether they self-referred to any of the Get Healthy Service® programs during the intervention period. During this phone call, participants who express subsequent interest in the Get Healthy Service® will be offered enrolment into the service.

Embedded qualitative study

We will conduct an embedded qualitative study of a sample of key stakeholders (including clinicians, trial participants, and health coaches and agents from the Get Healthy Service®) involved in the study. The purpose will be to identify factors related to the intervention, context, and individual, to inform the development of an implementation plan for scalability of the approach across New South Wales local health districts.

We will conduct a series of in-depth interviews and one or more focus groups to identify factors and processes that contributed to the program outcomes. The interviews and focus group(s) will be informed by the Consolidated Framework for Implementation Research (CFIR) [43], and will focus on exploring the following

CFIR constructs: (1) intervention characteristics (e.g., relative advantage, adaptability, cost); (2) outer setting (e.g., patient needs and resources, external policies and incentives); (3) inner setting (e.g., implementation climate, relative priority, available resources); (4) characteristics of individuals (e.g., knowledge and beliefs about the intervention, individual identification with organisation); (5) processes (e.g., executing, engaging, reflecting and evaluating).

Participants will be purposively selected to ensure a range of demographics, health services, and experiences are captured, and interviews will continue until theme saturation is reached. We expect to conduct in-depth interviews with approximately 30 clinicians and trial participants, and a focus group involving health coaches and agents from the Get Healthy Service®. A mixture of inductive and deductive (drawing on the CFIR) interview analysis will be undertaken. Key themes will be used to guide development of recommendations for scalability of the support system.

Data integrity and monitoring

A Data Monitoring Committee (DMC) will be convened to overview data collection and integrity. The DMC will approve the statistical analysis plan and research protocol. Interim analyses of baseline data may be undertaken, under the guidance and approval from the DMC. The integrity of trial data will be monitored by regularly scrutinising data sheets for omissions and errors. Data inconsistencies will be explored and resolved. The lead investigator will be responsible for overseeing trial safety and ensuring that the best interests of participants are observed at all times. The lead investigator will be blinded to allocation, unless unblinding is deemed essential to ensure participant safety. Adverse events will be reported to the reviewing Human Research Ethics Committee and study Sponsor in accordance with approved requirements. All data collected will be restricted to the lead investigator and select members of the research team.

Protocol amendments

Any modifications to the protocol will be submitted to the reviewing Human Research Ethics Committee and acknowledged by the trial sponsor before implementation. Amendments will be communicated to the relevant trial registries and included in publications of trial results.

Sample size calculation

The sample size is that required to detect a clinically meaningful between-group difference in the primary outcome, i.e., the total number of encounters with hospital, medical, and health services for LBP [44]. A total of 374 participants ($n = 187$ per group) will be recruited. The study will have 90% power to detect as significant, at the 5% level, a 30% difference in the rate of using hospital, medical, and health services for LBP between groups (i.e., an Incidence Rate Ratio of 0.70 using negative binomial regression analysis) over the 12-month study period. The 30% difference in the rate of using hospital, medical, and health services for LBP is based on our research of patients' perceptions of a clinical worthwhile effect of interventions for LBP [45]. Estimates were based on a base rate exposure (β0) of 0.2 [total of 2 care-seeking events in the usual care group per fortnight (data from pilot)], assuming a correlation of 0.3 ($R^2 = 0.09$) between covariates and predictor (treatment), using negative binomial regression model (G*Power® software) [46]. Estimates allow for a loss to follow-up of 10%.

Statistical analysis

The total number of encounters with hospital, medical, and health services for LBP per person, over 12 months from baseline assessment, will be analysed using negative binomial regression to estimate the between-group difference in the rate of using hospital, medical, and health services for LBP at 12-month follow-up. Negative binomial regression takes into account individual follow-up time, frequency of using hospital, medical, and health services for LBP, non-normal distribution over time, and non-independence of repeated measures [44]. The effect of baseline pain and disability levels, number of previous treatments, symptom length, co-morbidities, and age will be accounted for in the model. The effect of group allocation on continuous outcomes (e.g., physical function, physical activity) will be assessed using linear regression models. All analyses will be performed by intention to treat.

Health system resource use and costs

Each episode of using hospital, medical, and health services for LBP for all randomised participants will be identified through study records and valued using Australian Refined Diagnosis Related Groups (AR-DRG) cost weights and Net Efficient Pricing for in-patient admissions; and MBS items for outpatient care (e.g., health care visits, tests, procedures). Prescribed medicines will be identified and valued from PBS claims. In addition, we will collect study-related costs for the Get Healthy Service® health coaching intervention and its implementation (e.g., staff salary, consumables) and delivery of usual care. Total costs and mean (standard deviation) per patient costs by allocation at 6 and 12 months will be tabulated and compared. The difference in health care use, and costs between groups will be reported with 95% confidence intervals.

Economic evaluation

A within-trial cost-effectiveness analysis from an Australian health system perspective will be undertaken. The measure of effectiveness will be the quality-adjusted life year (QALY) based on utility weights from the AQoL-8D questionnaire and participant survival at 12 months. Quality of life data will be assessed for missingness, and imputation methods will be employed if appropriate. Mean per patient and total utilities and QALYs will be tabulated by allocation, with precision estimates for differences between groups. An incremental cost effectiveness ratio (ICER) will be calculated from the difference in costs (health care use) and QALYs gained. A confidence limit around the ICER will be calculated using a non-parametric bootstrapping approach. The probability of the support system being cost-effective will be assessed at different willingness to pay levels and plotted on a cost-effectiveness acceptability curve. Scenario analyses will be undertaken to explore cost-effectiveness for specific populations (e.g., by sex). The economic evaluation will follow best practice recommendations with further details in the health economics analysis plan (HEAP) [47].

Trial status

Trial recruitment will commence in July 2021. The current protocol is version 6, dated 26 May 2021.

Confidentiality

The confidentiality of participants and privacy of data will be protected during all publications, presentations, and dissemination activities. Data will be presented as summary statistics such that individual participants will not be identifiable in the research reports or presentations.

Dissemination policy

The research team will provide participants with a summary of the study findings in lay language. Study results will be submitted for publication in reports and peer-reviewed journals. Study results will also be presented in a variety of conferences and forums, targeting both researchers and the general community. All investigators will be considered for authorship on future publications in accordance with their contributions.

Discussion

Current models of care for LBP in the public health care systems of most countries, including Australia, lacks the capacity to support people with LBP after discharge from treatment. Whilst most patients achieve continual improvements after treatment cessation [7], approximately one in five experience worsening symptoms after discharge and seek further care again within 12 months [10, 11]. The economic and resource burden imposed on health care systems by this cyclical pattern is substantial, highlighting the persistence of an important gap in the chronic LBP clinical care pathway (i.e., abrupt therapeutic void and lack of support after treatment discharge).

From consultations with senior musculoskeletal clinicians and consumer groups representing patients with LBP, we identified that lack of a structured support system after completing hospital-based outpatient physiotherapy treatment for chronic LBP was considered a strong driving factor for patients seeking further treatment. This is consistent with findings from a systematic review examining perceived health information needs related to LBP: patients with LBP strongly express the desire to receive clear information about the ongoing availability of medical and allied health services, non-medical support from social networks and support groups, or work-specific support services [48]. Similarly, a qualitative study of patient perceptions of self-managing chronic LBP following discharge from physiotherapy care also identified a strongly perceived need for self-management support following discharge from treatment (i.e., direct access and/or review appointments, telephone calls) [49]. Together, these studies highlight that patients with LBP consistently desire the availability or awareness of support services after cessation of treatment; although, targeted patient education should be provided to contextualise the appropriate use of further medical and allied health services.

Currently in Australian public hospitals, local health district-driven approaches to support people with LBP after completion of hospital outpatient physiotherapy care are inconsistent, poorly coordinated, and generally lacking. Some hospitals may offer short-term general exercise classes or refer patients to local community exercise programs. However, the availability of such programs is highly variable across different hospitals and communities, and it is atypical for patients to receive further intentional follow-up appointments or support from their physiotherapist. Systematic reviews of international clinical guidelines and care pathways suggest that this pattern is similar globally. Guidelines also lack consistency in recommendations for provision of ongoing patient support [50, 51]. The existing model of care for chronic LBP globally appears insufficient to meet patient needs after treatment cessation.

There is an increasing global need to develop solutions for LBP that move beyond medicalised approaches for LBP [52]. Improved solutions for chronic LBP should focus on incorporating conservative strategies that link education about LBP with sustainable positive lifestyle changes and pain-coping behaviours [48, 52]. In

particular, the proposed solution should also take into consideration patient preferences, including the provision of consistent, high-quality, tailored education regarding self-management strategies and the availability of support services for LBP [48]. Further, there is increasing emphasis that care for chronic pain conditions, such as LBP, should be grounded in the community [53]. Taken together, it seems that a supported self-management approach which incorporates community-based services may be a promising choice. The implementation of a simple, low-cost but well-structured post-discharge support service into the clinical care pathway for LBP could fill this gap.

Health coaching is an innovative and viable solution with strong potential to support LBP patients after discharge from treatment. Evidence from our pilot study supports that telephone-based health coaching can result in clinically important improvements in physical activity in patients with chronic LBP [18] and reduce the rate of care-seeking for the condition by 38% [95% confidence interval 0.32 to 1.18], compared with usual post-discharge management [11]. The Get Healthy Service® currently offers an established, well-structured, telephone-based health coaching program which focuses on supporting participants to develop self-efficacy in increasing physical activity levels, reducing sedentary behaviour, and achieving sustainable patient-centred goals. The Get Healthy Service® is fully funded by the New South Wales Ministry of Health and is free to use for state residents of three states [22]. In this study, we will test whether the introduction of a support system at discharge from hospital outpatient physiotherapy treatment for chronic LBP (involving a coordinated referral pathway linking hospital-based outpatient physiotherapy services to the Get Healthy Service®), reduces the number of re-presentations to medical, hospital, or health care services for LBP, as evidence of better support for maintenance of clinical improvements.

This manuscript presents the rationale and design of a RCT testing a novel support system which involves a structured referral pathway linking hospital-based outpatient physiotherapy services for chronic LBP to a health coaching program delivered by the Get Healthy Service®. The contents of the health coaching program will be tailored to meet the needs of people with chronic LBP. The support system will be compared with the usual care provided at discharge from outpatient physiotherapy care at each participating hospital site. Findings will evaluate the effect of the support system on the future use of hospital, medical, and health services for LBP, in people recently discharged from hospital outpatient physiotherapy treatment for chronic LBP and test the effectiveness and cost-effectiveness of the support system for improving LBP symptom-related outcomes and behaviours (pain, disability, physical activity levels, quality of life). We also describe an embedded qualitative study designed to identify factors related to the intervention, context, individual, and implementation process which are likely to contribute to intervention success or otherwise. If positive, findings will inform the development of an implementation plan for scaling-up this approach, which could be disseminated across other health districts. Further, study findings could be disseminated across the general community to increase consumer awareness of the availability of physical activity-focused health coaching programs, which can be readily integrated into the discharge care pathway for patients receiving treatment for LBP.

Conclusion

Community-driven solutions that support people with chronic LBP to better self-manage their condition and potentially reduce their use of further hospital, medical, and health services, after discharge from treatment, are urgently needed. The proposed study will test a novel support system which involves a structured referral pathway that directly links hospital-based outpatient physiotherapy services to the Get Healthy Service®. If positive, study findings will help to inform health care policy and clinical practice for chronic LBP in Australia.

Abbreviations

AQoL: Assessment of Quality of Life; AR-DRG: Australian Refined Diagnosis Related Groups; BBQ: Back Beliefs Questionnaire; CFIR: Consolidated Framework for Implementation Research; CONSORT: CONsolidated Standards Of Reporting Trials; DMC: Data Monitoring Committee; GPAQ: Global Physical Activity Questionnaire; HEAP: health economics analysis plan; ICER: incremental cost effectiveness ratio; LBP: low back pain; NRS: Numerical Rating Scale; PMAQ: Pain Medication Attitudes Questionnaire; PSFS: Patient Specific Functional Scale; PSQI: Pittsburgh Sleep Quality Index; QALY: quality-adjusted life year; RMDQ: Roland–Morris Disability Questionnaire; SPIRIT: Standard Protocol Items: Recommendations for Intervention Trials; TIDieR: Template for Intervention Description and Replication

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-021-04479-z.

Additional file 1.
Additional file 2.
Additional file 3.
Additional file 4.
Additional file 5.
Additional file 6.
Additional file 7.
Additional file 8.
Additional file 9.

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Authors' contributions

EKH drafted the manuscript. All authors (EKH, MLF, AB, PWH, CGM, MS, RLM, CL, QL, MTB, ABA, DC, OC, MH, MJ, AK, KM, KR, TR, PHF) discussed study procedures and contributed substantially to revisions of the manuscript. PHF is lead investigator. PHF, MLF, AB, PWH, CGM, MS, RLM, CL, QL, MTB, MH, DC, KR, OC, ABA, MJ, EKH, KM and AK obtained funding for the study. TR contributed extensively to writing related to the intervention content, was involved in overseeing intervention implementation, and supported planning of intervention fidelity assessment. QL designed the statistical analysis plan. RM designed the health economic evaluation. All authors read and approved the final manuscript.

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Availability of data and materials

Not applicable.

Declarations

Ethics approval and consent to participate

The study has been prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000889954). Ethical approval has been prospectively granted by the Western Sydney Local Health District Human Research and Ethics Committee (2020/ETH00115). Written informed consent will be obtained from all participants. Participants may choose to withdraw consent at any point during the study duration without providing a reason. The relevant sponsor has reviewed the study protocol and consent form.

Consent for publication

Not applicable.

Competing interests

All authors have no competing interests to declare.

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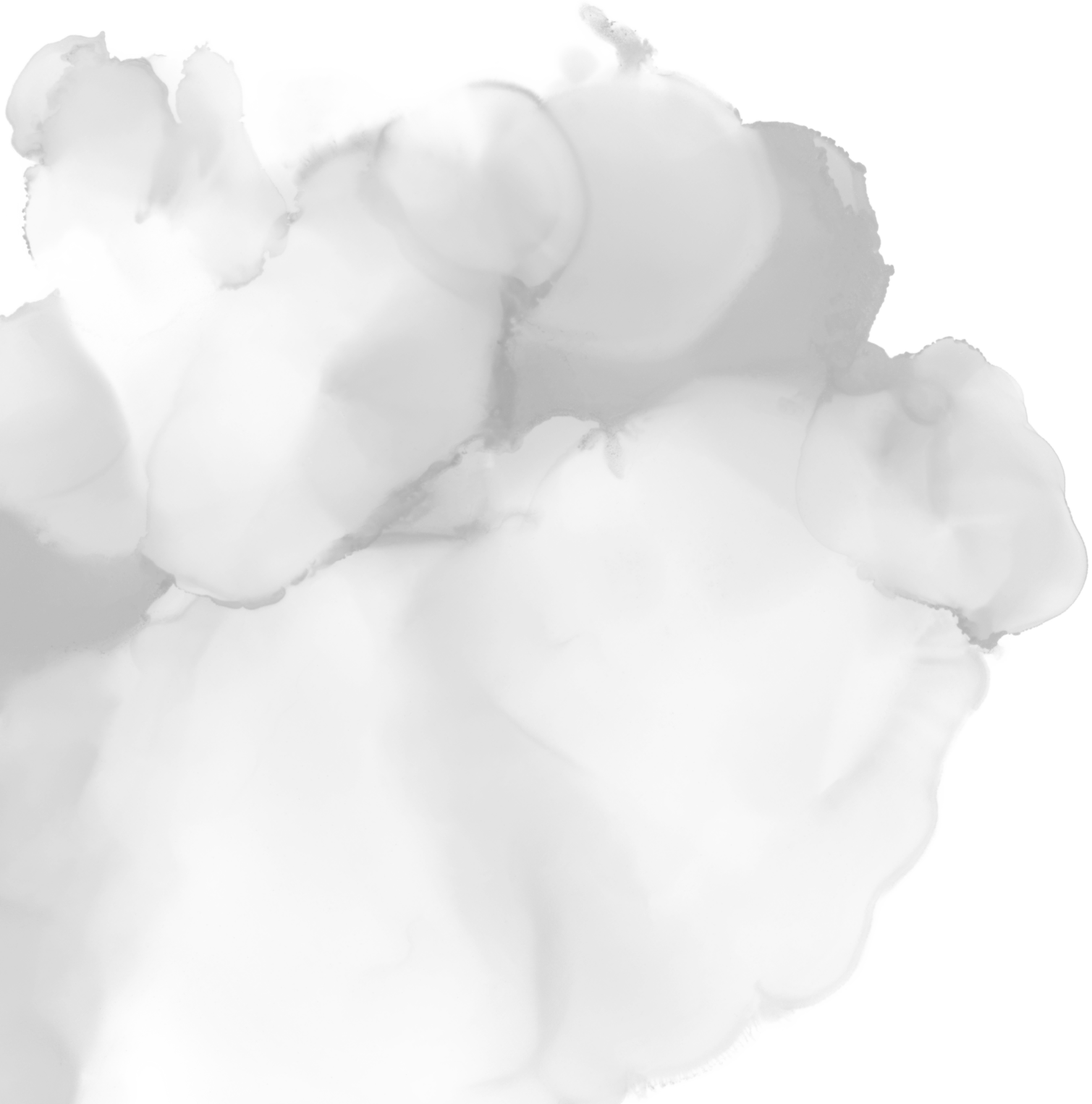
Publisher's Note

CHAPTER SEVEN



The Get Back to Healthy trial – a preliminary progress report and interim analysis plan of a large, multi-centre randomised controlled trial, investigating a discharge support system for patients with chronic non-specific low back pain.

Chapter 7 is presented as a traditional thesis chapter.

ABSTRACT

Background: In New South Wales, Australia, there is currently a lack of coordinated public health approaches to support people with chronic non-specific low back pain (LBP) to remain physically active and self-manage their condition in the community, after discharge from treatment. The Get Back to Healthy trial was designed to investigate the effect of a discharge support system (directly linking hospital outpatient physiotherapy services to a public health coaching service) on the future use of hospital, medical and health services for LBP, in people recently discharged from hospital outpatient physiotherapy treatment. The aim of this report was to summarise the current progress of the Get Back to Healthy trial and to describe the planned interim analysis which was impacted due to the COVID-19 pandemic.

Methods: We presented a narrative summary of the impact of the COVID-19 pandemic on trial recruitment, including an overview of the main strategies employed to overcome the associated challenges. We also provided an update on the total number and status of recruitment sites for the trial, including their corresponding recruitment rates. In addition, we summarised the enrolment status of all participants who have consented to the trial, to date. Preliminary data from participants who have completed their baseline assessment are also reported, including information on baseline participant characteristics, completion rates of data collection, and adverse events. Furthermore, we described the plan for a proposed interim statistical analysis, utilising baseline data from 50% (n = 187) of the Get Back to Healthy trial total sample size, which will be completed once sufficient data are available.

Results: This report was completed on 27 March 2022. Recruitment commenced in July 2021. In response to the adverse impact of the COVID-19 pandemic on trial recruitment, pragmatic modifications were made to the trial design, including the expansion of recruitment to the general community. At the time of reporting, six public hospital sites have been approved for recruitment. To date, 42 participants have been invited to participate in the trial, of which 23 provided informed consent. 12 participants have completed the baseline questionnaire, of which 10 have also completed the device-based assessment of baseline physical activity levels and subsequently been randomised. Four of the 10 participants who have been randomised were identified from partnering public hospitals and six from the general community. The response rate for the fortnightly questionnaires, designed to collect repeated measures of the primary outcome over one year, is 100%. No adverse events have been reported by trial participants.

Conclusion: Preliminary data from the Get Back to Healthy trial suggests that the current enrolment, data collection, and safety monitoring procedures for the trial are likely to be

feasible. The pragmatic modifications to the trial design appear to have increased overall trial recruitment rates; although, the impact of changes to the trial design should be examined through exploratory analyses once data collection has been completed. Based on the current recruitment rate, we anticipate that sufficient data to conduct the interim statistical analysis will be available by October 2022. We anticipate that recruitment of the total sample size (n = 374) will be achieved by June 2023, with follow-up data collection completed by June 2024.

INTRODUCTION

Low back pain (LBP) is the leading contributor to disability in Australia and globally.[1, 2] Currently, in the Australian state of New South Wales, there is a lack of coordinated public health approaches to systematically support people with chronic non-specific LBP to self-manage their condition within the community, after discharge from treatment. Senior musculoskeletal clinicians and consumer groups representing patients with LBP in New South Wales have indicated that this gap in the clinical care pathway may contribute to the pattern of one in five LBP patients returning to the health system for further treatment.[3] Preliminary evidence from the IMPACT pilot study suggests that lifestyle interventions, such as health coaching programs, are acceptable to patients with LBP, result in improvements in physical activity levels, and may reduce the rate of care-seeking for LBP, compared with usual care.[4] Therefore, health coaching has the potential to help support people with LBP to remain physically active and reduce their use of health services for LBP.

The Get Back to Healthy trial is an ongoing randomised controlled trial, conducted in New South Wales, Australia. The trial aims to investigate the effect of introducing a coordinated support system, which directly links hospital outpatient physiotherapy services for LBP to a public health coaching service (delivered by the Get Healthy Coaching Service®), at discharge from treatment.[3] The support system is being compared with the usual care provided at discharge from LBP treatment, and the primary outcome is the total number of encounters with hospital, medical, and health services for LBP, over a one-year period. The trial commenced recruitment in July 2021.

However, the COVID-19 pandemic has substantially hindered the progress of the Get Back to Healthy trial. Most significantly, the New South Wales state government-mandated restrictions (Public Health Orders) on the movement and gathering of people within residential and non-residential premises, to control COVID-19 community transmission rates, have caused major disruptions to recruitment and data collection. Initially, it was intended that by January 2022, baseline data for 50% of the total sample size (n = 187 of 374) would be available to conduct an interim statistical analysis for inclusion in this thesis. However, owing to prolonged delays with recruitment, the required sample size could not be achieved by this date, and the intended interim analysis could not be performed. Nonetheless, preliminary findings from the 23 participants who have consented to participate in the trial, at the time of reporting, are useful for evaluating the feasibility of the trial methodology and monitoring the trial efficiency.

Therefore, the aim of this report was to summarise the current progress of the Get Back to Healthy trial and to describe the planned interim analysis which will be performed once sufficient sample size for analysis is reached.

METHODS

This thesis chapter is a preliminary report of the Get Back to Healthy trial, which was completed on 27 March 2022. In this report, we presented a narrative summary of the impact of the COVID-19 pandemic on trial recruitment, including an overview of the main challenges hindering trial progress and the strategies employed to overcome them. We also provided an update on the total number and status of recruitment sites for the trial, including their corresponding recruitment rates. In addition, we summarised the enrolment status of all participants who have consented into the trial, to date. Preliminary data from participants who have completed their baseline assessment are also reported, including information on baseline characteristics of the participants, completion rates of data collection, and occurrence of adverse events. Furthermore, we described the plan for a proposed interim statistical analysis, which will be performed once sufficient data are available.

Overview of the Get Back to Healthy trial

Study design

The Get Back to Healthy trial is a randomised, single-blind, parallel, superiority clinical trial involving a 1:1 allocation ratio to either a support system in addition to usual care or usual care only. The total sample size for the trial is 374 participants. The trial is approved by the Western Sydney Local Health District Human Research and Ethics Committee (2020/ETH00115) and sponsored by the University of Sydney. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000889954) on 10 September 2020. The trial is funded by the National Health and Medical Research Council, and Sydney, Western Sydney, and South Western Sydney Local Health Districts. The trial commenced recruitment in July 2021.

Recruitment and randomisation

The protocol for the Get Back to Healthy trial, including information on the study design, recruitment and data collection procedures, interventions, and outcomes, has been published elsewhere (Chapter Six).[3] In summary, potential participants are identified by physiotherapists from the participating public hospital sites in New South Wales and

subsequently contacted by the central research team for informed consent and eligibility screening. Eligible participants are adults with chronic non-specific LBP recently discharged (≤ 2 weeks) from treatment for LBP from the outpatient physiotherapy departments of the participating hospital sites. The full eligibility criteria have been published in the protocol manuscript (Chapter Six).[3] After completing the informed consent and eligibility screening, participants are invited to take part in the baseline assessment. The baseline assessment involves the completion of an electronic questionnaire on the study outcomes, and a device-based assessment of physical activity which is collected via an Axivity tri-axial accelerometer. After completion of the baseline assessment, participants are individually randomised to either the support system or usual care group.

Interventions

All participants received the usual care provided at discharge from outpatient physiotherapy treatment from the participating hospitals. Participants may seek other forms of health care and treatments as desired. In addition, participants in the support system group are referred to the Get Healthy Coaching Service® (Get Healthy Service®), for enrolment in the *Standard Coaching* module with a physical activity goal. The *Standard Coaching* module is a telephone-based health coaching program involving up to 10 personalised telephone-based health coaching sessions delivered over a 6-month period. Sessions are approximately 17 minutes in duration and are led by health coaches with university qualifications in allied health (i.e., dietetics and/or exercise physiology). Health coaches utilise principles of behaviour change and self-regulation to assist participants with increasing physical activity levels, reducing sedentary behaviour, and achieving personal health-related goals. The content of the *Standard Coaching* module has been tailored to meet the needs of people with chronic LBP.[3] After completing the *Standard Coaching* module, participants can discontinue the program (i.e., graduate), re-enrol for further health coaching sessions, or opt into a free SMS maintenance support program (*Get Healthy Stay Healthy*) for an additional six months. The *Get Healthy Stay Healthy* maintenance support program provides participants with automated, standardised (pre-scripted) motivational SMS reminders tailored towards three distinct self-selected goal categories: (1) physical activity, (2) diet, and (3) weight maintenance.

Outcomes

The primary and secondary outcomes of the trial, including methods of assessment, are presented in Table 1. In addition, self-reported data on adverse events during the 6-month intervention period, are collected via a paper-based weekly diary.

Proposed statistical analysis

Descriptive statistics

Baseline characteristics were performed and summarised for participants who have completed their baseline assessment at the time of reporting.

Interim analysis plan

The planned interim analysis, which will be performed once sufficient data are available, is described below. The aim of the proposed interim analysis is to investigate the interaction between moderate-to-vigorous physical activity and sleep quality, on the utilisation of health services for LBP. The sample size for the interim analysis will be 187 participants (i.e., 50% of the total study sample size). The analysis will be performed using available aggregated baseline data (i.e., disregarding group allocation). Descriptive statistics summarising the baseline characteristics of the interim analysis sample, with and without stratification for baseline sleep quality, will be conducted and summarised in tables.

The explanatory variables will be moderate-to-vigorous intensity physical activity and sleep quality. Moderate-to-vigorous physical activity will be categorised into tertiles (low, medium, and high volumes), then dichotomised as low or medium-to-high volumes. Sleep quality will be dichotomised as good (Pittsburgh Sleep Quality Index (PSQI) <5) or poor sleep quality (PSQI ≥5). The primary outcome will be the utilisation of health services for LBP, defined as the total frequency (counts) of utilising hospital, medical, or health services for a current episode of LBP, over three months. Health services of interest will include care provided by a general practitioner, pharmacist, orthopaedic surgeon, pain physician, rheumatologist, neurologist, public or private hospital physiotherapist, private clinic physiotherapist, chiropractor, osteopath, public or private hospital exercise physiologist, private clinic exercise physiologist, massage therapist, public or private hospital psychiatrist, psychologist or counsellor, private clinic psychiatrist, psychologist or counsellor, health coach, natural therapist, or other health care provider.

Both the independent relationships between physical activity or sleep quality, and the utilisation of health services for LBP, and the interaction effect of physical activity and sleep quality, on the utilisation of health services for LBP, will be examined using negative binomial regression models. High physical activity, good sleep quality, or a combination of both, will be the reference comparisons. Analyses will be adjusted for potential confounders (i.e., age, sex, disability), which have been selected based on previous literature.[13-19]

Adjusted incident risk ratios (IRR) and 95% confidence intervals (CIs) will be used to describe the strength of association between the study outcomes and explanatory variables. To control for non-independence of data from complete twin pairs, a robust estimator of standard errors will be used in all analyses. All analyses will be performed using Stata (version 14).[20]

Expected findings

We anticipate that the results of the planned interim analyses may indicate:

- People engaged in medium-to-high baseline volumes of moderate-to-vigorous intensity physical activity may utilise less health services for LBP, compared with people engaged in lower volumes.
- People reporting good sleep quality may utilise less health services for LBP, compared with people reporting poor sleep quality.
- There may be an interaction effect between moderate-to-vigorous intensity physical activity and sleep quality, on the utilisation of health services for LBP.

Attempted analyses with alternative datasets

The relationship between moderate-to-vigorous intensity physical activity and the utilisation of health services for LBP was explored using the AUstralian Twin BACK pain (AUTBACK) dataset, as reported in Chapter Three of this thesis. Other analyses described above were also attempted using the AUTBACK dataset, but not performed, due to a lack of statistical power.

RESULTS

The main impact of COVID-19 on recruitment for the Get Back to Healthy trial

As described earlier, in response to increasing rates of community COVID-19 transmission within New South Wales, Australia, in June 2021, a series of Public Health Orders were issued by the New South Wales state government. The Public Health Orders restricted the non-

essential movement and gathering of people working or living in Greater Sydney (i.e., people living in affected regions were directed to stay at their place of residence unless a reasonable excuse was provided).[21-23] The first Public Health Order was issued on 26 June 2021, three days after Westmead Hospital, the first recruitment site for the trial, received approval to commence recruitment on 23 June 2021.

Although 'medical or caring reasons' were considered reasonable excuses for a person to leave their place of residence (i.e., patients were still permitted to attend health appointments), further directives from executives of Westmead Hospital imposed cascading disruptions on recruitment and data collection. For example, by mid-July 2021, clinicians from the outpatient physiotherapy department of Westmead Hospital were directed to transition to telehealth appointments only for patients with chronic conditions. This included patients receiving treatment for chronic non-specific LBP – the target population of the trial. However, clinicians reported challenges with the implementation of telehealth appointments, resulting in poor patient engagement. Concurrently, in-person research activities were also suspended at the hospital site, prohibiting trial staff from visiting the site to perform study-related procedures. At this stage, no potentially eligible participants had been identified. By August 2021, all musculoskeletal outpatient physiotherapy services for patients with chronic conditions at Westmead Hospital were suspended entirely, as staff were deployed to inpatient wards to combat the growing number of patients admitted with COVID-19,[24] further hindering recruitment. In total, the Public Health Orders remained in place for 106 consecutive days (until mid-October 2021). As Westmead Hospital was the only site approved for recruitment during this period, since other public hospital sites were also facing similar suspensions on clinical services and research activities, no participants were recruited between July to November 2021.

Several other COVID-19 related challenges adversely impacted trial productivity, for example, the transition to remote working and delays in receiving ethical and governance approvals. These challenges are discussed in more detail in Chapter Eight. However, the most detrimental impact of the COVID-19 pandemic on trial recruitment was the unanticipated suspension of clinical services for patients with chronic LBP, which led to no participants being enrolled into the study within the first five months of recruitment.

The response to challenges imposed by COVID-19 on the Get Back to Healthy trial

In response to significant delays with recruitment, the central research team employed several strategies including the addition of further hospital sites to support trial recruitment and altering the trial inclusion criteria. This process commenced in September 2021, whilst the Public Health Orders remained in place. An overview of the strategies employed has been provided below.

Addition of new hospital sites

Approval to commence recruitment at Concord Hospital, a public hospital based in Sydney, New South Wales, which was permitted to continue in-person clinical care for patients with LBP, was granted on 27 October 2021. On 25 November 2021, the first participant for the trial was identified from Concord Hospital. This participant completed their baseline assessment on 21 December 2021 and was successfully randomised on 23 December 2021. In December 2021, approval for recruitment was granted at Dubbo Base Hospital, a public hospital situated in regional New South Wales, and Liverpool and Campbelltown Hospitals, public hospitals situated in metropolitan New South Wales (Sydney). In March 2022, Royal North Shore Hospital, located in Sydney, was approved to commence recruitment for the trial. The timeline for the commencement of recruitment at each respective hospital site is presented in Table 2.

Modifications to the trial protocol

Due to the COVID-19 pandemic leading to the suspension of clinical services for patients with chronic non-specific LBP at several of our recruiting hospital sites, pragmatic modifications were made to the trial protocol to increase recruitment rates and to ensure timely study completion to meet funding deadlines. The changes primarily involved expanding recruitment to people in the general community who were recently discharged from treatment for chronic non-specific LBP from public or private physiotherapists, chiropractors, or general practitioners. The amendments were approved by the reviewing ethics committee on 9 February 2022 and were accompanied by a revision of the primary aims and eligibility criteria of the trial (Table 3, Table 4a, and Table 4b).

Overview of recruitment

Recruitment sites

As described earlier, six hospital sites across five local health districts, are currently approved for recruitment: Westmead Hospital (Western Sydney Local Health District), Concord

Repatriation General Hospital (Sydney Local Health District), Dubbo Base Hospital (Western New South Wales Local Health District), Liverpool and Campbelltown Hospitals (South Western Sydney Local Health District), and Royal North Shore Hospital (Northern Sydney Local Health District). Ethics approval to expand recruitment to the general community was obtained on 9 February 2022. Currently, three additional hospitals sites from South Western Sydney Local Health District are pending approval to commence recruitment: Fairfield, Bankstown, and Bowral Hospitals. Once approved, the total number of hospital sites supporting recruitment will be nine. The status of the approved recruitment sites, at the time of reporting, is summarised in Table 5. In summary, five of the six hospital sites are currently actively identifying potential participants. The trial is also actively identifying participants from the general community.

Recruitment rate

The recruitment rates at each recruitment site, and the overall recruitment rate for the trial (the percentage of identified participants who have been successfully randomised), are presented in Table 6. To date, 42 potential participants have expressed their interest in the trial. Most were identified from the general community (88%). After pre-screening potential participants, 27 were invited to take part in the trial, of which 23 provided informed consent. Based on the current recruitment rate, we anticipate achieving our total sample size by June 2023.

Status of consented participants

The status of the 23 participants who have consented into the trial are presented in Table 7. Out of the 23 participants who have consented into the trial, five participants were excluded after eligibility screening. The reasons for exclusion were medical clearance not provided by the participant's treating medical practitioner (n = 2), failing eligibility screening (i.e., the participant had a concurrent diagnosis of sciatica) (n = 2), and ineligible for the intervention (i.e., residing outside of Australian states of New South Wales or South Australia) (n = 1). Although, residing in the Australian states of New South Wales or South Australia is not a formal eligibility criterion, only people living in these states are eligible to enrol into the health coaching programs delivered by the NSW Get Healthy Service® (the trial intervention). Therefore, this participant was excluded after consenting, owing to the possibility of being ineligible to enrol into the health coaching program if randomised to the intervention group. One participant, who was deemed eligible to participate in the trial, withdrew from the study prior to completion of baseline assessment and randomisation. Lack of time was cited as the

reason for dropout. To date, 12 participants have completed the baseline questionnaire, of which two are pending completion of the device-based physical activity assessment. A further five participants have been invited to complete the baseline questionnaire, although their questionnaires are incomplete. In total, 10 of the 23 participants who have consented into the trial have been randomised.

Baseline characteristics of trial participants

Characteristics of the 12 participants who have completed the baseline questionnaire are presented in Table 8. The mean age of trial participants was 63.4 years (standard deviation (SD) 12.5), and the mean body mass index was 25.5kg/m^2 (SD 6.0). Most participants were male individuals (58%), who had completed vocational training (58%) and were currently working, either full-time (33%), or on a part-time or casual basis (25%), at baseline. Most participants were non-smokers (58%), consumed alcohol at least once per week (67%), and reported poor sleep quality (75%).

The average duration of LBP was 23.5 years (SD 21.7). At baseline, the average intensity of LBP was 4 (SD 2). Baseline levels of pain-related disability were relatively low (RMDQ: mean 8, SD S); although, function associated with self-selected activities of importance was also low (PSFS: mean 15, SD 9). Most participants held negative beliefs about back pain (BBQ: mean 17, SD 8). At baseline, 58% of participants reported using paracetamol, 33% reported using non-steroidal anti-inflammatory drugs, and 25% reported using opioids, within the last three months.

Completeness of data collection

The completion rates of data collection for all enrolled participants are presented in Table 9. At the time of reporting, eight of 10 participants (80%) who have completed the device-based physical activity assessment have worn the accelerometer for at least four out of seven days. On average, participants have worn the accelerometer for five days (range from 0 to 7 days). Overall, 15 out of 15 fortnightly questionnaires sent to participants have been answered, corresponding with an overall response rate of 100%. One participant required a reminder from the research team to complete an overdue fortnightly questionnaire, which was completed promptly by the participant upon receipt of the reminder. To date, no participants have reached their 6- or 12-month follow-up data collection.

Adverse events

None of the ten randomised participants have reported any adverse events. No participants have indicated any difficulties with the completion of the weekly diary.

Projected timeline

We expect to achieve the intended sample size for the intended interim analysis described earlier (187 participants) by October 2022. The interim analysis will be performed once sufficient data are available. We anticipate completing recruitment in June 2023 and finalising data collection (12-month follow-ups for all participants) by June 2024. We anticipate that the results of the Get Back to Healthy trial will be analysed and published in a peer-reviewed journal by January 2025.

DISCUSSION

The COVID-19 pandemic has caused major disruptions to the progress of clinical trials across the globe. The main challenge faced was the unanticipated suspension of clinical services for our target population at the sole recruiting site, during the first five months of recruitment. Nevertheless, the Get Back to Healthy trial employed several contingency strategies to support ongoing recruitment and data collection, including the addition of recruitment sites and the expansion of recruitment to the general community, which have led to improvements in recruitment rates. Once completed, the trial will provide evidence for the effect of a coordinated support system, linking people recently discharged from treatment for chronic non-specific LBP to a public health coaching service, on the use of hospital, medical, and health services for LBP.

Lessons learned from the rollout of the Get Back to Healthy trial are valuable for informing the conduct of a large multi-site randomised controlled trial, involving partners with multiple sectors. In the following chapter of this thesis (Chapter Eight), we elaborate on the adverse impacts of the COVID-19 pandemic on different partners of the trial during early implementation, describing the strategies employed to overcome them and the resultant impact on trial progress. Crucially, Chapter Eight summarises the key lesson lessons learned, which have been used to develop practical recommendations for improving the conduct and implementation of future clinical trials. We anticipate that the recommendations will benefit other researchers grappling with similar challenges during the current pandemic or other

natural disasters, and support the overall development of resilient clinical trials, conducted in any context, in the future.

CONCLUSION

The COVID-19 pandemic has significantly disrupted recruitment and data collection for the Get Back to Healthy trial in the early phases of implementation. Nonetheless, the Get Back to Healthy trial continues to recruit participants across six hospital sites and the general community. Preliminary data suggests that the current enrolment, data collection, and safety monitoring procedures for the trial are likely to be feasible and acceptable to people with chronic non-specific LBP. The pragmatic modifications to the trial design appear to have increased overall trial recruitment rates; although, the impact of changes to the trial design should be examined through exploratory analysis once data collection has been completed. To date, no adverse events have occurred. We anticipate that recruitment of the total sample size will be achieved by June 2023, with follow-up data collection completed by June 2024.

Table 1. Primary and secondary outcomes

Outcome	Assessment
Primary outcome	
Use of hospital, medical, and health services for LBP	The primary outcome is defined as the total number of encounters with hospital, medical, and health services for LBP, over 12 months. Data on the use of hospital, medical, and health services for LBP are collected at baseline, fortnightly, and at 6- and 12-months from baseline assessment, via electronic questionnaires specifically designed for the trial. In the baseline questionnaire, participants are asked whether they sought any care from a range of hospital, medical, and health services for LBP, within the last three months. For each type of care provider, participants are asked to indicate the total number (counts) of visits made within the last three months. Data are also collected via linkage to participants' Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data.
Secondary outcomes	
Self-reported physical activity levels	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Global Physical Activity Questionnaire (GPAQ),[31] which is administered electronically.
Objective physical activity levels	Device-based measures of physical activity are collected at baseline and at 6-months from baseline, via an Axivity tri-axial accelerometer,[32] assessed over a 7-day period.
Function	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Patient-Specific Functional Scale (PSFS),[5] which is administered electronically. Scores range from 0 to 30, with lower scores indicating worse function.
Pain intensity (i.e., mean intensity of LBP over the past fortnight)	Data collection occurs at baseline, fortnightly, and at 6- and 12-months from baseline assessment, via the Numerical Rating Scale (NRS),[6] which is administered electronically. Scores range from 0 to 10, with 0 representing 'no pain' and 10 representing 'worst possible pain.'
Disability	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Roland-Morris Disability Questionnaire (RMDQ),[7] which is administered electronically. Scores range from 0 to 24, with higher scores indicating higher disability levels.

Quality of life	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Assessment of Quality-of-Life questionnaire (AQoL-8D),[8, 9] which is administered electronically. Scores range from 35 to 176, with higher scores indicating poorer quality of life.
Self-management behaviours	Data collection occurs at baseline, fortnightly, and at 6- and 12-months from baseline assessment, via an electronic questionnaire specifically designed for this study.
Medication Use	Data collection occurs at baseline, fortnightly, and at 6- and 12-months from baseline assessment, via an electronic questionnaire specifically designed for this study.
Sleep quality	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Pittsburgh Sleep Quality Index (PSQI),[10] which is administered electronically. Scores range from 1 to 21, with PSQI scores >5 indicating poor sleep quality.
Attitudes regarding the use of pain medications	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Short-form Pain Medication Attitudes Questionnaire (PMAQ-14),[11] which is administered electronically. The PMAQ-14 is comprised of seven domains, with lower scores for each domain indicating more negative attitudes towards pain medications.
Beliefs about back pain	Data collection occurs at baseline, and at 6- and 12-months from baseline assessment, via the Back Beliefs Questionnaire (BBQ),[12] which is administered electronically. Lower scores indicate more negative beliefs about back pain.

LBP: low back pain

Table 2. Approval dates for recruiting hospital sites

Recruitment site	Approval date for commencing recruitment
Westmead Hospital	23 June 2021
Concord Repatriation General Hospital	27 October 2021
Dubbo Base Hospital	19 December 2021
Liverpool Hospital	23 December 2021
Campbelltown Hospital	23 December 2021
Royal North Shore Hospital	7 March 2022

Table 3. Previous and revised primary aims

Previous primary aims	Revised primary aims
1. To determine the effectiveness and cost-effectiveness of a discharge support system (incorporating referral to the Get Healthy Service®) for improving pain, disability, and physical activity levels, in people recently discharged from hospital outpatient physiotherapy treatment for chronic LBP. 2. To investigate the effect of a discharge support system (incorporating referral to the Get Healthy Service®) on the future use of hospital, medical and health services for LBP, in people recently discharged from hospital outpatient physiotherapy treatment for chronic LBP.	1. To determine the effectiveness and cost-effectiveness of a discharge support system (incorporating referral to the Get Healthy Service®) for improving pain, disability, and physical activity levels, in people recently discharged from hospital outpatient physiotherapy treatment, *or from public or private physiotherapy, chiropractic or general practitioner care for chronic LBP.* 2. To investigate the effect of a discharge support system (incorporating referral to the Get Healthy Service®) on the future use of hospital, medical and health services for LBP, in people recently discharged from hospital outpatient physiotherapy treatment, *or from public or private physiotherapy, chiropractic or general practitioner care,* for chronic LBP.

LBP: low back pain. Changes in the primary aims have been highlighted in italics

Table 4a. Previous and revised inclusion criteria

Previous inclusion criteria	Revised inclusion criteria
Potential participants will need to meet all the following inclusion criteria: 1. 18 years of age or older; 2. presentation of non-specific LBP of at least 12-week duration, with or without leg pain but without radicular (e.g., reflex changes, motor loss) symptoms. Non-specific LBP will be defined as LBP without a diagnosis of a specific cause, and the absence of serious spinal pathology or indicators of potentially serious conditions using 'red' flags; 3. recently discharged (< 4 weeks post-treatment) from outpatient physiotherapy treatment from a participating hospital site. This includes discharge from one-to-one physiotherapy care directly into the community, or from supervised group exercise programs offered by the outpatient physiotherapy department; 4. have adequate hearing and eyesight to participate safely in physical activity; 5. independent ambulatory status, with or without a gait aid.	To be included, they will need to meet all the following inclusion criteria: 1. 18 years of age or older; 2. present with a diagnosis of non-specific LBP of at least 12-week duration, with or without leg pain but without radicular (e.g., reflex changes, motor loss) symptoms. Non-specific LBP will be defined after screening for serious spinal pathology and indicators of potentially serious conditions using 'red' flags; 3. have been recently discharged (<4 weeks post-treatment) from physiotherapy treatment from outpatient physiotherapy departments at the participating hospital sites; *OR* *have been recently discharged (<6 months post-regular treatment) from a course of treatment by their physiotherapist, chiropractor, or general practitioner in either private or public practices (including hospitals). For participants recruited from the general community, the definition of a course of treatment will be at least one attendance to a physiotherapist, chiropractor, or general practitioner, which may include a clinical examination, provision of manual therapy, a home exercise program, back care education or medication. Discharge from regular treatment describes people who are no longer receiving weekly treatment from their health care professional for their LBP.* 4. have adequate hearing and eyesight to participate safely in physical activity; *5.* independent ambulatory status, with or without gait aid.

LBP: Low back pain. Changes in the eligibility criteria have been highlighted in italics.

Table 4b. Previous and revised exclusion criteria

Previous exclusion criteria	Revised inclusion criteria
Potential participants will be excluded if they have any of the following: 1. known or suspected serious spinal pathology (e.g., fracture, inflammatory disorder); diagnosis of specific LBP (e.g., sciatica, spinal stenosis grade 3 to 4); 2. co-morbid health condition(s) diagnosed by a medical practitioner that would prevent participation in physical activity or exercise programs; 3. fibromyalgia or systemic/inflammatory condition; 4. currently pregnant or planning to become pregnant over the study duration; 5. inadequate English to complete outcome measures or participate in the health coaching intervention; 6. spinal surgery in the past 12 months; 7. LBP caused by involvement in a road traffic crash in the last 12 months or ongoing compensation.	Potential participants will be excluded if they have any of the following: 1. known or suspected serious spinal pathology (fracture, inflammatory disorder); 2. diagnosis of specific LBP, e.g. sciatica, spinal stenosis (grade 3 to 4); 3. co-morbid health condition(s) preventing participation in physical activity or exercise programs as diagnosed by a medical practitioner; 4. fibromyalgia or systemic/inflammatory condition; 5. currently pregnant or planning to become pregnant over the study duration; 6. inadequate English to complete outcome measures or participate in the health coaching intervention; 7. spinal surgery in the past 12 months; 8. LBP caused by involvement in a road traffic accident in the last 12 months or ongoing compensation; *9. currently enrolled in the Get Healthy Service® Standard Coaching module.*

LBP: Low back pain. Changes in the eligibility criteria have been highlighted in italics.

Table 5. Status of recruitment sites

Recruitment site	Status
Westmead Hospital	All outpatient physiotherapy services for chronic LBP remain suspended at this site.
Concord Repatriation General Hospital	Actively identifying potential participants.
Dubbo Base Hospital	Face-to-face clinical services for chronic LBP patients were suspended between November 2021 to January 2022. At the time of reporting, the site is now actively identifying potential participants.
Liverpool Hospital	Face-to-face clinical services for chronic LBP patients were suspended between October 2021 to January 2022. At the time of reporting, the site is now actively identifying potential participants. Although, the number of patient presentations for chronic LBP is very low.
Campbelltown Hospital	Face-to-face clinical services for chronic LBP patients were suspended between October 2021 to January 2022. At the time of reporting, the site is now actively identifying potential participants. Although, the number of patient presentations for chronic LBP is very low.
Royal North Shore Hospital	Actively identifying potential participants.
General community	Actively identifying potential participants.

LBP: low back pain

Table 6. Recruitment rate for the Get Back to Healthy trial

Recruitment site	EOI (n)	Eligible (n)	Consented (n)	Randomised (n)	Recruitment rate[a] (%)
Westmead Hospital	0	0	0	0	0
Concord Repatriation General Hospital	5	5	5	4	100
Dubbo Base Hospital	0	0	0	0	0
Liverpool Hospital	0	0	0	0	0
Campbelltown Hospital	0	0	0	0	0
Royal North Shore Hospital	0	0	0	0	0
General Community	37	22	18	6	82
Overall (all sites)	**42**	**27**	**23**	**10**	**85**

EOI: expression of interest, n: number

[a] Percentage of participants invited to take part in the trial who have subsequently provided informed consent.

Table 7. Status of consented participants

Participant	Consent	Eligibility screening	Baseline assessment		Randomisation	Intervention period	Follow-up		
			Questionnaire	Physical activity			Fortnightly	6-month	12-month
02001	✓	✓	✓	✓	✓	✓			
02002	✓	✓	✓	✓	✓	✓			
02003	✓	✓	✓	✓	✓				
02004	✓	✓	Withdrew						
02005	✓	✓	✓	✓	✓	✓			
04001	✓	✓	✓	✓	✓	✓			
04002	✓	✓	✓	○					
04003	✓	✓	✓	✓	✓	✓			
04004	✓	✓	✓	✓	✓	✓			
04005	✓	✓	✓	✓	✓	✓			
04006	✓	✓	✓	✓	✓	✓			
04007	✓	✓	✓	○					
04008	✓	✓	✓	✓	✓	✓			
04009	✓	× Medical clearance declined							
04010	✓	× Medical clearance declined							
04011	✓	✓	○	○					
04012	✓	✓	○	○					
04013	✓	✓	○	○					
04014	✓	× Ineligible for intervention							
04015	✓	× Failed eligibility criteria							
04016	✓	✓	○	○					
04017	✓	✓	○	○					
04018	✓	× Failed eligibility criteria							

Key:
✓ completed
○ in progress
× not eligible

Table 8. Demographic and anthropometric characteristics

Variables	n	Mean ± SD (range)
Age (years)	12	63.4 ± 12.5 (34 to 81)
Sex (male)	12	58% (n = 7)
Body mass index (kg/m^2)	12	25.5 ± 6.0 (19.0 to 38.6)
Educational level	12	
High School		9% (n = 1)
Vocational training		58% (n = 7)
Bachelor's or Master's		33% (n = 4)
Doctorate		0% (n = 0)
Work status[a]	12	
Employed full time		33% (n = 4)
Employed part time or casual		25% (n = 3)
Unemployed		0% (n = 0)
Retired		33% (n = 4)
Unable to work		9% (n = 1)
Annual income (AUD)	12	
No or negative income		0% (n = 0)
$1 to $41,599/year		42% (n = 5)
$41,600 to $103,999/year		42% (n = 5)
≥$104,000/year		8% (n = 1)
Prefer not to answer		8% (n = 1)
Smoking history	12	
Never smoked		58% (n = 7)
Ex-smoker		33% (n = 4)
Current Smoker		9% (n = 1)
Alcohol use[b]	12	67% (n = 8)
Sleep quality[c]	12	75% (n = 9)
Quality of life (35 to 176)	12	75 ± 6 (51 to 103)
Duration of LBP (years)	11	23.5 ± 21.7 (1.2 to 60.0)
Pattern of LBP[d]	12	
Constant		50% (n = 6)
Recurrent back pain		50% (n = 6)
Current LBP intensity (0 to 10)	12	4 ± 2 (1 to 7)
Pain-related disability (0 to 24)	12	8 ± 3 (3 to 13)
Function (0 to 30)	10	15 ± 9 (1 to 30)
Beliefs about back pain (9 to 45)	12	17 ± 8 (4 to 31)
Using analgesic medications for LBP in last 3 months		
Paracetamol	12	58% (n = 7)
Non-steroidal anti-inflammatory drugs	12	33% (n = 4)
Opioids	12	25% (n = 3)

LBP: low back pain, n: number of participants providing responses, SD: standard deviation. All values are presented as mean, standard deviations, and ranges unless otherwise stated.
[a] Full time: ≥40 hours/week per week; Part time: <40 hours/week.
[b] Indicates consuming alcohol at least once per week.
[c] Indicates reporting poor sleep quality in the past month.
[d] Constant: always present, never fully recovers; Recurrent: periods of full recovery with no back pain, with intermittent episodes of back pain.

Table 9. Completion rate of data collection for participants

Participant	Baseline assessment		Fortnightly questionnaires	
	Questionnaire	Axivity	Completed/Sent	%
02001	✓	✓	6 / 6	100
02002	✓	✓	4 / 4	100
02003	✓	✓	2 / 2	100
02005	✓	✓	1 / 1	100
04001	✓	✓	1 / 1	100
04002	✓	○		
04003	✓	✓	0 / 0	-
04004	✓	✓	1 / 1	100
04005	✓	✓	0 / 0	-
04006	✓	✓	0 / 0	-
04007	✓	○		
04008	✓	✓	0 / 0	-
04011	○	○		
04012	○	○		
04013	○	○		
04016	○	○		
04017	○	○		

Key:
✓ completed
○ in progress

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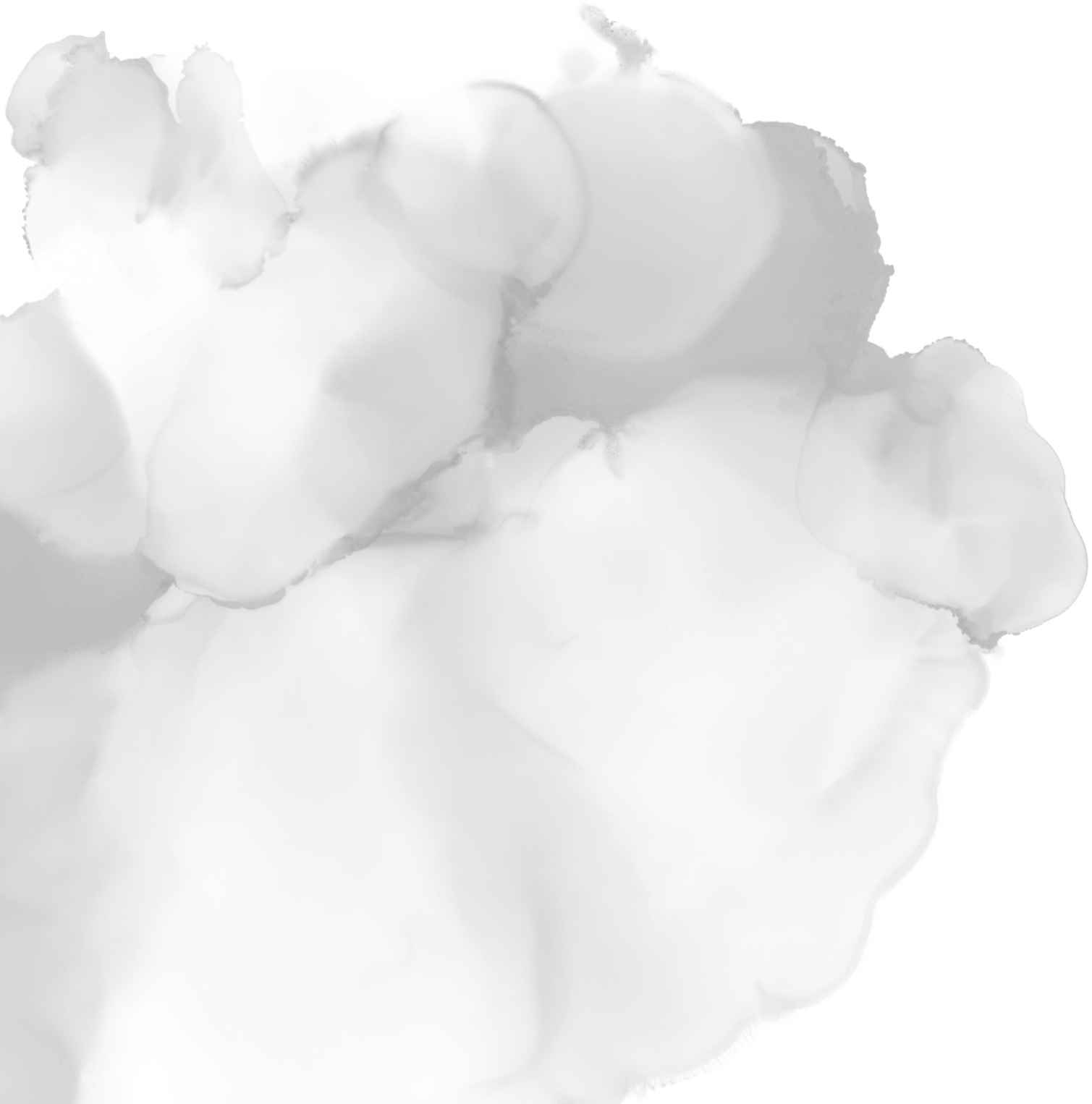
CHAPTER EIGHT



Developing resilient clinical trials: lessons learned from rolling out the Get Back to Healthy trial during a pandemic

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AUTHORSHIP STATEMENT

The co-authors of the paper "Ho EK, Ferreira ML, Hodge PW, Halliday M, Maka K, Ceprnja D, Jennings M, Amorim AB, Baysari MT, Ferreira PH. Developing resilient clinical trials: lessons learned from rolling out the Get Back to Healthy trial during a pandemic. *Health Research Policy and Systems,* Under review" confirm that Emma Kwan-Yee Ho has provided the following contributions to the study:

- conception and design of the research
- data acquisition
- data analysis and interpretation of findings
- writing of the manuscript and critical appraisal of the content

As the primary supervisor for the candidate upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Paulo Ferreira
date: 16th April 2022

Developing resilient clinical trials: lessons learned from rolling out the Get Back to Healthy trial during a pandemic

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ABSTRACT

Background: The COVID-19 pandemic has resulted in wide-spread disruptions to the conduct of clinical trials across the globe. The Get Back to Healthy trial is an ongoing randomised controlled trial, conducted in Australia. The trial aims to investigate the effect of introducing a coordinated support system, at discharge from treatment for low back pain (LBP), on the future use of health services for LBP. The support system links hospital outpatient physiotherapy services to a telephone-based public health coaching service. The current study aimed to provide an overview of the impact of the COVID-19 pandemic on roll out of the Get Back to Healthy trial, and practical recommendations to improve the conduct and implementation of clinical trials, in any context, in the future.

Methods: We briefly summarised the study design and partners involved in the Get Back to Healthy trial. We also presented a narrative summary of the COVID-related challenges faced by the partners during roll out of the trial, and described contingency strategies implemented to overcome them. Finally, we summarised the key lessons learned and provided recommendations to support the development of resilient clinical trials in the future.

Results: The main adverse impact of the pandemic on the trial was the alteration and suspension of clinical services for the trial target population, at the recruiting hospital sites. Other challenges were related to restrictions on face-to-face research activity, the transition to remote working, and delays in receiving approvals to implement contingency strategies. These challenges significantly affected recruitment and data collection. For future clinical trials, we recommend: (i) prioritising the safety of trial staff and participants, (ii) appointing clinical trial co-ordinators, and site co-ordinators for each recruitment site, (iii) nurturing existing relationships with established partners, (iv) adopting adaptable, flexible, and agile approaches to collaboration, particularly for pragmatic trials.

Conclusion: The implementation of large, pragmatic, multi-site randomised clinical trials, involving partners from multiple sectors, is always challenging. These challenges were amplified during the recent world pandemic. This study has highlighted the strategies that can be used to support the implementation of clinical trials conducted in any context.

Contributions to the literature

- The implementation of large, pragmatic, multi-site randomised clinical trials, involving partners from multiple sectors, is always challenging. These challenges have been amplified during the COVID-19 pandemic.
- Lessons learned from the Get Back to Healthy trial highlight the importance of prioritising the safety of trial staff and participants, appointing personnel with defined roles to support trial operations, nurturing existing relationships with established partners, and adopting adaptable, flexible, and agile approaches to collaboration, to ensure ongoing trial success.
- Recommendations provided may support the implementation of resilient clinical trials conducted in any context, including pandemics, war violence, and other natural disasters.

BACKGROUND

The COVID-19 pandemic has challenged the conduct of clinical trials across the globe. Between 1 December 2019 and 25 October 2021, a total of 2166 clinical trials listed on ClinicalTrials.gov were terminated, suspended, or withdrawn for COVID-19 explicit reasons.[1] The adoption of telehealth medicine,[2, 3] the cancellation or postponement of non-urgent health care visits,[4] and the secondment of healthcare workers from non-urgent chronic care to COVID-19 related medically-urgent acute cases are examples of changes adopted by public health services to cope with the increasing burden of COVID-19 on global health systems. Many academic institutions and public health services have also modified (i.e., remote follow-up visits via phone or videoconferencing) or suspended clinical research activities during the pandemic.[5] Unsurprisingly, the COVID-19 pandemic has increased complexity of maintaining trial staff and participant safety during the conduct of clinical trials, as well as recruitment and data collection procedures. For many reasons, it is difficult to achieve timely completion of clinical trials, particularly those involving multi-sector stakeholders, during a pandemic.

The Get Back to Healthy trial is an ongoing randomised controlled trial, conducted in New South Wales, Australia. The aim of the trial is to investigate the effect of introducing a coordinated support system, at discharge from treatment for low back pain (LBP), on the future use of health services for LBP. The support system links hospital outpatient physiotherapy services to a telephone-based public health coaching service and is being compared with usual care provided at discharge from treatment for LBP. The trial is predominantly funded by a partnership grant awarded by the National Health and Medical Research Council in Australia. Recruitment for the trial commenced in Sydney, New South Wales in June 2021. However, progress with recruitment and data collection have been significantly impacted by the COVID-19 pandemic.

Despite ongoing challenges with recruitment, valuable lessons have been learned during early implementation of the Get Back to Healthy trial which occurred during the peak of the COVID-19 pandemic in Sydney, Australia (between June to October 2021). This study aims to provide an overview of the impact of the COVID-19 pandemic during roll out of the Get Back to Healthy trial, and to provide practical recommendations to improve the conduct and implementation clinical trials, in any context, in the future.

METHODS

In this study, we provide a brief summary of the Get Back to Healthy trial and describe the specific roles and responsibilities of the academic, government, and health sector partners involved. Two analyses are also described. First, we present a narrative summary of the specific COVID-related challenges faced by the partners during roll out of the Get Back to Healthy trial. For each challenge, we describe the context, its implications, the strategies implemented to overcome them, and the impact of the strategy on trial progress. Then, we summarise the key lessons learned and provide recommendations to improve the conduct and implementation of clinical trials, in any context, in the future.

Conception and design of the Get Back to Healthy trial

The protocol of the Get Back to Healthy trial has been published.[6] The initial target population of the trial included adults recently discharged from hospital outpatient physiotherapy treatment for chronic non-specific LBP.[6] After enrolment and at treatment discharge, participants are randomised to a support system in addition to usual care (n = 187) or usual care alone (n = 187). The support system consists of up to ten telephone-based health coaching sessions, delivered by the Get Healthy Service®, over a 6-month period. The Get Healthy Service® is funded by the New South Wales Ministry of Health (NSW Health). Health coaches monitor and support participants to improve physical activity levels and achieve personal health-related goals. The primary outcome of the trial is the total number of encounters with hospital, medical, and health services for LBP, at 12 months from baseline. A within-trial economic evaluation will be performed to quantify the incremental costs and benefits of the support system from a health system perspective, to support reimbursement decision-making. The Get Back to Healthy trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (ACTRN12620000889954) on 10 September 2020. Ethical approval for the trial was obtained on 13 August 2020 from the Western Sydney Local Health District Human Research and Ethics Committee (2020/ETH00115), and recruitment commenced in July 2021.

Partners of the Get Back to Healthy trial

The Get Back to Healthy trial is predominantly funded by the National Health and Medical Research Council of Australia, and Sydney, Western Sydney, and South Western Sydney

Local Health Districts in New South Wales, Australia. The Get Back to Healthy trial involves a formal collaboration between partners across academic, government, and health sectors. The specific roles and responsibilities of each partner have been described in Table 1.

Academic Partners

University of Sydney

The University of Sydney is the leading academic institution and sponsor of the Get Back to Healthy trial. Several investigators of the trial, and the central operations who are responsible for overall co-ordination of trial research activities, are employed by the University of Sydney.

Other Academic Partners

Experienced researchers from national and international academic institutions also contributed substantially towards the design, overall direction, and monitoring of the trial. Researchers from these institutions occupy various roles within the trial steering committee, data management and safety committee, statistical analysis group, and health economics analysis group.

NSW Health

NSW Health is the ministerial department of the New South Wales government, responsible for developing, maintaining, and improving the health and wellbeing of the people living in New South Wales. NSW Health funds the Get Healthy Service®, a well-established public health service which co-ordinates the delivery of health coaching programs for people aged over 16 years who live in the Australian states of New South Wales and South Australia. In the Get Back to Healthy trial, participants who are randomised to the support system group are enrolled into the Standard (health) Coaching module offered by the Get Healthy Service®, which we have tailored for people with chronic LBP.

Partnering Local Health Districts

In New South Wales, Local Health Districts are responsible for managing and linking public hospitals, health institutions, and health services across defined geographical areas.[7] Three Local Health Districts, situated within metropolitan New South Wales, are partners

of the trial. Several senior clinicians from hospitals within these Local Health Districts are investigators of the trial. The main health services involved in the Get Back to Healthy trial are the hospital outpatient physiotherapy departments of the participating public hospitals.

RESULTS

Crucial to understanding the difficulties with rolling out the Get Back to Healthy trial is knowledge of the Australian state government's response to the peak of the COVID-19 pandemic in New South Wales (i.e., between June to October 2021). This period overlapped with the initiation of recruitment, which commenced in July 2021. On 26 June 2021, the first of a series of Public Health Orders were issued by the New South Wales state government to restrict the movement and gathering of people within Greater Sydney due to a rapid increase in community COVID-19 cases.[8-10] Greater Sydney is a geographical region predominantly comprised of metropolitan Sydney, which encompasses locations where recruitment sites for the Get Back to Healthy trial are based. People living within the Greater Sydney region were ordered to stay-at-home, other than for essential reasons including: (i) shopping for food or other essential goods and services, (ii) compassionate needs or medical care, (iii) exercise outdoors, (iv) essential work or education which cannot be performed from home. The stay-at-home restrictions remained in place for 106 consecutive days.

Parallel with the government-mandated Public Health Orders, partnering academic and government institutions and public health services issued further directives to their stakeholders to limit unnecessary physical contact and reduce exposure to COVID-19. Predominately, this included a transition to remote working for academic and government partners, and a reduction of the flow of patients (and visitors) into public hospitals managed by partnering Local Health Districts. Together, the Public Health Orders and directives have extensively disrupted the conduct and implementation of the Get Back to Healthy trial, with cascading effects on recruitment and data collection.

Partnering Local Health Districts

At conception of the trial, a staged implementation plan was devised: recruitment was to commence at a single major tertiary public hospital in Sydney, New South Wales, followed by the progressive roll out of additional public hospitals within partnering Local Health

Districts. As intended, the first hospital site received approval to commence recruitment on 23 June 2021. However, three days later, the rising public health risk of COVID-19 resulted in the first Public Health Order being issued for the Greater Sydney region. By early July 2021, most public hospitals in Sydney, New South Wales were overwhelmed with COVID-19 presentations, resulting in reduced workforce capacity to treat all inpatients requiring care.[11] Subsequently, many pragmatic decisions were made by hospital executives, and specially-formulated taskforces governing affected Local Health Districts, to manage the added challenges of the pandemic on usual health service delivery.[11] This included altering and/or suspending outpatient musculoskeletal physiotherapy care for patients with chronic conditions. The specific challenges and key strategies employed to overcome them are presented below.

Challenge #1: During the first five months of recruitment, only one hospital site was approved to recruit participants. At this site, outpatient physiotherapy clinical services for patients with chronic LBP were significantly altered, and eventually suspended, to cope with increased COVID-19 burden on the health system.[11]

Implications for the trial: Shortly after recruitment commenced at the sole hospital site approved for the trial, clinicians at this site were directed to transition to telehealth appointments exclusively, for outpatients presenting with LBP. Eventually, the outpatient musculoskeletal physiotherapy department at this site was directed to suspend clinical services entirely for patients with chronic LBP. No potential participants have been identified from this site since the start of recruitment.

Strategies employed: A three-step approach was employed to support recruitment:

1. Expansion of recruitment to three public hospitals that were continuing to provide physiotherapy services to people with LBP, from partnering Local Health Districts involved in the trial.
2. Expansion of recruitment to public hospitals located in regional New South Wales, which were impacted less significantly by the COVID-19 pandemic: One regional hospital site, from a non-partnering local health district with a history of collaboration with investigators of the trial, was added to support recruitment.
3. Adjustment of the trial protocol and inclusion criteria to capture a broader target population (see Additional file 1): Due to the limited ability to recruit participants from hospitals during the pandemic, the trial inclusion criteria were

expanded to include participants from the general community. Specifically, patients with chronic LBP recently discharged (<6 months) from treatment for LBP from private or public physiotherapists, chiropractors, and general practitioners, within the general community.

Impact of strategies employed: Immediately after the addition of a second hospital site in November 2021, we recruited three participants within two months. A further three hospital sites – two metropolitan and one regional public hospital – were approved for recruitment in December 2021. Whilst initiation of these sites (to commence recruitment) occurred promptly, these hospitals continue to face altered outpatient clinical services for patients with chronic LBP and have not yet identified any potential participants for the trial. We anticipate that clinical services at these sites will resume normal operations by June 2022, with a corresponding increase in recruitment rate for the trial. As the rate of recruitment increases, we will have greater capacity to explore further potential barriers towards recruitment and data collection, such as: (i) lack of patient interest, (ii) lack of patient or clinician time, (iii) lack of patient access to technology to complete online trial procedures, (iv) patient ineligibility due inadequate levels of English language, as the trial intervention is only delivered in English.

Crucially, we received ethical approval to expand recruitment to the general community on 9 February 2022. Within the first two weeks of expanding recruitment to the general community, 95 new potential participants were identified, 13 consented into the trial, and four were randomised from the general community alone. Based on the improved recruitment rate, we expect to complete recruitment (total n = 374) by June 2023. We acknowledge that changes to the aims and inclusion criteria of the trial may impact study findings. We have added exploratory analyses to assess the potential impact of changes in the trial design on treatment effectiveness.

Challenge #2: Suspension of face-to-face research activities at recruitment sites.[11]

Implications for the trial: Except for the first hospital site, which was initiated for recruitment prior to restrictions of face-to-face research, trial staff were unable to physically attend the hospital sites to conduct orientation sessions with clinicians to train them in identifying potential participants. Trial staff were also unable to perform face-to-face informed consent or baseline procedures with participants. It was intended that training

sessions would be conducted in-person, as face-to-face meetings can be advantageous for building relationships with trial stakeholders. It was also intended that informed consent and baseline assessment procedures would predominantly be performed face-to-face at hospital sites, since baseline assessment involves participants wearing an accelerometer device which is secured to their thigh with tape. Performing baseline assessment at the hospital site would allow trial staff to directly secure the accelerometer onto the participant's thigh to ensure accuracy of placement. Restrictions on face-to-face research activities prohibited in-person orientation sessions with clinicians, and participants were required to secure the accelerometer to their thigh by themselves, or with help from family members, at home.

Strategies employed:

1. In response to in-person research activities being restricted or suspended across some (but not all) hospital sites, training sessions with clinicians were conducted virtually through videoconferencing software.
2. The trial protocol proactively accounted for options to perform informed consent and data collection procedures remotely (via phone call or videoconferencing).

Impact of strategies employed: Hosting the orientation sessions remotely were advantageous as we were able to train numerous clinicians across various hospital sites simultaneously, which accelerated the timeframe for initiating new hospital sites for recruitment. However, it was more challenging to build relationships with clinicians due to the lack of face-to-face interaction. We expect that the resumption of face-to-face research activities at the hospital sites will help strengthen the collaboration between partners.

Implementation of remote consent and data collection methods appeared to be successful for most participants. To date, all participants recruited into the trial have consented and completed baseline assessment via remote methods. This includes participants independently securing the accelerometer to their thigh, with remote support provided by a member of the research team to confirm accurate placement. The exception was one culturally and linguistically diverse participant, identified from a participating hospital site, who withdrew after consenting into the trial. This participant reported general difficulties with communicating via the phone, and experienced further challenges with completing the online baseline questionnaire. This participant did not attempt to secure the accelerometer to their thigh independently. Overall, we have shown that performing consent and data collection procedures remotely is an acceptable alternative approach when face-to-face

research activities are suspended. However, certain participants may benefit from conducting trial procedures in-person with the trial team. The costs of performing enrolment and data collection procedures remotely, compared with utilising face-to-face approaches, should be evaluated in further trials.

Challenge #3: Clinicians balancing heavy clinical workloads to support management of inpatient COVID-19 patients, with reduced dedicated time to identify potential participants for the trial.

Implications for the trial: During the pandemic, many clinicians were seconded to support inpatient services for COVID-19 patients, as well as usual care practices for non-COVID patients in ward and intensive care settings. Workforce management strategies (i.e., splitting clinical teams into those treating or not treating COVID-19 patients) were also implemented for infection control. Clinicians raised concerns regarding barriers towards supporting recruitment (i.e., time and capacity to identify potential participants, time required to complete administrative tasks related to the trial).

Strategies employed: To reduce the potential burden of the trial on hospital clinicians, a local site co-ordinator was appointed for each site. The local site co-ordinator was responsible for management of administrative tasks involved in the study, including (i) collating contact information of potential participants, and (ii) managing the digital referrals to the Get Healthy Service® for participants randomised to the support system group.

Impact of strategies employed: At the second hospital site, the appointment of a local site co-ordinator corresponded with an increased number of potential participants being referred and enrolled into the trial.

Challenge #4: Expansion of recruitment to several public hospital sites and the general community imposed further challenges on central research team staffing and budget.

Implications for the trial: Within a period of three months, the number of recruitment sites increased from one to five hospital sites, with the addition of recruitment from the general community.

Strategies employed:

1. To cope with the increased number of recruitment sites, new personnel were onboarded into the central operations team to support efficiency of trial operations. Consequently, this warranted revisions to the trial budget.

2. Intensive efforts were made to ensure effective and balanced delegation of roles and responsibilities within the central operations team. Roles and responsibilities were reviewed and revised on a monthly-basis, or as needed.

Impact of strategies employed: Despite potential concerns, immediate revisions to the trial budget were made to ensure sufficient funds were available for successful trial completion. The addition of new personnel to the central operations team, combined with frequent review of roles and responsibilities, has resulted in ongoing efficiency of trial operations without disruptions to participant recruitment or data collection. The advantages of these strategies are described in further detail below.

Academic Partners

In response to Public Health Orders, executives of the University of Sydney requested that all non-essential staff and students transition to remote working. Face-to-face research activities at campus sites were prohibited without authorisation. The transition to remote working resulted in several limitations for the central operations team, which have been described below.

Challenge #1: The inability to conduct on-site feasibility, site initiation, and site monitoring visits.

Implications for the trial: Feasibility, site initiation, and site monitoring visits are essential to ensure that recruitment sites are well equipped to meet the needs of the trial and compliant with trial protocols and ethics, governance, and sponsor policies. These visits are also critical for building and maintaining relationships between partners of a trial, particularly to support recruitment for large studies. Traditionally, these visits involve an on-site meeting between the site Principal Investigator and the clinical trial co-ordinator to review a formal checklist of trial-specific items. The purpose of the feasibility, site initiation, and site monitoring visits have been described in Additional file 1.

Strategies employed:

1. On-site visits were replaced with virtual meetings, to ensure monitoring and reporting of trial compliance with ethical, governance, and sponsor requirements, were conducted in a timely manner.
2. Frequent communication was maintained with recruitment sites, to ensure ongoing adequacy of resources available to support trial implementation.

Impact of strategies employed: The transition to virtual meetings allowed for timely completion of visitations, enabling swift mitigation of potential issues affecting trial productivity. For example, prompt action was able to be taken when we identified that a particular site lacked sufficient equipment to perform baseline assessments. We redistributed the number of accelerometers to ensure all sites were adequately stocked.

Challenge #2: The inability to meet face-to-face with potential trial participants.
Implications for the trial: Due to restrictions on face-to-face meetings with trial participants, informed consent and data collection procedures could only be performed remotely via phone call or videoconferencing. It is possible that this may have deterred potential participants from taking part in the trial.
Strategies employed: The central operations team held several meetings with hospital clinicians to discuss optimal strategies to contact potential participants and engage interest in the trial. For example, we developed an ethically approved script to introduce the study to potential participants over the phone.
Impact of strategies employed: Implementation of these strategies appeared to be acceptable for most participants, particularly those recruited from the general community. No participants have declined to sign the online consent form. However, as described earlier, one participant, who was identified from a participating hospital site, withdrew from the study prior to randomisation. It is possible that the ability to perform the baseline assessment in person may have prevented the participant withdrawing from the trial. Nonetheless, given that that the trial intervention is delivered over the phone, it is unclear whether other factors may have impacted their ongoing participation.

Challenge #3: Delays in ethical, governance, and sponsor approvals, and establishment of formal research agreements with recruitment sites, due to sudden changes to workflow and reduced communication.
Implications for the trial: Without added challenges from the pandemic, obtaining the various approvals required before trial modifications can implemented can be a lengthy process. It can often take up to one to two months after submission before all approvals are received. The pandemic has caused further delays in obtaining approvals, which has hindered the pace at which contingency strategies could be employed. Delays were due to various governing committees and departments facing reduced workforce capacity and

having to transition to remote working. Consequently, the central operations team experienced great difficulty contacting the respective bodies for assistance with escalating approvals. Phone lines were unattended and email correspondence was inefficient (i.e., typically taking between two to five business days to obtain responses to queries).

Strategies employed: Again, the division of roles and responsibilities within the central research team was pivotal in overcoming this challenge. The clinical trial co-ordinator was delegated to specifically follow-up ethics and sponsor approvals. A central site co-ordinator was appointed for each site, to specifically follow-up governance approvals. Both roles involved maintenance of frequent and timely correspondence with the reviewing committees to resolve outstanding queries and escalate approvals.

Impact of strategies employed: Prior to implementation of these strategies, the time between submission and receipt of approvals for protocol amendments was approximately two to three months during the peak of the pandemic. After delegating ethical and sponsor approvals to the clinical trial co-ordinator, a notable reduction in this timeframe was observed (i.e., on average, the delay between submission and receipt of approval was reduced to one to two months). Most ethical amendment approvals were received within two weeks post-escalation by the clinical trial co-ordinator. The appointment of a central site co-ordinator for each hospital site also resulted in a significant reduction in the time taken to obtain governance approvals. Receipt of governance approvals, which are required for the initiation of new hospital sites, can typically take up to two months from submission. After the appointment of central site co-ordinators, on average, governance approvals were obtained within one-month post-submission. The effectiveness of this strategy was demonstrated through the swift and successful initiation of three new recruiting hospital sites, within a two-month period.

NSW Health (Get Healthy Service®)

It was highly advantageous for the trial that the health coaching programs offered by the Get Healthy Service® are delivered over the phone. Therefore, the trial intervention could be implemented successfully without change during the pandemic. Nonetheless, like other partners of the trial, staff members of the Get Healthy Service® transitioned to remote working during the peak of the pandemic. The implications and key strategies employed to overcome this challenge is presented below.

Challenge #1: Inability to perform face-to-face training sessions for the health coaches involved in delivering the trial intervention.

Implications for the trial: Conducting formal training with the health coaches prior to implementation of the trial intervention was vital to enhance fidelity of the health coaching programs, ensure participant safety, and build a relationship with the trial partners. This included training health coaches in the coaching content which we have tailored for people with chronic LBP, and the appropriate clinical escalation pathways.[6] We planned to conduct the training session in a hybrid format (i.e., the trial staff and Sydney-based health coaches would attend the session in person, whilst the meeting was broadcasted live to health coaches situated in other cities). However, due to the transition to remote working, the training session was only held virtually. We experienced several connectivity issues with the videoconferencing software, potentially due to the higher volume of individuals joining the meeting virtually. For example, several individuals, including the trial staff member who conducted the training, had trouble connecting to the videoconferencing platform. This resulted in delays in the training schedule, which led to reduced time for health coaches to ask questions related to the trial. Further, the videoconferencing software would intermittently lag, causing brief periods of audio delays.

Strategies employed: To ensure health coaches were informed about all contents of the consolidate learning, a copy of the training slideshow and a single-page summary document outlining key trial information were provided to the health coaches. Health coaches were also advised to contact the trial team directly for any further queries about the trial.

Impact of strategies employed: Despite the connectivity and audio issues experienced, the strategies employed ensured that the health coaches involved in delivering the trial were adequately trained and well informed about expectations regarding intervention delivery, trial safety procedures, and avenues to seek assistance.

DISCUSSION

Overview of challenges facing the Get Back to Healthy trial

The main challenge facing the Get Back to Healthy trial during the pandemic was the alteration and/or suspension of hospital outpatient physiotherapy clinical services for patients with chronic LBP in response to the COVID-19 pandemic. A reduction and eventually, cessation, of patient flow through these clinical services significantly affected the number of potential participants being identified for inclusion in the trial. To date, the

most effective strategy to mitigate this challenge was the expansion of recruitment to the general community, followed by the expansion of recruitment to additional public hospital sites. A sharp increase in trial recruitment rate was observed following implementation of these strategies. Other challenges faced were related to restrictions on face-to-face research activity, the transition to remote working, and delays in receiving approvals to implement contingency strategies to support trial progress. Many solutions were devised to overcome these challenges, which appear to have been effective at varying capacities. We anticipate that further challenges may arise due to the ongoing COVID-19 pandemic.

Key lessons learned

The implementation of large, multi-site clinical trials is costly and resource intensive. Unsurprisingly, the occurrence of a pandemic during roll out of a pragmatic, multi-site clinical trial, which has received federal funding based on an established partnership amongst multi-sector collaborators, is very challenging to navigate. In this report, we provide evidence for several strategies which may benefit the future implementation of clinical trials. In particular, we have demonstrated that obtaining informed consent and conducting baseline assessment procedures remotely is feasible for people with low back pain. This may provide people who would otherwise not participate in clinical trials, with an opportunity to be involved in research.

More broadly, the key lessons learned and recommendations for future clinical trials, include:

1. Safety of trial staff and participants takes precedence over conduct of the trial: It goes without saying that safety trumps trial conduct. This is clearly observed through mandatory compliance with directives to limit unnecessary physical contact and reduce potential exposure to infection, that were issue by the government and/or institutions during the pandemic. The lessons learnt from COVID is that all trials should include contingency strategies that would enable remote recruitment and patient follow up for times when in-person research is prohibited. Throughout the pandemic, replacing in-person meetings with other online forms of meeting was common. Virtual orientation sessions to train stakeholders in trial procedures is a viable alternative when in-person meetings are prohibited; however, face-to-face meetings are likely advantageous for building stronger relationships to support trial success.

2. Clinical trial co-ordinators and site co-ordinators are valuable members of a clinical trial project team: The lessons learnt from COVID is that that multi-site clinical trials likely benefit from the appointment of clinical trial co-ordinators to oversee overall trial activities. The complexity of covid-related changes in protocol and safety requirements, maintenance of financial budgets, and consistency of operations across all sites highlight the critical nature of this role. Further, the concurrent appointment of local and central site co-ordinators at each recruitment site is beneficial to circumvent potential problems related to the administrative burden and site-specific compliance with governance requirements. Grant applications should consider inclusion of these roles as standard.
3. Nurture relationships with established partners to build commitment to trial completion when faced with challenges: Experience with the pandemic highlighted the challenge to establish new relationships. When demands on partners are increased (e.g., public health and/or institution-specific directives issued to manage risk associated with infection), potential partners who have not previously been involved in the study can be too overwhelmed to cope with additional demands to support the trial. The lesson learnt from COVID is that nurturing pre-existing relationships and considering inclusion of a broader network of potential partners at the outset of a trial are useful strategies to enhance the potential for ongoing trial success.
4. Pragmatic clinical trials involving partnerships with government institutions and health services require adaptable, flexible, and agile approaches to collaboration: During a pandemic, trial partners will likely face competing demands with observing government policies and institutional-specific directives to prioritise safety of their stakeholders, coping with forced changes to usual operations, and continuing to support trial implementation. Particularly during a pandemic, the usual operations of public health services are likely to be affected, which may compromise the productivity of pragmatic trials utilising public health services as avenues for recruitment or intervention delivery. The lesson learnt from the COVID-19 pandemic is that prior to entering clinical trial partnerships, it is essential to ensure all partners are committed to supporting continued trial implementation despite unanticipated events. Trial partners must be also willing to pre-plan for agility and demonstrate flexibility with adapting usual operations to support trial progress. This includes the implementation of proactive and reactive strategies to combat evolving challenges facing trial implementation, to

optimise the chances of coping with forced changes and ensuring successful completion. A shared commitment to regular communication, particularly during turbulent periods of navigating challenges adversely impacting productivity, is also crucial.

A summary of lessons learned and recommendations for future clinical trials have been presented in Table 2. We acknowledge that some challenges described, and strategies employed, are specific to the Get Back to Healthy trial, or trials involving patients with low back pain or musculoskeletal conditions. Additional studies investigating the challenges towards implementation of other large, multi-site randomised clinical trials, which involve partners across multiple sectors, may be useful to substantiate the generalisability of the recommendations presented in this paper. Nevertheless, the four key recommendations pertaining to participant and staff safety, effective trial management, establishment and maintenance of collaborative research partnerships, and use of adaptable approaches for pragmatic trials, are broad recommendations which are relevant to the wider research context.

Future Directions for the Get Back to Healthy trial

As the world continues to navigate the ongoing public health and economic consequences of the COVID-19 pandemic, the conduct of clinical research will remain fraught with difficulty and volatile. Whilst the Get Back to Healthy trial has successfully negotiated many challenges during early implementation, future challenges related to analysis and interpretation of study outcome measures may arise. Namely, attempting to disentangle the adverse effects of COVID-19 on physical and mental health, with the clinical outcomes of interest, will be complex. Nonetheless, the Get Back to Healthy trial persists in actively recruiting participants from hospitals and the general community, to ensure timely and effective completion. Ultimately, successful completion of the trial will provide evidence for the potential effectiveness and cost-effectiveness of a co-ordinated support system, introduced at discharge from treatment for chronic non-specific LBP, for reducing the use of hospital, medical, and health services for LBP. The support system has been designed to link people recently discharged from treatment for chronic non-specific LBP to a public health coaching service. Findings may inform the development of an implementation plan

for scaling-up this approach across other health districts in Australia and may increase consumer awareness of the availability and potential benefit of physical activity-focused health coaching programs for this population. The results of the Get Back to Healthy trial will be reported according to the CONSERVE 2021 Statement,[12] which was developed as a guideline to support the reporting of trial protocols and completed trials that were modified due to the COVID-19 pandemic and other extenuating circumstances.

We anticipate that researchers will benefit from the key lessons learned from our experience of conducting and implementing a large, multi-site clinical trial, involving multi-sector partners, during a world pandemic. The challenges imposed by the pandemic on the Get Back to Healthy trial have highlighted strategies that would be of value, not only to trials impacted by a pandemic, or even war violence or other natural disasters (i.e., bushfires, floods), but in any context.

CONCLUSION

The implementation of large, multi-site clinical trials is costly and resource intensive. Owing to the unprecedented global impact of the COVID-19 pandemic, early implementation of the Get Back to Healthy trial – a large randomised clinical trial involving partners across academic, government, and health sectors – was difficult. Lessons learned from implementation of the Get Back to Healthy trial will likely enhance the conduct and implementation of more resilient clinical trials in the future.

ABBREVIATIONS

LBP: low back pain
NHMRC: National Health and Medical Research Council
NSW: New South Wales

DECLARATIONS

Ethics approval and consent to participate

The Get Back to Healthy trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000889954). Ethical approval has been prospectively granted by the Western Sydney Local Health District Human Research and Ethics Committee (2020/ETH00115). Written informed consent will be obtained from all

participants. Participants may choose to withdraw consent at any point during the study duration without providing a reason. The relevant sponsor has reviewed the study protocol and consent form.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

All authors have no competing interests to declare.

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Authors' contributions

EKH drafted the manuscript. All authors (EKH, MLF, PWH, MH, KM, DC, MJ, ABA, MTB, PHF) contributed substantially to revisions of the manuscript. PHF is lead investigator. PHF, MLF, PWH, MTB, MH, DC, ABA, MJ, EKH, and KM obtained funding for the study. All authors read and approved the final manuscript.

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Table 1. Roles and responsibilities of partners on the Get Back to Healthy trial

Trial Partner	Roles	Responsibilities
Academic Partners All[a]	Investigators	Investigators: • Overall responsibility for ensuring the trial is compliant with ethics, governance, and Sponsor requirements, as well as other relevant legislation. • Monitor overall trial participant safety, including reviewing adverse event reports to ensure accurate classification and reporting requirements are met.
University of Sydney	Central operations team	Clinical Trial Co-ordinator: • Act as conduit to co-ordinate all trial operations including management of communication between the trial partners and stakeholders. • Perform the randomisation procedure. • Co-ordinate implementation and ongoing compliance of recruitment sites. Central Site Co-ordinator: • Prepare governance applications, reports, and contracts for a respective site. • Provide support, as needed, to the respective local site co-ordinators. Research assistants: • Perform informed consent and data collection (outcomes, adverse events) procedures. • Monitor and maintain documentation of adverse events.
NSW Health	Manager of the Get Healthy Service®	• Oversee delivery of the trial intervention (health coaching program) • Liaise with Remedy Healthcare, the service provider of the health coaching programs for the Get Healthy Service® to monitor execution of any changes to the intervention delivery or processes, as necessary. • Facilitate training workshops between the central operations team, and health coaches from Remedy Healthcare, to ensure compliance with trial procedures (i.e., intervention content, clinical escalation pathways). • Liaise with study central operations team regarding study or safety-related procedures, if identified during the intervention period.

Local Health Districts	Site Investigator	• Maintain essential site documents to ensure compliance with ethics, governance, and Sponsor requirements. • Oversee participant safety at the respective site.
	Local site co-ordinator	• Collate and report contact information of potential participants, to the central study operations team. • Manage the digital referrals to the Get Healthy Service® for participants randomised to the support system group.
	Clinicians	• Identify and flag potential participants to the local site co-ordinator.

[a]University of Sydney, University of Queensland, Australian Catholic University, and The George Institute of Global Health.

Table 2. Key lessons learned and recommendations for future clinical trials

Key lessons	Recommendations
Safety of trial staff and participants takes precedence over conduct of the trial	All trials should include contingency strategies that enable remote recruitment and patient follow up, particularly for periods when in-person research is prohibited.
Clinical trial co-ordinators and site co-ordinators are valuable members of a clinical trial project team	The appointment of clinical trial co-ordinators, and site co-ordinators for each recruitment site, should be considered standard practice for large multi-site clinical trials. Clinical trial co-ordinators are vital for overseeing overall trial activities, and site co-ordinators are beneficial for management of administrative burden and site-specific compliance with governance requirements. Grant applications should consider inclusion of these roles as standard.
Nurture relationships with established partners to build commitment to trial completion when faced with challenges	Nurture pre-existing relationships and consider inclusion of a broader network of potential partners at the outset of a trial.
Pragmatic clinical trials involving partnerships with government institutions and health services require adaptable, flexible, and agile approaches to collaboration	Ensure all partners are committed to supporting continued trial implementation despite evolving challenges which may hinder trial implementation. Ensure trial partners are willing to pre-plan for agility, maintain regular communication, and demonstrate flexibility with adapting usual operations to support trial progress.

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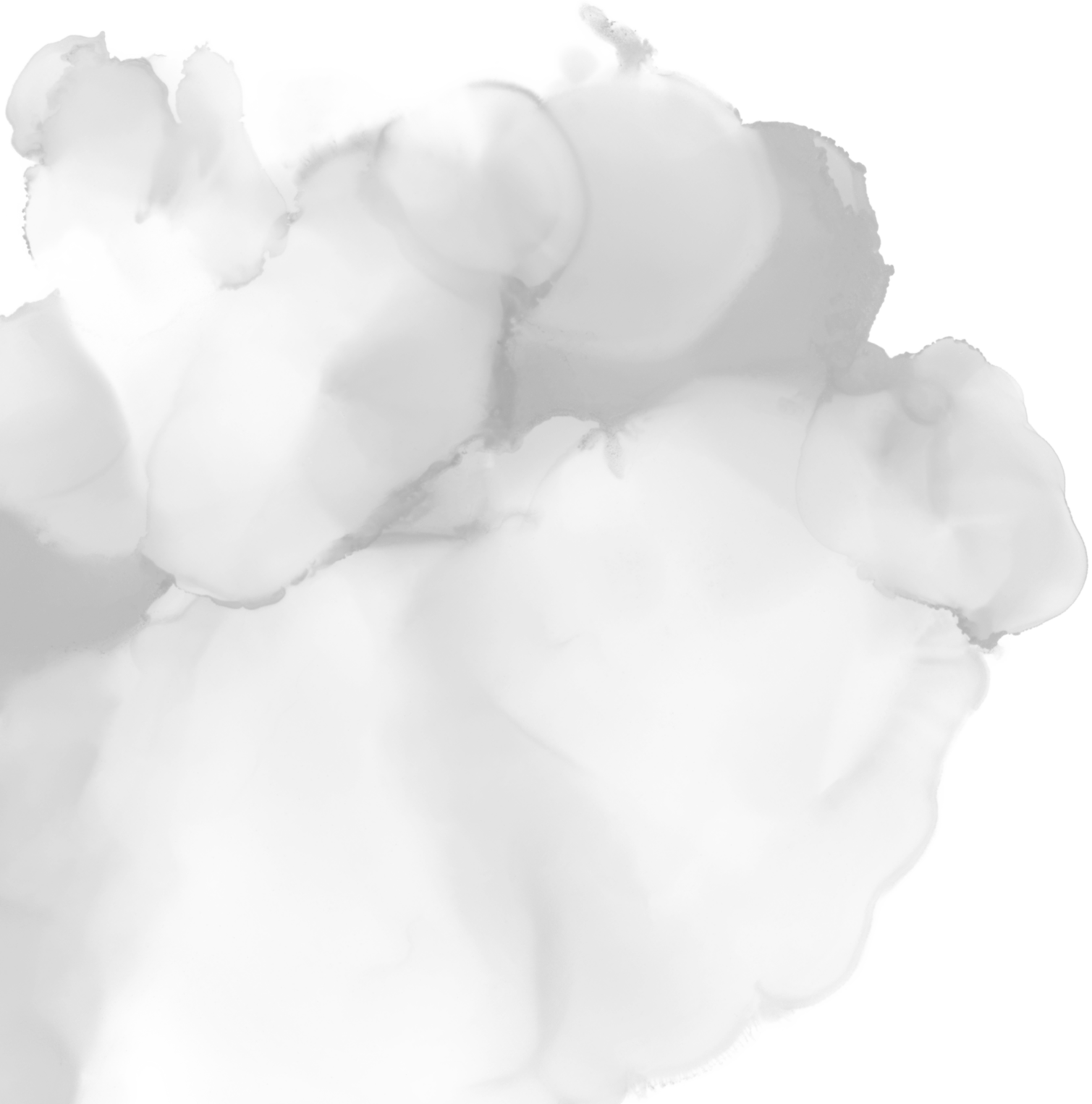
CHAPTER NINE



Discussion and Conclusion

Purpose of the thesis

The broad aim of this thesis was to investigate the health and lifestyle factors influencing health care utilisation for low back pain, and to examine the role of psychological interventions (including lifestyle interventions) for improving health outcomes and/or reducing health service utilisation in people with chronic non-specific low back pain. **Chapter One** provided background information on the key topics addressed in this thesis. Three specific aims were established to examine the broad aim of this thesis, which were addressed through a series of studies utilising various research designs (e.g., a cross-sectional study, a longitudinal cohort study, a systematic review with network meta-analysis, and a randomised controlled trial). These studies formed **Chapters Two to Eight** of this thesis.

Overview of findings

In **Chapter One,** specific gaps in the research evidence related to the utilisation of health care for low back pain and in the treatment approaches available for the condition were identified. Firstly, existing studies investigating the factors associated with health care utilisation for low back pain have mainly focused on the influence of symptom presentation (e.g., pain intensity, disability levels, previous history of low back pain) or sociodemographic factors (e.g., education level, income, job satisfaction). However, the relationship between health or lifestyle factors, and the use of care for low back pain, remains under-investigated. This is particularly important, as many health and lifestyle factors are modifiable, provided that appropriate interventions are administered. Further, the potential confounding influence of aggregated familial factors (e.g., genetics and the early shared environment) on these relationships have not been considered in previous studies, representing a research shortfall in the field. Secondly, whilst psychological interventions or strategies are beneficial for improving outcomes in patients with low back pain, there is uncertainty regarding the comparative effectiveness, longevity of treatment effectiveness, and safety of different types of psychological interventions for this population. This gap in knowledge may contribute to patients and clinicians being uncertain regarding the most optimal choice of psychological treatment for managing low back pain. Finally, lifestyle interventions, such as health coaching programs, have potential to bridge an important gap in the clinical care pathway for patients with low back pain (i.e., the lack of support available to patients after discharge from conservative health care for low back

pain). The lack of support available after discharge from conservative care has been identified as a strong driving factor for patients returning to the health care system for further treatment in Australia. Although, to date, no randomised controlled trial has investigated the effect of introducing a co-ordinated discharge support system, including the incorporation of a public health coaching service, on the utilisation of health services for low back pain.

The first aim of this thesis was to identify health and lifestyle factors associated with patients seeking care for low back pain**. Chapter Two** investigated the cross-sectional relationship between various anthropometric, sociodemographic, health, and lifestyle factors, and the use of medical care for chronic non-specific low back pain, whilst adjusting for the potential confounding influence of aggregated familial factors (e.g., genetics and the early shared environment).[1] The main finding from this study of 1605 adult twins was that in people with a history of chronic low back pain, those reporting poor sleep quality are more likely to seek medical care for low back pain in the long term (total sample: odds ratio (OR) = 1.58, 95% confidence interval (CI) 1.24 to 2.01; case-control analysis sample: OR = 1.75, 95% CI 1.14 to 2.69). These results were consistent with the evidence from the limited existing studies investigating the association between these two factors.[2-4] However, results from this study supported the existing body of evidence by demonstrating that the relationship between sleep and the use of care for low back pain is independent from aggregated familial factors. Since publication of the study results (2021),[1] a more recent longitudinal cohort study examined the influence of lifestyle and health-related factors on care-seeking for low back pain (i.e., the use of health care professionals, or medications, for low back pain).[5] This study also utilised a co-twin case control design and confirmed our findings that the relationship between poor sleep quality and care-seeking for low back pain is independent and not confounded by aggregated familial factors.[5] Whilst the confidence intervals were wide, the study concluded that the relationship between these factors is likely to be casual.[5]

Furthermore, the study presented in **Chapter Two** of this thesis found that males (case-control OR = 0.55, 95% CI 0.33 to 0.93), people with a history of diabetes (case-control OR = 0.50, 95% CI 0.25 to 0.97), and people reporting higher alcohol intake (case-control OR = 0.90, 95% CI 0.82 to 0.99) are less likely to seek medical care for low back pain; and

these relationships were not confounded by aggregated familial factors. Findings related to male sex and a history of diabetes were congruent with patterns of health care utilisation identified in previous literature.[6, 7] In the absence of studies investigating the relationship between alcohol intake and care-seeking for low back pain, results from this study contributed to new knowledge on this topic area.

From **Chapter Two**, several prevailing gaps in knowledge were identified. For example, clearer definitions of care-seeking behaviours for low back pain are necessary to improve understanding of the specific impact that distinct health and lifestyle factors may have on different patterns of health care utilisation for low back pain (e.g., use of health services, use of self-management strategies). Also, the relationship between lifestyle factors and health care utilisation for low back pain remains under-investigated. Specifically, a more comprehensive assessment of the relationship between physical activity and health care utilisation for low back pain is warranted, given the abundant evidence available supporting the health benefits of physical activity for musculoskeletal conditions.[8, 9] In the study presented in **Chapter Two**, the assessment of physical activity was relatively simplistic – self-reported physical activity data was dichotomised as participants meeting or not meeting the physical activity recommendations from the World Health Organisation. As self-reported measures of physical activity may be prone to bias and misclassification,[10] it was identified that future studies in the field should utilise device-based measures (e.g., accelerometry) of physical activity, where possible.

The gaps in knowledge and research methodology identified in **Chapter Two** were addressed in **Chapter Three.** The study reported in **Chapter Three** examined the longitudinal relationship between different volumes of sedentary behaviour or physical activity at baseline, and various care-seeking behaviours for low back pain assessed over one year. Six types of physical activity were assessed, which were categorised based on the intensity (i.e., moderate-to-vigorous intensity physical activity, physical workload) or domain of activity (i.e., work, transport, household, and leisure domain physical activity). Sedentary behaviour and moderate-to-vigorous intensity physical activity were device-based measures, assessed using an Actigraph accelerometer. All other physical activity measures were self-reported, in the absence of accurate and reliable device-based methods to assess these specific intensities or domains of physical activity. To provide clearer

definitions of care-seeking behaviours, outcome data was both aggregated for the primary outcome (i.e., overall utilisation of care for low back pain), and disaggregated into two secondary outcomes (the utilisation of health services for low back pain, and the utilisation of self-management strategies for low back pain).

Results from this study of 340 adult twins with a history of chronic non-specific low back pain demonstrated that medium-to-high baseline volumes of household domain physical activity were significantly associated with greater counts of overall care utilisation [risk ratio (RR) 2.09, 95% CI 1.27 to 3.43] and utilisation of self-management strategies (RR 1.62, 95% CI 1.04 to 2.53), over one year. Further, medium-to-high baseline volumes of physical workload (RR 2.67, 95%CI 1.20 to 5.94) and sedentary behaviour (RR 1.60, 95%CI 1.02 to 2.50) were significantly associated with greater counts of overall care utilisation and utilisation of self-management strategies, respectively, over one year. In contrast, medium-to-high baseline volumes of moderate-to-vigorous intensity physical activity appeared to be associated with fewer counts of overall care utilisation over one year (RR 0.56, 95% CI 0.32 to 1.01), compared to those engaged in low volumes. No other explanatory variables were associated with the utilisation of care for low back pain. Taken together, this study demonstrated that different amounts and/or intensities of physical activity and sedentary behaviour have different effects on different patterns of health care utilisation for low back pain. Study findings also confirmed similar patterns identified in **Chapter Two** – irrespective of the volume, intensity, or domain of physical activity, there does not appear to be a relationship between physical activity and the utilisation of health services, including medical care, for low back pain.

The second aim of this thesis was to investigate the comparative effectiveness and safety of psychological interventions for improving health outcomes in patients with chronic low back pain. **Chapter Four** described the protocol of a systematic review with network meta-analysis of psychological interventions for chronic non-specific low back pain.[11] The health outcomes of interest were physical function, pain intensity, fear avoidance, health-related quality of life and intervention compliance, and safety. **Chapter Four** provided background information to contextualise the clinical importance of the topic area for advancing management of low back pain. Expanding upon existing literature,[12] five main categories of psychological interventions for low back pain were defined: behavioural

therapy-based interventions, cognitive behavioural therapy-based interventions, mindfulness-based interventions, counselling-based interventions, and pain education-based interventions. These categories reflect the three 'waves' of traditional and contemporary psychological interventions emerging and evolving over time, commonly used in the management of chronic pain conditions. The goal of categorising the psychological interventions into five main categories was to assist patients and clinicians with understanding how different types of psychological interventions and strategies differ in their clinical focuses and theoretical underpinnings. This knowledge could subsequently aid patient and clinicians with interpreting the complex network meta-analysis results and translate findings into clinical practice more easily.

The results of the systematic review with network meta-analysis were presented in **Chapter Five.**[13] In total, 97 randomised controlled trials involving 13,136 participants and 17 treatment nodes were included in the review. The main finding of the study was that compared with physiotherapy care alone, psychological interventions are most effective for people with chronic non-specific low back pain when they are delivered in conjunction with physiotherapy care (mainly structured exercise). Specifically, pain education programs and behavioural therapy, delivered with physiotherapy care, offer the most sustainable effects of treatment for physical function and fear avoidance, and pain intensity, respectively. Whilst uncertainty remains regarding their long-term effectiveness (≥12 months post-intervention), limited but consistent evidence suggests that psychological interventions are likely safe for people with chronic non-specific low back pain. Therefore, evidence supports the clinical benefit of incorporating specific types of psychological interventions with physiotherapy care (mainly structured exercise) for improving physical function, fear avoidance, and pain intensity in low back pain. Due to heterogeneity of reporting, the comparative effectiveness of psychological interventions for improving health-related quality of life remains unclear.

The results of this review highlighted several ongoing gaps in the evidence related to psychological interventions for chronic non-specific low back pain: (i) high-quality randomised clinical trials of mindfulness (i.e., mindfulness-based stress reduction) and counselling-based interventions (i.e., lifestyle interventions) are lacking, (ii) randomised clinical trials with large sample sizes and longer follow-up periods (≥12 months post-

intervention) are needed, (iii) health-related quality of life is assessed infrequently and heterogeneously, (iv) the safety of psychological interventions is often poorly reported and the criteria for assessment is often inappropriate (i.e., based on criteria more suitable to drug trials).

To address the gaps in evidence related to counselling-based interventions, which includes lifestyle interventions, to support people with chronic non-specific low back pain, the third and final aim of this thesis was to evaluate the effectiveness of introducing a lifestyle intervention (i.e., health coaching program) into the discharge care pathway for patients with low back pain, to reduce the use of health services for low back pain and improve health outcomes. **Chapter Six**[14] presented the protocol of the Get Back to Healthy trial, a randomised controlled trial which was specifically designed to investigate this aim. Recruitment for the trial is currently ongoing. **Chapter Six** describes that the primary aim of the Get Back to Healthy trial is to evaluate the effect of introducing a coordinated support system, linking hospital outpatient physiotherapy services to a public health coaching service, at the point of discharge from treatment. The support system is being compared with usual care provided at discharge from treatment, and the primary outcome is the future use of hospital, medical, and health services for low back pain, over one year.

Due to the unprecedented global impact of the COVID-19 pandemic on health care systems and the conduct of research, recruitment for the Get Back to Healthy trial has stalled significantly. In response to persistent challenges with recruitment, pragmatic modifications were made to the trial design. The rationale for these changes were described in **Chapter Seven**. To summarise, the main amendment involved expanding the trial inclusion criteria. As described in **Chapter Six,** the original trial inclusion criteria were restricted to people recently discharged from treatment for chronic non-specific low back pain from public hospital outpatient physiotherapy departments. In **Chapters Seven and Eight,** the inclusion criteria were expanded to recruit people from the general community recently discharged from regular weekly treatment from public or private physiotherapy, chiropractic, or general practitioner care for chronic non-specific low back pain. This decision was based on lessons learned from the IMPACT pilot randomised controlled trial preceding this study,[15] which demonstrated a higher rate of recruitment from the general community, in comparison with recruitment from hospital settings. To accommodate this change, the overall primary aim of

the trial was adjusted to determine the effectiveness and cost-effectiveness of a discharge support system (incorporating referral to the Get Healthy Service®) for improving pain, disability, and physical activity levels, in people recently discharged from hospital outpatient physiotherapy treatment, or from public or private physiotherapy, chiropractic or general practitioner care for chronic low back pain.

Since expanding recruitment to the general community, the rate of recruitment has increased. For example, when recruitment was restricted to hospital settings, only two participants were recruited over seven months. In contrast, once we expanded recruitment to the general community, within the first two weeks, 13 participants consented into the trial and four were randomised, from the general community alone. Despite increased recruitment rates, there is currently insufficient data available to conduct the planned interim statistical analysis described in **Chapter Seven**, which aims to investigate the joint association between physical activity and sleep on various care-seeking behaviours for low back pain. Nonetheless, preliminary data from the 12 participants who had completed their baseline assessment for the Get Back to Healthy trial, as of 27 March 2022, suggests that the enrolment, data collection, and safety monitoring procedures for the trial are likely to be feasible. The pragmatic modifications to the trial design, namely the expansion of recruitment to the general community, appears to have increased overall trial recruitment rates. We anticipate that recruitment of the total sample size (n = 374) will be achieved by June 2023, with follow-up data collection completed by June 2024. Once completed, the trial will provide evidence for the effect of a co-ordinated support system, linking people recently discharged from treatment for chronic non-specific LBP to a public health coaching service, on the use of hospital, medical, and health services for LBP.

In **Chapter Eight**, a detailed report of the challenges that the COVID-19 pandemic imposed on different partners of the Get Back to Healthy trial were presented. The main challenges were related to: (i) the suspension of clinical services and face-to-face research activity at several recruiting sites for the trial, (ii) the transition to remote working, (iii) delays in ethical, governance, and contract approvals due to sudden changes in workload and reduced communication. The adverse impacts of these challenges on trial productivity were described, accompanied by an evaluation of the numerous strategies employed to overcome them. All in all, lessons learned from the Get Back to Healthy trial highlight the importance

of prioritising the safety of trial staff and participants, appointing personnel with defined roles to support trial operations, nurturing existing relationships with established partners, and adopting adaptable, flexible, and agile approaches to collaboration, to ensure ongoing trial success.

Clinical implications of the thesis

Factors associated with health care utilisation for low back pain

Chapter Two demonstrates that there is an association between poor sleep quality and the utilisation of medical care for low back pain, which is not confounded by shared familial factors. Whilst the direction of causality remains unclear, due to the cross-sectional study design, clinicians should consider screening patients with low back pain for indicators of poor sleep quality and provide appropriate referrals to interventions that target sleep. In turn, this may improve patient outcomes and reduce the utilisation of medical care for low back pain. Conversely, clinicians treating patients for poor sleep quality or other sleep dimensions should consider screening for the co-occurrence of low back pain. Timely referral to appropriate management for low back pain should be considered. **Chapter Three** identified that there is a prospective relationship between medium-to-high baseline volumes of specific types and intensities of physical activity or sedentary behaviour, and the utilisation of care for low back pain over a one-year period. Specifically, two recommendations for patients and clinicians can be derived from the results of Chapter Three. Firstly, patients and clinicians should collaborate to screen and develop strategies for modifying engagement in harmful volumes of domestic labour, physically demanding tasks at work, or sedentary behaviour, as these factors have been shown to increase the overall utilisation of care and/or utilisation of self-management strategies for low back pain. Secondly, given the well-established health benefits of engagement in moderate-to-vigorous intensity physical activity, patients and clinicians should consider strategising ways to increase physical activity levels across these intensities, to improve clinical outcomes and potentially reduce the use of care in people with low back pain.

Taken together, the results of **Chapters Two and Three** may assist clinicians with improving clinical assessment and treatment of people with low back pain and flagging patients who may be at greater risk of poorer or more complicated recovery (i.e., requiring more or prolonged care). Clinical guidelines currently lack clear recommendations

regarding the appropriate amounts of engagement in physical activity or sedentary behaviour, for people with low back pain. For example, the specific amounts, intensities and domains of physical activity, or sedentary behaviour, which are harmful or beneficial for people with low back pain. Further, recommendations related to assessment or treatment of sleep problems are also lacking in clinical guidelines for low back pain, despite evidence confirming that sleep disturbances are highly prevalent (59%) in people seeking care for the condition.[16] Findings from **Chapters Two and Three** have potential to inform clinical guideline recommendations regarding the assessment of comorbid sleep problems and prescription of appropriate amounts of specific types of physical activity or sedentary behaviour, in people with chronic non-specific low back pain.

Psychological interventions for chronic non-specific low back pain

Findings from the systematic review reported in **Chapters Four and Five** provide patients with evidence-based knowledge that the co-delivery of psychological interventions with physiotherapy care (mainly structured exercise), particularly at the outset of treatment, is more effective than physiotherapy care alone. Specifically, pain education delivered with physiotherapy care (mainly structured exercise) is most effective for improving physical function and fear avoidance, whilst behavioural therapy delivered with physiotherapy care is most effective for improving pain intensity. Results suggest that complex approaches involving several types of psychological interventions or strategies (i.e., combined psychological approaches) are not necessary for improving clinical outcomes in people with chronic non-specific low back pain. Overall, the benefits of integrating psychological interventions together with physiotherapy care (mainly structured exercise) are maintained at least in the short to mid-term period (i.e., up to six months) after the end of treatment. Ultimately, the choice of intervention should be selected based on the patients' primary complaints, treatment goals, and concurrent symptoms (e.g., leg pain), with the decision being made in conjunction with the treating clinician.

There are several clinical implications for health care providers, including but not limited to allied health professionals (e.g., exercise providers, psychologists), general practitioners, and medical specialists. Findings from the review highlighted that exercise providers (e.g., physiotherapists, chiropractors, exercise physiologists) should incorporate specific psychological strategies into the delivery of structured exercise programs, to maximise the

benefits of treatment. In parallel, psychologists treating patients with chronic non-specific low back pain should be reminded of the importance of exercise, as a component or adjunct, to psychological interventions. Findings from the review may also assist health care providers, such as general practitioners and medical specialists, who may refer patients to exercise providers or psychology services as part of their treatment plans for people with chronic low back pain. Health care providers can utilise the review findings to generate referrals with more specific instructions regarding the specific type of psychological intervention or strategy which should be prescribed to a patient, in conjunction with exercise, depending on the clinical outcomes of interest.

Expanding on these findings, practical suggestions for optimising the co-delivery of exercise and psychological therapies at the onset of treatment were discussed in **Chapter Five**. Firstly, a shift away from the traditional multi-disciplinary approach towards health care delivery (i.e., different health professions operating in siloed settings) was proposed. Instead, interdisciplinary or intradisciplinary approaches to health care delivery were suggested as feasible alternatives. An interdisciplinary approach to health care delivery describes the co-ordination of different health disciplines working together to optimise care delivery. For example, a psychologist and physiotherapist providing care to the same patient, separately, whilst maintaining frequent cross-discipline communication regarding the patient's progress and co-ordinating treatment approaches between providers. An intradisciplinary approach describes settings where a single health discipline blends skills within their own scope of practice, with concepts, methods, and/or techniques borrowed from other disciplines. For example, a physiotherapist integrating psychological strategies into treatment when prescribing tailored and structured exercise programs for their patients with chronic non-specific low back pain. In the literature, this has been termed *psychologically-informed practice*, and there is a growing body of evidence supporting the effectiveness of this approach for patients with musculoskeletal pain conditions.[17-19] Nonetheless, despite the pragmatic suggestions provided, **Chapter Five** concludes by acknowledging the ongoing challenges towards implementing interdisciplinary and intradisciplinary approaches into the existing model of health care delivery. Overall, by addressing an important gap in the evidence, the systematic review presented in **Chapters Four and Five** will likely inform specific international clinical guideline recommendations

regarding the use of psychological interventions for chronic non-specific low back pain, and ultimately, support improved clinical decision-making.

Lifestyle interventions to reduce health care utilisation for low back pain

It is well-established that effective discharge planning is pivotal for improving the continuity of care between hospital services and the home environment, to improve patient health outcomes and to reduce patient readmissions to hospital.[20] Part of effective discharge planning is ensuring that patients feel well-informed and adequately supported to self-manage their symptoms in the community. However, in **Chapter Six**, it was discussed that patients with low back pain consistently and strongly desire clearer information about the ongoing availability of support services after discharge from treatment.[21, 22] Interestingly, these patient-perceived needs are not unique to musculoskeletal conditions. Studies have shown that patients with type 2 diabetes,[23] patients undergoing cardiovascular surgery,[24] patients with non-malignant brain tumours (and their informal carers),[25] and older people in general,[26] also possess similar desires. Evidently, there appears to be a universal need for community-based support services, after discharge from treatment, for patients living with chronic diseases.

Existing evidence demonstrates that structured discharge planning, including linkage to co-ordinated community-based support services, can improve self-management and reduce hospital re-admissions for a range of chronic health conditions (i.e., diabetes,[27] cardiovascular diseases,[28] respiratory conditions[29]). A systematic review with meta-analysis of 19 randomised controlled trials has shown that communication interventions at discharge from formal care have potential to decrease hospital readmissions and improve treatment adherence and patient satisfaction.[30] However, there is currently a lack of community-based support services available for patients with low back pain, after discharge from formal care, in Australia. The Get Back to Healthy trial aims to address this clinical gap.

The Get Back to Healthy trial aims to provide evidence for the effectiveness and cost-effectiveness of integrating a co-ordinated support system at discharge from formal care for chronic non-specific low back pain, on the use of health services for low back pain. The support system being evaluated involves a structured approach linking patients to a public

health coaching service, at discharge from treatment, and is being compared with usual care provided at discharge. If the study results favour the support system group (i.e., the support system group utilises less health services for low back pain, over one year, compared with the usual care group), findings will help inform the development of an implementation plan for scaling-up this approach. The implementation plan will be disseminated across other public hospital health districts, as well as public and private general practitioner, physiotherapy, or chiropractic clinics, in Australia. Findings may also increase consumer and clinician awareness of the availability and potential benefit of physical activity-focused health coaching programs for supporting patients to effectively self-manage their low back pain symptoms within the community and reduce their reliance on health services. Even more broadly, findings will contribute further evidence towards the potential benefits of structured discharge planning – particularly, linkage to co-ordinated community-based support services – for improving self-management and reducing patient reliance of health services.

Undisputedly, the implementation of large, multi-site randomised clinical trials, which involve partners across multiple sectors, is costly and resource intensive. Unsurprisingly, the unexpected occurrence of a pandemic can significantly affect the conduct of a trial which relies heavily on public health services to support recruitment and intervention delivery. The analyses performed in **Chapter Eight,** evaluating the effectiveness of numerous contingency strategies employed to overcome challenges faced during implementation of the Get Back to Healthy trial, may assist international research efforts aiming to tackle similar obstacles. This is because many challenges described have universally and indiscriminately affected the conduct and implementation of clinical trials across the globe. It should be acknowledged that some challenges described, and the strategies employed, are specific to the Get Back to Healthy trial or trials involving patients with low back pain or musculoskeletal conditions and may not be generalisable to other health conditions. Nevertheless, the four key recommendations pertaining to participant and staff safety, effective trial management, establishment and maintenance of collaborative research partnerships, and use of adaptable approaches for pragmatic trials, are broadly relevant to the wider research context. It is also worth noting that, in **Chapter Eight**, it was identified that a telephone-based public health coaching program can be successfully implemented without change during a pandemic. This preliminary observation sheds light on the potential

feasibility of utilising telephone-based lifestyle interventions to support people with chronic non-specific low back pain. Overall, the practical recommendations for future clinical trials, presented in **Chapter Eight**, may help improve the overall conduct and implementation of more resilient clinical trials conducted in any context.

Strengths of this thesis

There are several strengths of this thesis. It involved a series of studies employing various research designs (e.g., a cross-sectional study, a longitudinal cohort study, a systematic review, a randomised controlled trial) and statistical methods (e.g., co-twin case-control design, network meta-analysis) meticulously selected to address the specific thesis aims. For example, the cohort study reported in **Chapter Two** utilised a co-twin design, involving discordant twin-pairs, unravelling possible causal relationships between various health and lifestyle factors, and the utilisation of medical care for low back pain. As explained in **Chapter Two**, this method naturally controls for a wide range of confounding aggregated familial factors (including genetics and the early shared environment),[31] which has been a limitation of previous related studies. **Chapter Three** utilised a longitudinal design to elucidate the relationship between device-based and self-reported physical activity or sedentary behaviour at baseline, and the utilisation of care for low back pain over one year. **Chapters Four and Five** described a systematic review with network meta-analysis. Network meta-analysis has significant advantages over traditional pairwise meta-analyses, as this statistical method allows for the synthesis of direct and indirect evidence to simultaneously compare numerous competing interventions within a single, coherent treatment network. This enables determination of the comparative effectiveness of a wide range of interventions available for a given health condition, supporting the improvement of clinical decision-making. **Chapters Six, Seven, and Eight** involved a randomised controlled trial design. Randomised controlled trials are considered gold-standard for effectiveness research, as the randomisation process reduces bias and enables examination of the causal relationship between interventions and outcomes.

Further strengths of this thesis include examining health care utilisation as the main outcome. Whilst studies of clinical populations typically focus on symptom-based outcomes (e.g., pain, disability, function), examining health care utilisation can be useful for identifying patient subpopulations at risk of utilising ineffective or potentially harmful health treatments, overutilising health services, or underutilising effective self-management

strategies. Also, as described earlier, there are several clinical implications from the studies reported in this thesis which may be directly applicable to clinical practice and/or have potential to inform clinical guidelines and policy.

There were also additional strengths of the individual studies. The longitudinal cohort study reported in **Chapter Three** involved sedentary behaviour and six physical activity variables, and three care-seeking outcomes. Given that different types of physical activity impact the risk or prevalence of low back pain in disparate ways, it was advantageous to categorise and assess physical activity data disaggregated according to distinct intensities and domains. A further strength was the use of device-based measures (e.g., accelerometry) of sedentary behaviour and moderate-to-vigorous intensity physical activity. In addition, to our knowledge, this is the first study repeatedly assessing care-seeking behaviours for low back pain on a weekly basis over one year, across a wide range of treatment options (e.g., a variety of health services and self-management strategies commonly utilised for low back pain). The frequent and repeated measures of care-seeking data minimised the effect of recall bias. Together, the numerous strengths of this study enabled a comprehensive examination of the specific impact that different intensities and domains of physical activity on different patterns of health care utilisation for low back pain.

The additional strengths of the systematic review reported in **Chapters Four and Five** was that the review was prospectively registered on PROSPERO (CRD42019138074), and the protocol paper was peer-reviewed and published, prior to database searching.[11] Moreover, the results of the systematic review were reported in accordance with standard reporting guidelines for systematic reviews[32] and network meta-analysis.[33] Crucially, the search strategy of the systematic review considered the wider collection of psychological interventions available for low back pain, including commonly used interventions (e.g., cognitive behavioural therapy, behavioural therapy) and also more recently developed interventions (e.g., acceptance and commitment therapy, cognitive functional therapy). In addition, safety was assessed as a secondary outcome of the review. As with any health intervention, understanding the safety profile of psychological interventions is essential for formulating a balanced judgement of their overall risk-benefit ratio for patients.

Finally, there are numerous strengths for the randomised controlled trial described in **Chapters Six, Seven, and Eight.** The first category of strengths pertains to design features of the Get Back to Healthy trial which were purposively included to address specific gaps in knowledge identified in **Chapter Five**. Firstly, the main intervention of the Get Back to Healthy trial involves a health coaching program, which is a type of counselling-based intervention frequently used in the management of health conditions. Once completed, the results of this trial will contribute towards the limited evidence currently available for counselling-based interventions for chronic non-specific low back pain. Secondly, the primary and secondary outcomes of the study will be assessed at 12-months from baseline, providing evidence for the mid to long-term effectiveness of counselling-based interventions. Furthermore, more appropriate criteria for assessing adverse events, for trials of psychological interventions, were selected (i.e., querying participants about experiences of emotional distress).

The second category of strengths pertains to the conception of the Get Back to Healthy trial. As discussed in **Chapter Six,** the design of the Get Back to Healthy trial was informed by a series of consultations with senior musculoskeletal physiotherapists and consumer representative of patients with low back pain. Also, the data collection procedures utilised in the trial were adapted based on findings from the pilot randomised controlled trial (IMPACT).[15] Further, the design of the trial involved input from multiple stakeholders spanning across academic, government, and health sectors, as well as a national consumer organisation representing people with musculoskeletal pain. Together, these strengths helped to ensure that the aims and design features of the trial were relevant, pragmatic, feasible, and acceptable to people with chronic non-specific low back pain.

The last category of strengths pertains to the ongoing conduct and reporting of the Get Back to Healthy trial. The trial received full ethical approval (Western Sydney Local Health District: 2020/ETH00115), was prospectively registered (Australian New Zealand Clinical Trials Registry: ACTRN12620000889954), and the protocol was published,[14] prior to implementation. This was advantageous to ensure that the trial protocol was assessed for scientific, ethical, and safety issues prior to commencement of recruitment. Importantly, detailed justifications for all amendment to the trial protocol, made in response to the COVID-19 pandemic, were reported transparently in **Chapters Seven and Eight**. Clear

documentation of protocol amendments safeguards the ongoing rigor of trial conduct and supports improved appraisal of the conduct and results of the trial after completion. Further, from **Chapter Eight**, it was established that obtaining informed consent and conducting baseline assessment procedures remotely is feasible for people with low back pain. This may provide people who would otherwise not participate in clinical trials, with an opportunity to be involved in research.

Limitations of the thesis and recommendations for future research

There are also some limitations of this thesis which should be acknowledged and used to guide future research in this topic area. Whilst health care utilisation was the main outcome of this thesis, health care utilisation was not assessed in the systematic review presented in **Chapters Four and Five**. This was due to an apriori perceived lack of available data in existing randomised controlled trials, which was subsequently observed during the eligibility screening process. Moreover, due to unexpected delays with trial implementation and recruitment, the randomised controlled trial described in **Chapters Six to Eight** remains incomplete. Consequently, the present thesis was unable to conclude the effectiveness and cost-effectiveness of integrating a lifestyle intervention into the discharge care pathway for patients with low back pain, to reduce the use of health services for low back pain and improve health outcomes.

There were also limitations of the individual studies. In **Chapter Two**, sleep quality was measured via a self-reported questionnaire (Pittsburgh Sleep Quality Index[34]). Studies have shown that subjective (i.e., self-reported) measures of sleep are poor predictors of objective measures of sleep (i.e., actigraphy), particularly in older adults.[35, 36] Whilst potential benefits of utilising subjective measures of sleep have been described in **Chapter Two**,[1] future studies should aim to incorporate objective measures of sleep quality, where feasible, to further elucidate the relationship between poor sleep quality and health care utilisation for low back pain. In addition, the study presented in **Chapter Two** employed a cross-sectional study design, which precluded determination of causality. Future longitudinal studies are necessary to further elucidate the causal relationship between sleep quality and medical care-seeking for low back pain. In **Chapter Three**, the study sample was recruited from across urban and regional Australia. Evidence suggests that regional areas have fewer health services available per capita, when compared with urban areas.[37]

However, the analyses performed in **Chapter Three** did not adjust for the geographical location of participants. Future studies should consider the potential confounding effects of geographical location, when examining patterns of health care utilisation. Also, the study was inadequately powered to perform sex-disaggregated analyses. Given that there is abundant evidence confirming sex and/or gender-related differences in the utilisation of care for low back pain,[1, 6, 38] and in sociocultural patterns of work, domestic labour, and physical activity,[39, 40] future studies with large sample sizes should examine the impact of sex and/or gender when investigating the relationship between health or lifestyle factors and health care utilisation for low back pain. Finally, there was substantial missing data on sleep quality in comparison with other covariates explored in **Chapter Three**. Missing data on sleep quality was due to incomplete Pittsburgh Sleep Quality Index questionnaires, which precluded calculation of a valid overall sleep quality score for many participants. This may have resulted in an attenuation of statistical power in univariate analyses involving sleep quality.

Together, the results and limitations of **Chapters Two and Three** reinforce the importance of investigating the relationship between modifiable health and lifestyle factors on the utilisation of care for low back pain, with consideration of the potential confounding influence of shared familial factors, geographical location, and sex and/or gender. Longitudinal study designs are beneficial to further elucidate the direction of causality between explanatory variables and outcomes of interest. Moreover, in addition to analysing aggregated patterns of health care utilisation for low back pain, performing analyses based on different types of care (e.g., health services only, self-management strategies only) can better inform the specific impact that factors may have on certain health behaviours of people with low back pain. Also, the utilisation of objective measurement tools, which are often considered more accurate, valid, and subsequently preferred over self-reported measures, should be considered when feasible and appropriate. Future studies of health care utilisation for low back pain should aim to address these ongoing gaps in knowledge.

There were also some limitations of the systematic review discussed in **Chapters Four and Five.** Whilst a clear rationale was given for organising the different types of psychological interventions into five distinct categories, a pragmatic decision was made to combine interventions involving two or more types of psychological approaches into a single

treatment node, *combined psychological approaches*. The advantage of this decision was gaining sufficient statistical power for analysis and providing a simpler framework to translate findings into clinical practice. However, this may have resulted in heterogeneity within this treatment node. Other limitations included the poor and inconsistent reporting of patient involvement in the design or development of the interventions described in the included studies, limiting assessment of patient acceptability of psychological interventions in clinical practice. Future studies, potentially involving surveys or focus groups, should investigate patients' perceptions regarding the acceptability of psychological interventions, delivered with or without structured exercise, for managing low back pain. Also, future studies should investigate patient and clinician perspectives regarding facilitators and barriers towards the uptake and adherence to both interventions (i.e., delivered in an intra-disciplinary or inter-disciplinary setting).

In addition, poor and inconsistent reporting of data on socioeconomic factors and comorbidities precluded examination of these factors as potential effect modifiers. Future randomised controlled trials of psychological interventions should take heed of the importance of assessing and reporting this information. Finally, the inherent inability to blind participants in clinical trials involving psychological interventions should also be considered as a potential source of bias (e.g., study results may favour psychological interventions, delivered with or without physiotherapy care, over comparison interventions such as usual care, no interventions or even physiotherapy care alone). This limitation will likely be challenging to address in future similar studies.

The main limitations of the randomised controlled trial reported in **Chapters Six, Seven, and Eight** was that the unprecedented impact of the COVID-19 pandemic resulted in several amendments to the trial protocol (i.e., expansion of the inclusion criteria from patients identified from public hospitals only, to those identified from the general community). Although patients recruited from both settings may be similar in terms of symptom presentation, it is possible that the stage of behaviour change, health literacy, care-seeking behaviours, type of care received, and other psychosocial factors, may differ between groups. There is potential for these factors to impact treatment effect estimates. Exploratory analyses will be performed if sufficient statistical power is available. It is possible that revisions to the study sample size, to ensure adequate power for sub-group

analyses, may also be required. Another limitation is that the Roland Morris Disability Questionnaire has not been administered in the validated form (i.e., instead of a single tick-box 'yes' option for each statement, both a 'yes' and 'no' option have been presented to participants). This will be acknowledged in manuscripts reporting the results of the completed study. Finally, a limitation of **Chapter Eight** is that some challenges described may be specific to trials of patients with low back pain or musculoskeletal conditions, or specific to the circumstances of the Get Back to Healthy trial (e.g., the type of intervention examined, or outcomes assessed). Additional studies investigating the challenges towards implementation of other large, multi-site randomised clinical trials, which involve partners across multiple sectors, may be useful to substantiate the generalisability of the recommendations presented in this chapter. Nevertheless, the key recommendations from this study are broadly relevant to the wider research context.

Conclusion

Overall, the studies included in this thesis aimed to investigate the health and lifestyle factors influencing health care utilisation for low back pain, and to examine the role of psychological interventions (including lifestyle interventions) for improving health outcomes and/or reducing health service utilisation in people with chronic non-specific low back pain. This thesis contributed additional knowledge regarding the harmful impact of various health (i.e., poor sleep quality) and lifestyle factors (i.e., higher levels of physically demanding work, domestic labour, or sedentarism) in people with low back pain. This thesis also provided new evidence for the comparative effectiveness and safety of the wide range of psychological approaches for chronic non-specific low back pain. Pragmatic recommendations for their use in clinical practice were also discussed. Finally, this thesis described the protocol of a randomised controlled trial investigating the effect of incorporating a lifestyle intervention at discharge from conservative treatment for chronic non-specific low back pain, to reduce the burden of health care utilisation for the condition. The lifestyle intervention involves a public health coaching program focused on the promotion of physical activity. Preliminary observations suggest that telephone-based public health coaching programs can be implemented successfully without change even during a global pandemic and may be a viable solution for supporting people with chronic non-specific low back pain after discharge from treatment.

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APPENDICES

Appendix 1: Supplementary Material for Chapter Three

Supplementary material

Supplementary Material

Items

Supplementary A. Assessment of outcome measures, explanatory variables, and covariates.

Supplementary methodsS1. Assessment of outcome measures

Outcome measure data were collected via weekly self-reported questionnaires. Participants indicating that they experienced low back pain (LBP) in the past week were asked the following follow-up questions related to their use of care for the condition. The questions and possible responses are described below. For each response selected (multiple allowed), participants were asked to indicate the frequency (number of days) of utilising each specific type of care (e.g., general practitioner, heat pack, non-opioid analgesics) over the past seven days (0 - 7).

Q1. "Have you sought any of the following treatments for this LBP in the last seven days?"
Possible responses (multiple responses were allowed):

- Health services for LBP:
    - General practitioner
    - Physiotherapist
    - Chiropractor
    - Emergency department
    - Surgical procedure
    - None
- Self-management strategies for LBP:
    - Heat pack
    - Bed rest
    - Light exercise (e.g., walking)
    - Hot shower
    - Seeking information on internet and books
    - Other
    - None

Q2: “Have you taken any of the following medications for your LBP in the last seven days?”

Possible responses (multiple responses were allowed):

- Non-opioid analgesics
- Weak opioid analgesics
- Strong opioid
- Antidepressants
- Natural pain relievers
- Other
- None

Supplementary methodsS2. Assessment of explanatory variables

In total, seven explanatory variables were included: moderate-to-vigorous intensity physical activity, sedentary behaviour, physical workload, and work, transport, household, and leisure domain physical activity. Moderate-to-vigorous intensity physical activity and sedentary behaviour were device-based measures, whilst physical workload and work, transport, household, and leisure domain physical activity were self-reported measures.

Moderate-to-vigorous intensity physical activity and sedentary behaviour

Moderate-to-vigorous intensity physical activity and sedentary behaviour were assessed at baseline via an Actigraph (GT1M/GT3X model) accelerometer, which has been widely used in clinical research and has good reliability and validity for assessing physical activity (Migueles et al., 2017; Knaier et al., 2019). Participants were asked to wear the accelerometer during their waking hours on seven consecutive days. The device was worn on the right hip, secured via an elastic belt (Troiano et al., 2014; Migueles et al., 2017; Knaier et al., 2019). Methods used to determine non-wear time have been described previously (Carvalho-e-Silva et al., 2020). Data on moderate-to-vigorous intensity physical activity and sedentary behaviour were assessed as total minutes per week (minutes/week).

Physical workload

Physical workload was assessed at baseline using the self-reported Physical Workload Index (Hollmann et al., 1999). Physical Workload Index scores were calculated as the weighted sum of scores across 15-items assessing the frequency of adopting different body postures and lifting loads of various weights, at work. Higher scores on the Physical Workload Index represent higher total physical workload.

Domain-specific physical activity

Four domain-specific physical activity variables were assessed at baseline using an electronic version of the self-reported International Physical Activity Questionnaire (long-form version) (Hagströmer et al., 2006): work, transport, household, and leisure domain physical activity. Examples of work physical activity included heavy lifting, digging, heavy construction, climbing stairs, carrying light loads, and walking. Examples of transport physical activity included bicycling and walking. Examples of household physical activity included housework, gardening, yard work, general maintenance, and caring for family

members. Examples of leisure physical activity included leisure-time walking, running, swimming, and playing tennis.

For each physical activity domain, data were initially assessed as total time per week (minutes/week), which we then transformed into total metabolic equivalent of task-minutes per week (MET-minutes/week).

Supplementary methodsS3. Assessment of covariates

Sex, age, body mass index, smoking history, recent episode of LBP at baseline (i.e., ≤ 4 weeks prior to baseline assessment), disability, sleep quality, depression, anxiety, and stress were considered as possible covariates. The methods used to assess the covariates of interest are summarised below.

Sex, age, and body mass index

Self-reported sex (male/female) was collected at baseline. Age was calculated based on the date of completing the baseline assessment and self-reported date of birth. Body mass index was calculated from self-reported measurements of weight and height. Sex was assessed as a dichotomous variable, whilst age and body mass index were assessed as continuous measures.

Smoking history

Smoking history was assessed via the question: "regarding your smoking habit, how would you classify yourself?" Responses were non-smoker, ex-smoker, occasional, or current smoker. Smoking history was assessed as a categorical measure.

Recent episode of LBP

To assess a recent episode of LBP, participants who reported a lifetime prevalence of LBP were asked: "in the past four weeks, have you had pain in your low back? Please do not report pain from feverish illness or menstruation" (yes/no). Recent episode of LBP was assessed as a dichotomous variable.

Disability

Those who responded yes to a recent episode of LBP were asked follow-up questions regarding disability due to LBP, assessed using the self-reported Roland Morris Disability Questionnaire (Roland and Morris 1983). Scores range from 1 to 24, with higher scores representing greater disability. Participants who did not report a recent episode of LBP at baseline were assigned a zero value to replace missing Roland Morris Disability Questionnaire scores. Disability was assessed as a continuous measure.

Sleep quality

Sleep quality was assessed using the self-reported Pittsburgh Sleep Quality Index (Buysse et al., 1989). Scores range from 1 to 24, with Pittsburgh Sleep Quality Index scores > 5 indicating poor sleep quality. Sleep quality was assessed as a continuous measure.

Depression, anxiety, and stress

Depression, anxiety, and stress were assessed as separate domains using the self-reported 21-item Depression Anxiety Stress Scale (Henry and Crawford 2005). Each of the three domains of the 21-item Depression Anxiety Stress Scale range from 1 to 42, with higher scores representing higher levels of each domain. Depression, anxiety, and stress were assessed as continuous measures.

Supplementary B. Results of univariate models

Supplementary tableS1. Results of univariate models of various covariates and overall care utilisation for LBP

		Overall care utilisation for LBP				
Variable Type[a]	**Covariate**	**Coef.**	**SE**	***p***	**95% CI**	**n**
Continuous	Age	1.16	0.73	0.116	-0.29 to 2.61	340
	Body mass index	-0.04	1.70	0.980	-3.39 to 3.31	335
	Disability	25.37	7.04	**<0.001**	11.49 to 39.26	340
	Sleep quality	4.63	2.56	**0.074**	-0.45 to 9.70	187
	Depression	1.75	1.93	0.364	-2.05 to 5.56	340
	Anxiety	3.89	1.50	0.121	-1.04 to 8.81	340
	Stress	3.39	1.73	**0.051**	-0.02 to 6.80	340
Variable Type[a]	**Covariate**	**z**		***p***		**n**
Dichotomous	Sex	2.48		**0.013**		340
	Recent episode of LBP[b]	-7.36		**<0.001**		334
Variable Type[a]	**Covariate**	***F***		***p***		**n**
Categorical	Smoking	1.32		0.267		337

Coef.: coefficient, CI: confidence interval, LBP: low back pain, n: number of participants, *p*: probability value, SE: standard error. Covariates demonstrating a p-value < 0.10 are highlighted in bold.

[a]Indicates how data for each respective covariate were analysed in the univariate and final models (if included).

[b]Recent episode of LBP was defined as experiencing LBP ≤ 4 weeks prior to completion of baseline assessment.

Supplementary tableS2. Results of univariate models of various covariates and utilisation of health services for LBP

		Utilisation of health services for LBP				
Variable Type[a]	**Covariate**	**Coef.**	**SE**	***p***	**95% CI**	**n**
Continuous	Age	0.04	0.04	0.371	-0.05 to 0.12	340
	Body mass index	0.03	0.07	0.664	-0.01 to 0.17	335
	Disability	0.74	0.34	**0.034**	0.06 to 1.42	340
	Sleep quality	0.13	0.11	0.244	-0.09 to 0.35	187
	Depression	0.02	0.03	0.631	-0.05 to 0.08	340
	Anxiety	0.03	0.04	0.478	-0.05 to 0.11	340
	Stress	0.07	0.05	0.168	-0.03 to 0.16	340
Variable Type[a]	**Covariate**	**z**		***p***		**n**
Dichotomous	Sex	2.98		**0.003**		340
	Recent episode of LBP[b]	-4.25		**<0.001**		334
Variable Type[a]	**Covariate**	***F***		***p***		**n**
Categorical	Smoking	1.44		0.230		336

Coef.: coefficient, CI: confidence interval, LBP: low back pain, n: number of participants, *p*: probability value, SE: standard error. Covariates demonstrating a p-value < 0.10 are highlighted in bold.

[a]Indicates how data for each respective covariate were analysed in the univariate and final models (if included).

[b]Recent episode of LBP was defined as experiencing LBP ≤ 4 weeks prior to completion of baseline assessment.

Supplementary tableS3. Results of univariate models of various covariates and utilisation of self-management strategies for LBP

		Utilisation of self-management strategies for LBP				
Variable Type[a]	**Covariate**	**Coef.**	**SE**	***p***	**95% CI**	**n**
Continuous	Age	0.72	0.50	0.147	-0.26 to 1.70	340
	Body mass index	-0.72	1.03	0.485	-2.75 to 1.30	335
	Disability	15.14	4.20	**<0.001**	6.87 to 23.41	340
	Sleep quality	1.79	1.35	0.186	-0.86 to 4.46	187
	Depression	0.59	1.13	0.600	-1.64 to 2.82	340
	Anxiety	1.98	1.43	0.168	-0.84 to 4.80	340
	Stress	1.67	1.00	**0.097**	-0/31 to 3.64	340
Variable Type[a]	**Covariate**	**z**		***p***		**n**
Dichotomous	Sex	2.52		**0.012**		340
	Recent episode of LBP[b]	-6.53		**<0.001**		334
Variable Type[a]	**Covariate**	***F***		***p***		**n**
Categorical	Smoking	1.57		0.198		336

Coef.: coefficient, CI: confidence interval, LBP: low back pain, n: number of participants, *p*: probability value, SE: standard error. Covariates demonstrating a p-value < 0.10 are highlighted in bold.

[a]Indicates how data for each respective covariate were analysed in the univariate and final models (if included).

[b]Recent episode of LBP was defined as experiencing LBP ≤ 4 weeks prior to completion of baseline assessment.

Supplementary C. Distribution of data for the explanatory variables

Supplementary tableS4. Distribution of data on physical activity variables and sedentary behaviour, classified into tertiles or dichotomised based on volume

Explanatory variable	Classified into tertiles			Classified into dichotomous variables		
	Volume	Median (IQR)	n	Volume	Median (IQR)	n
Sedentary behaviour	1 (Low)	2611 (2299 - 2852)	105	Low[a]	2611 (2299 - 2852)	105
	2 (Medium)	3321 (3208 - 3523)	104	Medium-to-high[b]	3635 (3321 – 3968)	208
	3 (High)	3968 (3774 - 4217)	104			
Moderate-to-vigorous intensity physical activity	1 (Low)	70 (45 - 96)	105	Low[a]	70 (45 – 96)	105
	2 (Medium)	180 (146 - 207)	104	Medium-to-high[b]	241.50 (180 – 340)	208
	3 (High)	340 (289 – 437)	104			
Physical workload	1 (Low)	2 (1 - 4)	79	Low[a]	2 (1 - 4)	79
	2 (Medium)	9 (7 - 11)	79	Medium-to-high[b]	13 (9 - 18)	157
	3 (High)	18 (15 - 26)	78			
Work domain physical activity	1 (Low)	0 (0 - 0)	92	Low[a]	0 (0 - 0)	92
	2 (Medium)	353 (129 - 603)	76	Medium-to-high[b]	1476 (389 – 5004)	159
	3 (High)	4590 (2346 - 10740)	83			
Transport domain physical activity	1 (Low)	0 (0 – 66)	125	Low[a]	0 (0 – 66)	125
	2 (Medium)	347 (231 - 462)	109	Medium-to-high[b]	594 (347 - 1386)	215
	3 (High)	1386 (891 - 1940)	106			
Household domain physical activity	1 (Low)	167 (0 - 300)	114	Low[a]	117 (0 - 300)	114
	2 (Medium)	983 (660 - 1320)	114	Medium-to-high[b]	1920 (975 - 3480)	226
	3 (High)	3540 (2580 - 5558)	112			
Leisure domain physical activity	1 (Low)	66 (0 - 219)	117	Low[a]	66 (0 - 219)	117
	2 (Medium)	743 (558 - 1032)	111	Medium-to-high[b]	1404 (743 - 2415)	223
	3 (High)	2412 (1780 - 3899)	112			

IQR: interquartile range, LBP: low back pain, n: number of participants. Median and IQR values are presented as metabolic equivalent of task minutes per week (MET-minutes/week).
[a]Participants classified into the *low* tertile were dichotomised as the *low* volume category for each explanatory variable, respectively.
[b]Participants classified into the *medium* or *high* tertiles were dichotomised as the *medium-to-high* volume category for each explanatory variable, respectively.

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Appendix 2: Supplementary Material for Chapter Four

Published supplementary material

PRISMA checklist (protocols)

PRISMA checklist (systematic reviews)

PRISMA checklist (network meta-analyses)

APPENDIX A

Database: Ovid MEDLINE

1. exp Back Pain/ or exp Low Back Pain/ or exp Backache/
2. (back pain or low back pain or lumbar pain or lumbago or dorsalgia or spinal pain or vertebral pain or backache or lumbar spine).ti,ab.
3. 1 or 2
4. exp Behavior Therapy/ or exp Cognitive Therapy/ or *Conditioning, Operant/ or exp Reinforcement, Psychology/
5. (operant conditioning or reinforcement or psychological intervention or psychological therapy).ab,ti.
6. (cognitiv* adj1 (treatment* or therap* or intervention*)).ab,ti.
7. (behavio?r* adj1 (treatment* or therap* or intervention* or techniqu* or modif* or change*)).ab,ti.
8. (graded exposure or desensiti* or imagery or goal setting).ab,ti.
9. (acceptance and commitment therapy or CBT).ab,ti.
10. 4 or 5 or 6 or 7 or 8 or 9
11. exp Mindfulness/ or *Mind-Body Therapies/ or exp Meditation/ or exp Relaxation/ or exp Relaxation Therapy/
12. (mindfulness based stress reduction*).ab,ti.
13. (mindfulness or mind-body therapies or meditation or relaxation or relaxation therap*).ab,ti.
14. (mbsr* or mbct*).ab,ti.
15. 11 or 12 or 13 or 14
16. (cognitive functional therapy or CFT).ab,ti.
17. exp Health Education/ or exp Health Promotion/ or exp Motivation/
18. (health education or health promotion or motivation).ab,ti.
19. ((health or wellness or life-style or behav*) adj1 coach*).ab,ti.
20. ((wellness or behav*) adj1 intervention*).ab,ti.
21. or/ 17 or 18 or 19 or 20
22. exp Biofeedback, Psychology/ or exp Feedback, Psychological/
23. (electromyograph* or electromyogram* or EMG*).ab,ti.
24. (bio-feedback or feedback).ab,ti.
25. 22 or 23 or 24

26. (pain neuroscience education or pain education or neuroscience education or pain physiology education or neuro-physiology education or therapeutic education).ab,ti.
27. exp Counseling/
28. (counseling or supportive psychotherap*).ab,ti.
29. 27 or 28
30. 10 or 15 or 16 or 21 or 25 or 26 or 29
31. 3 and 30
32. exp Randomized controlled trial/ or *Clinical Trial/ or *Random allocation/ or exp Controlled clinical trial/
33. randomized controlled trial.pt.
34. (random* adj3 trial).ab,ti.
35. (clinical trial or random allocation or controlled clinical trial).ab,ti.
36. 32 or 33 or 34 or 35
37. 31 and 36
38. limit 37 to humans

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2, 7
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	20
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Cover letter and Letter of reply to editor
Support:			
Sources	5a	Indicate sources of financial or other support for the review	1, 20
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-10
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10

Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Appendix A
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	11-13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	15-16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	16-19
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	16-19
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	16-19
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	20
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	20

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-7
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	7
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7-10
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	10
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix A
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	10
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	11-13
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	11-13
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	15-16
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	16-18
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	16-18

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	20
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	17-20
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	N/A – protocol paper
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	N/A – protocol paper
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A – protocol paper
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A – protocol paper
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A – protocol paper
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A – protocol paper
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A – protocol paper
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	N/A – protocol paper
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	N/A – protocol paper
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	N/A – protocol paper
FUNDING			

Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	22

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

PRISMA NMA Checklist of Items to Include When Reporting A Systematic Review Involving a Network Meta-analysis

Section/Topic	Item #	Checklist Item	Reported on Page #
TITLE			
Title	1	Identify the report as a systematic review *incorporating a network meta-analysis (or related form of meta-analysis).*	***1***
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: **Background:** main objectives **Methods:** data sources; study eligibility criteria, participants, and interventions; study appraisal; and *synthesis methods, such as network meta-analysis.* **Results:** number of studies and participants identified; summary estimates with corresponding confidence/credible intervals; *treatment rankings may also be discussed. Authors may choose to summarize pairwise comparisons against a chosen treatment included in their analyses for brevity.* **Discussion/Conclusions:** limitations; conclusions and implications of findings. **Other:** primary source of funding; systematic review registration number with registry name.	***2***
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known*, including mention of why a network meta-analysis has been conducted.*	***4-7***
Objectives	4	Provide an explicit statement of questions being addressed, with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	***7***
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists and if and where it can be accessed (e.g., Web address); and, if available, provide registration information, including registration number.	***7***
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. *Clearly describe eligible treatments included in the treatment network, and note whether any have been clustered or merged into the same node (with justification).*	***7-10***
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	***10***
Search	8	Present full electronic search strategy for at least one	***Appendix***

		database, including any limits used, such that it could be repeated.	***A***
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	***10***
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	***11-13***
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	***11-13***
Geometry of the network	**S1**	Describe methods used to explore the geometry of the treatment network under study and potential biases related to it. This should include how the evidence base has been graphically summarized for presentation, and what characteristics were compiled and used to describe the evidence base to readers.	***17***
Risk of bias within individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	***15-16***
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means). *Also describe the use of additional summary measures assessed, such as treatment rankings and surface under the cumulative ranking curve (SUCRA) values, as well as modified approaches used to present summary findings from meta-analyses.*	***16-18***
Planned methods of analysis	14	Describe the methods of handling data and combining results of studies for each network meta-analysis. This should include, but not be limited to: • *Handling of multi-arm trials;* • *Selection of variance structure;* • *Selection of prior distributions in Bayesian analyses; and* • *Assessment of model fit.*	***16-18***
Assessment of Inconsistency	**S2**	Describe the statistical methods used to evaluate the agreement of direct and indirect evidence in the treatment network(s) studied. Describe efforts taken to address its presence when found.	***18***
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	***20***
Additional analyses	16	Describe methods of additional analyses if done, indicating which were pre-specified. This may include, but not be limited to, the following: • Sensitivity or subgroup analyses; • Meta-regression analyses; • *Alternative formulations of the treatment network; and* • *Use of alternative prior distributions for Bayesian analyses (if applicable).*	***17-20***

RESULTS†			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	***N/A – protocol paper***
Presentation of network structure	**S3**	Provide a network graph of the included studies to enable visualization of the geometry of the treatment network.	***N/A – protocol paper***
Summary of network geometry	**S4**	Provide a brief overview of characteristics of the treatment network. This may include commentary on the abundance of trials and randomized patients for the different interventions and pairwise comparisons in the network, gaps of evidence in the treatment network, and potential biases reflected by the network structure.	***N/A – protocol paper***
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	***N/A – protocol paper***
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment.	***N/A – protocol paper***
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: 1) simple summary data for each intervention group, and 2) effect estimates and confidence intervals. *Modified approaches may be needed to deal with information from larger networks.*	***N/A – protocol paper***
Synthesis of results	21	Present results of each meta-analysis done, including confidence/credible intervals. *In larger networks, authors may focus on comparisons versus a particular comparator (e.g. placebo or standard care), with full findings presented in an appendix. League tables and forest plots may be considered to summarize pairwise comparisons.* If additional summary measures were explored (such as treatment rankings), these should also be presented.	***N/A – protocol paper***
Exploration for inconsistency	**S5**	Describe results from investigations of inconsistency. This may include such information as measures of model fit to compare consistency and inconsistency models, *P* values from statistical tests, or summary of inconsistency estimates from different parts of the treatment network.	***N/A – protocol paper***
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies for the evidence base being studied.	***N/A – protocol paper***
Results of additional analyses	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression analyses*, alternative network geometries studied, alternative choice of prior distributions for Bayesian analyses,* and so forth).	***N/A – protocol paper***
DISCUSSION			
Summary of evidence	24	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy-	***N/A – protocol paper***

		makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias). *Comment on the validity of the assumptions, such as transitivity and consistency. Comment on any concerns regarding network geometry (e.g., avoidance of certain comparisons).*	***N/A – protocol paper***
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	***N/A – protocol paper***
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. This should also include information regarding whether funding has been received from manufacturers of treatments in the network and/or whether some of the authors are content experts with professional conflicts of interest that could affect use of treatments in the network.	***22***

PICOS = population, intervention, comparators, outcomes, study design.
* Text in italics indicateS wording specific to reporting of network meta-analyses that has been added to guidance from the PRISMA statement.
† Authors may wish to plan for use of appendices to present all relevant information in full detail for items in this section.

Box. Terminology: Reviews With Networks of Multiple Treatments

Different terms have been used to identify systematic reviews that incorporate a network of multiple treatment comparisons. A brief overview of common terms follows.

Indirect treatment comparison: Comparison of 2 interventions for which studies against a common comparator, such as placebo or a standard treatment, are available (i.e., indirect information). The direct treatment effects of each intervention against the common comparator (i.e., treatment effects from a comparison of interventions made within a study) may be used to estimate an indirect treatment comparison between the 2 interventions (**Appendix Figure 1, A**). An indirect treatment comparison (ITC) may also involve multiple links. For example, in **Appendix Figure 1, B**, treatments B and D may be compared indirectly on the basis of studies encompassing comparisons of B versus C, A versus C, and A versus D.

Network meta-analysis or *mixed treatment comparison*: These terms, which are often used interchangeably, refer to situations involving the simultaneous comparison of 3 or more interventions. Any network of treatments consisting of strictly unclosed loops can be thought of as a series of ITCs (**Appendix Figure 1, A and B**). In mixed treatment comparisons, both direct and indirect information is available to inform the effect size estimates for at least some of the comparisons; visually, this is shown by closed loops in a network graph (**Appendix Figure 1, C**). Closed loops are not required to be present for every comparison under study. "Network meta-analysis" is an inclusive term that incorporates the scenarios of both indirect and mixed treatment comparisons.

Network geometry evaluation: The description of characteristics of the network of interventions, which may include use of numerical summary statistics. This does not involve quantitative synthesis to compare treatments. This evaluation describes the current evidence available for the competing interventions to identify gaps and potential bias. Network geometry is described further in **Appendix Box 4**.

Appendix Box 1. The Assumption of Transitivity for Network Meta-Analysis

Methods for indirect treatment comparisons and network meta-analysis enable learning about the relative treatment effects of, for example, treatments A and B through use of studies where these interventions are compared against a common therapy, C.

When planning a network meta-analysis, it is important to assess patient and study characteristics across the studies that compare pairs of treatments. These characteristics are commonly referred to as *effect modifiers* and include traits such as average patient age, gender distribution, disease severity, and a wide range of other plausible features.

For network meta-analysis to produce valid results, it is important that the distribution of effect modifiers is similar, for example, across studies of A versus B and A versus C. This balance increases the plausibility of reliable findings from an indirect comparison of B versus C through the common comparator A. When this balance is present, the assumption of transitivity can be judged to hold.

Authors of network meta-analyses should present systematic (and even tabulated) information regarding patient and study characteristics whenever available. This information helps readers to empirically evaluate the validity of the assumption of transitivity by reviewing the distribution of potential effect modifiers across trials.

Appendix Box 2. Differences in Approach to Fitting Network Meta-Analyses

Network meta-analysis can be performed within either a frequentist or a Bayesian framework. Frequentist and Bayesian approaches to statistics differ in their definitions of probability. Thus far, the majority of published network meta-analyses have used a Bayesian approach.

Bayesian analyses return the posterior probability distribution of all the model parameters given the data and prior beliefs (e.g., from external information) about the values of the parameters. They fully encapsulate the uncertainty in the parameter of interest and thus can make direct probability statements about these parameters (e.g., the probability that one intervention is superior to another).

Frequentist analyses calculate the probability that the observed data would have occurred under their sampling distribution for hypothesized values of the parameters. This approach to parameter estimation is more indirect than the Bayesian approach.

Bayesian methods have been criticized for their perceived complexity and the potential for subjectivity to be introduced by choice of a prior distribution that may affect study findings. Others argue that explicit use of a prior distribution makes transparent how individuals can interpret the same data differently. Despite these challenges, Bayesian methods offer considerable flexibility for statistical modeling.
In-depth introductions to Bayesian methods and discussion of these and other issues can be found elsewhere.

Appendix Box 3. Network Meta-Analysis and Assessment of Consistency

Network meta-analysis often involves the combination of direct and indirect evidence. In the simplest case, we wish to compare treatments A and B and have 2 sources of information: direct evidence via studies comparing A versus B, and indirect evidence via groups of studies comparing A and B with a common intervention, C. Together, this evidence forms a closed loop, ABC.

Direct and indirect evidence for a comparison of interventions should be combined only when their findings are similar in magnitude and interpretation. For example, for a comparison of mortality rates between A and B, an odds ratio determined from studies of A versus B should be similar to the odds ratio comparing A versus B estimated indirectly based on studies of A versus C and B versus C. This assumption of comparability of direct and indirect evidence is referred to as *consistency* of treatment effects.

When a treatment network contains a closed loop of interventions, it is possible to examine statistically whether there is agreement between the direct and indirect estimates of intervention effect.

Different methods to evaluate potential differences in relative treatment effects estimated by direct and indirect comparisons are grouped as *local approaches* and *global approaches.* Local approaches (e.g., the Bucher method or the node-splitting method) assess the presence of inconsistency for a particular pairwise comparison in the network, whereas global approaches (e.g., inconsistency models, I^2 measure for inconsistency) consider the potential for inconsistency in the network as a whole.

Tests for inconsistency can have limited power to detect a true difference between direct and indirect evidence. When multiple loops are being tested for inconsistency, one or a few may show inconsistency simply by chance. Further discussions of consistency and related concepts are available elsewhere.
Inconsistency in a treatment network can indicate lack of transitivity (see **Appendix Box 1**).

Appendix Box 4. Network Geometry and Considerations for Bias

The term *network geometry* is used to refer to the architecture of the treatment comparisons that have been made for the condition under study. This includes what treatments are involved in the comparisons in a network, in what abundance they are present, the respective numbers of patients randomly assigned to each treatment, and whether particular treatments and comparisons may have been preferred or avoided.

Networks may take on different shapes. Poorly connected networks depend extensively on indirect comparisons. Meta-analyses of such networks may be less reliable than those from networks where most treatments have been compared against each other.

Qualitative description of network geometry should be provided and accompanied by a network graph. Quantitative metrics assessing features of network geometry, such as *diversity* (related to the number of treatments assessed and the balance of evidence among them), *co-occurrence* (related to whether comparisons between certain treatments are more or less common), and *homophily* (related to the extent of comparisons between treatments in the same class versus competing classes), can also be mentioned.

Although common, established steps for reviewing network geometry do not yet exist, however examples of in-depth evaluations have been described related to treatments for tropical diseases and basal cell carcinoma and may be of interest to readers. An example based on 75 trials of treatments for pulmonary arterial hypertension (**Appendix Figure 3**) suggests that head-to-head studies of active therapies may prove useful to further strengthen confidence in interpretation of summary estimates of treatment comparisons.

Appendix Box 5. Probabilities and Rankings in Network Meta-Analysis

Systematic reviews incorporating network meta-analyses can provide information about the hierarchy of competing interventions in terms of treatment rankings.

The term *treatment ranking probabilities* refers to the probabilities estimated for each treatment in a network of achieving a particular placement in an ordering of treatment effects from best to worst. A network of 10 treatments provides a total of 100 ranking probabilities—that is, for each intervention, the chance of being ranked first, second, third, fourth, fifth, and so forth).

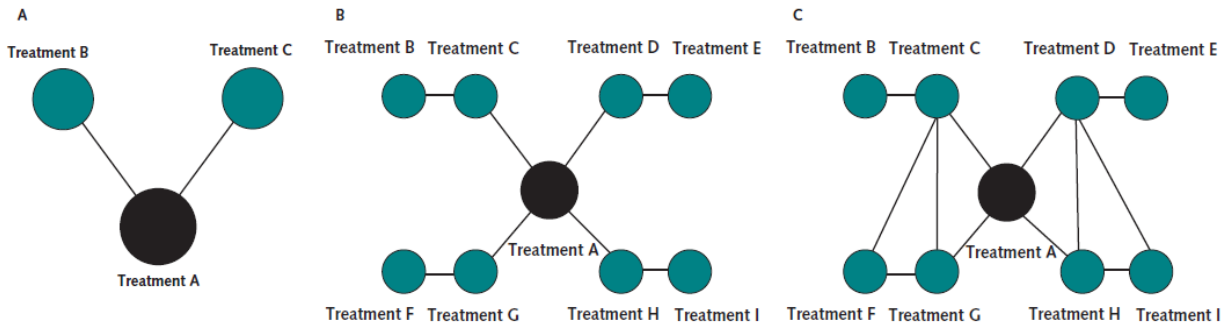
Several techniques are feasible to summarize relative rankings, and include graphical tools as well as different approaches for estimating ranking probabilities. **Appendix Figure 6** shows 2 approaches to presenting such information, on the basis of a comparison of adjuvant interventions for resected pancreatic adenocarcinoma.

Robust reporting of rankings also includes specifying median ranks with uncertainty intervals, cumulative probability curves, and the surface under the cumulative ranking (SUCRA) curve.

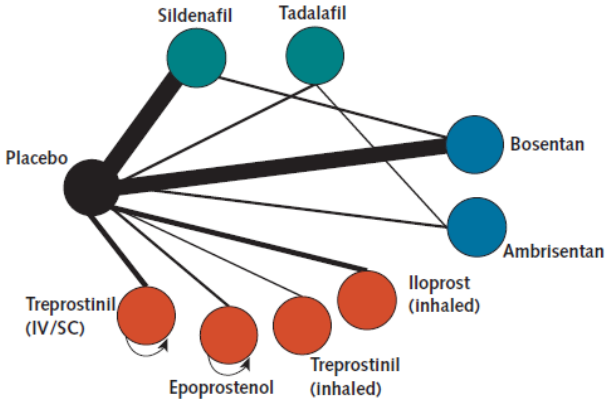
Rankings can be reported along with corresponding estimates of pairwise comparisons between interventions. Rankings should be reported with probability estimates to minimize misinterpretation from focusing too much on the most likely rank.

Rankings may exaggerate small differences in relative effects, especially if they are based on limited information. An objective assessment of the strength of information in the network and the magnitude of absolute benefits should accompany rankings to minimize potential biases.

Appendix Figure 1A-1C

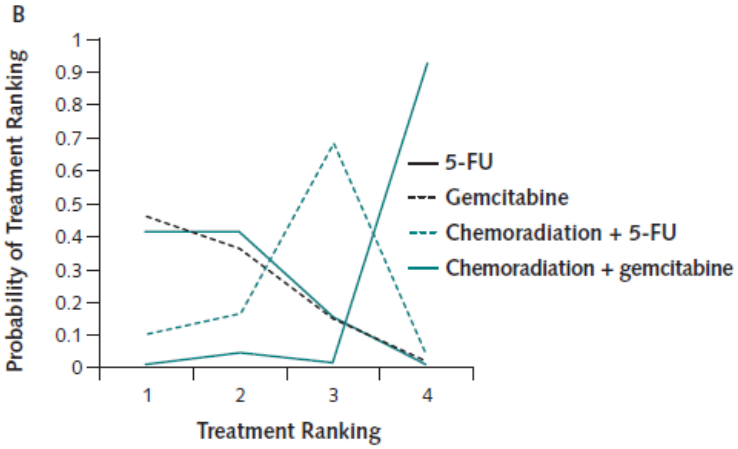


Appendix Figure 3



Appendix Figure 6

Ranking	Treatment and Cooresponding Ranking Probabilities Grade 3 or 4 Hematologic Toxicity			
	5-FU	Gemcitabine	Chemoradiation + 5-FU	Chemoradiation + gemcitabine
1	0.42	0.42	0.15	0.01
2	0.46	0.36	0.15	0.02
3	0.10	0.17	0.68	0.04
4	0.02	0.05	0.02	0.93



Appendix 3: Supplementary Material for Chapter Five

Published supplementary material

PRISMA checklist (network meta-analyses)

Supplementary Material

Items

Supplementary A. Search strategies

Database: Ovid MEDLINE

1. exp Back Pain/ or exp Low Back Pain/ or exp Backache/
2. (back pain or low back pain or lumbar pain or lumbago or dorsalgia or spinal pain or vertebral pain or backache or lumbar spine).ti,ab.
3. 1 or 2
4. exp Behavior Therapy/ or exp Cognitive Therapy/ or *Conditioning, Operant/ or exp Reinforcement, Psychology/
5. (operant conditioning or reinforcement or psychological intervention or psychological therapy).ab,ti.
6. (cognitiv* adj1 (treatment* or therap* or intervention*)).ab,ti.
7. (behavio?r* adj1 (treatment* or therap* or intervention* or techniqu* or modif* or change*)).ab,ti.
8. (graded exposure or desensiti* or imagery or goal setting).ab,ti.
9. (acceptance and commitment therapy or CBT).ab,ti.
10. 4 or 5 or 6 or 7 or 8 or 9
11. exp Mindfulness/ or *Mind-Body Therapies/ or exp Meditation/ or exp Relaxation/ or exp Relaxation Therapy/
12. (mindfulness based stress reduction*).ab,ti.
13. (mindfulness or mind-body therapies or meditation or relaxation or relaxation therap*).ab,ti.
14. (mbsr* or mbct*).ab,ti.
15. 11 or 12 or 13 or 14
16. (cognitive functional therapy or CFT).ab,ti.
17. exp Health Education/ or exp Health Promotion/ or exp Motivation/
18. (health education or health promotion or motivation).ab,ti.
19. ((health or wellness or life-style or behav*) adj1 coach*).ab,ti.
20. ((wellness or behav*) adj1 intervention*).ab,ti.
21. or/ 17 or 18 or 19 or 20
22. exp Biofeedback, Psychology/ or exp Feedback, Psychological/
23. (electromyograph* or electromyogram* or EMG*).ab,ti.
24. (bio-feedback or feedback).ab,ti.
25. 22 or 23 or 24
26. (pain neuroscience education or pain education or neuroscience education or pain physiology education or neuro-physiology education or therapeutic education).ab,ti.
27. exp Counseling/
28. (counseling or supportive psychotherap*).ab,ti.
29. 27 or 28
30. 10 or 15 or 16 or 21 or 25 or 26 or 29
31. 3 and 30
32. exp Randomized controlled trial/ or *Clinical Trial/ or *Random allocation/ or exp Controlled clinical trial/
33. randomized controlled trial.pt.
34. (random* adj3 trial).ab,ti.
35. (randomi?ed controlled trial or clinical trial or random allocation or controlled clinical trial).ab,ti.
36. 32 or 33 or 34 or 35

37. 31 and 36
38. limit 37 to humans

Database: Ovid EMBASE

1. exp Back Pain/ or exp Low Back Pain/ or exp Backache
2. (back pain or low back pain or backache or lumbar pain or lumbago or dorsalgia or spinal pain or vertebral pain or backache or lumbar spine).ti,ab.
3. 1 or 2
4. Exp Cognitive behavioral therapy/ or exp Cognitive behavioral stress management/ or exp Behavior Therapy/ or exp Cognitive Therapy or *Reinforcement/
5. (cognitiv$ adj1 (treatment$ or therap$ or intervention$)).ab,ti.
6. (behav$ adj1 (treatment$ or therap$ or intervention$ or technique$ or modif$ or change$)).ab,ti.
7. (cognitive behavio?ral therapy or cognitive behavio?ral stress management or reinforcement or graded exposure or desensiti$ or imagery or goal setting).ab,ti.
8. (acceptance and commitment therapy or CBT).ab,ti.
9. 4 or 5 or 6 or 7 or 8
10. Exp Mindfulness/ or exp Meditation/
11. (mindfulness or meditation or mindfulness based stress reduction$ or mbsr or mcbt or relaxation technique$ or relaxation therap$).ab,ti.
12. 10 or 11
13. (cognitive functional therapy or CFT).ab,ti.
14. Exp Health education/ or exp Health promotion/ or exp Psychoeducation/ or exp Motivation
15. (health education or health promotion or psychoeducation or motivation).ab,ti.
16. ((health or wellness or life-style or behav$) adj1 coach$).ab,ti.
17. ((wellness or behav$) adj1 intervention$).ab,ti.
18. 14 or 15 or 16 or 17
19. *Biofeedback/ or *Feedback System/ or *Electromyography/
20. (bio-feedback or feedback system or electromyography or electromyogram$ or EMG$).ab,ti.
21. 19 or 20
22. (pain neuroscience education or pain education or neuroscience education or pain physiology education or neuro-physiology education).ab,ti.
23. Exp Counseling/ or exp Directive counseling/ or exp Patient counseling/
24. (counseling or directive counseling or patient counseling or supportive psychotherap$).ab,ti.
25. 23 or 24
26. 9 or 12 or 13 or 18 or 21 or 22 or 25
27. exp Randomized controlled trial/ or exp Random allocation/ or exp Controlled clinical trial/ or exp Controlled study/
28. (random$ adj3 trial).ab,ti.
29. (random allocation or controlled clinical trial or controlled study).ab,ti.
30. 27 or 28 or 29
31. 3 and 26 and 30
32. limit 31 to human

Database: Web of Science

1. TS="Back Pain" or TS="Low Back Pain" or TS="Backache"
2. TS=("lumbar pain" or lumbago or dorsalgia or "spinal pain" or "vertebral pain" or "lumbar spine")
3. #2 OR #1
4. TS=("Behav* Therapy" or "Cognitive Therapy" or "Operant conditioning" or Reinforcement)
5. TS=("psychological intervention" or "psychological therapy")
6. TS=("cognitiv* treatment"* or "cognitiv* intervention*")
7. TS=("behav* treatment*" or "behav* intervention*" or "behav* techniqu*" or "behav* modif*" or "behav* change*")
8. TS=("graded exposure" or desensiti* or imagery or "goal setting")
9. TS=("acceptance and commitment therapy" or CBT)
10. #9 OR #8 OR #7 OR #6 OR #5 OR #4
11. TS=(Mindfulness or "Mind-Body Therapies" or Meditation or Relaxation or "Relaxation Therapy")
12. TS="mindfulness based stress reduction"
13. TS=(mbsr* or mbct*)
14. #13 OR #12 OR #11
15. TS=("cognitive functional therapy" or CFT)
16. TS=("Health Education" or "Health Promotion" or Motivation)
17. TS=(coach NEAR (health or wellness or life-style or behav*))
18. TS=(intervention* NEAR (wellness or behav*))
19. #18 OR #17 OR #16
20. TS=(Biofeedback or Feedback)
21. TS=(electromyograph* or electromyogram* or EMG*)
22. #21 OR #20
23. TS=("pain neuroscience education" or "pain education" or "neuroscience education" or "pain physiology education" or "neuro-physiology education" or "therapeutic education")
24. TS=(counseling or "supportive psychotherap*")
25. #24 OR #23 OR #22 OR #19 OR #15 OR #14 OR #10
26. #25 AND #3
27. TS=("random* controlled trial" or "clinical trial" or "random allocation" or "controlled clinical trial")
28. TS=(random* near trial)
29. #28 OR #27
30. #29 AND #26

Database: SCOPUS

(TITLE-ABS-KEY ("back pain" OR "low back pain" OR "back ache" OR "lumbar pain" OR lumbago OR dorsalgia OR "spinal pain" OR "vertebral pain" OR "lumbar spine")) AND ((TITLE-ABS-KEY ("Behav* Therapy" OR "Cognitive Therapy" OR "Operant Conditioning" OR "Reinforcement" OR "psychological intervention" OR "psychological therapy" OR "cognitiv* treatment*" OR "cognitiv* intervention*" OR "behav* treatment*" OR "behav* intervention*" OR "behav* techniqu*" OR "behav* modif*" OR "behav* change*" OR "graded exposure" OR desensiti* OR imagery OR "goal setting" OR "acceptance and commitment therapy" OR cbt)) OR (TITLE-ABS-KEY (mindfulness OR "Mind-Body Therapies" OR meditation OR relaxation OR "Relaxation Therapy" OR "mindfulness based stress reduction*" OR mbsr OR mbct)) OR (TITLE-ABS-KEY

("cognitive functional therapy" OR cft)) OR (TITLE-ABS-KEY ("Health Education" OR "Health Promotion" OR motivation OR "health coach*" OR "wellness coach*" OR "life-style coach*" OR "behav* coach*" OR "wellness intervention*" OR "behav* intervention*")) OR (TITLE-ABS-KEY ("pain neuroscience education" OR "pain education" OR "neuroscience education" OR "pain physiology education" OR "neuro-physiology education" OR "therapeutic education")) OR (TITLE-ABS-KEY (counseling OR "supportive psychotherap*"))) AND (TITLE-ABS-KEY ("Random* controlled trial" OR "Clinical Trial" OR "Random allocation" OR "Controlled clinical trial" OR "random* trial"))

Database: Ovid PsycINFO

1. exp Back Pain/
2. (back pain or low back pain or lumbar pain or lumbago or dorsalgia or spinal pain or vertebral pain or backache or lumbar spine).ti,ab.
3. 1 or 2
4. exp Cognitive Behavior Therapy/ or exp Cognitive Therapy/ or exp operant conditioning/ or exp negative reinforcement/ or exp positive reinforcement/ or behaviour change/
5. (cognitive behavio?ral therapy or cognitive therap* or operant conditioning or negative reinforcement or positive reinforcement or psychological intervention or psychological therap*).ab,ti.
6. (cognitiv* adj1 (treatment* or intervention*)).ab,ti.
7. (behavio?r* adj1 (treatment* or therap* or intervention* or techniqu* or modif* or change*)).ab,ti.
8. (graded exposure or desensiti* or imagery or goal setting).ab,ti.
9. ((acceptance and commitment therapy) or CBT).ab,ti.
10. 4 or 5 or 6 or 7 or 8 or 9
11. exp Mindfulness/ or exp Meditation/ or exp Relaxation/ or exp Relaxation Therapy
12. (mindfulness based stress reduction*).ab,ti.
13. (mindfulness or meditation or relaxation or relaxation therap* or mbsr* or mbct*).ab,ti.
14. 11 or 12 or 13
15. (cognitive functional therapy or CFT).ab,ti.
16. exp Health Education/ or exp Health Promotion/ or exp Life Coaching/ or exp Coaching Psychology/ or exp Motivation Training/
17. (health education or health promotion or life coaching or coaching psychology or motivation training wellness intervention*).ab,ti.
18. ((health or wellness or behav*) adj1 coach*).ab,ti.
19. 16 or 17 or 18
20. exp Biofeedback, Psychology/ or exp Feedback, Psychological/
21. (bio-feedback training or biofeedback or electromyograph* or electromyogram* or EMG).ab,ti.
22. 20 or 21
23. (pain neuroscience education or pain education or neuroscience education or pain physiology education or neuro-physiology education or therapeutic education).ab,ti.
24. exp Counseling/ or exp Counseling Psychology/ or exp Group Counseling/ or exp Rehabilitation Counseling/ or exp Psychotherapeutic Counseling/

25. (counseling or counseling psychology or group counseling or rehabilitation counseling or psychotherapeutic counseling or supportive psychotherap*).ab,ti.
26. 24 or 25
27. 10 or 14 or 15 or 19 or 22 or 23 or 26
28. 3 and 27
29. exp Randomized Controlled Trials/ or exp Clinical Trials/
30. (random* adj3 trial*).ab,ti.
31. (clinical trial or random allocation or controlled clinical trial).ab,ti.
32. 29 or 30 or 31
33. 28 and 32
34. limit 33 to humans

Database: Cochrane Central Register of Controlled Trials

1. exp Back Pain/ or exp Low Back Pain/
2. (back pain or low back pain or lumbar pain or lumbago or dorsalgia or spinal pain or vertebral pain or backache or lumbar spine).ti,ab.
3. 1 or 2
4. exp Behavior Therapy/ or exp Cognitive Therapy/ or *Conditioning, Operant/ or exp "reinforcement (psychology)"/
5. (operant conditioning or reinforcement or psychological intervention or psychological therapy).ab,ti.
6. (cognitiv* adj1 (treatment* or therap* or intervention*)).ab,ti.
7. (behavio?r* adj1 (treatment* or therap* or intervention* or techniqu* or modif* or change*)).ab,ti.
8. (graded exposure or desensiti* or imagery or goal setting).ab,ti.
9. ((acceptance and commitment therapy) or CBT).ab,ti.
10. 4 or 5 or 6 or 7 or 8 or 9
11. exp Mindfulness/ or exp Meditation/ or exp Relaxation/ or exp Relaxation Therapy/
12. (mindfulness based stress reduction* or mindfulness or meditation or relaxation or relaxation therap* or mbsr* or mbct*).ab,ti.
13. 11 or 12
14. (cognitive functional therapy or CFT).ab,ti.
15. exp Health Education/ or exp Health Promotion/ or exp Motivation/
16. (health education or health promotion or motivation).ab,ti.
17. ((health or wellness or life-style or behav*) adj1 coach*).ab,ti.
18. ((wellness or behav*) adj1 intervention*).ab,ti.
19. 15 or 16 or 17 or 18
20. exp Biofeedback, Psychology/ or exp Feedback, Psychological/
21. (electromyograph* or electromyogram* or EMG* or bio-feedback or feedback).ab,ti.
22. 20 or 21
23. (pain neuroscience education or pain education or neuroscience education or pain physiology education or neuro-physiology education or therapeutic education).ab,ti.
24. exp Counseling/ or exp Directive counseling/
25. (counseling or directive counseling or supportive psychotherap*).ab,ti.
26. 24 or 25
27. 10 or 13 or 14 or 19 or 22 or 23 or 26
28. 3 and 27

29. exp Randomized controlled trial/ or *Clinical Trial/ or *Random allocation/ or exp Controlled clinical trial/
30. randomized controlled trial.pt.
31. (random* adj3 trial).ab,ti.
32. (clinical trial or random allocation or controlled clinical trial).ab,ti.
33. 29 or 30 or 31 or 32
34. 28 and 33

Database: CINAHL

1. (MH "Low Back Pain") OR (MH "Back Pain+")
2. AB (“back pain” or “low back pain” or “lumbar pain” or lumbago or dorsalgia or “spinal pain” or “vertebral pain” or backache or “lumbar spine”) OR TI (“back pain” or “low back pain” or “lumbar pain” or lumbago or dorsalgia or “spinal pain” or “vertebral pain” or backache or “lumbar spine”)
3. S1 OR S2
4. (MH "Behavior Therapy") OR (MH "Cognitive Therapy") OR (MH "Reinforcement (Psychology)")
5. AB ("Reinforcement (Psychology)" OR "operant conditioning" OR "psychological intervention" OR "psychological therapy") OR TI ("Reinforcement (Psychology)" OR "operant conditioning" OR "psychological intervention" OR "psychological therapy")
6. AB (cognitiv* N1 (treatment* or therap* or intervention*)) OR TI (cognitiv* N1 (treatment* or therap* or intervention*))
7. AB (behavio?r* N1 (treatment* or therap* or intervention* or techniqu* or modif* or change*)) OR TI (behavio?r* N1 (treatment* or therap* or intervention* or techniqu* or modif* or change*))
8. AB (“graded exposure” or desensiti* or imagery or “goal setting”) OR TI (“graded exposure” or desensiti* or imagery or “goal setting”)
9. AB (“acceptance and commitment therapy” or CBT) OR TI (“acceptance and commitment therapy” or CBT)
10. S4 OR S5 OR S6 OR S7 OR S8 OR S9
11. (MH "Mindfulness") OR (MH "Mind Body Techniques") OR (MH "Relaxation") OR (MH "Relaxation Techniques")
12. AB (“mindfulness based stress reduction*” or mindfulness or “mind body techniques” or relaxation or “relaxation therap*” or “relaxation techniques” or mbsr* or mbct*) OR TI (“mindfulness based stress reduction*” or mindfulness or “mind body techniques” or relaxation or “relaxation therap*” or “relaxation techniques” or mbsr* or mbct*)
13. S11 OR S12
14. AB ("cognitive functional therapy" or CFT) or TI ("cognitive functional therapy" or CFT)
15. (MH "Health Education") OR (MH "Health Promotion") OR (MH "Motivation") OR (MH "Motivational Interviewing")
16. AB (“health education” or “health promotion” or motivation* or “motivational interviewing”) or TI (“health education” or “health promotion” or motivation* or “motivational interviewing”)
17. AB (coach* N1 (health or wellness or life-style or behav*)) OR TI (coach* N1 (health or wellness or life-style or behav*))
18. AB (intervention* N1 (wellness or behav*)) OR TI (intervention* N1 (wellness or behav*))

19. S15 OR S16 OR S17 OR S18
20. (MH "Biofeedback") OR (MH "Feedback")
21. AB (biofeedback or feedback or electromyograph* or electromyogram* or EMG*) OR TI (biofeedback or feedback or electromyograph* or electromyogram* or EMG*)
22. S20 OR S21
23. AB (“pain neuroscience education” or “pain education” or “neuroscience education” or “pain physiology education” or “neuro-physiology education” or “therapeutic education”) OR TI (“pain neuroscience education” or “pain education” or “neuroscience education” or “pain physiology education” or “neuro-physiology education” or “therapeutic education”)
24. (MH "Counseling+")
25. AB (counseling or “supportive psychotherap*”) OR TI (counseling or “supportive psychotherap*”)
26. S24 OR S25
27. S10 OR S13 OR S14 OR S19 OR S22 OR S23 OR S26
28. S3 AND S27
29. (MH "Randomized Controlled Trials+") OR (MH "Clinical Trials+") OR (MH "Random Assignment")
30. AB (random* N3 trial) OR TI (random* N3 trial)
31. AB (“clinical trial*” or “random assignment” or “random allocation” or “controlled clinical trial”) OR TI (“clinical trial*” or “random assignment” or “random allocation” or “controlled clinical trial”)
32. S29 OR S30 OR S31
33. S28 AND S32
34. S28 AND S32 (Limiters – Human)

Supplementary B. Treatment node classification

The process for classifying the study interventions into treatment nodes occurred in 4 stages:

1. Initial treatment nodes classification
2. Adjustments to pre-specified treatment nodes
3. Re-coding of treatment nodes
4. Confirmation of final treatment node classification

1. Initial treatment nodes classification

Firstly, psychological, non-psychological co-interventions, and comparison interventions were classified into the pre-specified treatment nodes (Supplementary Table 1.1). The rationale and methodology for classifying the interventions into the pre-specified treatment nodes have been described in detail in the published protocol paper.[1] Examples of interventions or approaches which were classified into the respective treatment nodes have been described in the published protocol paper.[1] This process was conducted by EK-YH, with input from clinical experts from the review team (psychologists: CEA-J, physiotherapists: PHF).

Supplementary Table 1.1 Initial treatment node classification

Decision set	Psychological intervention +/- co-intervention	BT	CBT	Mind	Csl	PE	Comb psych
		BT+Exs	CBT+Exs	Mind+Exs	Csl+Exs	PE+Exs	Comb psych+Exs
		BT+Passive	CBT+Passive	Mind+Passive	Csl+Passive	PE+Passive	Comb psych+Passive
		BT+Physio	CBT+Physio	Mind+Physio	Csl+Physio	PE+Physio	Comb psych+Physio
	Comparison intervention	Physio					
Supplementary set	Comparison intervention	Exs	Passive	GP care	Advice	No intervention	

Decision set - BT: behavioural therapy, BT+Exs: behavioural therapy delivered with exercise, BT+Passive: behavioural therapy delivered with passive treatment, BT+Physio: behavioural therapy delivered with physiotherapy, CBT: cognitive behavioural therapy, CBT+Exs: cognitive behavioural therapy delivered with exercise, CBT+Passive: cognitive behavioural therapy delivered with passive treatment, CBT+Physio: cognitive behavioural therapy delivered with physiotherapy, Comb psych: combined psychological approaches, Comb psych+Exs: combined psychological approaches delivered with exercise, Comb Psych+Passive: combined psychological approaches delivered with passive treatment, Comb Psych+Physio: combined psychological approaches delivered with physiotherapy, Csl: counselling, Csl+Exs: counselling delivered with exercise, Csl+Passive: counselling delivered with passive treatment, Csl+Physio: counselling delivered with physiotherapy, Mind: mindfulness, Mind+Exs: mindfulness delivered with exercise, Mind+Passive: mindfulness delivered with passive treatment, Mind+Physio: mindfulness delivered with physiotherapy, PE: pain education, PE+Exs: pain education delivered with exercise, PE+Passive: pain education delivered with passive treatment, PE+Physio: pain education delivered with physiotherapy, Physio: physiotherapy.

Supplementary set - Exs: exercise, GP care: general practitioner care, Passive: passive treatment.

2. Adjustments to pre-specified treatment nodes

After initial intervention coding was completed by EK-YH, clinical experts from the review team (psychologists: CEA-J, physiotherapists: PHF, MLF) were consulted to establish the appropriateness of lumping treatment nodes. For pragmatic reasons (i.e., provide a simpler framework from which study findings can be translated more easily into clinical practice), three comparison interventions (exercise, passive treatment, physiotherapy) were merged to form a single comparison node, *physiotherapy care*. For consistency, we also merged the three co-interventions (exercise, passive treatment, physiotherapy) into a singular co-intervention node, *physiotherapy care*. Finally, we added a supplementary comparison node, *usual care,* to classify usual care interventions which could not be accurately classified into the available comparison treatment nodes.

3. Re-coding of treatment nodes

EK-YH re-coded the treatment nodes according to the final framework presented below (see Supplementary Table 1.2). Descriptions of each treatment node have been summarised in Table 1 of the main paper, and in the published protocol paper.[1]

Supplementary Table 1.2 Revised treatment node classification

Decision set	Psychological intervention +/- co-intervention	BT	CBT	Mind	Csl	PE	Comb psych
		BT+PC	CBT+PC	Mind+PC	Csl+PC	PE+PC	Comb psych+PC
	Comparison intervention	PC					
Supplementary set	Comparison intervention	GP care	Advice	No intervention	Usual care		

Decision set - BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, Comb psych: combined psychological approaches, Comb psych+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PC: physiotherapy care.

Supplementary set - GP care: general practitioner care.

4. Confirmation of final treatment node classification

Finally, CEA-J (clinical psychologist) confirmed the accuracy of classifying the psychological components of interventions, and JC, DXMW and PHF (physiotherapists) confirmed the accuracy of classifying non-psychological components of interventions prior to conducting statistical analyses.

Supplementary C. Studies excluded at full text-level

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Ben Salah Frih Z, Fendri Y, Jellad A, Boudoukhane S, Rejeb N. Efficacy and treatment compliance of a home-based rehabilitation programme for chronic low back pain: a randomized, controlled study. Ann Phys Rehabil Med. 2009;52(6):485-496.

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Supplementary D. Individual study characteristics of included studies

Supplementary Table 2. Individual study characteristics of included studies for physical function and pain intensity

Author, Year	Study design	Psychological intervention setting	Coded interventions	Intervention duration (weeks)	Outcome scale		Funding
					Physical function	Pain intensity	
Alaranta, 1994[2]	RCT	Inpatient (Hospital)	CBT+PC, PC	3	PDI (Million)	Not assessed	-
Aliyu, 2018[3]	RCT	Outpatient	CBT+PC, PC	4	ODI	VAS	-
Altmaier, 1992[4]	RCT	Inpatient (Hospital)	CP+PC (2 arms)	3	LBP Rating Scale	MPQ	National Institute for Handicapped Research
Bagheri, 2020[5]	RCT	Outpatient	CP+PC, PC	8	RMDQ	Not assessed	Research Center (Semnan University of Medical Sciences)
Bendix 1998[6, 7] (Project A)	RCT	Outpatient	CP+PC, NI	6	Investigator-initiated questionnaire	Box Scale	Danish Rheumatism Association, the Danish Ministry of Health, the National Health Fund for Research and Development, the Danish Society for Manual Medicine, Minister Erna Hamilton's Foundation, the Foundation of Gerda and Aage Haensch, the Research Foundation of Copenhagen University, the Rockwool Foundation, and others.
Bendix 1998[6, 7] (Project B)	RCT	Outpatient	CP+PC, CBT+PC, PC	6	Investigator-initiated questionnaire	Box Scale	Danish Rheumatism Association, the Danish Ministry of Health, the National Health Fund for Research and Development, the Danish Society for Manual Medicine, Minister Erna Hamilton's Foundation, the Foundation of Gerda and Aage Haensch, the Research Foundation of Copenhagen University, the Rockwool Foundation, and others.
Bendix, 2000[8]	RCT	Outpatient	CBT+PC, PC	6	MRS (disability subscale)	Box Scale	Danish Rheumatism Association, the Gerda and Aage Hensch Foundation, the Director Ib Henriksen's Fund, the Insurance Company for Industrial Injuries, the Lily Benthine Lunds Fund, the DANICA Pension, the Municipal Pension Insurance Company td, and the Danish Society for Manual Medicine.
Brox, 2003[9]	RCT	Outpatient	CBT+PC, Lumbar fusion	3	ODI	VAS	Federal and Foundation funds
Cherkin, 1996[10]	RCT	Outpatient	PE (2 arms)	3 days	RMDQ	Not assessed	Agency of Health Care Policy and Research and the Northwest Health Services Research and Development Field Program (Seattle Veterans Affairs Medical Center)
Cherkin, 2016[11]	RCT	Outpatient	Mind, UC, CBT	8	RMDQ	GCPS	National Center for Complementary and Integrative Health (NICCIH) of the National Institutes of Health (NIH)

Chiauzzi, 2010[12]	RCT	Outpatient (Online only)	CBT, Adv	4	ODI	BPI	National Institute on Drug Abuse
Christiansen, 2010[13]	RCT	Outpatient	CBT+PC, PE+PC	3	Hannover ADL Questionnaire	NRS	-
Cuesta-Vargas, 2011[14]	RCT	Outpatient	PE+PC (2 arms)	15	RMDQ	VAS	-
Dufour, 2010[15]	RCT	Outpatient	CP+PC, PC	12	RMDQ	VAS	Funds were received, although source of funding was not specified.
Fairbank, 2005[16]	RCT	Outpatient	CBT+PC, Lumbar fusion	3	ODI	Not assessed	Medical Research Council NHS or private patient insurance funded the treatment of patients.
Farokhi, 2020[17]	RCT	Outpatient	CP+PC, BT+PC	8	ODI	Not assessed	Neuro-Musculoskeletal Rehabilitation Centre (Semnan University of Medical Sciences)
Friedrich, 1998[18] & 2005[19]	RCT	Outpatient	CP+PC, PC	3.5	LBOS	LBOS (pain sub-scale)	-
Frost, 1998[20]	RCT	Outpatient	CBT+PC, PC	10	ODI	Not assessed	-
Galan-Martin, 2020[21]	RCT	Outpatient	PE+PC, PC	11	RMDQ	VAS	Regional Health Management of Castilla
Gannon, 2019[22] (Study 1)	RCT	Outpatient	CP+PC, CP	8	RMDQ	NRS	-
Gannon, 2019[22] (Study 2)	RCT	Outpatient	CP+PC, CP	8	RMDQ	NRS	-
Gardner, 2019[23]	RCT	Outpatient	PE, PC	8	QBPDS	NRS	-
Ghadyani, 2017[24]	RCT	Outpatient	CBT+PC, Adv	1 day	RMDQ	VAS	Deputy of Tarbiat Modares University
Gibbs, 2018[25]	RCT	Outpatient	CP, NI	24	ODI	VAS	Virginia Kaufman Endowment Fund for Pain Research and National Institutes of Health
Glombiewski, 2010[26]	RCT	Outpatient	CBT, CBT	32	PDI	German Pain Questionnaire	-
Glombiewski, 2018[27]	RCT	Outpatient	CP (3 arms)	18-25	QBPDS	NRS	German Research Foundation (DFG)
Godfrey, 2019[28]	RCT	Outpatient	Mind+PC, PC	4	RMDQ	PNAS	National Institute for Health Research (NIHR)
Gould, 2020[29]	RCT	Outpatient	CP, GP	12	RMDQ	DDS	Office of Research and Development, Clinical Sciences Research and Development, Department of Veterans Affairs
Grande-Alonso, 2019[30]	RCT	Outpatient	CP+PC (2 arms)	4	RMDQ	VAS	-
Haas, 2005[31]	RCT	Outpatient	CP, NI	6	MVK (disability sub-scale)	MVK (pain sub-scale)	Health Resources and Services Administration, US Department of Health and Human Services
Harris, 2017[32]	RCT	Outpatient	CP+PC, CP (2 arms)	12	ODI	Not assessed	The Research Council of Norway, Norwegian Extra Foundation for Health and Rehabilitation

Jensen, 2012[33]	RCT	Outpatient	Csl, UC	12	RMDQ	NRS	Danish Research Fund for the Working Environment
Johnson, 2007[34]	RCT	Outpatient	CBT, GP	6	RMDQ	VAS	Charity funds were received, although source of funding was not specified.
Kapitza, 2010[35]	RCT	Outpatient	BT (2 arms)	2	PDI	VAS	-
Khan, 2014[36]	RCT	Outpatient	CBT+PC, PC	12	RMDQ	VAS	-
Khodadad, 2020[37]	RCT	Outpatient	CP+PC, PC (2 arms)	8	Not assessed	VAS	-
Krein, 2013[38]	RCT	Outpatient (Online only)	Csl, NI	Not reported clearly (self-directed website access and e-community)	RMDQ	NRS	Department of Veterans Affairs, Health Services Research and Development Services
Lamb, 2010[39, 40]	RCT	Outpatient	CBT, NI	6	RMDQ	MVK (pain sub-scale)	National Institute for Health Research Health Technology Assessment Programme
Lambeek, 2010[41]	RCT	Outpatient	CP, UC	12	RMDQ	NRS	VU University Medical Center, TNO Work and Employment, Dutch Health Insurance Executive Council, Stichting Institute GAK, and the Netherlands Organisation for Health Research and Development
Leeuw, 2008[42]	RCT	Outpatient	CBT, BT	Not reported clearly (~13 weeks)	RMDQ	VAS	-
Luedtke, 2016[43]	RCT	Outpatient	CP+PC (2 arms)	4	ODI	VAS	Deutsche Forschungsgemeinschaft (DFG)
Lorig, 2002[44]	RCT	Outpatient (Online only)	PE, UC	Not reported clearly (moderated email discussion group, pain education resources)	RMDQ	VAS	-
Louw, 2017[45]	RCT	Outpatient	PE+PC, PC	1 day	Not assessed	NRS	-
Macedo, 2012[46]	RCT	Outpatient	CP+PC, CP	8	RMDQ	NRS	Australian National Health and Medical Research Council
Magalhaes, 2017[47]	RCT	Outpatient	CP+PC, PC	6	RMDQ	NRS	Fundacao de Amparo a Pesquisa do Estado de Sao Paulo (FAPESP)
Magnussen, 2007[48]	RCT	Outpatient	CP, NI	1-2	RMDQ	Not assessed	Norwegian Foundation for Health and Rehabilitation
Mehling, 2005[49]	RCT	Outpatient	Mind+PC, PC	6-8	RMDQ	VAS	Mount Zion Health Fund (San Francisco) and Health Resources and Services Administration
Michaelson, 2016[50]	RCT	Outpatient	PE+PC (2 arms)	8	RMDQ	VAS	-
Monticone, 2013[51]	RCT	Outpatient	CBT+PC, PC	52	RMDQ	NRS	-
Monticone, 2016[52]	RCT	Outpatient	CBT+PC, PC	5	ODI	NRS	-
Moore, 2000[53]	RCT	Outpatient	CP, GP	2-3	RMDQ	NRS	National Institutes of Health, The Boeing Company and the Group Health Foundation

Morone, 2016[54]	RCT	Outpatient	Mind, Adv	8	RMDQ	NRS	National Institutes of Health
Moseley, 2002[55]	RCT	Outpatient	PE+PC, GP	4	RMDQ	NRS	-
Moseley, 2003[56]	RCT	Outpatient	PE+PC (2 arms)	4	RMDQ	NRS	-
Moseley, 2004[57]	RCT	Outpatient	PE, Adv	2-3	RMDQ	Not assessed	-
Nguyen, 2017[58]	RCT	Inpatient (Spa Centre)	PE+PC, PE	5 days	RMDQ	NRS	Association Francise pour la Recherche Thermale
Nicholas, 1991[59]	RCT	Outpatient	BT+PC (2 arms), CBT+PC (3 arms), PC	5	Not assessed	PRC	-
O'Keeffe, 2020[60]	RCT	Outpatient	CBT+PC, CP+PC	12	ODI	NRS	Health Research Institute (University of Limerick)
Paolucci, 2017[61]	RCT	Outpatient	Mind+PC, PC	5	Not assessed	VAS	-
Pardo, 2018[62]	RCT	Outpatient	PE+PC, PC	4	RMDQ	NRS	-
Petrozzi, 2019[63]	RCT	Outpatient	CBT+PC, PC	8	RMDQ	NRS	-
Pires, 2015[64]	RCT	Outpatient	PE+PC, PC	6	QBPDS	VAS	-
Poole, 2007[65]	RCT	Outpatient	BT, PC, UC	6	ODI	VAS	-
Rabiei, 2020[66]	RCT	Outpatient	PE+PC, PC	8	RMDQ	VAS	-
Reiner, 2019[67]	RCT	Outpatient	Mind, NI	8	Not assessed	BPI	-
Reme, 2016[68]	RCT	Outpatient	CP (2 arms)	8-12	ODI	NRS	-
Rizzo, 2018[69]	RCT	Outpatient	CP, PE	2	RMDQ	NRS	-
Rose, 1997[70] (Study 1)	RCT	Outpatient	CBT (2 arms)	1-2	RMDQ	VAS	-
Rose, 1997[70] (Study 2)	RCT	Outpatient	CBT (3 arms)	1-2	RMDQ	VAS	-
Sander, 2020[71]	RCT	Outpatient (Online only)	CP, UC	7-19	ODI	NRS	German Federal Ministry of Education and Research
Santaella da Fonseca, 2009[72]	RCT	Outpatient	CBT+PC, NI	8	RMDQ	VAS	-
Saper, 2017[73]	RCT	Outpatient	Mind+PC, PE	12 weeks treatment phase + 40 weeks maintenance phase	RMDQ	NRS	National Center for Complementary and Integrative Health (NICCIH) of the National Institutes of Health (NIH)
Saracoglu, 2020[74]	RCT	Outpatient	PE+PC, PC (2 arms)	4	ODI	NRS	-
Saracoglu, 2020[75]	RCT	Outpatient	PE+PC, PC	4	Not assessed	NRS	-
Schaller, 2016[76]	RCT	Inpatient (Hospital) and Outpatient	CP, Adv	Not reported clearly (Inpatient stay, aftercare delivered	Not assessed	SF-36 (bodily pain sub-scale)	German Statutory Pension Insurance Rhineland

				at 8 and 12 weeks post-discharge, self-directed internet-based aftercare program)			
Shariat, 2019[77]	RCT	Outpatient	BT+PC, BT, PC, NI	6	Not assessed	FRI	-
Siemonsma, 2013[78]	RCT	Outpatient	CBT, NI	12	QBPDS	Not assessed	Health Research and Development
Smeets, 2008[79]	RCT	Outpatient	CBT+PC, CBT, PC	10	RMDQ	VAS	Zorgonderzoek Nederland/Medische Wetenschappen Gran
Spinhoven, 2004[80]	RCT	Speciality Clinic	CBT, CP, NI	10			-
Soleymani, 2021[81]	RCT	Outpatient	CBT, GP	12-24	Not assessed	CPGQ	-
Sorensen, 2010[82]	RCT	Outpatient	PE+PC, PC	1-3	Not assessed	NRS	IMK Foundation, Health Insurance Foundation
Stuckey, 1986[83]	RCT	Outpatient	BT (2 arms), Adv	Not reported clearly (8 sessions)	ADL Questionnaire	PIQ	Doctors Education and Research Fund
Tan, 2015[84]	RCT	Outpatient	BT, hypnosis (3 arms)	8	Not assessed	BPI	Veterans Health Administration rehabilitation Research and Development Service
Tavafian, 2017[85]	RCT	Outpatient	CP, GP	1 week + monthly booster sessions delivered between 24 to 30 months post-intervention	RMDQ	SF-36 (bodily pain sub-scale)	Research Deputy of Tehran University of Medical Sciences
Tekur, 2008[86]	RCT	Inpatient (Health Centre)	Csl+PC, PE+PC	1	ODI	Not assessed	-
Tilbrook, 2011[87]	RCT	Outpatient	CP+PC, PE	12	RMDQ	Not assessed	Arthritis Research UK
Turner, 1982[88]	RCT	Outpatient	BT, CBT, NI	5	Not assessed	VAS	-
Turner, 1988[89]	RCT	Outpatient	CBT, BT, NI	8	Not assessed	MPQ	National Institute of Neurological and Communicative Disorders and Stroke and a National Institutes of Health Biomedical Research Grant RR 05432.
Turner, 1990[90]	RCT	Outpatient	BT+PC, BT, PC, NI	8	Not assessed	VAS	-
Turner, 1993[91]	RCT	Outpatient	CBT (2 arms), BT, NI	6	Not assessed	VAS	National Institute of Neurological and Communicative Disorders and Stroke
Unal, 2020[92]	RCT	Outpatient	PE, PC	8	RMDQ	MPQ	-
van der Roer, 2008[93]	RCT	Outpatient	BT+PC, PC	30	RMDQ	NRS	Netherlands Organisation for Health Research and Development
Vibe Fersum, 2019[94]	RCT	Outpatient	CBT+PC, PC	12	ODI	NRS	The Norwegian Fund for Post-Graduate Training in Physiotherapy
Von Korff, 2005[95]	RCT	Outpatient	CP, UC	4-8	RMDQ	NRS	National Institutes of Health

Vong, 2011[96]	RCT	Outpatient	Csl+PC, PC	8	RMDQ	VAS	-
Woods, 2008[97]	RCT	Outpatient	CBT, BT, NI	4	PDI	MPQ-SF (PRI)	Royal Bank of Canada and a Canadian Institutes of Health Research Investigator Award
Yao, 2020[98]	RCT	Outpatient	Mind+PC, PC	24	Not assessed	VAS	Shanghai Three Year Action Plan for Further Accelerate the Development of Chinese Medicine

ADL: Activities of Daily Living, Adv: advice, BPI: Brief Pain Inventory, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, CPGQ: Chronic Pain Grade Questionnaire, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, DDS: Descriptor Differential Scale, FRI: Functional Rating Index Test, GCPS: Graded Chronic Pain Scale, GP: general practitioner care, LBP: low back pain, LBOS: Low Back Outcome Score, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, MPQ: McGill Pain Questionnaire, MPQ-SF: McGill Pain Questionnaire Short Form, MPQ-SF (PRI): McGill Pain Questionnaire Pain Rating Index, MRS: Manniche's Rating Scale, MVK: Modified Von Korff Scale, NI: no intervention, NRS: Numeric Rating Scale, ODI: Oswestry Disability Index, PC: physiotherapy care, PDI: Pain Disability Index, PDI (Million): Pain Disability Index Million, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PIQ: Pain Intensity Questionnaire, PNAS: Pain Numeric Analogue Scale, PRC: Pain Rating Chart, QBPDS: Quebec Back Pain Disability Scale, RCT: randomised controlled trial, RMDQ: Roland Morris Disability Questionnaire, SF-36: 36-Item Short Form Survey, UC: usual care, VAS: Visual Analogue Scale.

Supplementary Table 3. Individual study characteristics of included studies for fear avoidance, health-related quality of life, intervention compliance and safety

Author, Year	Study Design	Psychological intervention setting	Coded interventions	Intervention duration (weeks)	Outcome				Funding
					Fear avoidance	HRQoL	Intervention compliance[a]	Safety[b]	
Aliyu, 2018[3]	RCT	Outpatient	CBT+PC, PC	4	FABQ (PA)	Not assessed	Sufficient data	-	-
Bagheri, 2020[5]	RCT	Outpatient	CP+PC, PC	8	FABQ (unclear which sub-scales were used)	Not assessed	Sufficient data	-	Research Centre (Semnan University of Medical Sciences)
Bendix 1998[6, 7] (Project A)	RCT	Outpatient	CP+PC, NI	6	Not assessed	Investigator-initiated question (0-5)	-	-	Danish Rheumatism Association, the Danish Ministry of Health, the National Health Fund for Research and Development, the Danish Society for Manual Medicine, Minister Erna Hamilton's Foundation, the Foundation of Gerda and Aage Haensch, the Research Foundation of Copenhagen University, the Rockwool Foundation, and others.
Bendix 1998[6, 7] (Project B)	RCT	Outpatient	CP+PC, CBT+PC, PC	6	Not assessed	Investigator-initiated question (0-5)	Sufficient data	-	Danish Rheumatism Association, the Danish Ministry of Health, the National Health Fund for Research and Development, the Danish Society for Manual Medicine, Minister Erna Hamilton's Foundation, the Foundation of Gerda and Aage Haensch, the Research Foundation of Copenhagen University, the Rockwool Foundation, and others.
Bendix, 2000[8]	RCT	Outpatient	CBT+PC, PC	6	Not assessed	Investigator-initiated question (0-5)	Sufficient data	-	Danish Rheumatism Association, the Gerda and Aage Hensch Foundation, the Director Ib Henriksen's Fund, the Insurance Company for Industrial Injuries, the Lily Benthine Lunds Fund, the DANICA Pension, the Municipal Pension Insurance Company td, and the Danish Society for Manua Medicine.
Brox, 2003[9]	RCT	Outpatient	CBT+PC, Lumbar fusion	3	FABQ (PA)	Not assessed	-	-	Federal and Foundation funds
Cherkin, 2016[11]	RCT	Outpatient	Mind, UC, CBT	8	Not assessed	SF-12 (PCS)	-	-	National Centre for Complementary and Integrative Health (NICCIH) of the National Institutes of Health (NIH)

Chiauzzi, 2010[12]	RCT	Outpatient (Online only)	CBT, Adv	4	FABQ (PA)	Not assessed	-	-	National Institute on Drug Abuse
Cuesta-Vargas, 2011[14]	RCT	Outpatient	PE+PC (2 arms)	15	Not assessed	SF-36 (PCS)	-	-	-
Dufour, 2010[15]	RCT	Outpatient	CP+PC, PC	12	Not assessed	SF-36 (all sub-scales)	-	-	Funds were received, although source of funding was not specified.
Fairbank, 2005[16]	RCT	Outpatient	CBT+PC, Lumbar fusion	3	Not assessed	SF-36 (PCS)	-	-	Medical Research Council NHS or private patient insurance funded the treatment of patients.
Farokhi, 2020[17]	RCT	Outpatient	CP+PC, BT+PC	8	FABQ (unclear which sub-scale was used)	Not assessed	-	-	Neuro-Musculoskeletal Rehabilitation Centre (Semnan University of Medical Sciences)
Galan-Martin, 2020[21]	RCT	Outpatient	PE+PC, PC	11	PCS	SF-36 (PCS)	-	Sufficient data	Regional Health Management of Castilla
Gannon 2019 (Study 1)[22]	RCT	Outpatient	CP+PC, CP	8	PCS	Not assessed	Sufficient data	-	-
Gannon 2019 (Study 2)[22]	RCT	Outpatient	CP+PC, CP	8	PCS	Not assessed	Sufficient data	-	-
Gardner, 2019[23]	RCT	Outpatient	PE, PC	8	TSK	SF-36 (overall score)	-	-	-
Gibbs, 2018[25]	RCT	Outpatient	CP, NI	24	Not assessed	Not assessed	-	Sufficient data	Virginia Kaufman Endowment Fund for Pain Research and National Institutes of Health
Glombiewski, 2010[26]	RCT	Outpatient	CBT, CBT	32	Not assessed	HRLSS	-	-	-
Godfrey, 2020[28]	RCT	Outpatient	Mind+PC, PC	4	Not assessed	SF-12 (PCS)	-	Sufficient data	National Institute for Health Research (NIHR)
Gould, 2020[29]	RCT	Outpatient	CP, GP	12	Not assessed	Not assessed	Sufficient data	-	Office of Research and Development, Clinical Sciences Research and Development, Department of Veterans Affairs
Grande-Alonso, 2019[30]	RCT	Outpatient	CP+PC (2 arms)	4	TSK	Not assessed	-	-	-
Haas, 2005[31]	RCT	Outpatient	CP, NI	6	Not assessed	SF-36 (general health, emotional well-being, and energy-fatigue sub-scales)	-	-	Health Resources and Services Administration, US Department of Health and Human Services
Harris, 2017[32]	RCT	Outpatient	CP+PC, CP (2 arms)	12	FABQ (PA)	Not assessed	-	-	The Research Council of Norway, Norwegian Extra Foundation for Health and Rehabilitation

Jensen, 2012[33]	RCT	Outpatient	Csl, UC	12	FABQ (PA)	SF-36 (physical functioning and bodily pain sub-scales)	-	-	Danish Research Fund for the Working Environment
Johnson, 2007[34]	RCT	Outpatient	CBT, GP	6	Not assessed	EQ-5D	-	-	Charity funds were received, although source of funding was not specified.
Khodadad, 2020[37]	RCT	Outpatient	CP+PC, PC (2 arms)	8	Not assessed	Not assessed	Sufficient data	-	-
Krein, 2013[38]	RCT	Outpatient (Online only)	Csl, NI	Nr clearly (self-directed website access and e-community)	FABQ (PA)	Not assessed	-	-	Department of Veterans Affairs, Health Services Research and Development Services
Lamb, 2010[39]	RCT	Outpatient	CBT, NI	6	FABQ (PA)	SF-12 (PCS)	-	Sufficient data	National Institute for Health Research Health Technology Assessment Programme
Lambeek, 2010[41]	RCT	Outpatient	CP, UC	12	Not assessed	Not assessed	Sufficient data	Sufficient data	VU University Medical Centre, TNO Work and Employment, Dutch Health Insurance Executive Council, Stichting Institute GAK, and the Netherlands Organisation for Health Research and Development
Leeuw, 2008[42]	RCT	Outpatient	CBT, BT	Nr clearly (~13 weeks)	PCS	Not assessed	Sufficient data	Sufficient data	-
Lorig, 2002[44]	RCT	Outpatient (Online only)	PE, UC	Nr clearly (moderated email discussion group, PE resources)	Not assessed	IIS	Sufficient data	-	-
Louw, 2017[45]	RCT	Outpatient	PE+PC, PC	1 day	FABQ (PA)	Not assessed	Sufficient data	-	-
Luedtke, 2016[43]	RCT	Outpatient	CP+PC (2 arms)	4	FABQ (PA)	SF-36 (all sub-scales)	-	-	Deutsche Forschungsgemeinschaft (DFG)
Macedo, 2012[46]	RCT	Outpatient	CP+PC, CP	8	Not assessed	SF-12 (PCS)	Sufficient data	-	Australian National Health and Medical Research Council
Magalhaes, 2017[47]	RCT	Outpatient	CP+PC, PC	6	TSK	SF-36 (physical role and emotional role sub-scales)	Sufficient data	Sufficient data	Fundacao de Amparo a Pesquisa do Estado de Sao Paulo (FAPESP)
Magnussen, 2007[48]	RCT	Outpatient	CP, NI	1-2	FABQ (PA)	Not assessed	-	-	Norwegian Foundation for Health and Rehabilitation

Mehling, 2005[49]	RCT	Outpatient	Mind+PC, PC	6-8	Not assessed	SF-36 (all sub-scales)	-	Sufficient data	Mount Zion Health Fund (San Francisco) and Health Resources and Services Administration
Michaelson, 2016[50]	RCT	Outpatient	PE+PC (2 arms)	8	Not assessed	SF-36 (all sub-scales)	-	-	-
Monticone, 2013[51]	RCT	Outpatient	CBT+PC, PC	52	TSK	SF-36 (all sub-scales)	-	-	-
Monticone, 2016[52]	RCT	Outpatient	CBT+PC, PC	5	PCS	SF-36 (all sub-scales)	-	-	-
Moore, 2000[53]	RCT	Outpatient	CP, GP	2-3	TSK	SF-36 (mental health sub-scale)	-	Sufficient data	National Institutes of Health, The Boeing Company, and the Group Health Foundation
Morone, 2016[54]	RCT	Outpatient	Mind, Adv	8	CSQ (catastrophising scale)	RAND-36 (global health and physical health sub-scales)	-	-	National Institutes of Health
Moseley, 2002[55]	RCT	Outpatient	PE+PC, GP	4	PCS	Not assessed	Sufficient data	-	-
Nguyen, 2017[58]	RCT	Inpatient (Spa Centre)	PE+PC, PE	5 days	Not assessed	SF-12 (PCS)	-	Sufficient data	Association Francise pour la Recherche Thermale
O'Keeffe, 2020[60]	RCT	Outpatient	CBT+PC, CP+PC	12	FABQ (PA)	SHCI	Sufficient data	Sufficient data	Health Research Institute (University of Limerick)
Paolucci, 2017[61]	RCT	Outpatient	Mind+PC, PC	5	Not assessed	SF-36 (vitality and social functioning sub-scales)	-	-	-
Pardo, 2018[62]	RCT	Outpatient	PE+PC, PC	4	PCS	Not assessed	Sufficient data	-	-
Petrozzi, 2019[63]	RCT	Outpatient	CBT+PC, PC	8	PCS	Not assessed	Sufficient data	Sufficient data	-
Pires, 2015[64]	RCT	Outpatient	PE+PC, PC	6	TSK	Not assessed	-	Sufficient data	-
Poole, 2007[65]	RCT	Outpatient	BT, PC, UC	6	Not assessed	SF-36 (all sub-scales)	-	-	-
Rabiei, 2020[66]	RCT	Outpatient	PE+PC, PC	8	FABQ (PA)	Not assessed	Sufficient data	Sufficient data	-
Reme, 2016[68]	RCT	Outpatient	CP (2 arms)	8-12	Not assessed	EQ-5D	-	-	-
Rizzo, 2018[69]	RCT	Outpatient	CP, PE	2	PCS	Not assessed	Sufficient data	Sufficient data	-
Sander, 2020[71]	RCT	Outpatient (Online only)	CP, UC	7-19	Not assessed	AQoL-6D	-	-	German Federal Ministry of Education and Research

Saper, 2017[73]	RCT	Outpatient	Mind+PC, PE	12 weeks treatment phase + 40 weeks maintenance phase	Not assessed	SF-36 (PCS)	-	-	National Centre for Complementary and Integrative Health (NICCIH) of the National Institutes of Health (NIH)
Saracoglu, 2020[74]	RCT	Outpatient	PE+PC, PC (2 arms)	4	TSK	Not assessed	Sufficient data	-	-
Saracoglu, 2020[75]	RCT	Outpatient	PE+PC, PC	4	Not assessed	SF-36 (all sub-scales)	Sufficient data	-	-
Shariat, 2019[77]	RCT	Outpatient	BT+PC, BT, PC, NI	6	Not assessed	QOLS	-	-	-
Siemonsma, 2013[78]	RCT	Outpatient	CBT, NI	12	Not assessed	Not assessed	-	Sufficient data	Health Research and Development
Smeets, 2008[79]	RCT	Outpatient	CBT+PC, CBT, PC	10	Not assessed	Not assessed	-	Sufficient data	Zorgonderzoek Nederland/Medische Wetenschappen Gran
Sorensen, 2010[82]	RCT	Outpatient	PE+PC, PC	1-3	FABQ (PA)	Not assessed	Sufficient data	Sufficient data	IMK Foundation, Health Insurance Foundation
Spinhoven, 2004[80]	RCT	Speciality Clinic	CBT, CP, NI	10	PCCL (catastrophising sub-scale)		-	-	-
Tavafian, 2017[85]	RCT	Outpatient	CP, GP	1 week + monthly booster sessions delivered between 24 to 30 months post-intervention	Not assessed	SF-36 (all sub-scales)	-	-	Research Deputy of Tehran University of Medical Sciences
Tilbrook, 2011[87]	RCT	Outpatient	CP+PC, PE	12	Not assessed	SF-12 (PCS)	-	-	Arthritis Research UK
Turner, 1982[88]	RCT	Outpatient	BT, CBT, NI	5	Not assessed	SIP	-	-	-
Turner, 1988[89]	RCT	Outpatient	CBT, BT, NI	8	Not assessed	SIP	Sufficient data	-	National Institute of Neurological and Communicative Disorders and Stroke and a National Institutes of Health Biomedical Research Grant RR 05432.
Turner, 1990[90]	RCT	Outpatient	BT+PC, BT, PC, NI	8	Not assessed	SIP	-	-	-
Turner, 1993[91]	RCT	Outpatient	CBT (2 arms), BT, NI	6	Not assessed	SIP	Sufficient data	-	National Institute of Neurological and Communicative Disorders and Stroke

Unal, 2020[92]	RCT	Outpatient	PE, PC	8	FABQ (unclear which sub-scale was used)	SF-36 (all sub-scales)	-	-	-
van der Roer, 2008[93]	RCT	Outpatient	BT+PC, PC	30	TSK	Not assessed	-	-	Netherlands Organisation for Health Research and Development
Vibe Fersum, 2019[94]	RCT	Outpatient	CBT+PC, PC	12	FABQ (PA)	Not assessed	Sufficient data	-	The Norwegian Fund for Post-Graduate Training in Physiotherapy
Von Korff, 2005[95]	RCT	Outpatient	CP, UC	4-8	TSK	SF-36 (social functioning and mental health sub-scales)	-	-	National Institutes of Health
Vong, 2011[96]	RCT	Outpatient	Csl+PC, PC	8	Not assessed	SF-36 (physical functioning, physical role, bodily pain, and global health sub-scales)	Sufficient data	Sufficient data	-
Woods, 2008[97]	RCT	Outpatient	CBT, BT, NI	4	PCS	Not assessed	Sufficient data	-	Royal Bank of Canada and a Canadian Institutes of Health Research Investigator Award
Yao, 2020[98]	RCT	Outpatient	Mind+PC, PC	24	Not assessed	SF-36 (PCS)	-	-	Shanghai Three Year Action Plan for Further Accelerate the Development of Chinese Medicine

[a]Only studies reporting sufficient data to assess intervention compliance have been reported in this table.

[b]Only studies which were included in the network meta-analysis for the primary outcomes of this review (physical function and pain intensity) and reported sufficient data for assessing safety, have been summarised in this table.

Adv: advice, AQoL: Assessment of Quality of Life Questionnaire, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, CSQ: Coping Strategies Questionnaire, EQ-5D: European Quality of Life Questionnaire, FABQ: Fear Avoidance Belief Questionnaire, FABQ (PA): Fear Avoidance Belief Questionnaire physical activity sub-scale, GP: general practitioner care, HRLSS: Health-Related Life Satisfaction Scale, HRQoL: health-related quality of life, IIS: Illness Intrusiveness Scale, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, Nr: not reported, PC: physiotherapy care, PCCL: Pain Coping and Cognition List, PCS: Pain Catastrophising Scale, PE: pain education, PE+PC: pain education delivered with physiotherapy care, QOLS: Quality of Life Scale, RCT: randomised controlled trial, SF-12 (PCS): 12-item Short-form Survey (physical component summary), SF-36 : 36-item Short-form Survey, SF-36 (PCS): 36-item Short-form Survey (physical component summary), SHCI: Subjective Health Complaints Inventory, SIP: Sickness Impact Profile, TSK: Tampa Scale of Kinesiophobia, UC: usual care.

Supplementary E. Individual patient characteristics of included studies

Supplementary Table 4. Individual patient characteristics of studies included in the network meta-analysis for physical function and pain intensity

Author, Year	Sample size	Mean age (years)	Sex (% male)	Physical function		Pain intensity	
				Scale	Baseline score	Scale	Baseline score
Alaranta, 1994[2]	293	40.45	45.39	PDI (Million) (0-100)	44.8	Not assessed	-
Aliyu, 2018[3]	46	42.32	43.26	ODI (0-100)	45.8	VAS (0-10)	6.2
Bagheri, 2020[5]	45	37.23	0	RMDQ (0-100)	37.9	Nr	-
Bendix, 2000[8]	138	40.54	34.65	MRS (disability subscale) (0-30)	16.0	Box Scale (0-10)	5.6
Cherkin, 2016[11]	342	49.30	65.68	RMDQ (0-23)	11.4	GCPS (0-10)	5.9
Chiauzzi, 2010[12]	209	46.14	32.32	ODI (0-100)	46.0	BPI (0-10)	5.6
Christiansen, 2010[13]	75	47.75	38.50	Hannover ADL Questionnaire (0-100)	65.9	NRS (0-10)	5.8
Dufour, 2010[15]	286	40.88	43.77	RMDQ (0-24)	12.5	VAS (0-100)	57.3
Farokhi, 2020[17]	40	28.33	0.00	ODI (0-100)	28.1	Not assessed	-
Friedrich, 1998[18] & 2005[19]	93	44.12	49.47	LBOS (0-75)	42.7	LBOS (pain sub-scale) (0-100)	52.5
Frost, 1998[20]	81	37.80	45.16	ODI (0-100)	24.0	Not assessed	-
Galan-Martin, 2020[21]	154	Nr for chronic LBP only	Nr for chronic LBP only	RMDQ (0-24)	9.0	VAS (0-100)	71.2
Gannon, 2019[22] (Study 1)	66	53.30	61.60	RMDQ (0-24)	10.2	NRS (0-10)	5.3
Gannon, 2019[22] (Study 2)	67	62.40	88.20	RMDQ (0-24)	11.2	NRS (0-10)	5.0
Gardner, 2019[23]	75	44.49	42.92	QBPDS (0-100)	42.9	NRS (0-10)	6.4
Ghadyani, 2017[24]	136	37.67	27.24	RMDQ (0-24)	6.8	VAS (0-10)	4.5
Gibbs, 2018[25]	27	51.48	22.22	ODI (0-100)	24.1	VAS (0-10)	4.8
Godfrey, 2019[28]	248	47.90	40.70	RMDQ (0-24)	10.8	PNAS (0-10)	6.0
Gould, 2020[29]	72	57.12	87.33	RMDQ (0-24)	11.7	DDS (0-20)	10.7
Haas, 2005[31]	120	77.20	15.60	MVK (disability sub-scale) (0-100)	42.1	MVK (pain sub-scale) (0-100)	48.8
Harris, 2017[32]	215	44.81	49.52	ODI (0-100)	28.7	Not assessed	-
Jensen, 2012[33]	300	45.39	45.09	RMDQ (0-23)	11.4	NRS (0-10)	6.4
Johnson, 2007[34]	234	47.91	40.17	RMDQ (0-24)	10.8	VAS (0-100)	48.3
Khan, 2014[36]	54	39.61	46.30	RMDQ (0-24)	13.3	VAS (0-10)	6.8

Khodadad, 2020[37]	54	44.30	100.00	Not assessed	-	VAS (0-10)	5.8
Krein, 2013[38]	229	51.56	87.45	RMDQ (0-24)	9.5	NRS (0-10)	6.1
Lamb, 2010[39, 40]	701	54.00	40.09	RMDQ (0-24)	9.0	MVK (pain sub-scale) (0-100)	59.0
Lambeek, 2010[41]	134	46.16	58.06	RMDQ (0-24)	14.9	NRS (0-10)	6.0
Leeuw, 2008[42]	85	45.32	51.80	RMDQ (0-24)	14.7	VAS (0-100)	53.6
Lorig, 2002[44]	580	45.51	61.51	RMDQ (0-24)	9.9	VAS (0-10)	3.9
Louw, 2017[45]	62	60.14	43.55	Not assessed	-	NRS (0-10)	4.0
Macedo, 2012[46]	172	49.15	40.70	RMDQ (0-24)	11.3	NRS (0-10)	6.1
Magalhaes, 2017[47]	66	46.90	25.76	RMDQ (0-24)	13.3	NRS (0-10)	7.4
Magnussen, 2007[48]	89	49.05	37.08	RMDQ (0-24)	14.0	Not assessed	-
Mehling, 2005[49]	36	49.27	35.73	RMDQ (0-24)	10.0	VAS (0-10)	4.8
Monticone, 2013[51]	90	49.34	42.22	RMDQ (0-24)	15.1	NRS (0-10)	7.0
Monticone, 2016[52]	150	53.50	38.67	ODI (0-100)	33.4	NRS (0-10)	6.3
Moore, 2000[53]	226	49.45	46.02	RMDQ (0-24)	8.4	NRS (0-10)	5.3
Morone, 2016[54]	282	74.50	33.70	RMDQ (0-24)	15.5	NRS (0-20)	10.7
Moseley, 2004[57]	58	43.40	43.10	RMDQ (0-18)	15.0	Not assessed	-
Nguyen, 2017[58]	88	47.00	41.38	RMDQ (0-18)	49.3	NRS (0-100)	58.3
Nicholas, 1991[59]	62	41.20	48.28	Not assessed	-	PRC (0-5)	2.9
O'Keeffe, 2020[60]	206	48.71	26.73	ODI (0-100)	32.8	NRS (0-10)	5.9
Paolucci, 2017[61]	53	60.95	20.75	Not assessed	-	VAS (0-10)	5.4
Pardo, 2018[62]	56	47.05	21.42	RMDQ (0-24)	12.3	NRS (0-10)	7.9
Petrozzi, 2019[63]	108	50.40	50.00	RMDQ (0-24)	9.9	NRS (0–10)	5.0
Pires, 2015[64]	62	50.95	35.48	QBPDS (0-100)	30.1	VAS (0-100)	42.9
Poole, 2007[65]	243	46.72	40.60	ODI (0-100)	34.2	VAS (0-100)	41.9
Rabiei, 2020[66]	80	43.31	46.57	RMDQ (0-24)	14.8	VAS (0-10)	6.4
Reiner, 2019[67]	67	58.03	27.78	Not assessed	-	BPI (0-10)	4.8
Rizzo, 2018[69]	100	50.05	20.00	RMDQ (0-24)	14.1	NRS (0-10)	6.9
Sander, 2020[71]	295	52.80	37.63	ODI (0-100)	27.1	NRS (0-10)	1.6
Santaella da Fonseca, 2009[72]	60	46.39	28.33	RMDQ (0-24)	11.3	VAS (0-10)	5.3

Saper, 2017[73]	191	45.66	40.31	RMDQ (0-23)	14.3	NRS (0-10)	7.1
Saracoglu, 2020[74]	69	40.42	52.63	ODI (0-100)	33.7	NRS (0-10)	7.4
Saracoglu, 2020[75]	36	39.36	51.43	Not assessed	-	NRS (0-10)	7.2
Schaller, 2016[76]	412	50.42	69.42	Not assessed	-	SF-36 (bodily pain scale) (1-6)	4.6
Shariat, 2019[77]	76	35.39	69.44	Not assessed	-	FRI (range of scores unclear)	12.8
Siemonsma, 2013[78]	156	46.10	46.10	QBPDS (0-100)	40.4	Not assessed	-
Smeets, 2008[79]	172	41.91	54.07	RMDQ (0-24)	13.8	VAS (0-100)	48.6
Soleymani, 2021[81]	30	41.97	14.95	Not assessed	-	CPGQ (0-100)	38.1
Sorensen, 2010[82]	207	39.00	48.00	Not assessed	-	NRS (0-10)	6.2
Stuckey, 1986[83]	24	41.10	45.83	ADL Questionnaire (1-7)	2.4	PIQ (0-100)	35.2
Tavafian, 2017[85]	197	46.02	19.18	RMDQ (0-24)	10.0	SF-36 (bodily pain scale) (1-100)	45.8
Tekur, 2008[86]	91	48.50	55.00	ODI (0-100)	37.7	Not assessed	-
Tilbrook, 2011[87]	313	46.35	29.71	RMDQ (0-24)	7.8	Not assessed	-
Turner, 1982[88]	36	42.00	8.33	Not assessed	-	VAS (0-100)	56.0
Turner, 1988[89]	81	46.00	62.96	Not assessed	-	MPQ (0-78)	21.4
Turner, 1990[90]	96	44.00	52.08	Not assessed	-	VAS (0-100)	50.5
Turner, 1993[91]	102	42.00	46.07	Not assessed	-	VAS (0-100)	54.5
Unal, 2020[92]	40	41.93	50.00	RMDQ (0-24)	15.8	MPQ (0-78)	52.0
Vibe Fersum, 2019[94]	121	43.00	47.62	ODI (0-100)	22.8	NRS (0-10)	5.0
Von Korff, 2005[95]	240	49.75	37.52	RMDQ (0-23)	11.8	NRS (0-10)	5.8
Vong, 2011[96]	88	44.85	36.84	RMDQ (0-24)	10.0	VAS (0-10)	5.3
Woods, 2008[97]	83	46.45	34.09	PDI (0-100)	22.2	MPQ-SF (PRI) (0-45)	14.8
Yao, 2020[98]	72	53.40	19.44	Not assessed	-	VAS (0-10)	5.1

ADL: Activities of Daily Living, BPI: Brief Pain Inventory, CPGQ: Chronic Pain Grade Questionnaire, DDS: Descriptor Differential Scale, FRI: Functional Rating Index Test, GCPS: Graded Chronic Pain Scale, LBOS: Low Back Outcome Score, MPQ: McGill Pain Questionnaire, MPQ-SF: McGill Pain Questionnaire Short Form, MPQ-SF (PRI): McGill Pain Questionnaire Pain Rating Index, MRS: Manniche's Rating Scale, MVK: Modified Von Korff Scale, Nr: not reported, NRS: Numeric Rating Scale, ODI: Oswestry Disability Index, PDI: Pain Disability Index, PDI (Million): Pain Disability Index Million, PIQ: Pain Intensity Questionnaire, PNAS: Pain Numeric Analogue Scale, PRC: Pain Rating Chart, QBPDS: Quebec Back Pain Disability Scale, RMDQ: Roland Morris Disability Questionnaire, SF-36: 36-Item Short Form Survey, VAS: Visual Analogue Scale.

Supplementary Table 5. Individual patient characteristics of studies included in the network meta-analysis for fear avoidance

Author, Year	Total sample size	Mean age (years)	Sex (% male)	Fear avoidance scale	Baseline fear avoidance score
Aliyu, 2018[3]	46	42.3	43	FABQ (PA) (0-24)	17.7
Chiauzzi, 2010[12]	209	46.1	32	FABQ (PA) (0-24)	14.9
Galan-Martin, 2020[21]	154	Nr for chronic LBP sub-group	Nr for chronic LBP sub-group	PCS (0-52)	29.5
Gannon 2019[22] (Study 1)	66	53.3	62	PCS (0-52)	17
Gannon 2019[22] (Study 2)	67	62.4	88	PCS (0-52)	14
Gardner, 2019[23]	75	44.5	43	TSK (17-68)	38.3
Harris, 2017[32]	215	44.8	50	FABQ (PA) (0-24)	12.2
Krein, 2013[38]	229	51.6	87	FABQ (PA) (0-24)	14.5
Lamb, 2010[39]	701	54.0	40	FABQ (PA) (0-24)	13.6
Leeuw, 2008[42]	85	45.3	52	PCS (0-52)	22.9
Magalhaes, 2017[47]	66	46.9	26	TSK (17-68)	44
Magnussen, 2007[48]	89	49.1	37	FABQ (PA) (0-24)	14.4
Monticone, 2013[51]	90	49.3	42	TSK (13-52)	41.7
Monticone, 2016[52]	150	53.5	39	PCS (0-52)	27.1
Moore, 2000[53]	226	49.5	46	TSK (1-4)	2.3
Morone, 2016[54]	282	74.5	34	CSQ (catastrophising scale) (0-6)	1.2
Moseley, 2004[57]	58	43.4	43	PCS (0-52)	37.5
O'Keeffe, 2020[60]	206	48.7	27	FABQ (PA) (0-24)	15.1
Pardo, 2018[62]	56	47.1	21	PCS (0-52)	33.1
Petrozzi, 2019[63]	108	50.4	50	PCS (0-52)	20.5
Pires, 2015[64]	62	51.0	35	TSK (13-52)	28.9
Rabiei, 2020[66]	80	43.3	47	FABQ (PA) (0-24)	16.5
Rizzo, 2018[69]	100	50.1	20	PCS (0-52)	28.5
Saracoglu, 2020[74]	69	40.4	53	TSK (17-68)	45
Sorensen, 2010[82]	207	39.0	48	FABQ (PA) (0-24)	13
Spinhoven, 2004[80]	148.00	39.8	36	PCCL (catastrophising sub-scale) (12-72)	40.7

Vibe Fersum, 2019[94]	121	43.0	48	FABQ (PA) (0-24)	11.5
Von Korff, 2005[95]	240	49.8	38	TSK (17-68)	41.3
Woods, 2008[97]	83	46.5	34	PCS (0-52)	19.6

CSQ: Coping Strategies Questionnaire, FABQ: Fear Avoidance Belief Questionnaire, FABQ (PA): Fear Avoidance Belief Questionnaire physical activity sub-scale, Nr: not reported, PCCL: Pain Coping and Cognition List, PCS: Pain Catastrophising Scale, TSK: Tampa Scale of Kinesiophobia.

Supplementary F. Summary of physiotherapy care treatment node

The following table provides a summary of all studies included in the review, for which at least one intervention arm involved physiotherapy care as a non-psychological co-intervention or comparison intervention. We delineated between instances where the physiotherapy care node consisted of exercise alone ("exs"), passive therapy alone ("passive"), or exercise delivered with passive therapy ("exs+passive").

Supplementary Table 6. Summary of individual studies involving physiotherapy care as a co-intervention or comparison intervention

Author, Year	Total study arms included[a]	Study arms involving physiotherapy care		Non-physiotherapy care arm(s)
		As a co-intervention	As a comparison intervention	
Alaranta, 1994[2]	2	CBT+exs	Exs+passive	-
Aliyu, 2018[3]	2	CBT+exs	Exs	-
Bagheri, 2020[5]	2	Comb psych+exs	Exs	-
Bendix, 2000[8]	2	CBT+exs	Exs	-
Christiansen, 2010[13]	2	CBT+exs+passive; PE+exs+passive	-	-
Dufour, 2010[15]	2	Comb psych+exs	Exs	-
Farokhi, 2020[17]	2	Comb psych+exs; BT+exs	-	-
Friedrich, 1998[18] & 2005[19]	2	Comb psych+exs	Exs	-
Frost, 1998[20]	2	CBT+exs	Exs	-
Galan-Martin, 2020[21]	2	PE+exs	Exs+passive	-
Gannon, 2019[22] (Study 1)	2	Comb psych+exs	-	Comb psych
Gannon, 2019[22] (Study 2)	2	Comb psych+exs	-	Comb psych
Gardner, 2019[23]	2	-	Exs	PE
Ghadyani, 2017[24]	2	CBT+exs	-	Advice
Godfrey, 2019[28]	2	Mindfulness+exs+passive	Exs+passive	-
Harris, 2017[32]	3	Comb psych+exs	-	Comb psych (2 arms pooled)
Khan, 2014[36]	2	CBT+exs	Exs	-
Khodadad, 2020[37]	3	Comb psych+exs	Exs	Exs+passive
Louw, 2017[45]	2	PE+passive	Passive	-
Macedo, 2012[46]	2	Comb psych+exs	-	Comb psych
Magalhaes, 2017[47]	2	Comb psych+exs+passive	Exs	-

Mehling, 2005[49]	2	Mindfulness+exs	Exs+passive	-
Monticone, 2013[51]	2	CBT+exs	Exs+passive	-
Monticone, 2016[52]	2	CBT+exs	Exs+passive	-
Nguyen, 2017[58]	2	PE+exs	-	PE
Nicholas, 1991[59]	6	BT+exs (2 arms pooled); CBT+exs (3 arms pooled)	-	Exs
O'Keeffe, 2020[60]	2	CBT+exs; Comb psych+exs	-	-
Paolucci, 2017[61]	2	Mindfulness+exs	Exs	-
Pardo, 2018[62]	2	PE+exs	Exs	-
Petrozzi, 2019[63]	2	CBT+exs+passive	Exs+passive	-
Pires, 2015[64]	2	PE+exs	Exs	-
Poole, 2007[65]	3	-	Passive	BT, UC
Rabiei, 2020[66]	2	PE+exs	Exs	-
Petrozzi, 2019[63]	2	CBT+exs	-	NI
Pires, 2015[64]	2	Mindfulness+exs	-	PE
Saracoglu, 2020[74]	3	PE+exs+passive	Exs+passive; Passive (2 arms pooled)	-
Saracoglu, 2020[75]	2	PE+passive	Passive	-
Shariat, 2019[77]	4	BT+exs	Exs	BT; NI
Smeets, 2008[79]	3	CBT+exs	Exs	CBT
Sorensen, 2010[82]	2	PE+exs	Exs	-
Tekur, 2008[86]	2	Csl+exs; PE+exs	-	-
Tilbrook, 2011[87]	2	Comb psych+exs	-	PE
Turner, 1990[90]	4	BT+exs	Exs	BT; NI
Unal, 2020[92]	2	-	Passive	PE
Vibe Fersum, 2019[94]	2	CBT+exs	Exs+passive	-
Vong, 2011[96]	2	Csl+exs+passive	Exs+passive	-
Yao, 2020[98]	2	Mindfulness+exs	Exs	-

[a]Total study arms included in the network meta-analysis.
BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, Csl: counselling, Exs: exercise, NI: no intervention, PE: pain education, Passive: passive therapy, UC: usual care.

Supplementary G. Studies not included in the network meta-analysis

Studies not included in the network meta-analysis for the primary outcomes

Overall, 20 articles reporting data on 21 unique studies were not included in the network meta-analysis (NMA) for physical function and/or pain intensity. Out of the excluded studies, 19 unique studies reported data on physical function and 20 unique studies reported data on pain intensity. Reasons for exclusion from the NMA included: only compared the same type of psychological intervention with no other comparison interventions (e.g., comparison of group and individual cognitive behavioural therapy interventions) (13 studies); insufficient data available for pooling (five studies); only involved comparison interventions which did not match our treatment node definitions (three studies).

Exclusion reason 1: Studies only comparing the same type of psychological intervention with no other comparison interventions

Studies which only compared the same type of psychological interventions, with no other comparison interventions, evaluated the following: combined psychological approaches delivered with physiotherapy care (three studies);[4, 30, 43] pain education delivered with physiotherapy care (three studies);[50, 56, 99] combined psychological approaches (two studies, with one involving three arms);[27, 68] cognitive behavioural therapy (three studies, where two studies were reported within the same article and the third study involved three arms);[26, 70] behavioural therapy (one study);[35] pain education (one study).[10] We did not present the effect estimates of studies comparing the same type of intervention. Overall, the majority of studies found that the psychological interventions under investigation improved physical function and/or reduced pain intensity.

Exclusion reason 2: Studies with insufficient data available for pooling

Five studies did not have sufficient data available for pooling. Effect estimates for these studies are summarised in Supplementary Table 7.

Exclusion reason 3: Studies only involving comparison interventions which did not match our treatment node definitions

Three studies only involved comparison interventions which did not match our treatment node definitions. As there were no other comparison interventions matching our pre-defined treatment nodes in these studies, this precluded their inclusion in the network. Two of these studies compared cognitive behavioural therapy delivered with physiotherapy care to the same non-psychological comparison intervention (i.e., lumbar fusion surgery). The effect estimates for these studies are summarised in Supplementary Table 7.

One study compared behavioural therapy to an alternative psychological intervention (i.e., hypnosis) which did not match our initial pre-specified decision set for psychological interventions (see Supplementary B).[84] Consensus within the review team resulted in the inclusion of the study in the review, however we excluded the study from the NMA for the following reasons: (i) the intervention did not match our pre-defined treatment nodes, (ii) if included, the intervention would become disconnected from the network due insufficient studies available for comparison. The effect estimates from this study have been summarised in Supplementary Table 7.

Supplementary Table 7. Effect estimates for studies excluded from the network meta-analysis for physical function and pain intensity

Study	Treatment nodes	Physical function[a]	Pain intensity[a]
Studies with insufficient data available for pooling			
Bendix, 1998[6] & 1998[7] (Project A)	CP+PC vs NI	2-year follow-up: p = 0.90 5-year follow-up: p = 0.20	2-year follow-up: p = 0.08 5-year follow-up: p = 1.00
Bendix, 1998[6] & 1998[7] (Project B)	CP+PC vs PC vs CBT+PC	2-year follow-up: **p = 0.003 (favouring CP+PC)** 5-year follow-up: **p = 0.02 (favouring CP+PC)**	2-year follow-up: **p = 0.08 (favouring CP+PC)** 5-year follow-up: p = 0.30
Moseley, 2002[55]	PE+PC vs GP care	**3.9 (2.30 to 5.80), p = 0.03 (favouring PE+PC)**	**1.50 (0.70 to 2.30), p = 0.03 (favouring PE+PC)**
Spinhoven 2004[80]	CBT vs CP vs NI	Not assessed	Psychological intervention groups combined (CBT and CP) vs NI: p > 0.05
van der Roer, 2008[93]	BT+PC vs PC	Overall effect: chi^2 = 0.98; 4df, p = 0.91	Overall effect: chi^2 = 5.21; 4df, p = 0.27
Studies only involving comparison interventions which did not match our treatment node definitions			
Brox, 2003[9]	CBT+PC vs Lumbar Fusion	2.30 (-6.70 to 11.40), p = 0.33	8.6 (-3.0 to 20.1), p = 0.14
Fairbank, 2005[16]	CBT+PC vs Lumbar Fusion	**-4.10 (-8.10 to -0.10), p = 0.045 (favouring lumbar fusion)**	4.1 (−1.67 to 10.0), p = 0.16
Tan, 2015[84]	BT vs Hypnosis (HYP-8) vs Hypnosis (HYP-PRAC-8) vs Hypnosis (HYP-PRAC-2)	Not assessed	Hypnosis groups pooled vs BT: ***F* 4.29 (*df* 1, 98), ηp^2 0.04, p < 0.05 (favouring hypnosis)** HYP-8 vs HYP-PRAC-8 vs HYP-PRAC-2: *F* 1.18 (*df* 2, 72), ηp^2 0.03, p >0.05

[a] Values are mean difference between groups (95% confidence interval), unless stated otherwise.

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, NI: no intervention, PC: physiotherapy care, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$.

Studies not included in the network meta-analysis for the secondary outcomes

Overall, out of 37 unique studies assessing fear avoidance, eight studies were not included in the NMA for fear avoidance. Reasons for exclusion from the NMA included: only compared the same type of psychological intervention with no other comparison interventions (two studies); insufficient data available for pooling (two studies); only involved comparison interventions which did not match our treatment node definitions (one study); ambiguous methods used to score the Fear Avoidance Beliefs Questionnaire (FABQ) (three studies).

Exclusion reason 1: Studies only comparing the same type of psychological intervention with no other comparison interventions

Two studies involved the comparison of two interventions coded as the same type of psychological intervention, with no other comparison interventions.[30, 43] Both studies evaluated combined psychological interventions delivered with physiotherapy care, compared with another intervention involving combined psychological interventions delivered with physiotherapy care. Overall, both studies demonstrated within-group differences for fear avoidance for each intervention group; although, there were no statistically significant between-group differences following the interventions (95% confidence interval for differences between groups: -4.75 to 5.32, p = 0.91)[43] or for group-by-time interactions (F = 1.16, p = 0.32).[30]

Exclusion reason 2: Studies with insufficient data available for pooling

Two studies did not have sufficient data available for pooling. Effect estimates for these studies are summarised in Supplementary Table 8.

Exclusion reason 3: Studies only involving comparison interventions which did not match our treatment node definitions

One study involved a comparison intervention which did not match our treatment node definitions. As there were no other comparison interventions matching our pre-defined treatment nodes, this precluded inclusion of the study in the network. The study compared cognitive behavioural therapy delivered with physiotherapy care to lumbar fusion surgery). The effect estimates for this study is presented in Supplementary Table 8.

Exclusion reason 4: Studies using ambiguous methods to score the FABQ

Three studies were excluded from the NMA for fear avoidance due to using ambiguous methods to score the FABQ, which were inconsistent with validated recommendations. Explicitly, results of the (two) sub-scales of the FABQ, work and physical activity sub-scales, should be presented and/or analysed independently.[100, 101] However, in these three studies, study authors presented a combined (overall) score.[17, 92] Consensus within the review team resulted in the exclusion of these studies to minimise potential heterogeneity for assessing fear avoidance. These studies compared: (i) combined psychological approaches delivered with physiotherapy care, with physiotherapy care;[5] (ii) combined psychological approaches delivered with physiotherapy care, with behavioural therapy delivered with physiotherapy care[17], (iii) pain education alone with physiotherapy care alone.[92] The effect estimates for these studies are presented below in Supplementary Table 8.

Supplementary Table 8. Effect estimates for studies excluded from the network meta-analysis for fear avoidance

Study	Treatment Nodes	Fear avoidance[a]
Studies with insufficient data available for pooling		
Jensen, 2012[33]	Csl vs UC	FABQ (physical activity sub-scale): **3.10 (1.50 to 4.70), favouring Csl.** FABQ (work sub-scale): 0.10 (-1.50 to 1.60)
van der Roer, 2008[93]	BT+PC vs PC	TSK - overall effect: $\chi^2 = 1.83$; df = 4, p = 0.77
Studies only involving comparison interventions which did not match our treatment node definitions		
Brox, 2003[9]	CBT+PC vs Lumbar Fusion	FABQ (physical activity sub-scale): **-7.70 (-11.60 to -3.80), p < 0.0001, favouring CBT+PC.** FABQ (work sub-scale): **-8.30 (-13.70 to -3.0), p = 0.002, favouring CBT+PC.**
Studies excluded due to ambiguous use of FABQ score		
Bagheri, 2020 [5]	CP+PC vs PC	FABQ (no sub-scale scores provided, no overall range of scores provided): -23.05 (-30.34 to 8.45), p = 0.02
Farokhi, 2020[17]	CP+PC vs BT+PC	FABQ (no sub-scale scores provided, no overall range provided): **p < 0.05, favouring CP+PC.**
Unal, 2020[92]	PE vs PC	FABQ score (no sub-scale scores provided, only reporting an overall score range of 0 to 60): **p = < 0.001, favouring PE.**

[a] Values are mean difference between groups (95% confidence interval), unless stated otherwise.

Csl: counselling, BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP+PC: combined psychological approaches delivered with physiotherapy care, FABQ: Fear Avoidance Belief Questionnaire, PC: physiotherapy care, PE: pain education, TSK: Tampa Scale of Kinesiophobia, UC: usual care. Estimates in bold denote significance at $p<0.05$.

Supplementary H. Assessment of transitivity

Supplementary Table 9.1 Assessment of transitivity: network of interventions for improving physical function

Comparisons	n studies	Mode study setting[a]	Intervention duration (weeks)	Mode mean age (years)	Mode sex (% males)	Outcome measures
Adv:BT	1	Outpatient	Unclear (8 sessions)	<50	<50%	ADL Questionnaire
Adv:CBT	1	Outpatient (Online only)	4	<50	<50%	ODI
Adv:CBT+PC	1	Outpatient	1 day	<50	<50%	RMDQ
Adv:Mind	1	Outpatient	8	≥50	<50%	RMDQ
Adv:PE	1	Outpatient	2-3	<50	<50%	RMDQ
BT:CBT	2	Outpatient	4-13	<50	<50%, ≥50%	PDI, RMDQ
BT:NI	1	Outpatient	4	<50	<50%	PDI
BT:PC	1	Outpatient	6	<50	<50%	ODI
BT:UC	1	Outpatient	6	<50	<50%	ODI
BT+PC:CP+PC	1	Outpatient	8	<50	<50%	ODI
CBT:CBT+PC	1	Outpatient	10	<50	≥50%	RMDQ
CBT:GP	1	Outpatient	6	<50	<50%	RMDQ
CBT:Mind	1	Outpatient	8	<50	≥50%	RMDQ
CBT:NI	3	Outpatient	4-12	<50	<50%	PDI, QBPDS, RMDQ
CBT:PC	1	Outpatient	10	<50	≥50%	RMDQ
CBT:UC	1	Outpatient	8	<50	≥50%	RMDQ
CBT+PC:CP+PC	1	Outpatient	12	<50	<50%	ODI
CBT+PC:NI	1	Outpatient	8	<50	<50%	RMDQ
CBT+PC:PC	10	Outpatient	3-52	<50	<50%	MRS, ODI, PDI (Million), RMDQ
CBT+PC:PE+PC	1	Outpatient	3	<50	<50%	Hannover ADL Questionnaire
CP:GP	3	Outpatient	2-12	<50	<50%	RMDQ
CP:NI	3	Outpatient	6-24	≥50	<50%	MVK, ODI, RMDQ

CP:PE	1	Outpatient	2	≥50	<50%	RMDQ
CP:UC	3	Outpatient	4-19	<50	<50%	ODI, RMDQ
CP+PC:PC	4	Outpatient	3.5-12	<50	<50%	LBOS, RMDQ
CP+PC:PE	1	Outpatient	12	<50	<50%	RMDQ
Csl:NI	1	Outpatient (Online only)	Unclear (self-directed website access and e-community)	≥50	≥50%	RMDQ
Csl:UC	1	Outpatient	12	<50	<50%	RMDQ
Csl+PC:PC	1	Outpatient	8	<50	<50%	RMDQ
Csl+PC:PE+PC	1	Inpatient	1	<50	≥50%	ODI
Mind:UC	1	Outpatient	8	<50	≥50%	RMDQ
Mind+PC:PC	2	Outpatient	4-8	<50	<50%	RMDQ
Mind+PC:PE	1	Outpatient	12 week treatment phase + 40 week maintenance phase	<50	<50%	RMDQ
PC:UC	1	Outpatient	6	<50	<50%	ODI
PE:PC	2	Outpatient	8	<50	<50%, ≥50%	QBPDS, RMDQ
PE:PE+PC	1	Inpatient	5 days	<50	<50%	RMDQ
PE:UC	1	Outpatient (Online only)	Unclear (moderated email discussion group, pain education resources)	<50	≥50%	RMDQ
PE+PC:PC	5	Outpatient	4-11	<50	<50%	ODI, QBPDS, RMDQ

[a] Categories for mode study setting were inpatient, outpatient, and outpatient (online only). ADL: activities of daily living, Adv: advice, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, LBOS: Low Back Outcome Score, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, MRS: Manniche's Rating Scale, MVK: Modified Von Korff Scale, n, number: NI: no intervention, ODI: Oswestry Disability Index, PC: physiotherapy care, PDI (Million): Pain Disability Index (Million), PDI: Pain Disability Index, PE: pain education, PE+PC: pain education delivered with physiotherapy care, QBPDS: Quebec Back Pain Disability Score, RMDQ: Roland Morris Disability Questionnaire, UC: usual care.

Supplementary Table 9.2 Assessment of transitivity: network of interventions for reducing pain intensity

Comparisons	n studies	Mode study setting[a]	Intervention duration (weeks)	Mode mean age (years)	Mode sex (% males)	Outcome measures
Adv:BT	1	Outpatient	Unclear (8 sessions)	<50	<50	PIQ
Adv:CBT	1	Outpatient	4	<50	<50	BPI
Adv:CBT+PC	1	Outpatient	1 day	<50	<50	VAS
Adv:CP	1	Inpatient (Hospital) and Outpatient	Unclear (Inpatient stay, aftercare delivered at 8 and 12 weeks post-discharge, self-directed internet-based aftercare program)	≥50	≥50	SF-36 (bodily pain sub-scale)
Adv:Mind	1	Outpatient	8	≥50	<50	NRS
BT:BT+PC	2	Outpatient	6-8	<50	≥50	FRI, VAS
BT:CBT	5	Outpatient	4-8	<50	<50	MPQ, MPQ-SF, VAS
BT:NI	6	Outpatient	4-8	<50	<50, ≥50	FRI, MPQ, MPQ-SF, VAS
BT:PC	3	Outpatient	6-8	<50	≥50	FRI, VAS
BT:UC	1	Outpatient	6	<50	<50	VAS
BT+PC:CBT+PC	1	Outpatient	5	<50	<50	PRC
BT+PC:PC	3	Outpatient	5-8	<50	≥50	FRI, PRC, VAS
CBT:CBT+PC	1	Outpatient	10	<50	≥50	VAS
CBT:GP	2	Outpatient	6-24	<50	<50	CPGQ, VAS
CBT:Mind	1	Outpatient	8	<50	≥50	GCPS
CBT:NI	5	Outpatient	4-8	<50	<50	MPQ, MPQ-DQ, MVK, VAS
CBT:PC	1	Outpatient	10	<50	≥50	VAS
CBT:UC	1	Outpatient	8	<50	≥50	GCPS
CBT+PC:CP+PC	1	Outpatient	12	<50	<50	NRS
CBT+PC:NI	1	Outpatient	8	<50	<50	VAS
CBT+PC:PC	9	Outpatient	3-52	<50	<50	Box Scale, NRS, PRC, VAS
CBT+PC:PE+PC	1	Outpatient	3	<50	<50	NRS
CP:CP+PC	3	Outpatient	8	≥50	≥50	NRS

CP:GP	3	Outpatient	2-12	<50	<50	DDS, NRS, SF-36 (bodily pain sub-scale)
CP:NI	2	Outpatient	6-24	≥50	<50	MVK (pain sub-scale), VAS
CP:PE	1	Outpatient	2	≥50	<50	NRS
CP:UC	3	Outpatient	4-19	<50	<50	NRS
CP+PC:PC	4	Outpatient	3.5-12	<50	<50	LBOS (pain sub-scale), NRS, VAS
Csl:NI	1	Outpatient (Online only)	Unclear (self-directed website access and e-community)	≥50	≥50	NRS
Csl:UC	1	Outpatient	12	<50	<50	NRS
Csl+PC:PC	1	Outpatient	8	<50	<50	VAS
Mind:NI	1	Outpatient	8	≥50	<50	BPI
Mind:UC	1	Outpatient	8	<50	≥50	GCPS
Mind+PC:PC	4	Outpatient	4-24	<50, ≥50	<50	PNAS, VAS
Mind+PC:PE	1	Outpatient	12 week treatment phase + 40 week maintenance phase	<50	<50	NRS
PC:UC	1	Outpatient	6	<50	<50	VAS
PE:PC	2	Outpatient	8	<50	<50, ≥50	MPQ, NRS
PE:PE+PC	1	Inpatient (Spa Centre)	5 days	<50	<50	NRS
PE:UC	1	Outpatient (Online only)	Unclear (moderated email discussion group, pain education resources)	<50	≥50	VAS
PE+PC:PC	8	Outpatient	1 day-11 weeks	<50	<50	NPRS, NRS, VAS

[a] Categories for mode study setting were inpatient, outpatient, and outpatient (online only). Adv: advice, BPI: Brief Pain Inventory, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, CPGQ: Chronic Pain Grade Questionnaire, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, DDS: Descriptor Differential Scale, FRI: Functional Rating Index, GCPS: Graded Chronic Pain Scale, GP: general practitioner care, LBOS: Low Back Outcome Score, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, MPQ: McGill Pain Questionnaire, MPQ-SF: McGill Pain Questionnaire Short-Form, MVK: Modified Von Korff Scale, n: number, NI: no intervention, NRS: Numeric Rating Scale, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PIQ: Pain Intensity, PNAS: Pain Numeric Analogue Scale, PRC: Pain Rating Chart, SF-36: 36-Item Short Form Survey, UC: usual care, VAS: Visual Analogue Scale.

Supplementary Table 9.3 Assessment of transitivity: network of interventions for reducing fear avoidance

Comparisons	n studies	Mode study setting[a]	Intervention duration (weeks)	Mode mean age (years)	Mode sex (% males)	Outcome measures
Adv:CBT	1	Outpatient (Online only)	4	<50	<50	FABQ
Adv:Mind	1	Outpatient	8	≥50	<50	CSQ
Adv:PE	1	Outpatient	2-3	<50	<50	PCS
BT:CBT	2	Outpatient	4-13	<50	<50, ≥50	PCS
BT:NI	1	Outpatient	4	<50	<50	FABQ
CBT:CP	1	Inpatient and Outpatient	10	<50	<50	PCCL
CBT:NI	3	Outpatient	4-10	<50	<50	FABQ, PCCL
CBT+PC:CP+PC	1	Outpatient	12	<50	<50	FABQ
CBT+PC:PC	5	Outpatient	4-52	<50	<50	FABQ, PCS, TSK
CP:CP+PC	3	Outpatient	8-12	≥50	≥50	FABQ, PCS
CP:GP	1	Outpatient	2-3	<50	<50	TSK
CP:NI	2	Inpatient and Outpatient	1-10	<50	<50	FABQ, PCCL
CP:PE	1	Outpatient	2	≥50	<50	PCS
CP:UC	1	Outpatient	4-8	<50	<50	TSK
CP+PC:PC	1	Outpatient	6	<50	<50	TSK
Csl:NI	1	Outpatient (Online only)	Unclear (self-directed website access and e-community)	≥50	≥50	FABQ
PC:PE	1	Outpatient	8	<50	<50	TSK
PC:PE+PC	6	Outpatient	4-11	<50	<50	FABQ, PCS, TSK

[a] Categories for mode study setting were inpatient, outpatient, and outpatient (online only). Adv: advice, BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, CSQ: Coping Strategies Questionnaire, FABQ: Fear Avoidance Beliefs Questionnaire, GP: general practitioner care, Mind: mindfulness, n: number, NI: no intervention, PC: physiotherapy care, PCCL: Pain Coping and Cognition List, PCS: Pain Catastrophising Scale, PE: pain education, PE+PC: pain education delivered with physiotherapy care, TSK: Tampa Scale for Kinesiophobia, UC: usual care.

Supplementary Table 9.4 Assessment of transitivity: network of interventions for improving intervention compliance

Comparisons	n studies	Mode study setting[a]	Intervention duration (weeks)	Mode mean age (years)	Mode sex (% males)
BT+PC:CP+PC	1	Outpatient	8	<50	<50
CBT+PC:CP+PC	2	Outpatient	6-12	<50	<50
CBT+PC:PC	5	Outpatient	4-12	<50	<50
CP:CP+PC	3	Outpatient	8-8	≥50	≥50
CP:GP	1	Outpatient	12	≥50	≥50
CP:PE	1	Outpatient	2	≥50	<50
CP:UC	1	Outpatient	12	<50	≥50
CP+PC:PC	3	Outpatient	6-8	<50	<50
Csl+PC:PC	1	Outpatient	8	<50	<50
GP:PE+PC	1	Outpatient	4	<50	<50
PE:PC	1	Outpatient	8	<50	<50
PE:UC	1	Outpatient (Online only)	Unclear (moderated email discussion group, pain education resource and videotape)	<50	≥50
PE+PC:PC	6	Outpatient	4-8	<50	<50

[a] Categories for mode study setting were inpatient, outpatient, and outpatient (online only). BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary I. Results from direct and network evidence for physical function and pain intensity

Interpretation of network results:
In this review, we analysed change from baseline scores. Therefore, a positive change score corresponded with higher/worsening of pain (over time), whilst a negative score indicated a lower/improvement in pain (over time). Results in the league tables below are presented as standardised mean differences (SMD), with the corresponding 95% confidence interval (CI). To interpret our results, a negative SMD value indicates that results favoured the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 10.1 Physical function at post intervention

PC (reference)	**1.14 (0.65,1.63)**	-0.03 (-0.72,0.65)			**0.78 (0.16,1.39)**		-0.17 (-1.52,1.18)	0.13 (-1.24,1.49)			0.02 (-0.81,1.21)			-0.18 (-1.52,1.17)	0.26 (-1.21,1.73)	0.16 (-1.17,1.48)
1.01 (0.58,1.44)	CBT+PC	-0.68 (-2.03,0.66)		-0.04 (-1.42,1.34)	-0.39 (-1.79,1.00)			0.12 (-1.21,1.44)								
0.21 (-0.31,0.74)	**-0.80 (-1.42,-0.18)**	CP+PC	-0.03 (-0.82,0.77)							-0.14 (-1.58,1.29)	-0.38 (-1.71,0.94)					
0.35 (-0.31,1.01)	-0.67 (-1.39,0.06)	0.14 (-0.48,0.75)	CP	-0.74 (-2.26,0.77)			-0.21 (-0.98,0.57)				-0.36 (-1.73,1.02)	-0.14 (-1.54,1.25)				
0.23 (-0.56,1.02)	-0.78 (-1.58,0.02)	0.02 (-0.83,0.87)	-0.12 (-0.93,0.69)	No intervention				0.21 (-0.57,1.00)						-0.02 (-1.46,1.41)		
0.62 (0.08,1.17)	-0.39 (-1.04,0.26)	0.41 (-0.34,1.16)	0.27 (-0.58,1.12)	0.39 (-0.55,1.34)	PE+PC											1.06 (-0.28,2.40)
0.38 (-0.70,1.45)	-0.64 (-1.75,0.47)	0.16 (-0.95,1.28)	0.03 (-1.04,1.10)	0.15 (-0.97,1.26)	-0.24 (-1.44,0.95)	Mindfulness	-0.37 (-1.71,0.97)	-0.01 (-1.35,1.33)	-0.30 (-1.63,1.04)							
0.06 (-0.69,0.81)	**-0.95 (-1.76,-0.14)**	-0.15 (-0.92,0.63)	-0.28 (-0.92,0.35)	-0.17 (-1.04,0.71)	-0.56 (-1.48,0.36)	-0.31 (-1.34,0.72)	Usual care	0.36 (-0.98,1.70)					-0.20 (-1.51,1.11)	-0.01 (-1.36,1.35)		
0.39 (-0.30,1.08)	-0.62 (-1.35,0.11)	0.18 (-0.58,0.95)	0.05 (-0.68,0.78)	0.16 (-0.49,0.82)	-0.23 (-1.10,0.64)	0.02 (-0.96,0.99)	0.33 (-0.43,1.09)	CBT	-0.04 (-1.38,1.29)			-0.06 (-1.40,1.28)		-0.35 (-1.34,0.64)		
0.03 (-0.88,0.94)	**-0.98 (-1.94,-0.03)**	-0.18 (-1.14,0.78)	-0.32 (-1.26,0.63)	-0.20 (-1.18,0.77)	-0.59 (-1.64,0.46)	-0.35 (-1.32,0.63)	-0.03 (-0.99,0.92)	-0.36 (-1.18,0.46)	Advice		0.55 (-0.86,1.96)			0.00 (-1.56,1.56)		
0.07 (-1.46,1.60)	-0.94 (-2.50,0.62)	-0.14 (-1.58,1.29)	-0.28 (-1.84,1.28)	-0.16 (-1.83,1.51)	-0.55 (-2.17,1.07)	-0.31 (-2.12,1.51)	0.01 (-1.62,1.64)	-0.32 (-1.95,1.30)	0.04 (-1.68,1.77)	BT+PC						
0.15 (-0.50,0.81)	**-0.86 (-1.61,-0.11)**	-0.06 (-0.76,0.65)	-0.19 (-0.95,0.56)	-0.08 (-1.00,0.85)	-0.47 (-1.31,0.38)	-0.22 (-1.35,0.91)	0.09 (-0.77,0.95)	-0.24 (-1.07,0.59)	0.12 (-0.80,1.05)	0.08 (-1.51,1.68)	PE				0.04 (-1.31,1.39)	
0.27 (-0.84,1.38)	-0.74 (-1.88,0.40)	0.06 (-1.06,1.18)	-0.08 (-1.10,0.95)	0.04 (-1.10,1.18)	-0.35 (-1.58,0.88)	-0.11 (-1.45,1.24)	0.21 (-0.91,1.33)	-0.12 (-1.13,0.89)	0.24 (-1.00,1.49)	0.20 (-1.62,2.02)	0.12 (-1.07,1.30)	GP care				
-0.14 (-1.65,1.37)	-1.15 (-2.69,0.39)	-0.35 (-1.87,1.17)	-0.49 (-1.94,0.97)	-0.37 (-1.94,1.21)	-0.76 (-2.36,0.84)	-0.51 (-2.18,1.15)	-0.20 (-1.51,1.11)	-0.53 (-2.05,0.98)	-0.17 (-1.79,1.46)	-0.21 (-2.30,1.88)	-0.29 (-1.86,1.28)	-0.41 (-2.14,1.32)	Csl			
0.03 (-0.79,0.85)	**-0.98 (-1.85,-0.11)**	-0.18 (-1.07,0.71)	-0.31 (-1.18,0.55)	-0.20 (-1.05,0.65)	-0.59 (-1.56,0.39)	-0.34 (-1.45,0.76)	-0.03 (-0.89,0.83)	-0.36 (-1.08,0.36)	0.00 (-0.91,0.92)	-0.04 (-1.72,1.65)	-0.12 (-1.06,0.82)	-0.24 (-1.42,0.95)	0.17 (-1.40,1.74)	BT		
0.22 (-0.82,1.26)	-0.79 (-1.91,0.32)	0.01 (-1.11,1.13)	-0.13 (-1.29,1.04)	-0.01 (-1.27,1.26)	-0.40 (-1.57,0.77)	-0.15 (-1.59,1.28)	0.16 (-1.07,1.39)	-0.17 (-1.37,1.03)	0.19 (-1.11,1.49)	0.15 (-1.67,1.97)	0.07 (-0.95,1.09)	-0.05 (-1.52,1.42)	0.36 (-1.44,2.16)	0.19 (-1.09,1.47)	Mind+PC	
0.91 (-0.10,1.91)	-0.10 (-1.18,0.97)	0.70 (-0.43,1.83)	0.56 (-0.64,1.76)	0.68 (-0.59,1.95)	0.29 (-0.72,1.29)	0.53 (-0.93,2.00)	0.84 (-0.41,2.09)	0.51 (-0.70,1.73)	0.88 (-0.47,2.23)	0.84 (-0.99,2.66)	0.75 (-0.44,1.95)	0.64 (-0.85,2.13)	1.05 (-0.77,2.86)	0.87 (-0.42,2.17)	0.69 (-0.76,2.13)	Csl+PC

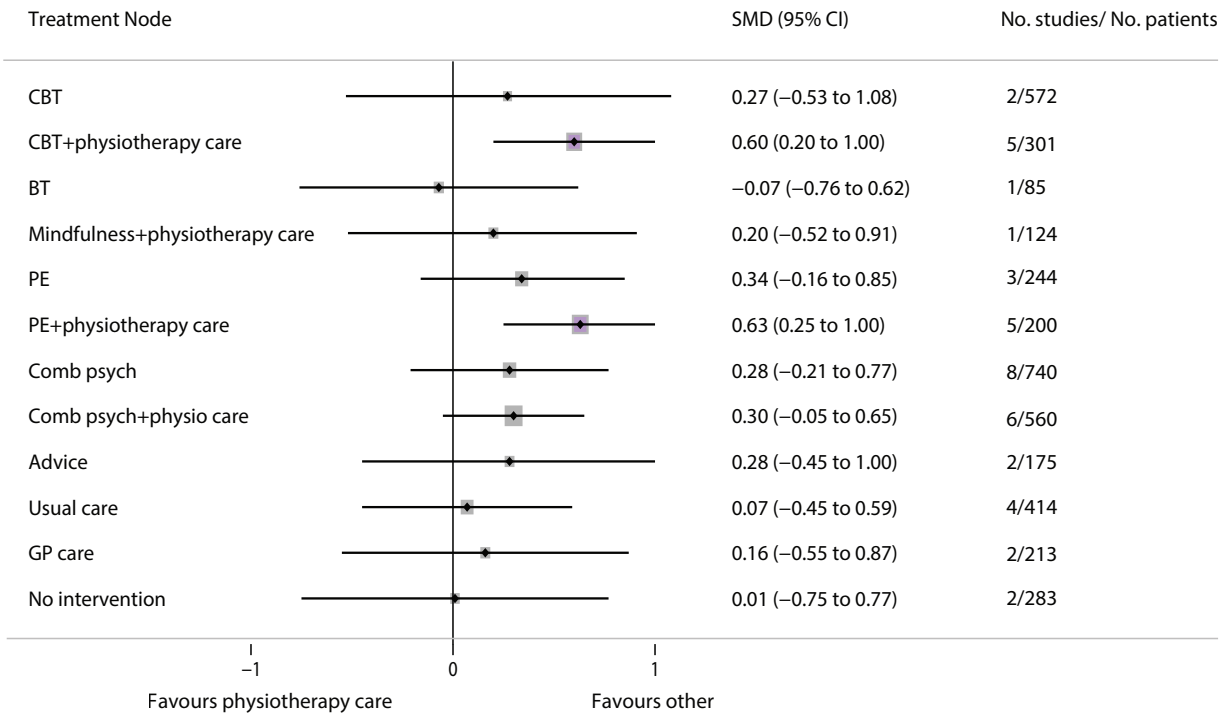
Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 10.2 Physical function at short-term treatment sustainability

PC (reference)	**0.83 (0.48,1.19)**			0.14 (-0.32,0.60)	0.21 (-0.25,0.66)	**1.01 (0.27,1.75)**				-0.02 (-0.78,0.75)		-0.11 (-0.88,0.65)
0.63 (0.25,1.00)	PE+PC			**0.73 (0.03,1.43)**								
0.27 (-0.53,1.08)	-0.35 (-1.22,0.51)	CBT	0.01 (-0.75,0.77)						-0.27 (-0.99,0.45)			
0.28 (-0.45,1.00)	-0.35 (-1.14,0.44)	0.00 (-0.64,0.64)	Advice	0.33 (-0.45,1.11)								
0.60 (0.20,1.00)	-0.03 (-0.52,0.46)	0.32 (-0.46,1.11)	0.32 (-0.34,0.98)	CBT+PC	-0.46 (-1.21,0.28)							
0.30 (-0.05,0.65)	-0.32 (-0.82,0.18)	0.03 (-0.79,0.85)	0.03 (-0.72,0.77)	-0.29 (-0.75,0.16)	CP+PC	-0.26 (-0.96,0.43)		-0.13 (-0.89,0.63)				
0.34 (-0.16,0.85)	-0.28 (-0.91,0.34)	0.07 (-0.81,0.95)	0.07 (-0.76,0.90)	-0.25 (-0.85,0.35)	0.04 (-0.45,0.53)	PE		0.16 (-0.64,0.95)				
0.20 (-0.52,0.91)	-0.43 (-1.24,0.38)	-0.08 (-1.15,1.00)	-0.08 (-1.10,0.94)	-0.40 (-1.22,0.42)	-0.11 (-0.90,0.69)	-0.15 (-1.02,0.73)	Mind+PC					
0.28 (-0.21,0.77)	-0.35 (-0.96,0.26)	0.01 (-0.78,0.79)	0.00 (-0.77,0.77)	-0.32 (-0.89,0.26)	-0.02 (-0.50,0.46)	-0.07 (-0.60,0.47)	0.08 (-0.78,0.95)	CP	-0.26 (-1.05,0.53)		-0.12 (-0.63,0.39)	
0.01 (-0.75,0.77)	-0.62 (-1.45,0.22)	-0.26 (-0.88,0.36)	-0.26 (-1.04,0.51)	-0.59 (-1.36,0.19)	-0.29 (-1.05,0.47)	-0.33 (-1.15,0.48)	-0.19 (-1.23,0.85)	-0.27 (-0.93,0.40)	No intervention	-0.18 (-0.62,0.25)		
0.07 (-0.45,0.59)	-0.56 (-1.19,0.08)	-0.20 (-1.04,0.64)	-0.21 (-1.02,0.61)	-0.53 (-1.14,0.09)	-0.23 (-0.77,0.31)	-0.27 (-0.88,0.33)	-0.13 (-1.01,0.76)	-0.21 (-0.59,0.17)	0.06 (-0.69,0.81)	Usual care		-0.10 (-0.86,0.67)
0.16 (-0.55,0.87)	-0.47 (-1.26,0.33)	-0.11 (-1.05,0.82)	-0.12 (-1.04,0.81)	-0.44 (-1.21,0.33)	-0.14 (-0.84,0.56)	-0.18 (-0.93,0.56)	-0.04 (-1.04,0.97)	-0.12 (-0.63,0.39)	0.15 (-0.69,0.99)	0.09 (-0.55,0.73)	GP care	
-0.07 (-0.76,0.62)	-0.70 (-1.48,0.09)	-0.34 (-1.35,0.67)	-0.34 (-1.31,0.62)	-0.67 (-1.44,0.11)	-0.37 (-1.11,0.37)	-0.41 (-1.22,0.39)	-0.27 (-1.26,0.72)	-0.35 (-1.08,0.38)	-0.08 (-1.03,0.87)	-0.14 (-0.83,0.55)	-0.23 (-1.12,0.66)	BT

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PC: physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 1. Forest plots of network results for physical function at short-term treatment sustainability



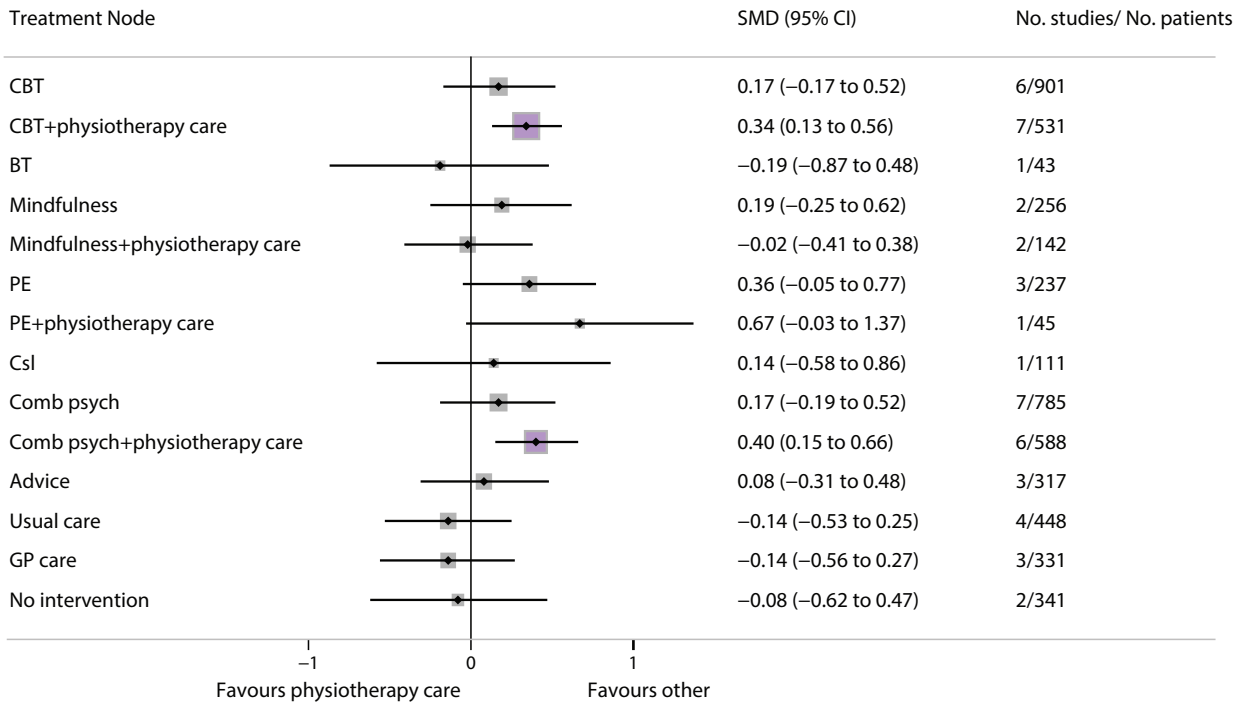
BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 10.3 Physical function at mid-term treatment sustainability

PC (reference)	**0.23 (0.03,0.43)**			0.11 (-0.45,0.66)		**0.45 (0.08,0.81)**	**0.91 (0.35,1.46)**							
0.34 (0.13,0.56)	CBT+PC			0.23 (-0.25,0.71)	-0.37 (-0.90,0.16)	**-0.42 (-0.8,-0.05)**								
0.19 (-0.25,0.62)	-0.16 (-0.58,0.27)	Mindfulness	-0.29 (-0.78,0.19)	0.01 (-0.48,0.50)	-0.14 (-0.61,0.34)									
-0.14 (-0.53,0.25)	**-0.48 (-0.87,-0.09)**	-0.32 (-0.72,0.07)	Usual care	0.30 (-0.19,0.79)					**0.31 (0.03,0.60)**					
0.17 (-0.17,0.52)	-0.17 (-0.50,0.17)	-0.01 (-0.37,0.35)	0.31 (-0.02,0.65)	CBT	0.03 (-0.45,0.52)					-0.26 (-0.74,0.23)		-0.25 (-0.67,0.17)	-0.37 (-0.95,0.21)	
0.08 (-0.31,0.48)	-0.26 (-0.63,0.11)	-0.10 (-0.46,0.25)	0.22 (-0.19,0.63)	-0.09 (-0.42,0.24)	Advice									
0.40 (0.15,0.66)	0.06 (-0.22,0.35)	0.22 (-0.22,0.66)	**0.54 (0.18,0.90)**	0.23 (-0.12,0.58)	0.32 (-0.09,0.73)	CP+PC	-0.33 (-0.70,0.03)		-0.29 (-0.64, 0.07)					
0.36 (-0.05,0.77)	0.02 (-0.42,0.46)	0.18 (-0.39,0.74)	0.50 (-0.01,1.01)	0.19 (-0.31,0.68)	0.28 (-0.26,0.82)	-0.04 (-0.42,0.34)	PE							0.31 (-0.27,0.88)
-0.02 (-0.41,0.38)	-0.36 (-0.81,0.09)	-0.20 (-0.79,0.39)	0.12 (-0.44,0.68)	-0.19 (-0.72,0.33)	-0.10 (-0.66,0.46)	-0.42 (-0.90,0.05)	-0.38 (-0.96,0.19)	Mind+PC						
0.17 (-0.19,0.52)	-0.18 (-0.53,0.18)	-0.02 (-0.43,0.39)	**0.30 (0.05,0.55)**	-0.01 (-0.34,0.32)	0.08 (-0.32,0.49)	-0.24 (-0.54,0.06)	-0.20 (-0.67,0.28)	0.18 (-0.35,0.71)	CP	-0.34 (-0.69,0.01)				
-0.14 (-0.56,0.27)	**-0.49 (-0.90,-0.07)**	-0.33 (-0.78,0.12)	-0.01 (-0.37,0.35)	-0.32 (-0.67,0.03)	-0.23 (-0.67,0.22)	**-0.55 (-0.94,-0.16)**	-0.51 (-1.04,0.02)	-0.13 (-0.70,0.45)	**-0.31 (-0.60,-0.02)**	GP care				
0.14 (-0.58,0.86)	-0.20 (-0.91,0.51)	-0.05 (-0.77,0.68)	0.28 (-0.43,0.99)	-0.03 (-0.66,0.59)	0.06 (-0.65,0.77)	-0.26 (-0.99,0.46)	-0.22 (-1.02,0.58)	0.16 (-0.66,0.98)	-0.03 (-0.73,0.68)	0.28 (-0.43,1.00)	Csl	-0.22 (-0.68,0.25)		
-0.08 (-0.62,0.47)	-0.42 (-0.95,0.12)	-0.26 (-0.81,0.29)	0.06 (-0.48,0.60)	-0.25 (-0.67,0.17)	-0.16 (-0.69,0.38)	-0.48 (-1.03,0.07)	-0.44 (-1.09,0.21)	-0.06 (-0.73,0.61)	-0.24 (-0.77,0.29)	0.07 (-0.48,0.61)	-0.22 (-0.68,0.25)	No intervention		
-0.19 (-0.87,0.48)	-0.54 (-1.20,0.13)	-0.38 (-1.06,0.30)	-0.06 (-0.72,0.61)	-0.37 (-0.95,0.21)	-0.28 (-0.94,0.39)	-0.60 (-1.28,0.08)	-0.56 (-1.32,0.21)	-0.18 (-0.96,0.61)	-0.36 (-1.02,0.30)	-0.05 (-0.73,0.62)	-0.33 (-1.19,0.52)	-0.12 (-0.83,0.60)	BT	
0.67 (-0.03,1.37)	0.33 (-0.39,1.05)	0.48 (-0.32,1.29)	**0.81 (0.04,1.58)**	0.50 (-0.26,1.25)	0.59 (-0.20,1.37)	0.26 (-0.42,0.95)	0.31 (-0.27,0.88)	0.69 (-0.12,1.50)	0.50 (-0.24,1.25)	**0.81 (0.03,1.59)**	0.53 (-0.45,1.51)	0.75 (-0.12,1.61)	0.86 (-0.09,1.82)	PE+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approach, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 2. Forest plots of network results for physical function at mid-term treatment sustainability



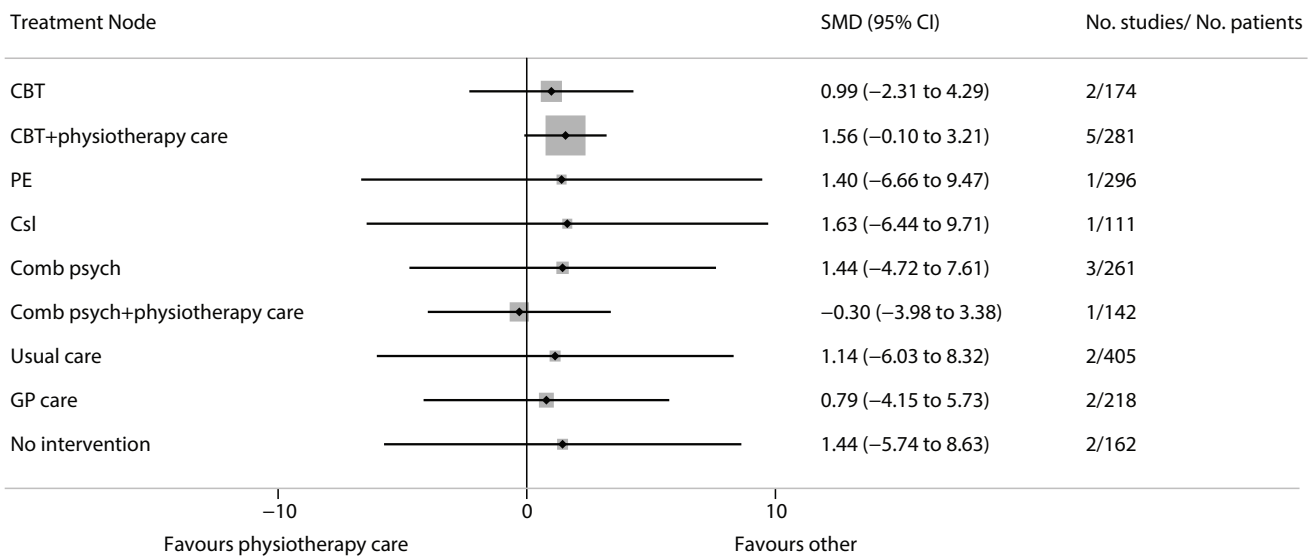
BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, Csl: counselling, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 10.4 Physical function at long-term treatment sustainability

PC (reference)		1.56 (-0.10,3.21)	0.09 (-3.52,3.71)						
-0.30 (-3.98,3.38)	CP+PC								
1.56 (-0.10,3.21)	1.86 (-2.18,5.89)	CBT+PC	0.33 (-3.28,3.94)						
0.99 (-2.31,4.29)	1.29 (-3.65,6.24)	-0.57 (-3.87,2.74)	CBT	-0.20 (-3.88,3.48)					
0.79 (-4.15,5.73)	1.09 (-5.07,7.25)	-0.77 (-5.71,4.18)	-0.20 (-3.88,3.48)	GP care					0.65 (-3.03,4.34)
1.63 (-6.44,9.71)	1.94 (-6.93,10.81)	0.08 (-7.99,8.15)	0.64 (-6.72,8.01)	0.85 (-5.54,7.23)	Csl	-0.19 (-3.87,3.49)			
1.44 (-5.74,8.63)	1.75 (-6.33,9.82)	-0.11 (-7.30,7.07)	0.45 (-5.93,6.84)	0.65 (-4.56,5.87)	-0.19 (-3.87,3.49)	No intervention			0.00 (-3.69,3.69)
1.40 (-6.66,9.47)	1.71 (-7.16,10.57)	-0.15 (-8.21,7.91)	0.41 (-6.94,7.77)	0.62 (-5.76,6.99)	-0.23 (-7.59,7.13)	-0.04 (-6.42,6.34)	PE	-0.26 (-3.94,3.41)	
1.14 (-6.03,8.32)	1.45 (-6.62,9.51)	-0.41 (-7.59,6.77)	0.15 (-6.22,6.53)	0.35 (-4.85,5.56)	-0.49 (-6.87,5.89)	-0.30 (-5.51,4.92)	-0.26 (-3.94,3.41)	Usual Care	0.30 (-3.38,3.98)
1.44 (-4.72,7.61)	1.75 (-5.43,8.92)	-0.11 (-6.28,6.05)	0.45 (-4.75,5.66)	0.65 (-3.03,4.34)	-0.19 (-5.41,5.02)	0.00 (-3.69,3.69)	0.04 (-5.16,5.24)	0.30 (-3.38,3.98)	CP

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP care: general practitioner care, PC: physiotherapy care, PE: pain education. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 3. Forest plots of network results for physical function at long-term treatment sustainability



CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, Csl: counselling, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 10.5 Pain intensity at post intervention

PC (reference)		0.64 (-0.31, 1.60)	0.42 (-0.53,1.38)	-0.45 (-1.37, 0.47)			0.42 (-0.74, 1.59)	0.28 (-0.52,1.08)		-0.65 (-2.22, 0.91)		0.22 (-1.37, 1.81)	**0.92 (0.34, 1.50)**	**-1.90 (-3.09,-0.72)**		**-1.12 (-1.69,-0.55)**
0.14 (-1.45,1.72)	Csl+PC															
1.08 (0.22,1.94)	0.94 (-0.86,2.75)	BT+PC		-1.08 (-2.27,0.1)										**-2.41 (-3.65,-1.17)**		-0.08 (-1.75,1.58)
0.42 (-0.41,1.26)	0.29 (-1.50,2.08)	-0.66 (-1.85,0.54)	Mind+PC				-0.21 (-1.79,1.37)									
0.04 (-0.65,0.73)	-0.10 (-1.82,1.63)	**-1.04 (-1.97,-0.11)**	-0.38 (-1.46,0.69)	BT					-0.19 (-1.96,1.57)	-0.41 (-1.98,1.17)		0.20 (-0.54,0.94)		**-0.84 (-1.53,-0.15)**		
-1.69 (-3.45,0.07)	-1.83 (-4.19,0.54)	**-2.77 (-4.68,-0.86)**	**-2.11 (-4.05,-0.18)**	-1.73 (-3.51,0.05)	Csl					**1.55 (0.00,3.1)**						
-0.42 (-1.54,0.70)	-0.56 (-2.49,1.38)	**-1.50 (-2.82,-0.18)**	-0.84 (-2.22,0.54)	-0.46 (-1.56,0.64)	1.27 (-0.68,3.22)	GP care						0.78 (-0.39,1.96)			0.30 (-1.31,1.92)	
0.21 (-0.64,1.07)	0.08 (-1.72,1.87)	-0.87 (-2.06,0.33)	-0.21 (-1.23,0.81)	0.17 (-0.88,1.23)	1.90 (-0.00,3.81)	0.63 (-0.71,1.98)	PE								0.31 (-1.29,1.90)	
0.13 (-0.50,0.76)	-0.00 (-1.71,1.70)	-0.95 (-1.98,0.08)	-0.29 (-1.33,0.74)	0.09 (-0.77,0.95)	**1.82 (0.03,3.62)**	0.55 (-0.63,1.73)	-0.08 (-1.09,0.92)	CP+PC							0.14 (-0.78,1.07)	0.93 (-0.64,2.50)
0.01 (-1.15,1.16)	-0.13 (-2.09,1.83)	-1.07 (-2.40,0.25)	-0.42 (-1.83,1.00)	-0.03 (-1.08,1.01)	1.70 (-0.28,3.67)	0.42 (-0.96,1.81)	-0.21 (-1.61,1.19)	-0.13 (-1.38,1.13)	Advice		0.14 (-1.42,1.71)	0.10 (-1.47,1.68)				
-0.14 (-0.98,0.70)	-0.28 (-2.07,1.51)	**-1.22 (-2.34,-0.10)**	-0.57 (-1.73,0.60)	-0.18 (-1.05,0.69)	1.55 (-0.00,3.10)	0.28 (-0.91,1.46)	-0.36 (-1.47,0.76)	-0.27 (-1.18,0.63)	-0.15 (-1.38,1.08)	Usual care	0.44 (-1.13,2.01)	0.34 (-1.23,1.91)			0.08 (-0.82,0.98)	
0.15 (-0.94,1.24)	0.01 (-1.91,1.94)	-0.93 (-2.21,0.35)	-0.27 (-1.64,1.09)	0.11 (-0.92,1.14)	1.84 (-0.06,3.74)	0.57 (-0.78,1.91)	-0.06 (-1.40,1.28)	0.02 (-1.17,1.20)	0.14 (-0.97,1.26)	0.29 (-0.81,1.40)	Mindfulness	-0.10 (-1.67,1.47)		-0.52 (-2.21,1.17)		
0.23 (-0.47,0.94)	0.10 (-1.64,1.83)	-0.85 (-1.82,0.13)	-0.19 (-1.27,0.89)	0.19 (-0.40,0.78)	**1.92 (0.16,3.69)**	0.65 (-0.33,1.63)	0.02 (-1.04,1.08)	0.10 (-0.76,0.96)	0.23 (-0.79,1.25)	0.38 (-0.48,1.23)	0.08 (-0.90,1.06)	CBT		**-0.76 (-1.5,-0.02)**		-0.21 (-1.77,1.35)
0.91 (0.37,1.45)	0.78 (-0.90,2.45)	-0.17 (-1.18,0.84)	0.49 (-0.51,1.48)	**0.87 (0.00,1.74)**	**2.60 (0.76,4.44)**	**1.33 (0.10,2.57)**	0.70 (-0.31,1.71)	0.78 (-0.04,1.60)	0.91 (-0.36,2.18)	**1.06 (0.06,2.05)**	0.76 (-0.45,1.97)	0.68 (-0.20,1.56)	PE+PC			0.06 (-1.56,1.67)
-0.62 (-1.31,0.07)	-0.75 (-2.48,0.97)	**-1.70 (-2.63,-0.76)**	-1.04 (-2.12,0.03)	**-0.66 (-1.26,-0.06)**	1.07 (-0.71,2.85)	-0.20 (-1.29,0.89)	-0.83 (-1.88,0.22)	-0.75 (-1.60,0.10)	-0.62 (-1.71,0.46)	-0.48 (-1.35,0.40)	-0.77 (-1.76,0.23)	**-0.85 (-1.44,-0.26)**	**-1.53 (-2.40,-0.66)**	No intervention	0.71 (-1.02,2.44)	0.11 (-1.45,1.68)
0.12 (-0.61,0.86)	-0.01 (-1.76,1.73)	-0.95 (-2.02,0.11)	-0.30 (-1.38,0.78)	0.08 (-0.75,0.92)	**1.81 (0.10,3.53)**	0.54 (-0.54,1.62)	-0.09 (-1.07,0.90)	-0.01 (-0.73,0.72)	0.12 (-1.10,1.34)	0.27 (-0.47,1.00)	-0.02 (-1.16,1.11)	-0.11 (-0.92,0.71)	-0.79 (-1.69,0.12)	0.74 (-0.07,1.56)	CP	
0.92 (0.43,1.42)	0.79 (-0.87,2.45)	-0.16 (-1.07,0.76)	0.50 (-0.47,1.47)	**0.88 (0.11,1.66)**	**2.61 (0.81,4.42)**	**1.34 (0.18,2.51)**	0.71 (-0.26,1.68)	**0.79 (0.06,1.53)**	0.92 (-0.28,2.12)	**1.07 (0.15,1.99)**	0.77 (-0.36,1.91)	0.69 (-0.08,1.46)	0.01 (-0.68,0.70)	1.54 (0.79,2.30)	0.80 (-0.03,1.63)	CBT+PC

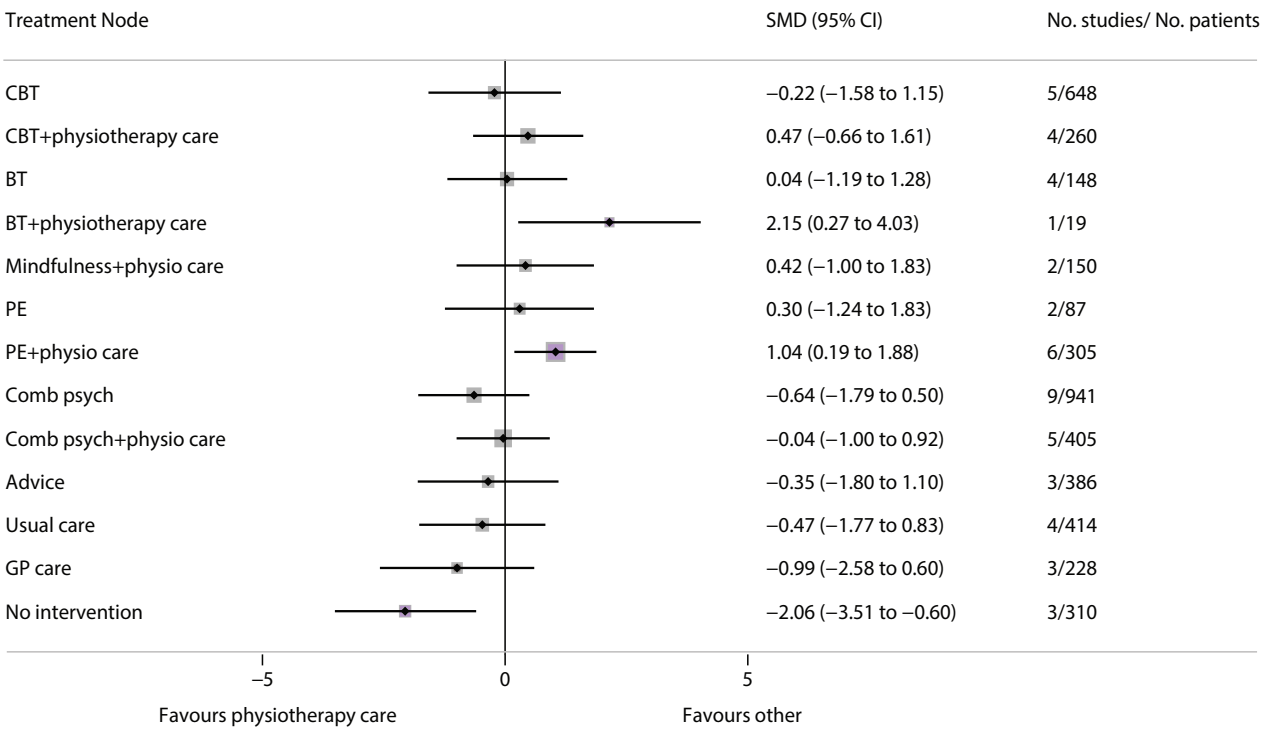
Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: Mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 10.6 Pain intensity at short-term treatment sustainability

PC (reference)	**1.22 (0.32,2.12)**			0.10 (-1.95, 2.14)	0.16 (-1.02, 1.34)	1.30 (-0.66, 3.27)			**-5.15 (-6.87, -3.43)**	-0.24 (-2.29, 1.80)		-0.36 (-1.79, 1.07)	1.08 (-0.78, 2.95)
1.04 (0.19,1.88)	PE+PC			0.32 (-1.69, 2.32)									
-0.22 (-1.58,1.15)	-1.26 (-2.83,0.32)	CBT	-0.20 (-2.24, 1.84)						-0.30 (-2.12, 1.52)		-1.97 (-4.05, 0.12)	0.00 (-1.47, 1.48)	
-0.35 (-1.80,1.10)	-1.39 (-3.01,0.23)	-0.13 (-1.55,1.28)	Advice	0.37 (-1.66, 2.40)				0.09 (-1.93, 2.11)					
0.47 (-0.66,1.61)	-0.56 (-1.82,0.69)	0.69 (-0.89,2.28)	0.83 (-0.64,2.29)	CBT+PC	-0.48 (-2.52, 1.56)								
-0.04 (-1.00,0.92)	-1.07 (-2.31,0.16)	0.18 (-1.35,1.72)	0.32 (-1.25,1.88)	-0.51 (-1.76,0.74)	CP+PC			0.00 (-2.02,2.02)					
0.30 (-1.24,1.83)	-0.74 (-2.48,1.00)	0.52 (-1.34,2.37)	0.65 (-1.26,2.56)	-0.18 (-2.01,1.65)	0.33 (-1.38,2.05)	PE		0.04 (-1.90, 1.98)					
0.42 (-1.00,1.83)	-0.62 (-2.27,1.03)	0.64 (-1.33,2.60)	0.77 (-1.26,2.80)	-0.06 (-1.87,1.76)	0.45 (-1.26,2.17)	0.12 (-1.97,2.21)	Mind+PC						
-0.64 (-1.79,0.50)	**-1.68 (-3.07,-0.29)**	-0.42 (-1.70,0.86)	-0.29 (-1.64,1.06)	-1.12 (-2.54,0.30)	-0.61 (-1.87,0.65)	-0.94 (-2.47,0.59)	-1.06 (-2.88,0.76)	CP	0.00 (-1.89,1.89)	0.02 (-1.15, 1.19)	0.16 (-1.19, 1.51)		
-2.06 (-3.51,-0.60)	**-3.10 (-4.76,-1.44)**	**-1.84 (-3.19,-0.48)**	**-1.71 (-3.38,-0.03)**	**-2.53 (-4.24,-0.82)**	**-2.02 (-3.64,-0.41)**	**-2.36 (-4.27,-0.44)**	**-2.48 (-4.51,-0.44)**	**-1.42 (-2.76,-0.07)**	No intervention			**4.44 (2.50, 6.37)**	**6.54 (4.79, 8.28)**
-0.47 (-1.77,0.83)	-1.51 (-3.03,0.02	-0.25 (-1.72,1.22)	-0.12 (-1.70,1.47)	-0.94 (-2.53,0.64)	-0.43 (-1.89,1.02)	-0.77 (-2.51,0.98)	-0.89 (-2.81,1.04)	0.17 (-0.83,1.18)	**1.59 (0.03,3.15)**	Usual care		0.05 (-1.97, 2.08)	
-0.99 (-2.58,0.60)	**-2.03 (-3.80,-0.25**	-0.77 (-2.25,0.71)	-0.64 (-2.34,1.07)	-1.46 (-3.25,0.33)	-0.95 (-2.64,0.74)	-1.28 (-3.21,0.64)	-1.40 (-3.53,0.72)	-0.34 (-1.58,0.89)	1.07 (-0.62,2.76)	-0.52 (-2.07,1.03)	GP care		
0.04 (-1.19,1.28)	-1.00 (-2.47,0.48)	0.26 (-0.89,1.41)	0.39 (-1.16,1.95)	-0.43 (-1.98,1.12)	0.08 (-1.38,1.54)	-0.25 (-2.07,1.56)	-0.37 (-2.25,1.50)	0.69 (-0.61,1.98)	**2.10 (0.67,3.53)**	0.51 (-0.89,1.91)	1.03 (-0.59,2.65)	BT	1.61 (-0.48, 3.70)
2.15 (0.27,4.03)	1.11 (-0.94,3.16)	**2.37 (0.33,4.41)**	**2.50 (0.29,4.72)**	1.68 (-0.46,3.81)	**2.19 (0.12,4.25)**	1.85 (-0.49,4.20)	1.73 (-0.62,4.09)	**2.79 (0.77,4.82)**	**4.21 (2.16,6.26)**	**2.62 (0.50,4.73)**	**3.14 (0.86,5.41)**	**2.11 (0.22,3.99)**	BT+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 4. Forest plots of network results for pain intensity at short-term treatment sustainability



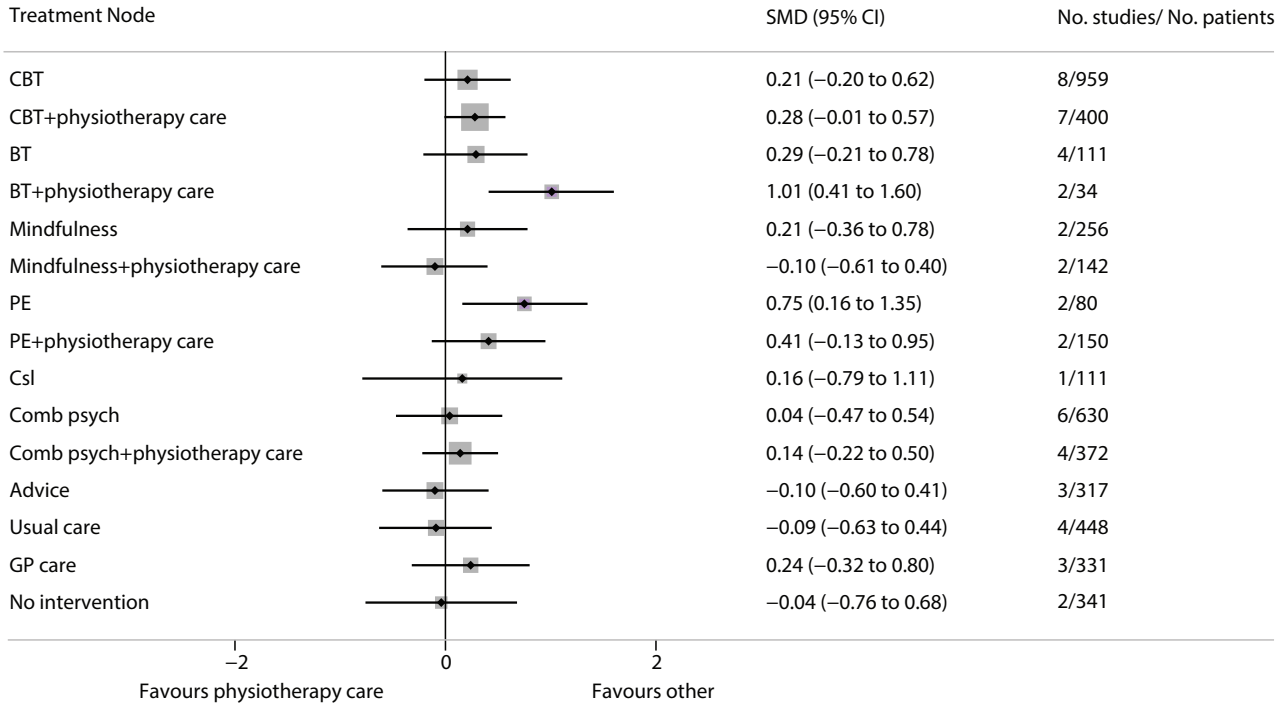
BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 10.7 Pain intensity at mid-term treatment sustainability

PC (reference)	0.21 (-0.12,0.53)			0.05 (-0.64,0.74)		0.35 (-0.10,0.79)	**1.27 (0.58,1.97)**						0.02 (-0.79,0.82)	0.05 (-0.51,0.61)	**1.01 (0.32,1.70)**
0.28 (-0.01,0.57)	CBT+PC			0.25 (-0.42,0.91)	-0.48 (-1.16,0.20)	-0.43 (-1.05,0.19)									0.73 (-0.25,1.71)
0.21 (-0.36,0.78)	-0.07 (-0.63,0.49)	Mindfulness	-0.27 (-0.92,0.38)	0.03 (-0.62,0.68)	-0.35 (-0.99,0.29)										
-0.09 (-0.63,0.44)	-0.37 (-0.91,0.16)	-0.30 (-0.83,0.23)	Usual care	0.30 (-0.35,0.95)								0.13 (-0.24,0.51)			
0.21 (-0.20,0.62)	-0.07 (-0.48,0.34)	-0.00 (-0.48,0.47)	0.30 (-0.15,0.75)	CBT	-0.17 (-0.82,0.47)				-0.09 (-0.73,0.55)		-0.25 (-0.84,0.34)		0.13 (-0.32,0.58)		
-0.10 (-0.60,0.41)	-0.38 (-0.85,0.09)	-0.31 (-0.79,0.17)	-0.01 (-0.56,0.55)	-0.31 (-0.74,0.12)	Advice										
0.14 (-0.22,0.50)	-0.14 (-0.53,0.25)	-0.07 (-0.67,0.53)	0.23 (-0.30,0.77)	-0.07 (-0.54,0.40)	0.24 (-0.31,0.79)	CP+PC						0.00 (-0.66,0.66)			
0.75 (0.16,1.35)	0.47 (-0.19,1.13)	0.54 (-0.28,1.37)	**0.85 (0.05,1.64)**	0.54 (-0.18,1.27)	**0.85 (0.07,1.63)**	0.61 (-0.08,1.31)	PE							0.11 (-0.53,0.75)	
-0.10 (-0.61,0.40)	-0.39 (-0.97,0.20)	-0.31 (-1.08,0.45)	-0.01 (-0.75,0.72)	-0.31 (-0.97,0.34)	-0.01 (-0.72,0.71)	-0.24 (-0.87,0.38)	**-0.86 (-1.64,-0.08)**	Mind+PC							
0.24 (-0.32,0.80)	-0.04 (-0.60,0.52)	0.03 (-0.58,0.64)	0.33 (-0.15,0.81)	0.03 (-0.44,0.50)	0.34 (-0.26,0.94)	0.10 (-0.47,0.66)	-0.51 (-1.33,0.30)	0.34 (-0.41,1.10)	GP care			-0.27 (-0.73,0.19)			
0.16 (-0.79,1.11)	-0.12 (-1.07,0.83)	-0.05 (-1.03,0.93)	0.25 (-0.72,1.22)	-0.05 (-0.91,0.81)	0.26 (-0.70,1.22)	0.02 (-0.96,1.00)	-0.59 (-1.72,0.53)	0.26 (-0.81,1.34)	-0.08 (-1.06,0.90)	Csl	-0.20 (0.83,0.42)				
-0.04 (-0.76,0.68)	-0.33 (-1.04,0.39)	-0.26 (-1.01,0.50)	0.05 (-0.69,0.79)	-0.25 (-0.84,0.34)	0.05 (-0.68,0.78)	-0.19 (-0.94,0.57)	-0.80 (-1.73,0.13)	0.06 (-0.82,0.94)	-0.29 (-1.04,0.47)	-0.20 (-0.83,0.42)	No intervention				
0.04 (-0.47,0.54)	-0.25 (-0.76,0.27)	-0.18 (-0.73,0.38)	0.13 (-0.21,0.46)	-0.17 (-0.62,0.27)	0.13 (-0.43,0.69)	-0.11 (-0.59,0.38)	-0.72 (-1.50,0.06)	0.14 (-0.58,0.86)	-0.21 (-0.60,0.19)	-0.12 (-1.09,0.84)	0.08 (-0.66,0.82)	CP			
0.29 (-0.21,0.78)	0.00 (-0.50,0.51)	0.08 (-0.53,0.68)	0.38 (-0.20,0.96)	0.08 (-0.32,0.47)	0.38 (-0.18,0.95)	0.14 (-0.41,0.70)	-0.47 (-1.24,0.30)	0.39 (-0.32,1.10)	0.05 (-0.55,0.64)	0.13 (-0.82,1.07)	0.33 (-0.38,1.04)	0.25 (-0.32,0.82)	BT		0.71 (-0.11,1.53)
0.41 (-0.13,0.95)	0.13 (-0.49,0.74)	0.20 (-0.59,0.99)	0.50 (-0.26,1.26)	0.20 (-0.48,0.88)	0.51 (-0.23,1.25)	0.27 (-0.38,0.92)	-0.34 (-0.92,0.23)	0.51 (-0.23,1.26)	0.17 (-0.61,0.95)	0.25 (-0.84,1.35)	0.45 (-0.44,1.35)	0.38 (-0.37,1.12)	0.12 (-0.61,0.86)	PE+PC	
1.01 (0.41,1.60)	**0.72 (0.11,1.33)**	**0.80 (0.03,1.56)**	**1.10 (0.35,1.84)**	**0.80 (0.15,1.44)**	**1.10 (0.38,1.83)**	**0.87 (0.20,1.53)**	0.25 (-0.59,1.09)	**1.11 (0.33,1.89)**	**0.77 (0.00,1.53)**	0.85 (-0.23,1.92)	**1.05 (0.17,1.93)**	**0.97 (0.24,1.70)**	**0.72 (0.07,1.37)**	0.60 (-0.21,1.40)	BT+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 5. Forest plots of network results for pain intensity at mid-term treatment sustainability



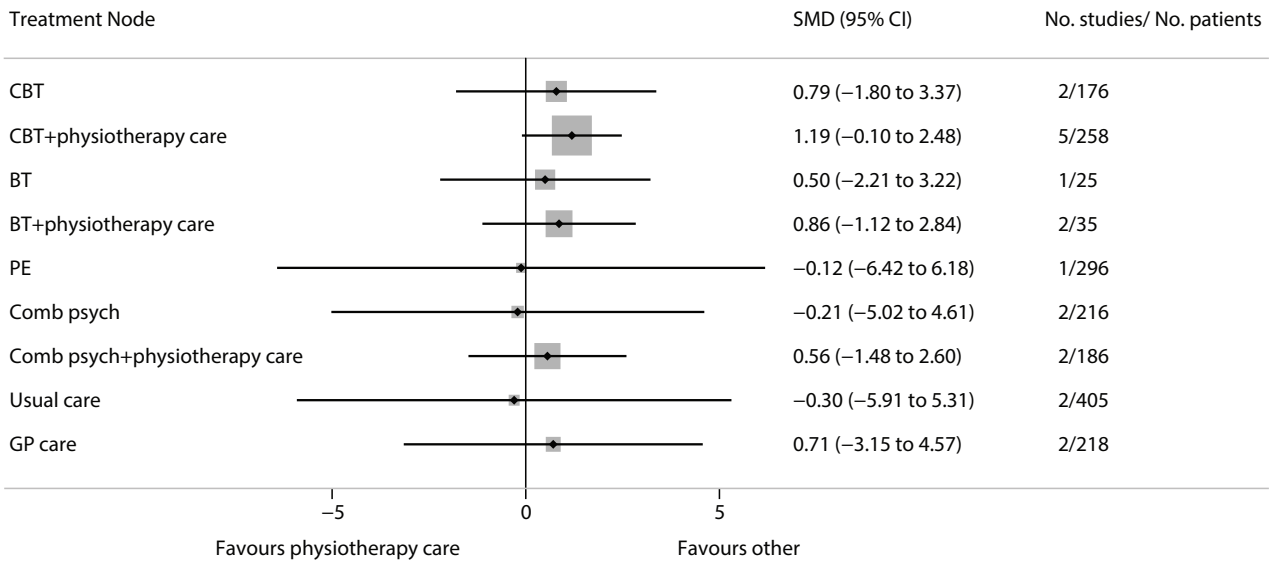
BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, Csl: counselling, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 10.8 Pain intensity at long-term treatment sustainability

PC (reference)		0.03 (-2.77,2.83)				1.21 (0.22,2.64)	0.77 (-1.52,3.06)		0.40 (-2.79,3.59)
0.56 (-1.48,2.60)	CP+PC								
0.79 (-1.80,3.37)	0.22 (-3.07,3.51)	CBT	-0.07 (-2.95,2.80)			-0.35 (-3.15, 2.45)			
0.71 (-3.15,4.57)	0.15 (-4.22,4.52)	-0.07 (-2.95,2.80)	GP care					-0.92 (-3.80, 1.96)	
-0.12 (-6.42,6.18)	-0.68 (-7.30,5.94)	-0.90 (-6.65,4.84)	-0.83 (-5.80,4.15)	PE	-0.18 (-3.05,2.68)				
-0.30 (-5.91,5.31)	-0.86 (-6.83,5.10)	-1.09 (-6.06,3.89)	-1.01 (-5.08,3.05)	-0.18 (-3.05,2.68)	Usual Care			0.09 (-2.78, 2.97)	
1.19 (-0.10,2.48)	0.63 (-1.79,3.04)	0.40 (-2.18,2.98)	0.48 (-3.39,4.34)	1.31 (-4.99,7.60)	1.49 (-4.12,7.10)	CBT+PC	-0.05 (-3.27,3.17)		
0.86 (-1.12,2.84)	0.30 (-2.54,3.14)	0.08 (-3.10,3.25)	0.15 (-4.13,4.43)	0.98 (-5.58,7.54)	1.16 (-4.74,7.07)	-0.33 (-2.47,1.81)	BT+PC		-0.25 (-3.44,2.93)
-0.21 (-5.02,4.61)	-0.77 (-6.00,4.46)	-0.99 (-5.06,3.07)	-0.92 (-3.79,1.96)	-0.09 (-4.15,3.97)	0.09 (-2.78,2.97)	-1.39 (-6.21,3.42)	-1.07 (-6.23,4.09)	CP	
0.50 (-2.21,3.22)	-0.06 (-3.45,3.34)	-0.28 (-3.99,3.43)	-0.21 (-4.90,4.49)	0.62 (-6.22,7.46)	0.81 (-5.40,7.01)	-0.68 (-3.60,2.24)	-0.36 (-3.07,2.35)	0.71 (-4.79,6.22)	BT

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, PC: physiotherapy care, PE: pain education. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 6. Forest plots of network results for pain intensity at long-term treatment sustainability



BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary J. Risk of bias judgments

In the following tables, we present the risk of bias judgments for studies included in the NMA for physical function, pain intensity and fear avoidance.

Supplementary Table 11.1 Risk of bias judgments for studies assessing physical function

Author, Year	Domain 1: Randomization process	Domain 2: Deviations from intended interventions	Domain 3: Missing outcome data	Domain 4: Measurement of the outcome	Domain 5: Selection of the reported result	Overall risk of bias
Alaranta, 1994[2]	Some concerns	Low	Low	High	Some concerns	High
Aliyu, 2018[3]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Bagheri, 2020[5]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Bendix, 2000[8]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Cherkin, 2016[11]	Low	Low	Low	Some concerns	Low	Some concerns
Chiauzzi, 2010[12]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Christiansen, 2010[13]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Dufour, 2010[15]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Farokhi, 2020[17]	Some concerns	low	Low	Some concerns	Some concerns	Some concerns
Friedrich, 1998[18] & 2005[19]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Frost, 1998[20]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Galan-Martin, 2020[21]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gannon, 2019[22] (Study 1)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gannon, 2019[22] (Study 2)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gardner, 2019[23]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Ghadyani, 2017[24]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Gibbs, 2018[25]	Low	Low	Low	Some concerns	High	Some concerns
Godfrey, 2019[28]	Low	Some concerns	Low	Some concerns	Some concerns	Some concerns
Gould, 2020[29]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Haas, 2005[31]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Harris, 2017[32]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Jensen, 2012[33]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Johnson, 2007[34]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Khan, 2014[36]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Krein, 2013[38]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Lamb, 2010[39, 40]	Low	Low	Low	Some concerns	Low	Some concerns
Lambeek, 2010[41]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Leeuw, 2008[42]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Lorig, 2002[44]	Low	Low	High	Some concerns	Some concerns	High
Macedo, 2012[46]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Magalhaes, 2017[47]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Magnussen, 2007[48]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Mehling, 2005[49]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Monticone, 2013[51]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Monticone, 2016[52]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Moore, 2000[53]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Morone, 2016[54]	Low	Low	Low	Some concerns	Low	Some concerns
Moseley, 2004[57]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Nguyen, 2017[58]	Low	Low	Low	Some concerns	Some concerns	Some concerns
O'Keeffe, 2020[60]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Pardo, 2018[62]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Petrozzi, 2019[63]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Pires, 2015[64]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Poole, 2007[65]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Rabiei, 2020[66]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Rizzo, 2018[69]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Sander, 2020[71]	Low	Low	Low	Some concerns	Low	Some concerns
Santaella da Fonseca, 2009[72]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Saper, 2017[73]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Saracoglu, 2020[74]	Low	Some concerns	Low	Some concerns	Some concerns	Some concerns
Siemonsma, 2013[78]	Low	Some concerns	Low	Some concerns	Some concerns	Some concerns
Smeets, 2008[79]	Low	Some concerns	Low	Some concerns	Low	Some concerns
Stuckey, 1986[83]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns

Tavafian, 2017[85]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Tekur, 2008[86]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Tilbrook, 2011[87]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Unal, 2020[92]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Vibe Fersum, 2019[94]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Von Korff, 2005[95]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Woods, 2008[97]	Low	Low	High	Some concerns	Some concerns	High

Supplementary Table 11.2 Risk of bias judgments for studies assessing pain intensity

Author, Year	Domain 1: Randomization process	Domain 2: Deviations from intended interventions	Domain 3: Missing outcome data	Domain 4: Measurement of the outcome	Domain 5: Selection of the reported result	Overall risk of bias
Aliyu, 2018[3]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Bendix, 2000[8]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Cherkin, 2016[11]	Low	Low	Low	Some concerns	Low	Some concerns
Chiauzzi, 2010[12]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Christiansen, 2010[13]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Dufour, 2010[15]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Friedrich, 1998[18] & 2005[19]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Galan-Martin, 2020[21]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gannon, 2019[22] (Study 1)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gannon, 2019[22] (Study 2)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gardner, 2019[23]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Ghadyani, 2017[24]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Gibbs, 2018[25]	Low	Low	Low	Some concerns	High	Some concerns
Godfrey, 2019[28]	Low	Some concerns	Low	Some concerns	Some concerns	Some concerns
Gould, 2020[29]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Haas, 2005[31]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Jensen, 2012[33]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Johnson, 2007[34]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Khan, 2014[36]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Khodadad, 2020[37]	Low	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns
Krein, 2013[38]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Lamb, 2010[39, 40]	Low	Low	Low	Some concerns	low	Some concerns
Lambeek, 2010[41]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Leeuw, 2008[42]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Lorig, 2002[44]	Low	Low	High	Some concerns	Some concerns	High
Louw, 2017[45]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Macedo, 2012[46]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Magalhaes, 2017[47]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Mehling, 2005[49]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Monticone, 2013[51]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Monticone, 2016[52]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Moore, 2000[53]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Morone, 2016[54]	Low	Low	Low	Some concerns	Low	Some concerns
Nguyen, 2017[58]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Nicholas, 1991[59]	Low	Low	Low	Some concerns	High	High
O'Keeffe, 2020[60]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Paolucci, 2017[61]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Pardo, 2018[62]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Petrozzi, 2019[63]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Pires, 2015[64]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Poole, 2007[65]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Rabiei, 2020[66]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Reiner, 2019[67]	Low	Low	Low	Some concerns	High	High
Rizzo, 2018[69]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Sander, 2020[71]	Low	Low	Low	Some concerns	Low	Some concerns
Santaella da Fonseca, 2009[72]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Saper, 2017[73]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Saracoglu, 2020[74]	Low	Some concerns	Low	Some concerns	Low	Some concerns
Saracoglu, 2020[75]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns
Schaller, 2016[76]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Shariat, 2019[77]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns

Smeets, 2008[79]	Low	Some concerns	Low	Some concerns	Low	Some concerns
Soleymani, 2021[81]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Sorensen, 2010[82]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Stuckey, 1986[83]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns
Tavafian, 2017[85]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Turner, 1982[88]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns
Turner, 1988[89]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns
Turner, 1990[90]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns
Turner, 1993[91]	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns

Supplementary Table 11.3 Risk of bias judgments for studies assessing fear avoidance

Author, Year	Domain 1: Randomization process	Domain 2: Deviations from intended interventions	Domain 3: Missing outcome data	Domain 4: Measurement of the outcome	Domain 5: Selection of the reported result	Overall risk of bias
Aliyu, 2018[3]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Chiauzzi, 2010[12]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Farokhi, 2020[17]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Galan-Martin, 2020[21]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gannon, 2019[22] (Study 1)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gannon, 2019[22] (Study 2)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Gardner, 2019[23]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Jensen, 2012[33]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Krein, 2013[38]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Lamb, 2010[39, 40]	Low	Low	Low	Some concerns	Low	Some concerns
Leeuw, 2008[42]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Magalhaes, 2017[47]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Magnussen, 2007[48]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Monticone, 2013[51]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Monticone, 2016[52]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Moore, 2000[53]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Morone, 2016[54]	Low	Low	Low	Some concerns	Low	Some concerns
Moseley, 2004[57]	Low	Low	Low	Some concerns	Some concerns	Some concerns
O'Keeffe, 2020[60]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Pardo, 2018[62]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Petrozzi, 2019[63]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Pires, 2015[64]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Rabiei, 2020[66]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Rizzo, 2018[69]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Sorensen, 2010[82]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Unal, 2020[92]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Vibe Fersum, 2019[94]	Low	Low	Low	Some concerns	Some concerns	Some concerns
Von Korff, 2005[95]	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Woods, 2008[97]	Low	Low	High	Some concerns	Some concerns	High

Supplementary K. CINeMA results for physical function and pain intensity

Judgments of the confidence in cumulative evidence were evaluated using the Confidence in Network Meta-Analysis (CINeMA) framework,[102-104] a web application of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) ratings approach.

In CINeMA, the default confidence rating for each comparison is "high confidence." Confidence ratings per comparison were assessed according to the following steps. First, we assigned a point scale to the domain-level judgments: "no concerns" was 0 points, "some concerns" was 0.5 points, "major concerns" was 1 point. Then, we downgraded the confidence rating, for each comparison, by: (i) one level (i.e., "moderate confidence"), if there was a reduction of ≥1 but <2 points across all domains; two levels (i.e., "low confidence"), if there was a reduction of ≥2 but <3 points across all domains; (ii) three levels (i.e., "very low confidence"), if there was a reduction of ≥3 points across all domains.

Supplementary Table 12.1 Physical function at post-intervention

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:BT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CBT	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:Mind	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CBT+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:GP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:Mind	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:NI	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT+PC:NI	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate

CBT+PC:PE+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PC	8	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:GP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:CP+PC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:NI	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:UC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PC	4	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:PE+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	Some concerns	Low
Csl+PC:PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
Mind:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:PC	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE+PC:PC	5	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
PC:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:BT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CBT+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Adv:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

BT:BT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CBT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CBT:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT+PC:Csl	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT+PC:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate

CP+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP: Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

Mind:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE+PE:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate

Adv: advice, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 12.2 Physical function at short-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:CBT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CBT+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT+PC:PE+PC	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low
CBT+PC:PC	2	Some concerns	Undetected	No concerns	No concerns	Some concerns	Some concerns	Moderate
CP:CP+PC	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate

CP:GP	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PE	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:UC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PE	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:PC	3	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Mind+PC:PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
PE:PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Some concerns	Moderate
PE+PC:PC	4	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
PC:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:BT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:CBT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
BT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
BT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low

CBT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
GP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
GP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
GP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
GP:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Mind+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Mind+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low

Mind+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Mind+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
NI:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
PE:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
PE:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
PE+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low

Adv: advice, BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 12.3 Physical function at mid-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:CBT	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Adv:CBT+PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Adv:Mind	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:CBT	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Moderate
CBT:CBT+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Moderate
CBT:GP	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT:Mind	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT:NI	1	No concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Moderate
CBT:PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT:UC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Moderate
CBT+PC:PC	5	Some concerns	Undetected	No concerns	No concerns	Some concerns	Some concerns	Moderate
CP:CP+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate

CP:CP+PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Moderate
CP:GP	2	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:UC	3	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP+PC:PE	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Moderate
CP+PC:PC	2	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Csl:NI	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Moderate
Mind:UC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Mind+PC:PC	2	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Moderate
PE:PE+PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Moderate
PE:PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Moderate
Adv:BT	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:CP	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:GP	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Adv:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:CP	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:CP+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
BT:Csl	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:Mind	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low

BT:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
BT:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:CP	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT+PC:CP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CBT+PC:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CBT+PC:PE	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low
CBT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CP:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:Mind	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP:NI	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP:PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low

CP+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:GP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CP+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CP+PC:Csl	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:GP	0	Some concerns	Undetected	No concerns	No concerns	No concerns	Major concerns	Moderate
CP+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:NI	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CP+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CP+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	No concerns	Major concerns	Moderate
Csl:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Csl:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Csl:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
GP:Mind	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
GP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
GP:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
GP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
GP:PC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low
GP:UC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low

Mind:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Mind:NI	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Mind:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Mind:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Mind:PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Mind+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Mind+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Mind+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
Mind+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
NI:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
PE:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
PE+PC:PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
PE+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	Major concerns	Low
PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	Major concerns	Low

Adv: advice, BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP: general practitioner care, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 12.4 Physical function at long-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
CBT:CBT+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:GP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PC	5	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CP:GP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:NI	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:NI	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:UC	1	Major concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Low
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

Csl:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP: general practitioner care, NI: no intervention, PC: physiotherapy care, PE: pain education, UC: usual care.

Supplementary Table 12.5 Pain intensity at post-intervention

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:BT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CBT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Mind	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:BT+PC	2	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:CBT	5	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:NI	4	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
BT:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CBT+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PC	3	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT:CBT+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:GP	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:Mind	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CBT:NI	5	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT:PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT+PC:NI	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
CBT+PC:PC	8	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT+PC:PE+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:CP+PC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:GP	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:UC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PC	4	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:UC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Csl+PC:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:NI	1	Major concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Low
Mind:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:PC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PC:PE	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PC:PE+PC	8	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
PC:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:BT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Csl	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Adv:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

Adv:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Csl	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:CBT	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:Csl	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
BT+PC:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:GP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:NI	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:Csl	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High

CBT:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT+PC:Csl	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
CBT+PC:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:GP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:Csl	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
CP:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:Csl	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
CP+PC:Csl+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:Csl+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Csl:GP	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Csl:Mind	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High

Csl:Mind+PC	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
Csl:NI	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Csl:PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Csl:PE	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
Csl:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
Csl+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

PE:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate

Adv: advice, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care. For pain intensity at post-intervention, CINeMA was unable to perform the GRADE assessment when studies with more than three arms were included in the network. This affected two studies, which had four treatment arms each: Shariat et al., 2019 (BT+PC, BT, PC, NI);[77] Turner et al., 1990 (BT+PC, BT, PC, NI).[90] In order to successfully perform the GRADE assessment via CINeMA, we excluded the NI arm from these two studies. Sensitivity analyses excluding alternative treatment arms and excluding the studies altogether did not result in any changes to the overall confidence ratings.

Supplementary Table 12.6 Pain intensity at short-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:CBT	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:CBT+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:CP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:BT+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:CBT	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Some concerns	Moderate
BT:PC	2	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT:GP	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PE+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PC	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP:CP+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:GP	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Some concerns	Low

CP:NI	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Some concerns	Low
CP:UC	3	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PC	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:PC	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE:PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Some concerns	Low
PE+PC:PC	5	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
PC:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:BT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:BT+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Major concerns	No concerns	Moderate
Adv:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:CBT	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:CP+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate

BT+PC:GP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	Some concerns	No concerns	Moderate
CBT:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	Some concerns	No concerns	Moderate
CBT:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

GP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate

Adv: advice, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care. For pain intensity at post-intervention, CINeMA was unable to perform the GRADE assessment when studies with more than three arms were included in the network. This affected two studies, which had four treatment arms each: Shariat et al., 2019 (BT+PC, BT, PC, NI);[77] Turner et al., 1990 (BT+PC, BT, PC, NI).[90] In order to successfully perform the GRADE assessment via CINeMA, we excluded the NI arm from these two studies. Sensitivity analyses excluding alternative treatment arms and excluding the studies altogether did not result in any changes to the overall confidence ratings.

Supplementary Table 12.7 Pain intensity at mid-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:CBT	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Adv:CBT+PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Adv:Mind	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT:BT+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT:CBT	3	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
BT:PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT+PC:CBT+PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:PC	2	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
CBT:CBT+PC	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT:GP	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT:Mind	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:UC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PC	5	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CP:CP+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:GP	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:UC	3	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:PC	2	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
Csl:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind:UC	1	No concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:PC	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE:PE+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Some concerns	Low
PE:PC	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	Major concerns	Low
PE+PC:PC	1	Some concerns	Undetected	No concerns	Some concerns	No concerns	Some concerns	Moderate
Adv:BT	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate

Adv:BT+PC	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
Adv:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Adv:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
BT:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT+PC:CBT	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:CP	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:CP+PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
BT+PC:Csl	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
BT+PC:NI	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate

BT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
BT+PC:UC	0	Some concerns	Undetected	No concerns	No concerns	No concerns	No concerns	High
CBT:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CBT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CP:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CP+PC:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Csl:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:Mind+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Csl:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Mind:Mind+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind:PE	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
Mind+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind+PC:PE	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
Mind+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
Mind+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
NI:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

PE:UC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
PE+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	No concerns	No concerns	Moderate
PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate

Adv: advice, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP: general practitioner care, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 12.8 Pain intensity at long-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
BT:BT+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CBT+PC	1	Major concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Low
BT+PC:PC	2	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CBT+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:GP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PC	5	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:PC	2	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:GP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:UC	1	Major concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Low
BT:CBT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

BT+PC:CBT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

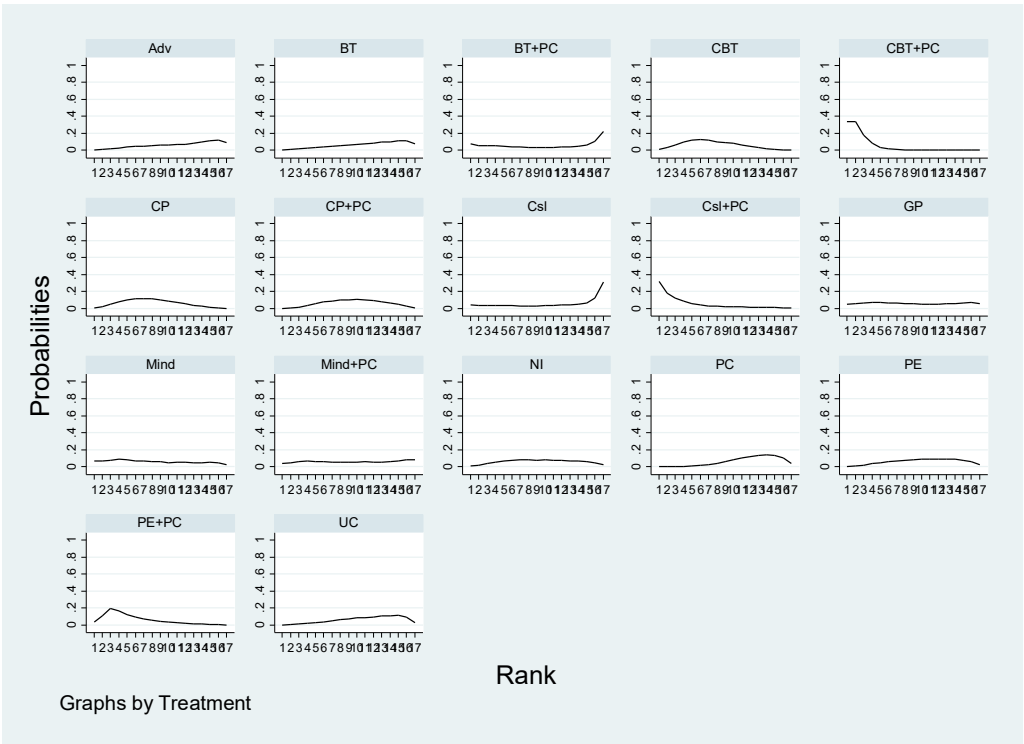
BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP: general practitioner care, PC: physiotherapy care, PE: pain education, UC: usual care.

Supplementary L. Rank results for physical function and pain intensity

Supplementary Table 13.1 Physical function at post-intervention

Rank	Treatment Node	SUCRA	Mean Rank
1st	CBT+PC	92.3	2.2
2nd	Csl+PC	81.8	3.9
3rd	PE+PC	72.6	5.4
4th	CBT	60.3	7.4
5th	CP	56.9	7.9
6th	Mindfulness	56.4	8
7th	General practitioner care	50.4	8.9
8th	No intervention	46.9	9.5
9th	Mindfulness+PC	46.8	9.5
10th	CP+PC	45.4	9.7
11th	PE	41	10.4
12th	BT+PC	40.4	10.5
13th	Usual care	34	11.6
14th	Advice	33.3	11.7
15th	BT	32.9	11.7
16th	Csl	30.8	12.1
17th	Physiotherapy care	27.8	12.5

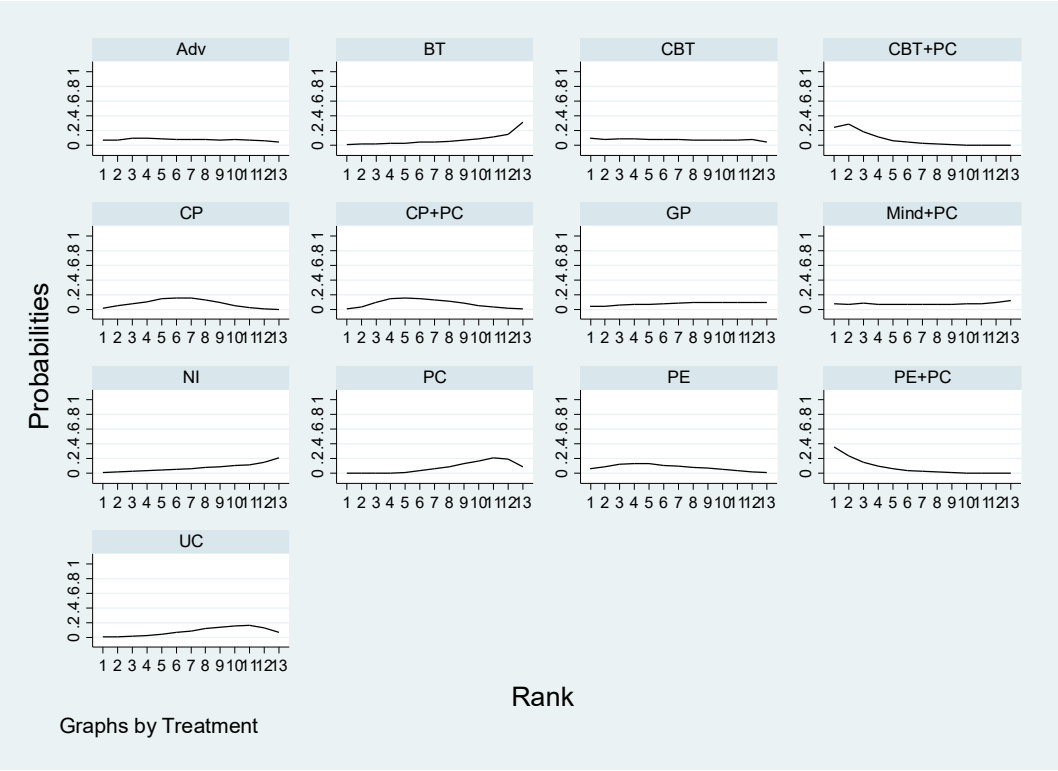
BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.2a Physical function at short-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	PE+PC	85.6	2.7
2nd	CBT+PC	84.5	2.9
3rd	PE	61.4	5.6
4th	CP+PC	57.2	6.1
5th	CP	56.1	6.3
6th	CBT	53.7	6.6
7th	Advice	53.5	6.6
8th	Mindfulness+PC	46.6	7.4
9th	General practitioner care	43.4	7.8
10th	Usual care	32	9.2
11th	No intervention	28.8	9.5
12th	BT	23.7	10.2
13th	Physiotherapy care	23.5	10.2

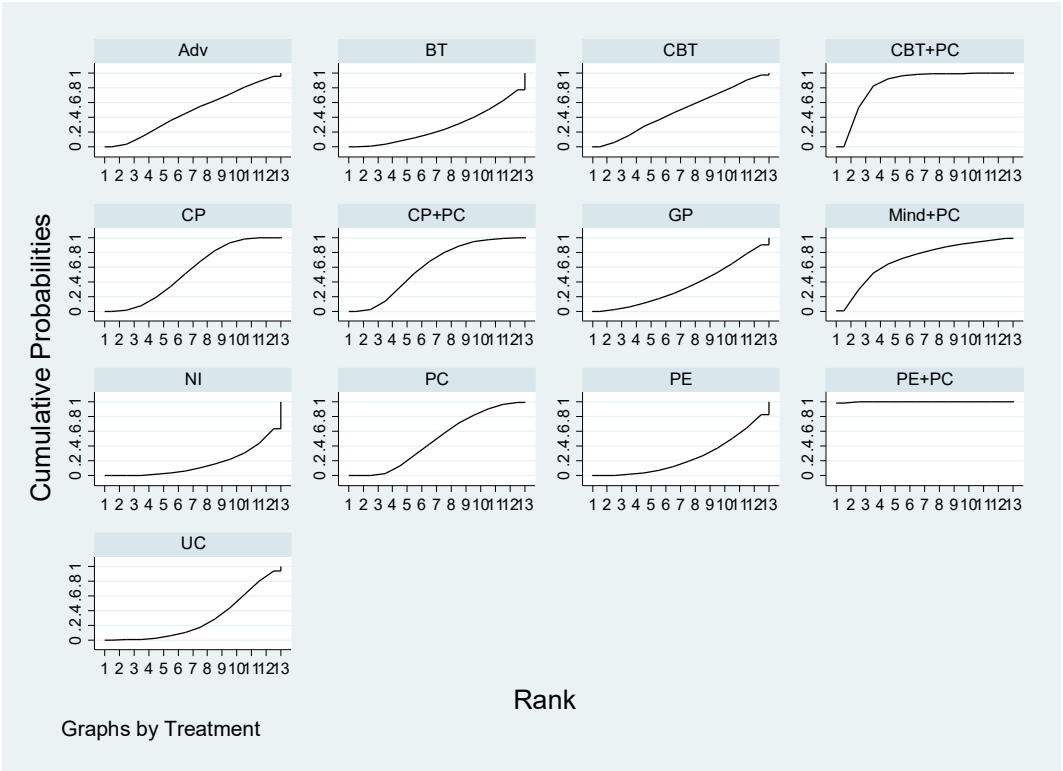
BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.2b Physical function at short-term treatment sustainability, after removing inconsistency

Rank	Treatment Node	SUCRA	Mean Rank
1st	PE+PC	99.9	1
2nd	CBT+PC	85.2	2.8
3rd	Mindfulness+PC	70.6	4.5
4th	CP+PC	60.5	5.7
5th	CP	54.4	6.5
6th	CBT	49.4	7.1
7th	Physiotherapy care	48.6	7.2
8th	Advice	48.3	7.2
9th	General practitioner care	35.1	8.8
10th	Usual care	28.5	9.6
11th	BT	27.4	9.7
12th	PE	25.6	9.9
13th	No intervention	16.5	11

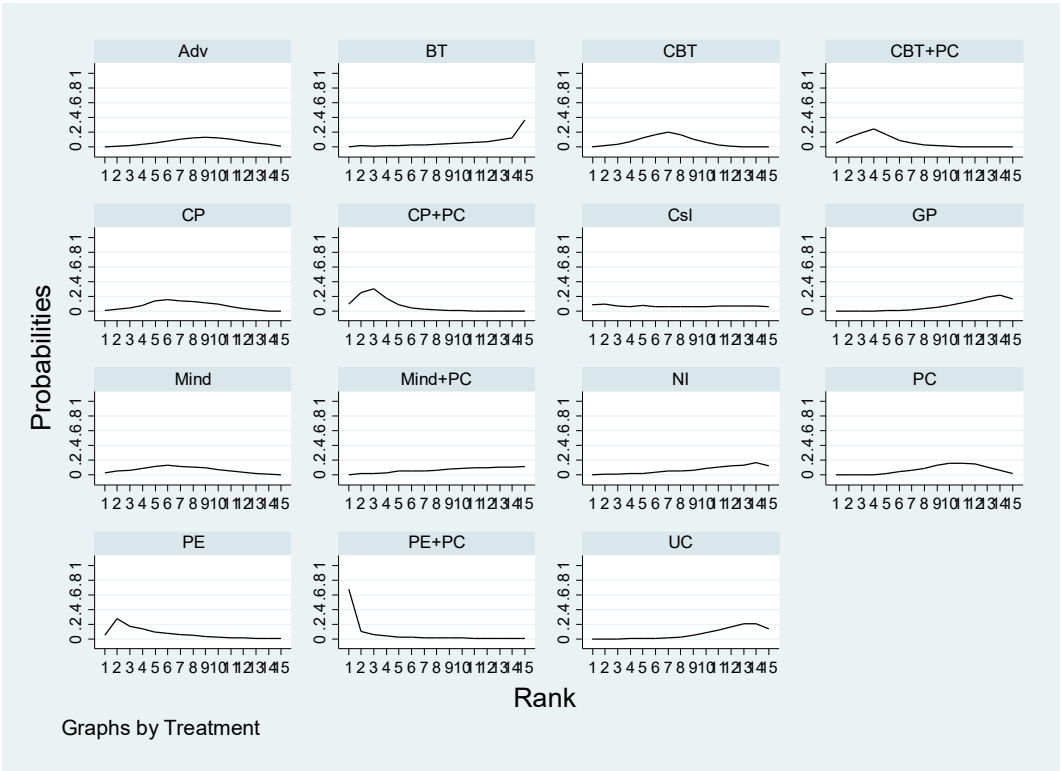
BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.3a Physical function at mid-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	PE+PC	90.7	2.3
2nd	CP+PC	83.9	3.3
3rd	CBT+PC	77.6	4.1
4th	PE	75.5	4.4
5th	Mindfulness	58.9	6.8
6th	CBT	58.3	6.8
7th	CP	56.3	7.1
8th	Csl	52.4	7.7
9th	Advice	44.8	8.7
10th	Mindfulness+PC	33.7	10.3
11th	Physiotherapy care	33.4	10.3
12th	No intervention	27.2	11.2
13th	BT	20.6	12.1
14th	Usual care	18.5	12.4
15th	General practitioner care	18.5	12.4

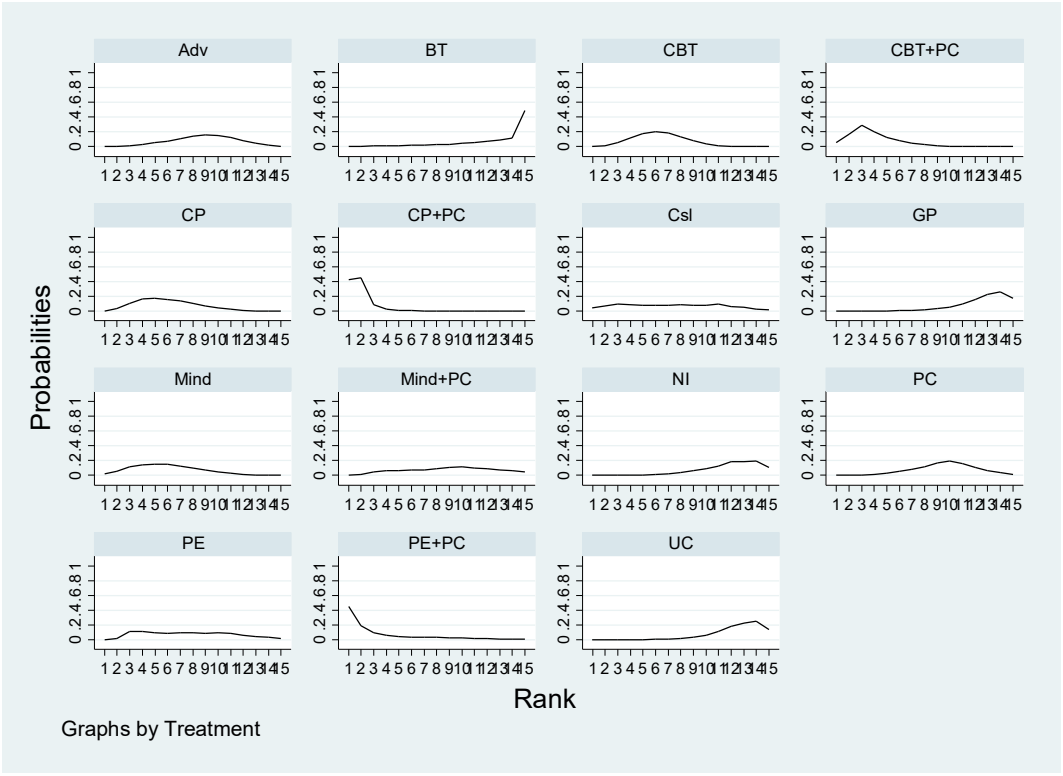
BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approach, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.3b Physical function at mid-term treatment sustainability, after removing inconsistency

Rank	Treatment Node	SUCRA	Mean Rank
1st	CP+PC	94.6	1.8
2nd	PE+PC	84.5	3.2
3rd	CBT+PC	79.5	3.9
4th	Mindfulness	65.1	5.9
5th	CP	64.8	5.9
6th	CBT	62.3	6.3
7th	Csl	55.1	7.3
8th	PE	52.1	7.7
9th	Advice	43.8	8.9
10th	Mindfulness+PC	42.7	9
11th	Physiotherapy care	38.1	9.7
12th	No intervention	20.8	12.1
13th	Usual care	16.2	12.7
14th	General practitioner care	15.3	12.9
15th	BT	15.1	12.9

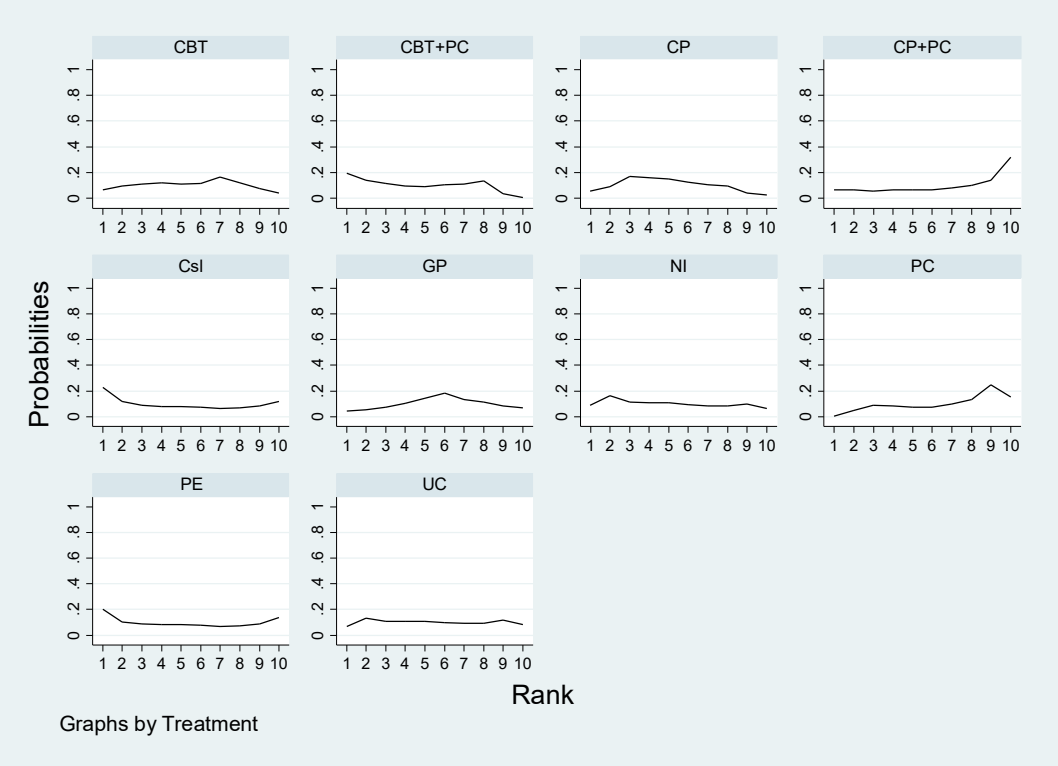
BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approach, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.4 Physical function at long-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	CBT+PC	62.7	4.4
2nd	Csl	57.2	4.8
3rd	CP	56.2	4.9
4th	No intervention	55	5
5th	PE	53.9	5.1
6th	CBT	50.8	5.4
7th	Usual care	50.3	5.5
8th	General practitioner care	45.9	5.9
9th	Physiotherapy care	34.1	6.9
10th	CP+PC	33.8	7

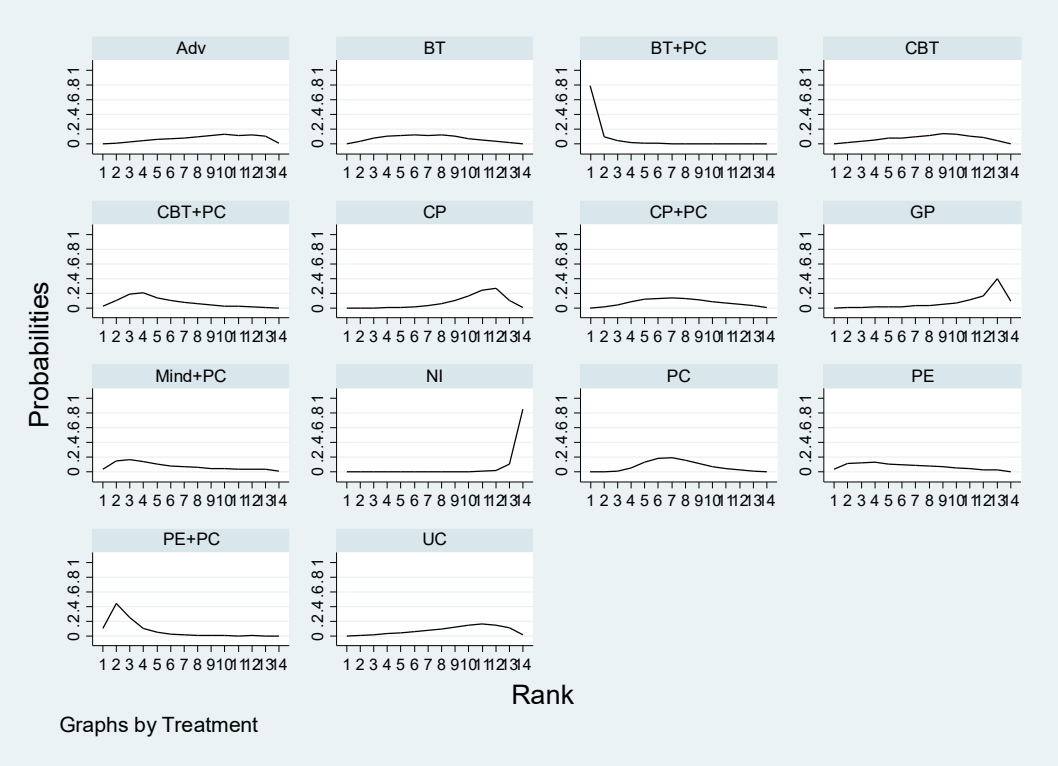
CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, PE: pain education.



Supplementary Table 13.5 Pain intensity at post-intervention

Rank	Treatment Node	SUCRA	Mean Rank
1st	BT+PC	91.2	2.4
2nd	CBT+PC	88.6	2.8
3rd	PE+PC	87.8	3
4th	Mindfulness+PC	65.3	6.6
5th	CBT	57.3	7.8
6th	PE	54.3	8.3
7th	Mindfulness	51.3	8.8
8th	CP	50.2	9
9th	CP+PC	50	9
10th	Csl+PC	49.8	9
11th	BT	44.9	9.8
12th	Advice	44.2	9.9
13th	Physiotherapy care	41	10.4
14th	Usual care	34.2	11.5
15th	General practitioner care	23.9	13.2
16th	No intervention	12.5	15
17th	Csl	3.4	16.4

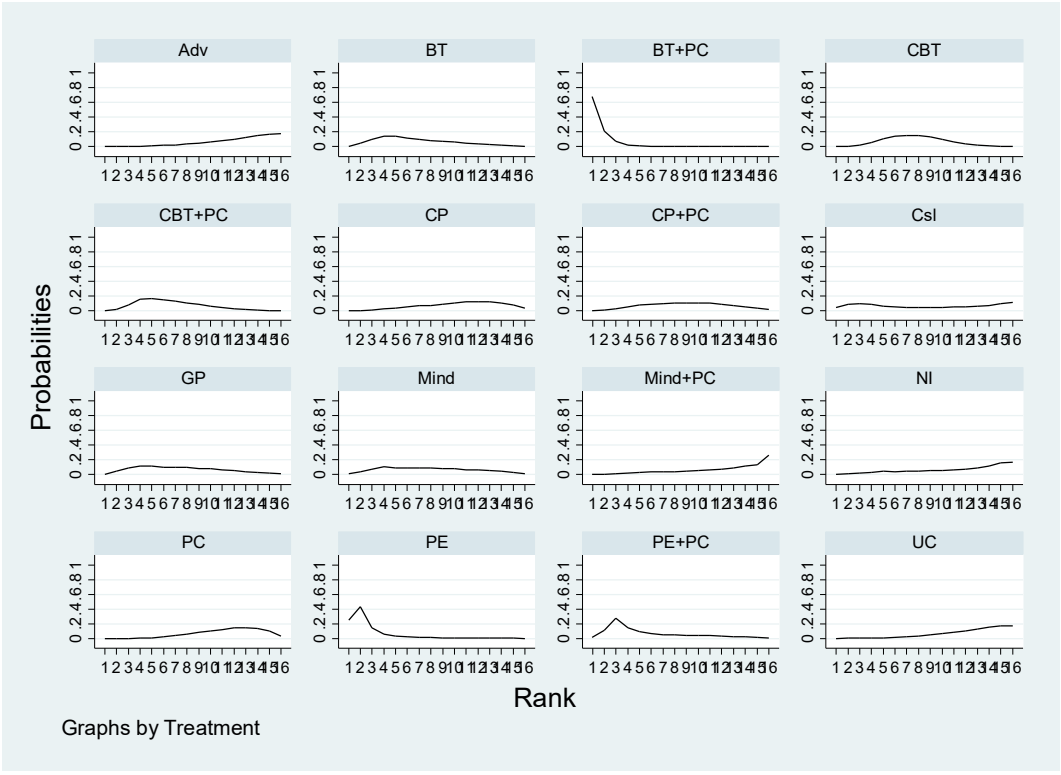
BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, Mindfulness+PC: Mindfulness delivered with physiotherapy care, NI: no intervention, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.6a Pain intensity at short-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	BT+PC	96.7	1.4
2nd	PE+PC	86.3	2.8
3rd	CBT+PC	69.6	4.9
4th	Mindfulness+PC	65.5	5.5
5th	PE	62.2	5.9
6th	BT	54.4	6.9
7th	Physiotherapy care	51.4	7.3
8th	CP+PC	49.9	7.5
9th	CBT	43.9	8.3
10th	Advice	38.7	9
11th	Usual care	34.4	9.5
12th	CP	26.4	10.6
13th	General practitioner care	18.9	11.5
14th	No intervention	1.6	13.8

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.

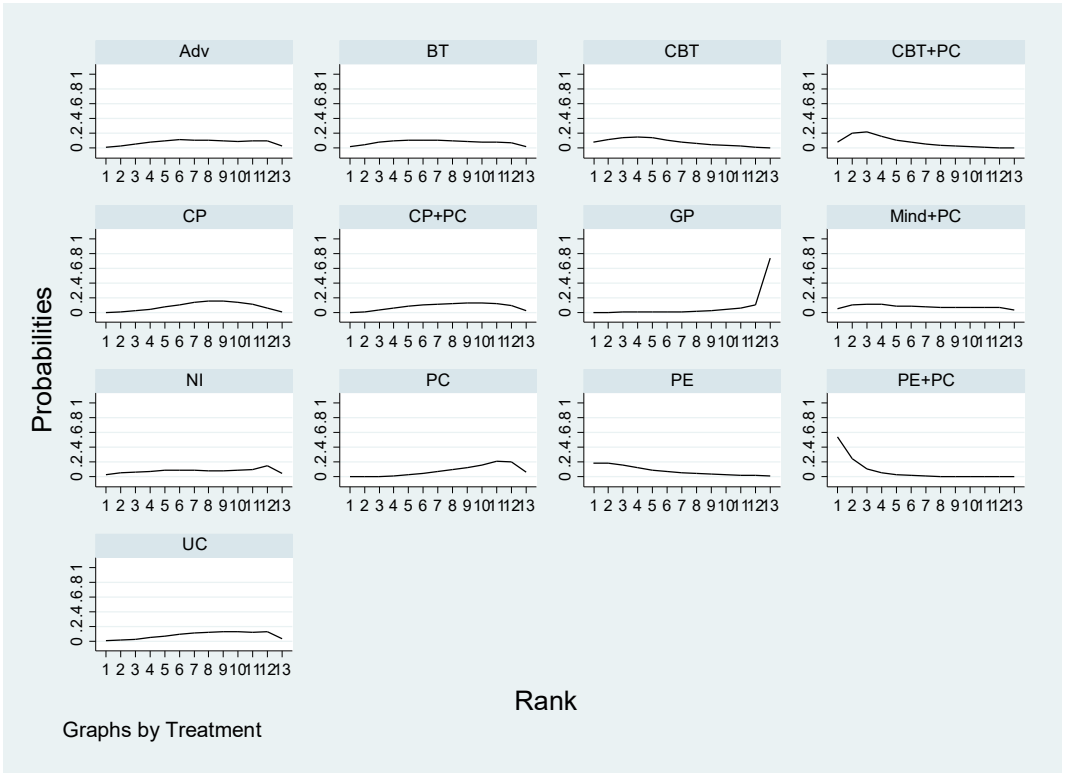


Supplementary Table 13.6b Pain intensity at short-term treatment sustainability, after removing inconsistency

Rank	Treatment Node	SUCRA	Mean Rank
1st	PE+PC	92.3	1.9
2nd	CBT+PC	74.6	4
3rd	PE	73.7	4.2
4th	CBT	67	5
5th	Mindfulness+PC	55.5	6.3
6th	BT	49.5	7.1
7th	Advice	44.9	7.6
8th	No intervention	43.5	7.8
9th	CP	40.5	8.1
10th	CP+PC	39.2	8.3
11th	Usual care	37.6	8.5
12th	Physiotherapy care	25.6	9.9
13th	General practitioner care	5.9	12.3

BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.

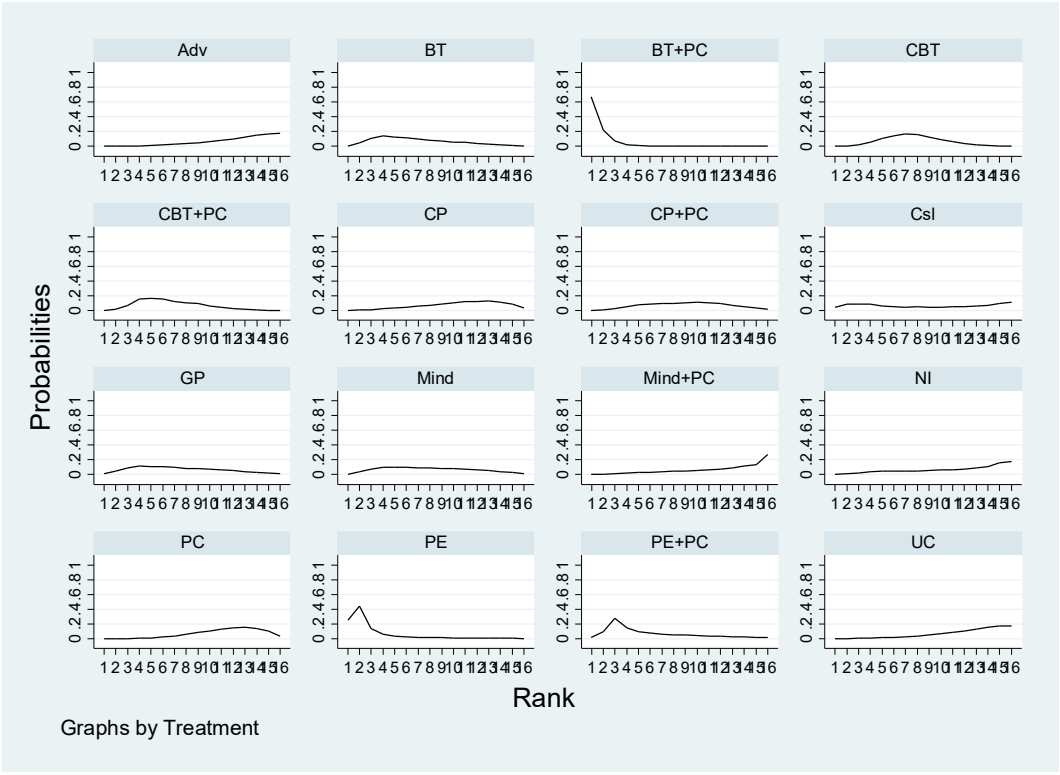
Note: Behavioural therapy delivered with physiotherapy care (BT+PC) became disconnected from the network in sensitivity analyses performed to remove inconsistency at short-term treatment sustainability, for pain intensity. No surface under the cumulative ranking (SUCRA) results are available for BT+PC at this time point.



Supplementary Table 13.7 Pain intensity at mid-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	BT+PC	96.6	1.5
2nd	PE	89	2.6
3rd	PE+PC	68.9	5.7
4th	CBT+PC	63	6.6
5th	BT	61.8	6.7
6th	General practitioner care	57.6	7.4
7th	CBT	55	7.7
8th	Mindfulness	54.2	7.9
9th	Csl	48.4	8.7
10th	CP+PC	46.6	9
11th	CP	34.5	10.8
12th	No intervention	29.3	11.6
13th	Physiotherapy care	28.9	11.7
14th	Mindfulness+PC	23.5	12.5
15th	Advice	21.6	12.8
16th	Usual care	21.3	12.8

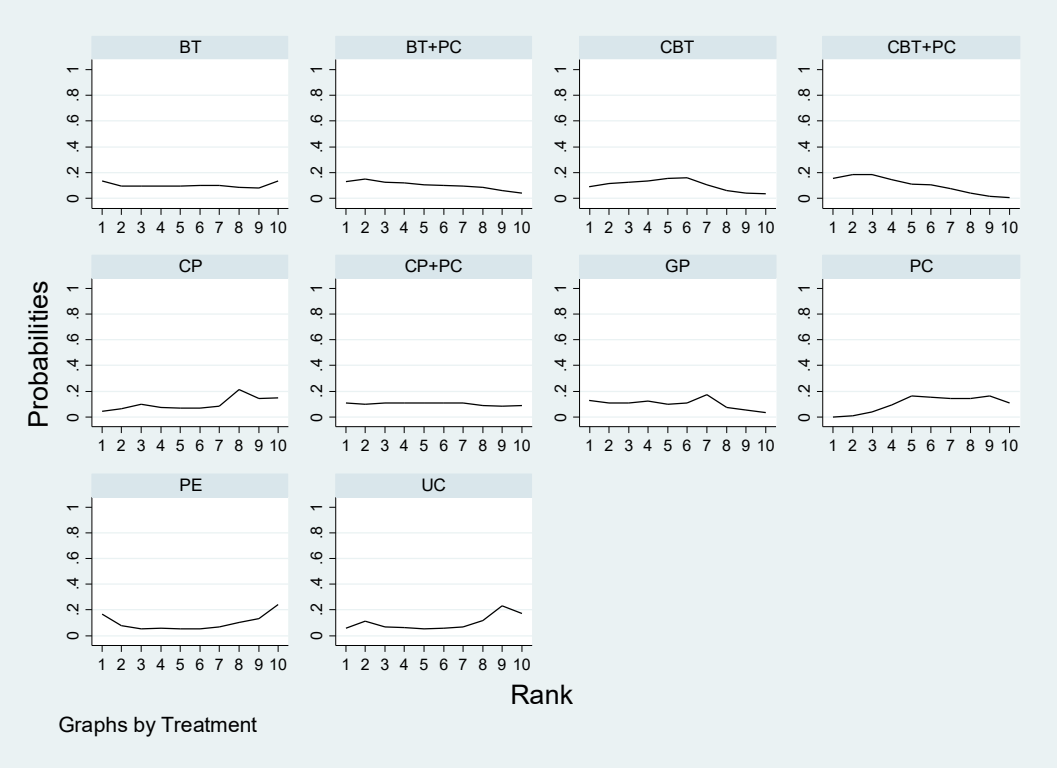
BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Mindfulness+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.



Supplementary Table 13.8 Pain intensity at long-term treatment sustainability

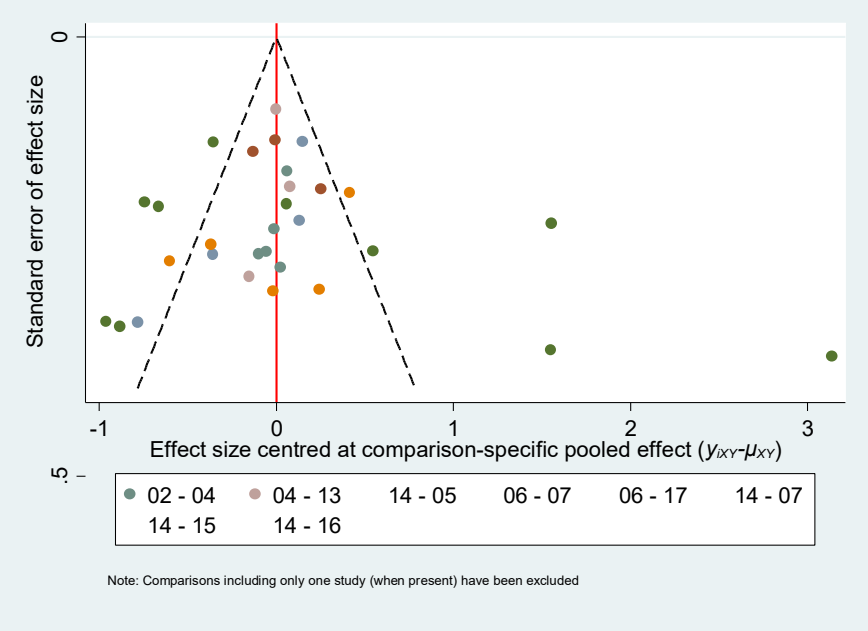
Rank	Treatment Node	SUCRA	Mean Rank
1st	CBT+PC	69.2	3.8
2nd	BT+PC	59	4.7
3rd	CBT	57.8	4.8
4th	General practitioner care	57.3	4.8
5th	CP+PC	51.7	5.3
6th	BT	50.4	5.5
7th	PE	42.6	6.2
8th	CP	39	6.5
9th	Usual care	38.6	6.5
10th	Physiotherapy care	34.4	6.9

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, PE: pain education.



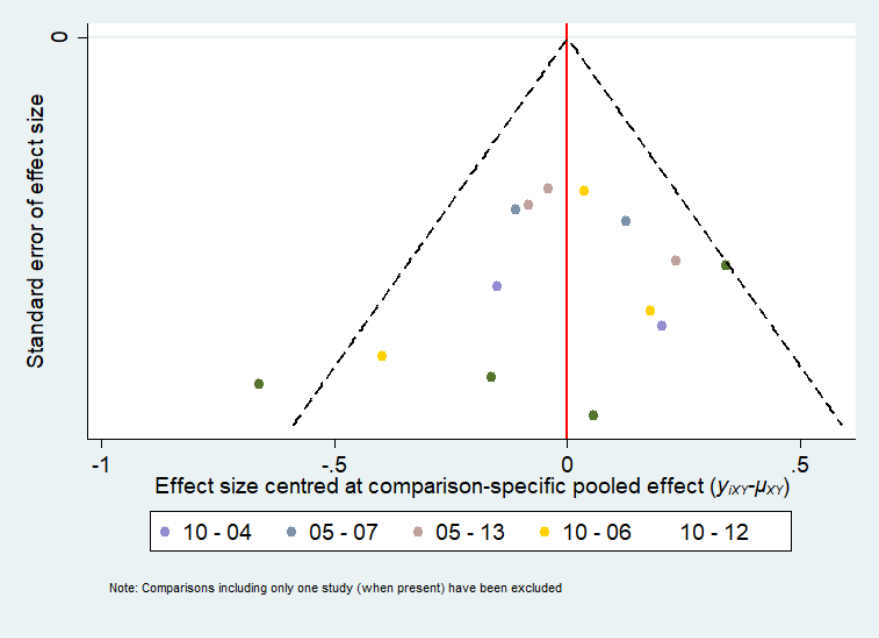
Supplementary M. Comparison-adjusted funnel plot for physical function and pain intensity

Supplementary Figure 7. Physical function at post-intervention



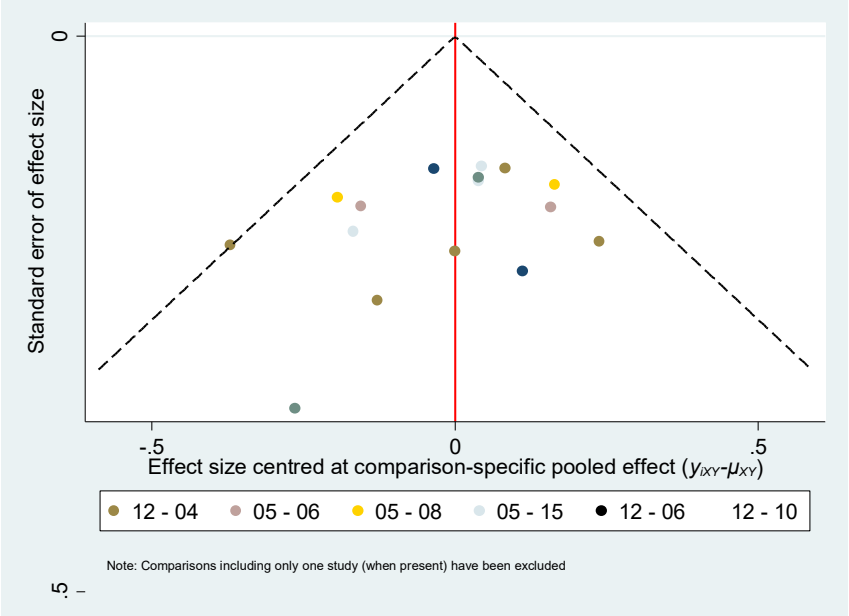
01: advice, 02: behavioural therapy, 03: behavioural therapy delivered with physiotherapy care, 04: cognitive behavioural therapy, 05: cognitive behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches, 07: combined psychological approaches delivered with physiotherapy care, 08: counselling, 09: counselling delivered with physiotherapy care, 10: general practitioner care, 11: mindfulness, 12: mindfulness delivered with physiotherapy care, 13: no intervention, 14: physiotherapy care, 15: pain education, 16: pain education delivered with physiotherapy care, 17: usual care.

Supplementary Figure 8. Physical function at short-term treatment sustainability



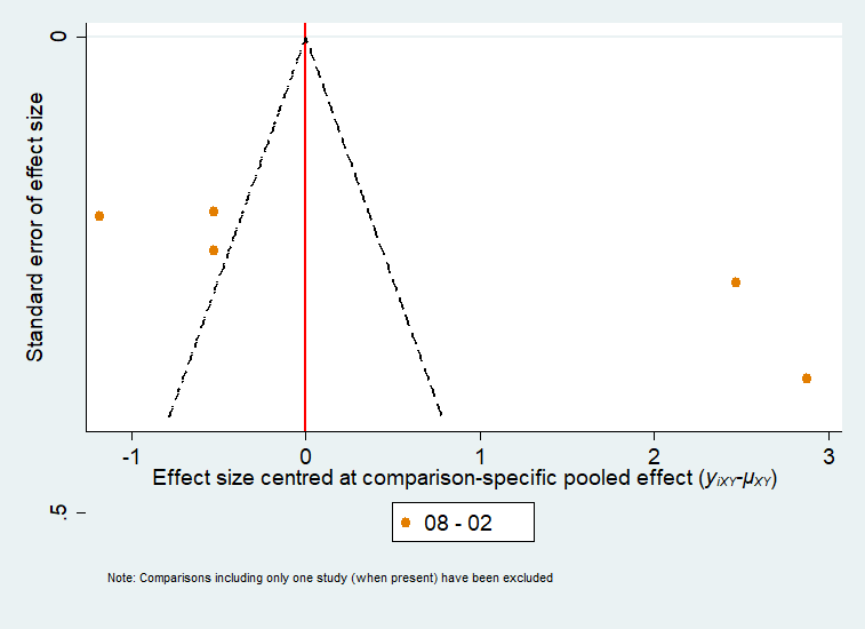
01: advice, 02: behavioural therapy, 03: cognitive behavioural therapy, 04: cognitive behavioural therapy delivered with physiotherapy care, 05: combined psychological approaches, 06: combined psychological approaches delivered with physiotherapy care, 07: general practitioner care, 08: mindfulness delivered with physiotherapy care, 09: no intervention, 10: physiotherapy care, 11: pain education, 12: pain education delivered with physiotherapy care, 13: usual care.

Supplementary Figure 9. Physical function at mid-term treatment sustainability



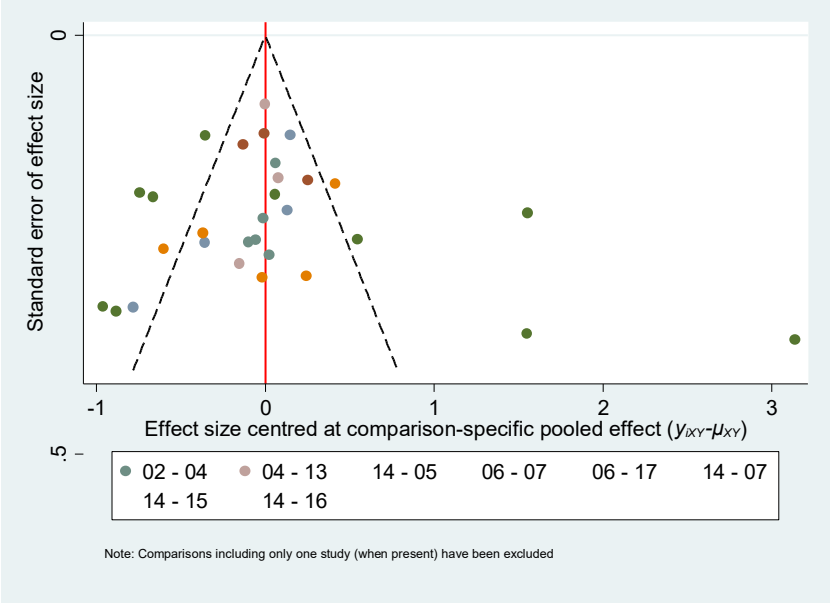
01: advice, 02: behavioural therapy, 03: cognitive behavioural therapy, 04: cognitive behavioural therapy delivered with physiotherapy care, 05: combined psychological approaches, 06: combined psychological approaches delivered with physiotherapy care, 07: counselling, 08: general practitioner care, 09: mindfulness, 10: mindfulness delivered with physiotherapy care, 11: no intervention, 12: physiotherapy care, 13: pain education, 14: pain education delivered with physiotherapy care, 15: usual care.

Supplementary Figure 10. Physical function at long-term treatment sustainability



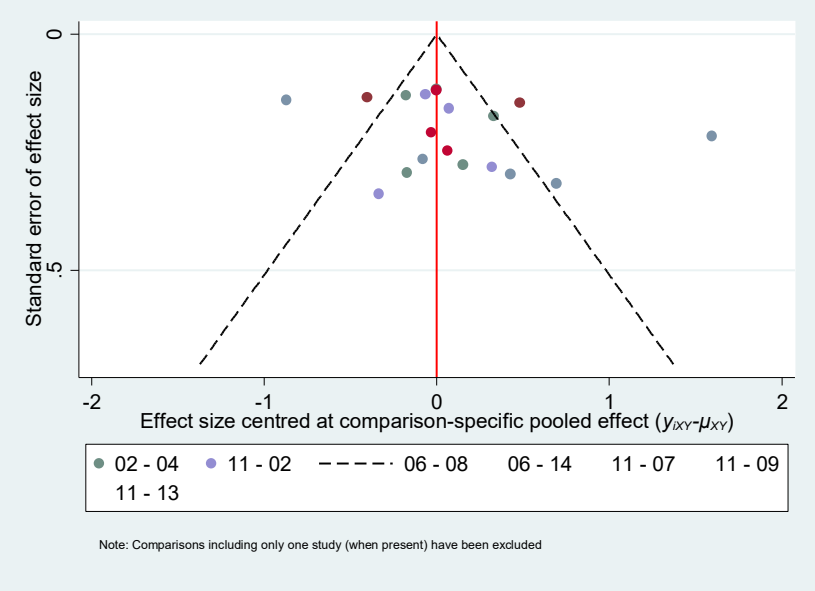
01: cognitive behavioural therapy, 02: cognitive behavioural therapy delivered with physiotherapy care, 03: combined psychological approaches, 04: combined psychological approaches delivered with physiotherapy care, 05: counselling, 06: general practitioner care, 07: no intervention, 08: physiotherapy care, 09: pain education, 10: usual care.

Supplementary Figure 11. Pain intensity at post-intervention



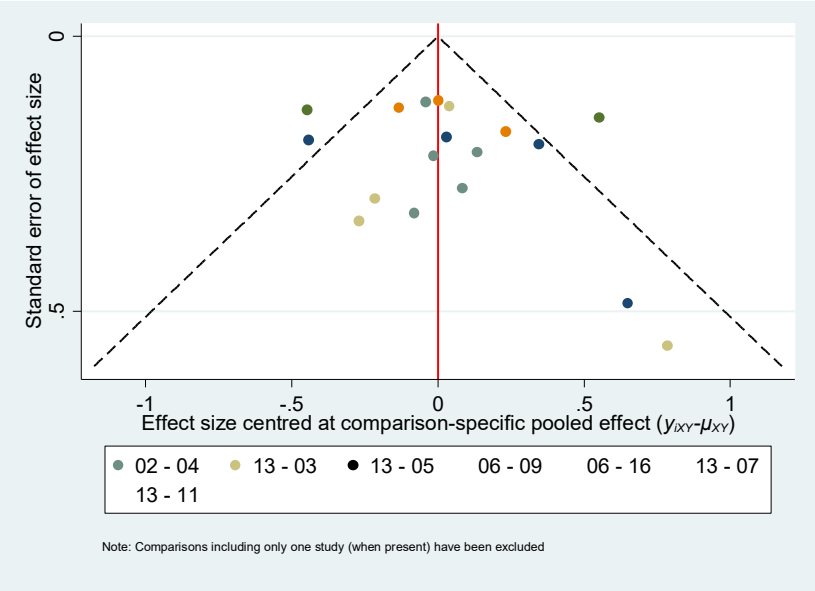
01: advice, 02: behavioural therapy, 03: behavioural therapy delivered with physiotherapy care, 04: cognitive behavioural therapy, 05: cognitive behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches, 07: combined psychological approaches delivered with physiotherapy care, 08: counselling, 09: counselling delivered with physiotherapy care, 10: general practitioner care, 11: mindfulness, 12: mindfulness delivered with physiotherapy care, 13: no intervention, 14: physiotherapy care, 15: pain education, 16: pain education delivered with physiotherapy care, 17: usual care.

Supplementary Figure 12. Pain intensity at short-term treatment sustainability



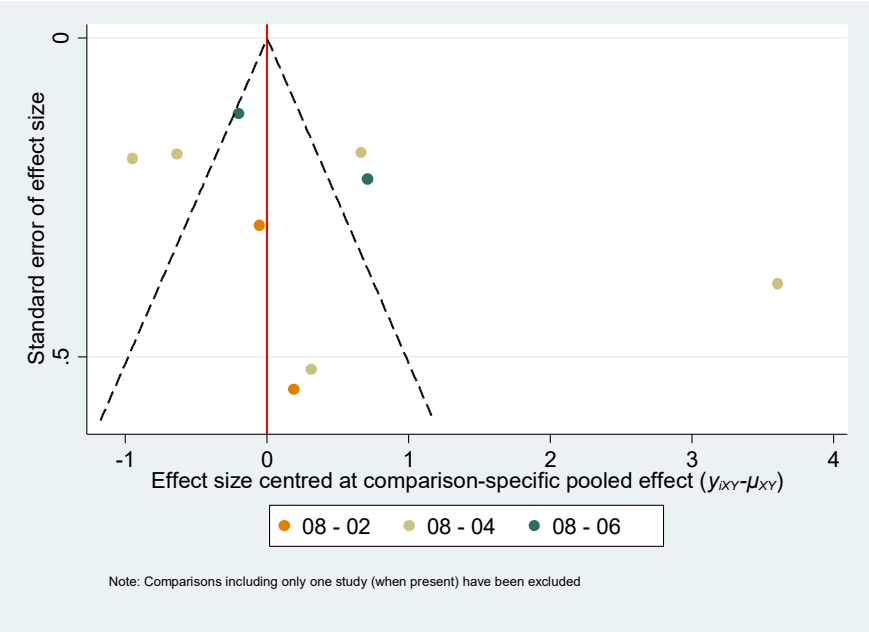
01: advice, 02: behavioural therapy, 03: behavioural therapy delivered with physiotherapy care, 04: cognitive behavioural therapy, 05: cognitive behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches, 07: combined psychological approaches delivered with physiotherapy care, 08: general practitioner care, 09: mindfulness delivered with physiotherapy care, 10: no intervention, 11: physiotherapy care, 12: pain education, 13: pain education delivered with physiotherapy care, 14: usual care.

Supplementary Figure 13. Pain intensity at mid-term treatment sustainability



01: advice, 02: behavioural therapy, 03: behavioural therapy delivered with physiotherapy care, 04: cognitive behavioural therapy, 05: cognitive behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches, 07: combined psychological approaches delivered with physiotherapy care, 08: counselling, 09: general practitioner care, 10: mindfulness, 11: mindfulness delivered with physiotherapy care, 12: no intervention, 13: physiotherapy care, 14: pain education, 15: pain education delivered with physiotherapy care, 16: usual care.

Supplementary Figure 14. Pain intensity at long-term treatment sustainability



01: behavioural therapy, 02: behavioural therapy delivered with physiotherapy care, 03: cognitive behavioural therapy, 04: cognitive behavioural therapy delivered with physiotherapy care, 05: combined psychological approaches, 06: combined psychological approaches delivered with physiotherapy care, 07: general practitioner care, 08: physiotherapy care, 09: pain education, 10: usual care.

Supplementary N. Sensitivity analyses for physical function and pain intensity

Supplementary Table 14.1 Physical function at post-intervention, excluding studies with high risk of bias

PC (reference)	**1.26 (0.72,1.81)**	-0.03 (-0.74,0.67)			**0.78 (0.14,1.42)**		-0.17 (-1.57,1.23)	0.13 (-1.28,1.54)			0.20 (-0.85,1.24)			-0.18 (-1.57,1.22)	0.26 (-1.26,1.77)	0.16 (-1.21,1.52)
1.09 (0.62,1.57)	CBT+PC	-0.68 (-2.08,0.71)		-0.04 (-1.46,1.38)	-0.39 (-1.84,1.05)			0.12 (-1.25,1.48)								
0.23 (-0.31,0.77)	**-0.87 (-1.52,-0.22)**	CP+PC	-0.03 (-0.85,0.79)							-0.14 (-1.62,1.33)	-0.38 (-1.76,0.99)					
0.37 (-0.31,1.05)	-0.72 (-1.49,0.04)	0.14 (-0.49,0.78)	CP	-0.74 (-2.30,0.81)			-0.21 (-1.01,0.60)				-0.36 (-1.78,1.06)	-0.14 (-1.58,1.30)				
0.32 (-0.56,1.20)	-0.77 (-1.65,0.11)	0.09 (-0.84,1.03)	-0.05 (-0.94,0.84)	No intervention				0.16 (-0.83,1.14)								
0.63 (0.07,1.20)	-0.46 (-1.15,0.22)	0.40 (-0.37,1.18)	0.26 (-0.61,1.14)	0.31 (-0.72,1.34)	PE+PC											1.06 (-0.33,2.44)
0.39 (-0.73,1.50)	-0.71 (-1.86,0.45)	0.16 (-0.99,1.31)	0.02 (-1.09,1.13)	0.07 (-1.15,1.28)	-0.25 (-1.49,0.99)	Mindfulness	-0.37 (-1.76,1.02)	-0.01 (-1.40,1.38)	-0.30 (-1.68,1.09)							
0.08 (-0.70,0.85)	**-1.02 (-1.87,-0.17)**	-0.15 (-0.96,0.65)	-0.29 (-0.95,0.36)	-0.24 (-1.22,0.73)	-0.56 (-1.51,0.40)	-0.31 (-1.38,0.75)	Usual care	0.36 (-1.03,1.75)					-0.20 (-1.56,1.16)	-0.01 (-1.41,1.39)		
0.41 (-0.32,1.14)	-0.68 (-1.45,0.09)	0.18 (-0.62,0.99)	0.04 (-0.73,0.81)	0.09 (-0.68,0.87)	-0.22 (-1.13,0.69)	0.02 (-0.99,1.04)	0.34 (-0.46,1.13)	CBT	-0.04 (-1.43,1.34)			-0.06 (-1.45,1.33)		-0.33 (-1.76,1.10)		
0.03 (-0.91,0.98)	**-1.06 (-2.06,-0.06)**	-0.19 (-1.19,0.80)	-0.34 (-1.32,0.64)	-0.29 (-1.37,0.80)	-0.60 (-1.69,0.49)	-0.35 (-1.37,0.66)	-0.04 (-1.03,0.95)	-0.38 (-1.24,0.48)	Advice		0.55 (-0.91,2.00)			0.00 (-1.61,1.61)		
0.09 (-1.49,1.66)	-1.01 (-2.62,0.61)	-0.14 (-1.62,1.33)	-0.28 (-1.89,1.32)	-0.23 (-1.98,1.51)	-0.55 (-2.21,1.12)	-0.30 (-2.17,1.57)	0.01 (-1.67,1.69)	-0.32 (-2.01,1.36)	0.05 (-1.73,1.83)	BT+PC						
0.16 (-0.51,0.84)	**-0.93 (-1.72,-0.15)**	-0.07 (-0.80,0.66)	-0.21 (-0.99,0.57)	-0.16 (-1.17,0.85)	-0.47 (-1.35,0.40)	-0.23 (-1.40,0.95)	0.09 (-0.81,0.98)	-0.25 (-1.12,0.62)	0.13 (-0.83,1.09)	0.08 (-1.57,1.72)	PE				0.04 (-1.36,1.44)	
0.29 (-0.86,1.44)	-0.80 (-1.99,0.38)	0.06 (-1.10,1.22)	-0.08 (-1.14,0.98)	-0.03 (-1.26,1.20)	-0.34 (-1.61,0.93)	-0.10 (-1.49,1.30)	0.22 (-0.95,1.38)	-0.12 (-1.17,0.93)	0.26 (-1.03,1.55)	0.20 (-1.67,2.08)	0.13 (-1.10,1.36)	GP care				
-0.12 (-1.69,1.44)	-1.22 (-2.82,0.38)	-0.35 (-1.93,1.22)	-0.50 (-2.00,1.01)	-0.45 (-2.12,1.22)	-0.76 (-2.42,0.90)	-0.51 (-2.24,1.21)	-0.20 (-1.56,1.16)	-0.54 (-2.11,1.04)	-0.16 (-1.84,1.52)	-0.21 (-2.37,1.95)	-0.29 (-1.91,1.34)	-0.42 (-2.21,1.37)	Csl			
0.01 (-0.92,0.95)	**-1.08 (-2.08,-0.09)**	-0.22 (-1.22,0.79)	-0.36 (-1.34,0.63)	-0.31 (-1.41,0.79)	-0.62 (-1.71,0.46)	-0.38 (-1.58,0.83)	-0.06 (-1.03,0.90)	-0.40 (-1.29,0.49)	-0.02 (-1.02,0.98)	-0.08 (-1.86,1.71)	-0.15 (-1.20,0.89)	-0.28 (-1.58,1.02)	0.14 (-1.53,1.80)	BT		
0.23 (-0.85,1.30)	-0.87 (-2.03,0.29)	-0.00 (-1.16,1.15)	-0.14 (-1.35,1.06)	-0.09 (-1.44,1.25)	-0.41 (-1.62,0.80)	-0.16 (-1.65,1.33)	0.15 (-1.12,1.42)	-0.19 (-1.44,1.06)	0.19 (-1.15,1.54)	0.14 (-1.73,2.01)	0.06 (-0.99,1.12)	-0.07 (-1.59,1.46)	0.35 (-1.51,2.21)	0.21 (-1.16,1.59)	Mind+PC	
0.91 (-0.12,1.95)	-0.18 (-1.30,0.94)	0.69 (-0.48,1.85)	0.54 (-0.69,1.78)	0.59 (-0.76,1.95)	0.28 (-0.76,1.32)	0.53 (-0.99,2.04)	0.84 (-0.45,2.13)	0.50 (-0.76,1.77)	0.88 (-0.52,2.28)	0.83 (-1.05,2.71)	0.75 (-0.48,1.99)	0.62 (-0.92,2.17)	1.04 (-0.84,2.92)	0.90 (-0.49,2.30)	0.69 (-0.80,2.18)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.2 Physical function at post-intervention, only including studies using intention-to-treatment analysis

PC (reference)			**0.87 (0.07,1.66)**	0.13 (-1.20,1.45)		-0.17 (-1.48,1.14)		**1.47 (0.91,2.03)**	0.14 (-0.62,0.90)		0.92 (-0.43,2.27)		-0.18 (-1.49,1.13)	0.26 (-1.19,1.71)	
0.58 (-0.10,1.25)	CP	-0.74 (-2.23,0.74)				-0.21 (-0.97,0.55)			0.03 (-0.75,0.81)		-0.36 (-1.70,0.99)	-0.14 (-1.51,1.23)			
0.48 (-0.32,1.28)	-0.10 (-0.90,0.71)	No intervention		0.21 (-0.56,0.99)				0.04 (-1.30,1.38)					-0.02 (-1.43,1.38)		
0.87 (0.19,1.56)	0.30 (-0.64,1.24)	0.39 (-0.63,1.42)	PE+PC					0.39 (-0.98,1.77)							
0.65 (-0.07,1.36)	0.07 (-0.67,0.81)	0.17 (-0.48,0.81)	-0.23 (-1.19,0.74)	CBT	0.01 (-1.31,1.33)	-0.36 (-1.68,0.96)	-0.04 (-1.37,1.28)	-0.12 (-1.41,1.17)				-0.06 (-1.38,1.25)	-0.35 (-1.32,0.62)		
0.72 (-0.43,1.86)	0.14 (-0.98,1.27)	0.24 (-0.91,1.38)	-0.16 (-1.47,1.16)	0.07 (-0.92,1.06)	Mindfulness	-0.37 (-1.69,0.95)	-0.30 (-1.61,1.02)								
0.28 (-0.48,1.03)	-0.30 (-0.92,0.33)	-0.20 (-1.06,0.66)	-0.60 (-1.60,0.41)	-0.37 (-1.12,0.38)	-0.44 (-1.50,0.62)	Usual care							-0.01 (-1.33,1.32)		
0.51 (-0.71,1.74)	-0.06 (-1.29,1.16)	0.03 (-1.17,1.24)	-0.36 (-1.75,1.02)	-0.14 (-1.17,0.90)	-0.21 (-1.24,0.83)	0.23 (-0.96,1.43)	Advice								
1.29 (0.82,1.77)	0.72 (-0.02,1.46)	**0.81 (0.01,1.62)**	0.42 (-0.34,1.18)	0.65 (-0.10,1.39)	0.58 (-0.60,1.75)	**1.02 (0.20,1.84)**	0.78 (-0.46,2.03)	CBT+PC	-0.68 (-2.01,0.64)						
0.45 (-0.11,1.01)	-0.12 (-0.73,0.49)	-0.03 (-0.89,0.83)	-0.42 (-1.29,0.45)	-0.20 (-0.99,0.60)	-0.27 (-1.45,0.91)	0.17 (-0.60,0.95)	-0.06 (-1.33,1.20)	**-0.84 (-1.50,-0.19)**	CP+PC	-0.14 (-1.55,1.26)	-0.38 (-1.69,0.92)				
0.31 (-1.21,1.82)	-0.27 (-1.80,1.27)	-0.17 (-1.82,1.48)	-0.57 (-2.22,1.09)	-0.34 (-1.95,1.28)	-0.41 (-2.25,1.43)	0.03 (-1.58,1.64)	-0.20 (-2.09,1.69)	-0.99 (-2.54,0.57)	-0.14 (-1.55,1.26)	BT+PC					
0.37 (-0.41,1.14)	-0.21 (-1.03,0.61)	-0.11 (-1.14,0.91)	-0.51 (-1.53,0.52)	-0.28 (-1.25,0.68)	-0.35 (-1.66,0.95)	0.09 (-0.86,1.04)	-0.15 (-1.53,1.23)	**-0.93 (-1.80,-0.06)**	-0.09 (-0.87,0.70)	0.06 (-1.55,1.67)	PE			0.04 (-1.29,1.36)	
0.51 (-0.59,1.61)	-0.06 (-1.07,0.94)	0.03 (-1.09,1.15)	-0.36 (-1.64,0.92)	-0.13 (-1.13,0.86)	-0.20 (-1.56,1.15)	0.24 (-0.86,1.33)	0.00 (-1.41,1.42)	-0.78 (-1.91,0.35)	0.06 (-1.05,1.17)	0.20 (-1.59,2.00)	0.15 (-1.09,1.39)	GP care			
0.23 (-0.63,1.09)	-0.34 (-1.25,0.56)	-0.25 (-1.11,0.62)	-0.64 (-1.73,0.44)	-0.42 (-1.17,0.34)	-0.49 (-1.68,0.71)	-0.05 (-0.93,0.84)	-0.28 (-1.54,0.98)	**-1.06 (-1.97,-0.15)**	-0.22 (-1.16,0.72)	-0.08 (-1.77,1.61)	-0.13 (-1.22,0.95)	-0.28 (-1.47,0.91)	BT		
0.34 (-0.71,1.39)	-0.24 (-1.40,0.92)	-0.14 (-1.42,1.13)	-0.54 (-1.79,0.71)	-0.31 (-1.54,0.92)	-0.38 (-1.89,1.13)	0.06 (-1.17,1.29)	-0.17 (-1.75,1.40)	-0.96 (-2.09,0.18)	-0.11 (-1.23,1.00)	0.03 (-1.77,1.82)	-0.03 (-1.05,0.99)	-0.18 (-1.65,1.29)	0.11 (-1.22,1.43)	Mind+PC	
0.16 (-1.17,1.49)	-0.42 (-1.91,1.07)	-0.32 (-1.87,1.23)	-0.72 (-2.21,0.78)	-0.49 (-2.00,1.02)	-0.56 (-2.32,1.19)	-0.12 (-1.65,1.41)	-0.36 (-2.16,1.45)	-1.14 (-2.55,0.27)	-0.29 (-1.74,1.15)	-0.15 (-2.17,1.86)	-0.21 (-1.75,1.33)	-0.36 (-2.08,1.37)	-0.07 (-1.66,1.51)	-0.18 (-1.87,1.51)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.3 Physical function at post-intervention, excluding studies published prior to year 1995

PC (reference)																
1.09 (0.63,1.55)	CBT+PC															
0.23 (-0.31,0.76)	**-0.86 (-1.50,-0.22)**	CP+PC														
0.37 (-0.31,1.04)	-0.72 (-1.47,0.03)	0.14 (-0.49,0.76)	CP													
0.26 (-0.54,1.07)	**-0.82 (-1.64,-0.01)**	0.04 (-0.83,0.90)	-0.10 (-0.93,0.72)	No intervention												
0.63 (0.08,1.19)	-0.46 (-1.13,0.22)	0.40 (-0.36,1.17)	0.27 (-0.60,1.13)	0.37 (-0.59,1.33)	PE+PC											
0.40 (-0.71,1.50)	-0.69 (-1.84,0.46)	0.17 (-0.97,1.31)	0.03 (-1.07,1.13)	0.13 (-1.02,1.29)	-0.24 (-1.47,1.00)	Mindfulness										
0.08 (-0.68,0.85)	-1.01 (-1.84,-0.17)	-0.15 (-0.94,0.64)	-0.28 (-0.93,0.36)	-0.18 (-1.07,0.71)	-0.55 (-1.49,0.39)	-0.32 (-1.38,0.75)	Usual care									
0.42 (-0.28,1.13)	-0.67 (-1.41,0.08)	0.19 (-0.59,0.97)	0.05 (-0.69,0.80)	0.16 (-0.51,0.82)	-0.21 (-1.10,0.67)	0.02 (-0.99,1.03)	0.34 (-0.43,1.11)	CBT								
0.05 (-0.96,1.06)	-1.04 (-2.10,0.02)	-0.18 (-1.23,0.87)	-0.32 (-1.36,0.72)	-0.22 (-1.30,0.87)	-0.59 (-1.73,0.56)	-0.35 (-1.37,0.67)	-0.03 (-1.09,1.02)	-0.37 (-1.30,0.55)	Advice							
0.09 (-1.47,1.64)	-1.00 (-2.59,0.59)	-0.14 (-1.60,1.31)	-0.28 (-1.87,1.30)	-0.18 (-1.87,1.52)	-0.55 (-2.19,1.10)	-0.31 (-2.16,1.54)	0.00 (-1.65,1.66)	-0.33 (-1.99,1.32)	0.04 (-1.76,1.83)	BT+PC						
0.16 (-0.51,0.83)	**-0.92 (-1.70,-0.15)**	-0.06 (-0.78,0.66)	-0.20 (-0.97,0.57)	-0.10 (-1.05,0.84)	-0.47 (-1.33,0.39)	-0.23 (-1.39,0.92)	0.08 (-0.80,0.97)	-0.26 (-1.10,0.59)	0.12 (-0.88,1.11)	0.08 (-1.55,1.70)	PE					
0.29 (-0.83,1.42)	-0.79 (-1.96,0.37)	0.07 (-1.07,1.21)	-0.07 (-1.11,0.97)	0.03 (-1.13,1.19)	-0.34 (-1.59,0.91)	-0.10 (-1.49,1.28)	0.21 (-0.93,1.35)	-0.13 (-1.16,0.90)	0.25 (-1.08,1.57)	0.21 (-1.64,2.06)	0.13 (-1.08,1.34)	GP care				
-0.12 (-1.66,1.42)	-1.21 (-2.78,0.37)	-0.35 (-1.90,1.20)	-0.49 (-1.97,1.00)	-0.38 (-1.99,1.22)	-0.75 (-2.38,0.88)	-0.52 (-2.22,1.19)	-0.20 (-1.54,1.13)	-0.54 (-2.08,1.00)	-0.17 (-1.87,1.54)	-0.21 (-2.33,1.92)	-0.28 (-1.89,1.32)	-0.41 (-2.17,1.34)	Csl			
0.06 (-0.82,0.94)	**-1.03 (-1.96,-0.10)**	-0.17 (-1.12,0.78)	-0.31 (-1.24,0.62)	-0.21 (-1.11,0.69)	-0.58 (-1.61,0.45)	-0.34 (-1.55,0.87)	-0.03 (-0.94,0.89)	-0.36 (-1.15,0.42)	0.01 (-1.14,1.16)	-0.03 (-1.77,1.71)	-0.11 (-1.13,0.91)	-0.24 (-1.47,1.00)	0.18 (-1.44,1.80)	BT		
0.23 (-0.83,1.29)	-0.86 (-2.00,0.28)	-0.00 (-1.14,1.14)	-0.14 (-1.33,1.05)	-0.04 (-1.33,1.25)	-0.41 (-1.60,0.79)	-0.17 (-1.64,1.30)	0.15 (-1.11,1.40)	-0.19 (-1.42,1.03)	0.18 (-1.19,1.55)	0.14 (-1.71,1.99)	0.06 (-0.98,1.10)	-0.07 (-1.57,1.43)	0.35 (-1.48,2.18)	0.17 (-1.17,1.51)	Mind+PC	
0.91 (-0.11,1.93)	-0.17 (-1.28,0.93)	0.69 (-0.46,1.84)	0.55 (-0.67,1.77)	0.65 (-0.64,1.94)	0.28 (-0.74,1.30)	0.52 (-0.99,2.02)	0.83 (-0.44,2.10)	0.49 (-0.74,1.73)	0.87 (-0.57,2.30)	0.83 (-1.03,2.68)	0.75 (-0.47,1.97)	0.62 (-0.90,2.14)	1.03 (-0.81,2.88)	0.86 (-0.49,2.20)	0.69 (-0.78,2.16)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.4 Physical function at post-intervention, excluding studies published prior to year 2000

PC (reference)	**1.26 (0.72,1.81)**	-0.14 (-0.96,0.67)			**0.78 (0.14,1.42)**	0.13 (-1.29,1.54)		-0.17 (-1.57,1.23)			0.20 (-0.85,1.24)			-0.18 (-1.57,1.22)	0.26 (-1.26,1.77)	0.16 (-1.21,1.53)
1.09 (0.62,1.56)	CBT+PC	-0.68 (-2.08,0.71)		-0.04 (-1.46,1.38)	-0.39 (-1.84,1.05)	0.12 (-1.26,1.49)										
0.22 (-0.37,0.81)	**-0.87 (-1.55,-0.19)**	CP+PC	-0.03 (-0.85,0.79)							-0.14 (-1.62,1.34)	-0.38 (-1.76,1.00)					
0.36 (-0.34,1.06)	-0.73 (-1.50,0.04)	0.14 (-0.50,0.79)	CP	-0.74 (-2.30,0.81)				-0.21 (-1.01,0.60)			-0.36 (-1.78,1.07)	-0.14 (-1.58,1.30)				
0.26 (-0.56,1.08)	-0.83 (-1.66,0.00)	0.04 (-0.85,0.94)	-0.10 (-0.94,0.74)	No intervention		0.21 (-0.60,1.03)								-0.02 (-1.50,1.46)		
0.63 (0.07,1.20)	-0.46 (-1.14,0.23)	0.42 (-0.39,1.22)	0.27 (-0.62,1.16)	0.37 (-0.61,1.35)	PE+PC											1.06 (-0.33,2.44)
0.42 (-0.30,1.14)	-0.67 (-1.43,0.09)	0.20 (-0.61,1.01)	0.06 (-0.70,0.82)	0.16 (-0.52,0.83)	-0.22 (-1.12,0.69)	CBT	0.01 (-1.39,1.40)	-0.36 (-1.75,1.03)	-0.04 (-1.43,1.34)			-0.06 (-1.45,1.33)		-0.35 (-1.37,0.67)		
0.39 (-0.74,1.52)	-0.69 (-1.86,0.47)	0.18 (-1.00,1.35)	0.03 (-1.09,1.16)	0.13 (-1.04,1.31)	-0.24 (-1.49,1.02)	-0.02 (-1.05,1.00)	Mindfulness	-0.37 (-1.76,1.03)	-0.30 (-1.68,1.09)							
0.08 (-0.71,0.86)	**-1.01 (-1.86,-0.16)**	-0.14 (-0.95,0.67)	-0.28 (-0.94,0.37)	-0.18 (-1.09,0.72)	-0.56 (-1.51,0.40)	-0.34 (-1.12,0.44)	-0.32 (-1.40,0.77)	Usual care					-0.20 (-1.56,1.16)	-0.01 (-1.41,1.40)		
0.04 (-0.99,1.07)	-1.04 (-2.12,0.03)	-0.17 (-1.25,0.91)	-0.32 (-1.38,0.74)	-0.22 (-1.32,0.88)	-0.59 (-1.75,0.58)	-0.37 (-1.32,0.57)	-0.35 (-1.39,0.69)	-0.03 (-1.11,1.04)	Advice		0.55 (-0.91,2.00)					
0.07 (-1.52,1.67)	-1.01 (-2.64,0.61)	-0.14 (-1.62,1.34)	-0.29 (-1.90,1.33)	-0.19 (-1.91,1.54)	-0.56 (-2.24,1.13)	-0.34 (-2.03,1.34)	-0.32 (-2.20,1.57)	-0.00 (-1.69,1.68)	0.03 (-1.80,1.86)	BT+PC						
0.16 (-0.53,0.84)	**-0.93 (-1.72,-0.14)**	-0.06 (-0.80,0.69)	-0.20 (-0.99,0.58)	-0.10 (-1.06,0.86)	-0.47 (-1.35,0.41)	-0.26 (-1.12,0.60)	-0.23 (-1.41,0.94)	0.08 (-0.82,0.98)	0.12 (-0.90,1.13)	0.08 (-1.57,1.74)	PE				0.04 (-1.36,1.44)	
0.29 (-0.86,1.44)	-0.80 (-1.98,0.39)	0.07 (-1.09,1.24)	-0.07 (-1.13,0.99)	0.03 (-1.16,1.21)	-0.34 (-1.62,0.93)	-0.13 (-1.18,0.92)	-0.10 (-1.51,1.30)	0.21 (-0.95,1.37)	0.25 (-1.10,1.60)	0.21 (-1.67,2.10)	0.13 (-1.10,1.36)	GP care				
-0.12 (-1.69,1.45)	-1.21 (-2.82,0.39)	-0.34 (-1.93,1.24)	-0.48 (-1.99,1.03)	-0.39 (-2.02,1.25)	-0.76 (-2.42,0.91)	-0.54 (-2.11,1.03)	-0.52 (-2.26,1.22)	-0.20 (-1.56,1.16)	-0.17 (-1.90,1.57)	-0.20 (-2.37,1.97)	-0.28 (-1.91,1.35)	-0.41 (-2.20,1.38)	Csl			
0.05 (-0.84,0.95)	**-1.03 (-1.98,-0.09)**	-0.16 (-1.14,0.82)	-0.31 (-1.25,0.64)	-0.21 (-1.12,0.70)	-0.58 (-1.63,0.47)	-0.36 (-1.16,0.43)	-0.34 (-1.57,0.89)	-0.02 (-0.96,0.91)	0.01 (-1.16,1.18)	-0.02 (-1.80,1.75)	-0.11 (-1.14,0.93)	-0.24 (-1.49,1.02)	0.18 (-1.47,1.83)	BT		
0.22 (-0.85,1.30)	-0.86 (-2.02,0.30)	0.01 (-1.16,1.18)	-0.14 (-1.35,1.07)	-0.04 (-1.35,1.27)	-0.41 (-1.62,0.81)	-0.19 (-1.44,1.05)	-0.17 (-1.66,1.33)	0.15 (-1.13,1.42)	0.18 (-1.21,1.58)	0.15 (-1.73,2.04)	0.07 (-0.99,1.12)	-0.06 (-1.59,1.46)	0.35 (-1.52,2.21)	0.17 (-1.19,1.53)	Mind+PC	
0.91 (-0.12,1.95)	-0.17 (-1.30,0.95)	0.70 (-0.49,1.89)	0.55 (-0.69,1.80)	0.65 (-0.66,1.97)	0.28 (-0.76,1.32)	0.50 (-0.76,1.76)	0.52 (-1.01,2.05)	0.84 (-0.46,2.13)	0.87 (-0.59,2.33)	0.84 (-1.06,2.74)	0.75 (-0.49,2.00)	0.62 (-0.92,2.17)	1.04 (-0.84,2.92)	0.86 (-0.51,2.23)	0.69 (-0.81,2.18)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.5 Physical function at post-intervention, excluding studies published prior to year 2005

PC (reference)																
1.10 (0.62,1.58)	CBT+PC															
0.21 (-0.38,0.81)	**-0.89 (-1.57,-0.20)**	CP+PC														
0.38 (-0.33,1.08)	-0.72 (-1.50,0.05)	0.17 (-0.48,0.81)	CP													
0.32 (-0.52,1.16)	-0.78 (-1.62,0.07)	0.11 (-0.80,1.02)	-0.06 (-0.91,0.80)	No intervention												
0.63 (0.07,1.20)	-0.47 (-1.16,0.23)	0.42 (-0.39,1.23)	0.26 (-0.64,1.15)	0.31 (-0.68,1.31)	PE+PC											
0.57 (-0.64,1.79)	-0.53 (-1.77,0.72)	0.36 (-0.90,1.62)	0.20 (-1.00,1.39)	0.25 (-0.97,1.47)	-0.06 (-1.39,1.27)	Mindfulness										
0.13 (-0.67,0.92)	**-0.97 (-1.84,-0.11)**	-0.09 (-0.92,0.74)	-0.25 (-0.92,0.41)	-0.20 (-1.11,0.72)	-0.51 (-1.48,0.46)	-0.45 (-1.58,0.69)	Usual care									
0.51 (-0.25,1.26)	-0.59 (-1.38,0.19)	0.29 (-0.55,1.14)	0.13 (-0.65,0.91)	0.19 (-0.50,0.87)	-0.13 (-1.06,0.80)	-0.07 (-1.12,0.99)	0.38 (-0.41,1.18)	CBT								
0.37 (-0.93,1.67)	-0.73 (-2.05,0.59)	0.16 (-1.19,1.51)	-0.01 (-1.31,1.29)	0.05 (-1.23,1.33)	-0.26 (-1.68,1.15)	-0.20 (-1.31,0.90)	0.24 (-1.03,1.52)	-0.14 (-1.24,0.97)	Advice							
0.07 (-1.53,1.67)	-1.03 (-2.67,0.61)	-0.14 (-1.63,1.34)	-0.31 (-1.93,1.31)	-0.25 (-1.99,1.49)	-0.56 (-2.26,1.13)	-0.50 (-2.45,1.45)	-0.05 (-1.76,1.65)	-0.44 (-2.15,1.27)	-0.30 (-2.31,1.71)	BT+PC						
0.07 (-0.65,0.79)	**-1.03 (-1.86,-0.20)**	-0.14 (-0.92,0.64)	-0.31 (-1.14,0.52)	-0.25 (-1.28,0.78)	-0.56 (-1.48,0.35)	-0.50 (-1.85,0.85)	-0.05 (-1.02,0.91)	-0.44 (-1.41,0.53)	-0.30 (-1.73,1.13)	0.00 (-1.68,1.68)	PE					
0.34 (-0.82,1.51)	-0.76 (-1.95,0.44)	0.13 (-1.05,1.32)	-0.03 (-1.10,1.04)	0.02 (-1.17,1.22)	-0.29 (-1.58,1.00)	-0.23 (-1.68,1.22)	0.22 (-0.95,1.39)	-0.16 (-1.22,0.90)	-0.03 (-1.53,1.48)	0.27 (-1.63,2.17)	0.27 (-1.01,1.56)	GP care				
-0.08 (-1.66,1.51)	-1.18 (-2.79,0.44)	-0.29 (-1.89,1.31)	-0.45 (-1.98,1.07)	-0.40 (-2.04,1.25)	-0.71 (-2.39,0.97)	-0.65 (-2.43,1.13)	-0.20 (-1.57,1.17)	-0.58 (-2.17,1.00)	-0.45 (-2.32,1.43)	-0.15 (-2.33,2.04)	-0.15 (-1.82,1.53)	-0.42 (-2.22,1.38)	Csl			
0.11 (-0.80,1.03)	**-0.99 (-1.95,-0.03)**	-0.10 (-1.10,0.90)	-0.26 (-1.22,0.69)	-0.21 (-1.13,0.71)	-0.52 (-1.59,0.54)	-0.46 (-1.73,0.81)	-0.01 (-0.95,0.93)	-0.39 (-1.20,0.41)	-0.26 (-1.60,1.08)	0.04 (-1.75,1.83)	0.04 (-1.06,1.14)	-0.23 (-1.50,1.03)	0.19 (-1.47,1.85)	BT		
0.18 (-0.91,1.27)	-0.92 (-2.10,0.25)	-0.04 (-1.22,1.15)	-0.20 (-1.43,1.03)	-0.14 (-1.49,1.20)	-0.46 (-1.68,0.77)	-0.40 (-2.00,1.21)	0.05 (-1.25,1.36)	-0.33 (-1.62,0.96)	-0.19 (-1.86,1.48)	0.11 (-1.79,2.01)	0.11 (-0.96,1.18)	-0.17 (-1.72,1.39)	0.25 (-1.64,2.14)	0.06 (-1.33,1.46)	Mind+PC	
0.92 (-0.13,1.96)	-0.18 (-1.32,0.95)	0.70 (-0.50,1.90)	0.54 (-0.72,1.79)	0.59 (-0.74,1.93)	0.28 (-0.76,1.33)	0.34 (-1.26,1.94)	0.79 (-0.52,2.10)	0.41 (-0.88,1.69)	0.55 (-1.12,2.21)	0.84 (-1.06,2.75)	0.84 (-0.42,2.11)	0.57 (-0.99,2.13)	0.99 (-0.90,2.89)	0.80 (-0.58,2.19)	0.74 (-0.77,2.25)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.6 Physical function at post-intervention, excluding studies of patients with leg pain

PC (reference)	**0.62 (0.21,1.04)**	-0.14 (-0.67,0.40)					-0.17 (-1.02,0.68)				0.24 (-0.43,0.91)			-0.18 (-1.02,0.67)		
0.56 (0.21,0.91)	CBT+PC	-0.68 (-1.51,0.15)		-0.04 (-0.94,0.86)												
0.05 (-0.33,0.44)	**-0.51 (-0.96,-0.05)**	CP+PC	0.02 (-0.63,0.67)							-0.14 (-1.12,0.84)	-0.38 (-1.16,0.40)					
0.21 (-0.27,0.70)	-0.35 (-0.89,0.20)	0.16 (-0.30,0.62)	CP	-0.74 (-1.84,0.35)			-0.21 (-0.69,0.27)				-0.36 (-1.23,0.52)	-0.14 (-1.06,0.78)				
-0.02 (-0.61,0.57)	-0.58 (-1.18,0.02)	-0.07 (-0.69,0.55)	-0.23 (-0.80,0.34)	No intervention				0.26 (-0.35,0.86)						-0.02 (-1.00,0.95)		
0.92 (0.47,1.37)	0.36 (-0.22,0.93)	**0.86 (0.27,1.46)**	**0.70 (0.04,1.37)**	**0.94 (0.19,1.68)**	PE+PC											
0.20 (-0.52,0.92)	-0.36 (-1.12,0.40)	0.15 (-0.59,0.89)	-0.01 (-0.69,0.67)	0.22 (-0.51,0.95)	-0.72 (-1.57,0.13)	Mindfulness	-0.37 (-1.20,0.46)	-0.01 (-0.84,0.83)	-0.30 (-1.12,0.53)							
-0.08 (-0.59,0.44)	**-0.64 (-1.22,-0.06)**	-0.13 (-0.66,0.40)	-0.29 (-0.69,0.11)	-0.06 (-0.65,0.53)	**-0.99 (-1.68,-0.31)**	-0.28 (-0.92,0.36)	Usual care	0.36 (-0.47,1.19)					-0.20 (-1.00,0.59)	-0.01 (-0.85,0.84)		
0.16 (-0.42,0.74)	-0.40 (-1.02,0.22)	0.11 (-0.50,0.71)	-0.05 (-0.58,0.48)	0.18 (-0.33,0.68)	**-0.76 (-1.49,-0.02)**	-0.04 (-0.66,0.57)	0.24 (-0.28,0.75)	CBT	-0.04 (-0.86,0.78)			-0.06 (-0.89,0.77)		-0.37 (-1.31,0.57)		
-0.13 (-0.77,0.51)	**-0.69 (-1.38,-0.00)**	-0.18 (-0.84,0.48)	-0.34 (-0.96,0.28)	-0.11 (-0.78,0.56)	**-1.05 (-1.83,-0.26)**	-0.33 (-0.93,0.27)	-0.05 (-0.67,0.56)	-0.29 (-0.83,0.26)	Advice		0.55 (-0.39,1.48)			0.00 (-1.15,1.15)		
-0.09 (-1.14,0.97)	-0.65 (-1.73,0.43)	-0.14 (-1.12,0.84)	-0.30 (-1.39,0.78)	-0.07 (-1.23,1.09)	-1.01 (-2.15,0.14)	-0.29 (-1.52,0.94)	-0.01 (-1.13,1.11)	-0.25 (-1.40,0.91)	0.04 (-1.15,1.22)	BT+PC						
0.05 (-0.42,0.51)	-0.51 (-1.06,0.03)	-0.01 (-0.49,0.48)	-0.17 (-0.68,0.35)	0.07 (-0.59,0.72)	**-0.87 (-1.52,-0.22)**	-0.15 (-0.89,0.58)	0.12 (-0.44,0.69)	-0.11 (-0.73,0.50)	0.18 (-0.45,0.80)	0.14 (-0.96,1.23)	PE				0.04 (-0.78,0.86)	
0.08 (-0.68,0.84)	-0.48 (-1.27,0.32)	0.03 (-0.73,0.80)	-0.13 (-0.79,0.54)	0.10 (-0.65,0.86)	-0.83 (-1.72,0.05)	-0.12 (-0.95,0.72)	0.16 (-0.55,0.87)	-0.07 (-0.72,0.57)	0.21 (-0.58,1.00)	0.17 (-1.07,1.42)	0.04 (-0.74,0.82)	GP care				
-0.28 (-1.23,0.67)	-0.84 (-1.82,0.14)	-0.33 (-1.29,0.63)	-0.49 (-1.38,0.40)	-0.26 (-1.25,0.73)	**-1.20 (-2.25,-0.15)**	-0.48 (-1.50,0.54)	-0.20 (-1.00,0.59)	-0.44 (-1.39,0.51)	-0.15 (-1.15,0.85)	-0.19 (-1.56,1.18)	-0.33 (-1.30,0.65)	-0.36 (-1.43,0.70)	Csl			
-0.13 (-0.73,0.47)	**-0.69 (-1.34,-0.04)**	-0.18 (-0.83,0.46)	-0.34 (-0.95,0.27)	-0.11 (-0.74,0.52)	**-1.05 (-1.80,-0.30)**	-0.33 (-1.07,0.41)	-0.05 (-0.64,0.53)	-0.29 (-0.87,0.29)	-0.00 (-0.65,0.64)	-0.04 (-1.22,1.13)	-0.18 (-0.84,0.49)	-0.21 (-1.01,0.58)	0.15 (-0.84,1.13)	BT		
0.09 (-0.86,1.03)	-0.48 (-1.46,0.51)	0.03 (-0.92,0.98)	-0.13 (-1.09,0.84)	0.10 (-0.94,1.15)	-0.83 (-1.87,0.21)	-0.12 (-1.21,0.98)	0.16 (-0.83,1.16)	-0.07 (-1.10,0.95)	0.21 (-0.82,1.25)	0.17 (-1.19,1.54)	0.04 (-0.78,0.86)	0.00 (-1.13,1.13)	0.36 (-0.91,1.64)	0.22 (-0.84,1.27)	Mind+PC	
0.16 (-0.71,1.02)	-0.40 (-1.34,0.53)	0.10 (-0.85,1.05)	-0.06 (-1.05,0.94)	0.18 (-0.88,1.23)	-0.76 (-1.74,0.22)	-0.04 (-1.17,1.08)	0.23 (-0.78,1.25)	-0.00 (-1.05,1.04)	0.29 (-0.79,1.37)	0.25 (-1.12,1.61)	0.11 (-0.88,1.09)	0.07 (-1.08,1.23)	0.44 (-0.85,1.72)	0.29 (-0.77,1.34)	0.07 (-1.21,1.35)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.7 Physical function at mid-term treatment sustainability, excluding studies involving data imputed from median and interquartile ranges

PC (reference)														
0.37 (0.14,0.60)	CBT+PC													
0.21 (-0.24,0.65)	-0.17 (-0.60,0.26)	Mindfulness												
-0.12 (-0.52,0.27)	**-0.50 (-0.89,-0.10)**	-0.33 (-0.72,0.07)	Usual care											
0.19 (-0.16,0.54)	-0.18 (-0.52,0.16)	-0.01 (-0.37,0.35)	0.31 (-0.02,0.65)	CBT										
0.11 (-0.30,0.51)	-0.27 (-0.64,0.10)	-0.10 (-0.46,0.26)	0.23 (-0.19,0.64)	-0.09 (-0.42,0.25)	Advice									
0.42 (0.15,0.68)	0.04 (-0.24,0.33)	0.21 (-0.23,0.66)	**0.54 (0.17,0.90)**	0.22 (-0.13,0.58)	0.31 (-0.10,0.73)	CP+PC								
0.37 (-0.04,0.79)	-0.00 (-0.45,0.45)	0.17 (-0.40,0.74)	0.49 (-0.02,1.01)	0.18 (-0.32,0.68)	0.27 (-0.27,0.81)	-0.04 (-0.43,0.34)	PE							
-0.02 (-0.42,0.38)	-0.39 (-0.85,0.07)	-0.22 (-0.82,0.37)	0.10 (-0.46,0.67)	-0.21 (-0.74,0.32)	-0.12 (-0.69,0.44)	-0.44 (-0.92,0.04)	-0.39 (-0.97,0.19)	Mind+PC						
0.18 (-0.18,0.54)	-0.19 (-0.55,0.17)	-0.02 (-0.44,0.39)	**0.30 (0.05,0.56)**	-0.01 (-0.34,0.32)	0.08 (-0.33,0.49)	-0.24 (-0.54,0.07)	-0.19 (-0.67,0.29)	0.20 (-0.34,0.74)	CP					
-0.13 (-0.55,0.29)	**-0.50 (-0.92,-0.08)**	-0.33 (-0.79,0.12)	-0.01 (-0.37,0.36)	-0.32 (-0.67,0.03)	-0.23 (-0.68,0.22)	**-0.54 (-0.94,-0.15)**	-0.50 (-1.04,0.04)	-0.11 (-0.69,0.47)	**-0.31 (-0.61,-0.01)**	GP care				
0.16 (-0.57,0.88)	-0.21 (-0.93,0.51)	-0.05 (-0.78,0.68)	0.28 (-0.44,1.00)	-0.03 (-0.67,0.60)	0.05 (-0.66,0.77)	-0.26 (-0.99,0.47)	-0.21 (-1.02,0.59)	0.18 (-0.65,1.01)	-0.02 (-0.74,0.69)	0.29 (-0.44,1.01)	Csl			
-0.06 (-0.61,0.49)	-0.43 (-0.97,0.11)	-0.26 (-0.82,0.30)	0.06 (-0.48,0.61)	-0.25 (-0.68,0.18)	-0.16 (-0.70,0.38)	-0.47 (-1.03,0.08)	-0.43 (-1.09,0.23)	-0.04 (-0.72,0.64)	-0.24 (-0.78,0.30)	0.07 (-0.48,0.62)	-0.22 (-0.69,0.26)	No intervention		
-0.18 (-0.85,0.50)	-0.55 (-1.22,0.12)	-0.38 (-1.07,0.30)	-0.05 (-0.73,0.62)	-0.37 (-0.95,0.21)	-0.28 (-0.95,0.39)	-0.59 (-1.28,0.09)	-0.55 (-1.32,0.22)	-0.16 (-0.95,0.63)	-0.36 (-1.03,0.31)	-0.05 (-0.73,0.63)	-0.33 (-1.20,0.53)	-0.12 (-0.84,0.60)	BT	
0.68 (-0.03,1.39)	0.31 (-0.42,1.04)	0.47 (-0.34,1.28)	**0.80 (0.03,1.58)**	0.49 (-0.28,1.25)	0.57 (-0.22,1.37)	0.26 (-0.43,0.96)	0.31 (-0.27,0.88)	0.70 (-0.12,1.52)	0.50 (-0.25,1.25)	**0.81 (0.02,1.59)**	0.52 (-0.47,1.51)	0.74 (-0.14,1.61)	0.86 (-0.11,1.82)	PE+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.8 Physical function at short-term treatment sustainability, removing portions of the evidence in the network to address inconsistency

PC (reference)				0.14 (-0.20,0.49)	0.14 (-0.20,0.47)				-0.02(-0.49,0.46)		-0.11 (-0.58,0.36)	
0.85 (0.56,1.15)	PE+PC											
-0.00 (-0.48,0.48)	**-0.86 (-1.42,-0.30)**	Advice	-0.01 (-0.47,0.45)		0.33 (-0.18,0.83)							
0.00 (-0.51,0.52)	**-0.85 (-1.44,-0.26)**	0.00 (-0.39,0.39)	CBT					-0.27 (-0.68,0.14)				
0.07 (-0.20,0.34)	**-0.78 (-1.18,-0.39)**	0.07 (-0.41,0.55)	0.07 (-0.44,0.58)	CP+PC	**0.46 (0.08,0.85)**		-0.13 (-0.60,0.35)					-0.26 (-0.70,0.17)
0.31 (0.01,0.61)	**-0.54 (-0.96,-0.13)**	0.31 (-0.11,0.73)	0.31 (-0.18,0.80)	0.24 (-0.07,0.55)	CBT+PC							
0.20 (-0.22,0.62)	**-0.66 (-1.17,-0.14)**	0.20 (-0.44,0.84)	0.20 (-0.47,0.86)	0.13 (-0.37,0.62)	-0.11 (-0.63,0.40)	Mind+PC						
0.02 (-0.32,0.36)	**-0.84 (-1.28,-0.39)**	0.02 (-0.47,0.51)	0.02 (-0.46,0.50)	-0.05 (-0.35,0.25)	-0.29 (-0.67,0.09)	-0.18 (-0.71,0.36)	CP	-0.26 (-0.78,0.26)	-0.19 (-0.45,0.07)	-0.12 (-0.43,0.18)		-0.16 (-0.70,0.39)
-0.26 (-0.75,0.24)	**-1.11 (-1.69,-0.54)**	-0.26 (-0.72,0.21)	-0.26 (-0.60,0.09)	-0.33 (-0.81,0.15)	**-0.57 (-1.06,-0.08)**	-0.45 (-1.10,0.19)	-0.28 (-0.70,0.15)	No intervention				
-0.14 (-0.48,0.20)	**-0.99 (-1.44,-0.54)**	-0.14 (-0.65,0.38)	-0.14 (-0.66,0.38)	-0.21 (-0.55,0.13)	**-0.45 (-0.85,-0.05)**	-0.33 (-0.87,0.21)	-0.16 (-0.39,0.08)	0.12 (-0.35,0.60)	Usual care		-0.10 (-0.57,0.38)	
-0.10 (-0.56,0.35)	**-0.96 (-1.50,-0.42)**	-0.10 (-0.67,0.47)	-0.10 (-0.67,0.47)	-0.17 (-0.60,0.26)	-0.41 (-0.90,0.07)	-0.30 (-0.92,0.32)	-0.12 (-0.43,0.18)	0.16 (-0.37,0.68)	0.03 (-0.35,0.42)	GP care		
-0.17 (-0.60,0.26)	**-1.03 (-1.55,-0.51)**	-0.17 (-0.78,0.44)	-0.17 (-0.80,0.45)	-0.24 (-0.71,0.23)	-0.48 (-0.98,0.02)	-0.37 (-0.97,0.23)	-0.19 (-0.65,0.27)	0.09 (-0.51,0.69)	-0.04 (-0.46,0.39)	-0.07 (-0.62,0.48)	BT	
-0.17 (-0.58,0.24)	**-1.02 (-1.53,-0.52)**	-0.17 (-0.73,0.39)	-0.17 (-0.74,0.40)	-0.24 (-0.58,0.10)	**-0.48 (-0.92,-0.04)**	-0.37 (-0.95,0.22)	-0.19 (-0.56,0.18)	0.09 (-0.45,0.63)	-0.03 (-0.45,0.38)	-0.07 (-0.55,0.41)	0.00 (-0.54,0.55)	PE

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PC: physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Final results of global test for inconsistency: $chi^2 = 1.92$, $p = 0.75$. No local inconsistency was detected in the side-splitting approach.

Justification:
Although we used standardised mean differences to estimate treatment effects, for physical function at short-term treatment sustainability, we examined transitivity across studies included in the analysis. We explored whether the use of different measurement scales in sides demonstrating $p<0.05$ from the side-splitting approach contributed to inconsistency within the network.

We examined the impact on global inconsistency tests after excluding Christiansen et al. (2010)[13] and Friedrich et al. (1998 and 2005).[18, 19] These studies contributed to sides 02 05, 02 07, 01 02 and 01 05, and utilised the Hannover ADL Questionnaire and Low Back Outcome Scale, respectively. For these measurement tools, higher scores corresponded with higher physical function/less disability. Therefore, to include them in the primary analysis, we had previously reversed the signal of the scores, since most studies utilised the Roland Morris Disability Questionnaire and Oswestry Disability questionnaire (where higher scores corresponded with worse disability/lower physical function). Removal of these studies resulted in a reduction in global inconsistency ($chi^2 = 10.86$, $p = 0.05$); although, local inconsistency persisted in the side 02 07 (i.e., physiotherapy care compared with pain education).

We subsequently visually inspected possible causes of intransitivity of studies contributing to the side 02 07. We examined the impact of further excluding Gardner et al. (2019)[23] from the analysis, as the study authors assessed physical function using the Quebec Back Pain Disability Scale, whilst study authors of the other studies contributing directly to side 02 07 utilised the Roland Morris Disability Questionnaire. After further removing Gardner et al. (2019),[23] global inconsistency ($chi^2 = 1.92$, $p = 0.75$) and local inconsistency were removed entirely.

As seen, statistically significant findings for comparisons with physiotherapy care remain similar to our primary analysis. Notably, the effect estimates for pain education delivered with physiotherapy care, compared with physiotherapy care, increased to a large and clinically important effect. On the other hand, effect estimates for cognitive behavioural therapy delivered with physiotherapy care, compared with physiotherapy care, reduced to a small and non-clinically important effect.

Supplementary Table 14.9. Physical function at mid-term treatment sustainability, removing portions of the evidence in the network to address inconsistency

PC (reference)	**0.23 (0.06,0.41)**	0.11 (-0.30,0.52)				**0.39 (0.10,0.68)**								
0.25 (0.09,0.41)	CBT+PC	0.23 (-0.13,0.59)			-0.37 (-0.73,0.00)									
0.13 (-0.11,0.37)	-0.12 (-0.36,0.13)	CBT	-0.01 (-0.32,0.30)	-0.30 (-0.62,0.01)	0.03 (-0.27,0.34)				-0.26 (-0.57,0.05)		**-0.25 (-0.46,-0.04)**	-0.37 (-0.82,0.08)		
0.15 (-0.15,0.44)	-0.10 (-0.39,0.19)	0.02 (-0.21,0.24)	Mindfulness	-0.29 (-0.61,0.02)	-0.14 (-0.43,0.16)									
-0.15 (-0.43,0.12)	**-0.40 (-0.68,-0.12)**	**-0.29 (-0.50,-0.07)**	**-0.30 (-0.55,-0.05)**	Usual care				**0.30 (0.12,0.49)**						
0.03 (-0.24,0.31)	-0.21 (-0.47,0.04)	-0.10 (-0.31,0.12)	-0.11 (-0.33,0.10)	0.19 (-0.08,0.46)	Advice									
0.41 (0.18,0.64)	0.17 (-0.10,0.43)	**0.28 (0.02,0.54)**	0.27 (-0.04,0.57)	**0.57 (0.32,0.82)**	**0.38 (0.08,0.68)**	CP+PC		**-0.29 (-0.53,-0.04)**					**-0.33 (-0.59,-0.07)**	
0.02 (-0.25,0.28)	-0.23 (-0.54,0.07)	-0.11 (-0.47,0.25)	-0.13 (-0.52,0.26)	0.17 (-0.21,0.55)	-0.02 (-0.39,0.36)	**-0.40 (-0.75,-0.05)**	Mind+PC							
0.15 (-0.11,0.40)	-0.10 (-0.37,0.17)	0.02 (-0.20,0.23)	-0.00 (-0.27,0.26)	**0.30 (0.14,0.46)**	0.11 (-0.16,0.39)	**-0.27 (-0.47,-0.06)**	0.13 (-0.24,0.50)	CP	**-0.33 (-0.56,-0.11)**					
-0.17 (-0.45,0.12)	**-0.41 (-0.71,-0.12)**	**-0.30 (-0.52,-0.07)**	**-0.31 (-0.60,-0.03)**	-0.01 (-0.24,0.22)	-0.20 (-0.49,0.09)	**-0.58 (-0.85,-0.31)**	-0.18 (-0.57,0.21)	**-0.31 (-0.50,-0.12)**	GP care					
0.10 (-0.34,0.53)	-0.15 (-0.59,0.28)	-0.03 (-0.39,0.33)	-0.05 (-0.48,0.37)	0.25 (-0.17,0.67)	0.06 (-0.36,0.48)	-0.32 (-0.76,0.13)	0.08 (-0.43,0.59)	-0.05 (-0.47,0.37)	0.26 (-0.16,0.68)	Csl	-0.22 (-0.51,0.08)			
-0.12 (-0.44,0.20)	**-0.37 (-0.69,-0.05)**	**-0.25 (-0.46,-0.04)**	-0.27 (-0.57,0.04)	0.03 (-0.27,0.34)	-0.15 (-0.45,0.15)	**-0.53 (-0.87,-0.20)**	-0.14 (-0.55,0.28)	-0.27 (-0.57,0.03)	0.05 (-0.26,0.35)	-0.22 (-0.51,0.08)	No intervention			
-0.24 (-0.75,0.27)	-0.49 (-1.00,0.03)	-0.37 (-0.82,0.08)	-0.39 (-0.89,0.12)	-0.08 (-0.58,0.42)	-0.27 (-0.77,0.23)	**-0.65 (-1.17,-0.13)**	-0.26 (-0.83,0.32)	-0.39 (-0.89,0.11)	-0.07 (-0.57,0.43)	-0.33 (-0.91,0.24)	-0.12 (-0.61,0.38)	BT		
0.08 (-0.27,0.43)	-0.17 (-0.54,0.20)	-0.05 (-0.42,0.32)	-0.07 (-0.47,0.33)	0.24 (-0.12,0.60)	0.05 (-0.35,0.45)	**-0.33 (-0.59,-0.07)**	0.06 (-0.37,0.50)	-0.07 (-0.40,0.27)	0.25 (-0.12,0.62)	-0.01 (-0.53,0.50)	0.20 (-0.22,0.63)	0.32 (-0.26,0.90)	PE	0.31 (-0.13,0.75)
0.39 (-0.17,0.95)	0.14 (-0.43,0.72)	0.26 (-0.32,0.83)	0.24 (-0.35,0.84)	0.54 (-0.03,1.11)	0.36 (-0.24,0.95)	-0.02 (-0.54,0.49)	0.37 (-0.25,0.99)	0.24 (-0.31,0.79)	0.55 (-0.02,1.13)	0.29 (-0.38,0.97)	0.51 (-0.10,1.12)	0.63 (-0.10,1.36)	0.31 (-0.13,0.75)	PE+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Final results of global test for inconsistency: $chi^2 = 6.88$, p = 0.22. No local inconsistency was detected in the side-splitting approach.

Justification:
To maintain consistency with the sensitivity analysis performed to remove inconsistency for physical function at short-term treatment sustainability, we also removed Christiansen et al. (2010),[13] Friedrich et al. (1998 and 2005),[18, 19] and Gardner et al. (2019)[23] in the sensitivity analysis of physical function at mid-term treatment sustainability. However, global inconsistency persisted within the network ($chi^2 = 26.79$, $p < 0.001$).

We then explored the sides which continued to demonstrate $p < 0.05$ from the side-splitting approach, which were 02 08 (physiotherapy care compared with pain education), 01 02 (cognitive behavioural therapy delivered with physiotherapy care compared with physiotherapy care), 01 05 (cognitive behavioural therapy delivered with physiotherapy care compared with physiotherapy care), 01 07 (cognitive behavioural therapy delivered with physiotherapy care compared with combined psychological approaches), and 07 08 (combined psychological approaches delivered with physiotherapy care compared with pain education). We visually inspected possible sources of intransitivity and performed numerous sensitivity analysis by (i) removing studies with inpatient study settings, (ii) removing individual and multiple studies with intervention durations outside the range of 6 to 12 weeks, (iii) removing individual and multiple studies utilising different outcome scales, (iv) removing individual studies and multiple studies based on baseline levels of physical function. None of these sensitivity analyses resolved concerns regarding global inconsistency.

After removing the study conducted by O'Keeffe et al. (2020),[60] the single study directly comparing the side 01 07, this removed global ($chi^2 = 6.88$, $p = 0.22$) and local inconsistency from the network.

As seen, the effect estimates for our main findings, cognitive behavioural therapy compared with physiotherapy care, and combined psychological approaches delivered with physiotherapy care compared with physiotherapy care, remained very similar in magnitude and statistical significance to the primary analysis.

Supplementary Table 14.10 Pain intensity at post-intervention, excluding studies with high risk of bias

PC (reference)		0.52 (-0.66,1.70)	0.42 (-0.58,1.42)	-0.46 (-1.41,0.49)			0.42 (-0.80,1.64)	0.28 (-0.56,1.13)		-0.65 (-2.30,1.00)		0.22 (-1.46,1.90)	**0.92 (0.31,1.53)**	**-1.95 (-3.18,0.71)**		**1.14 (0.51,1.77)**
0.14 (-1.53,1.80)	Csl+PC															
1.14 (0.04,2.24)	1.01 (-0.99,3.00)	BT+PC		-1.10 (-2.34,0.14)										**-2.46 (-3.74,-1.18)**		
0.42 (-0.46,1.30)	0.29 (-1.60,2.17)	-0.72 (-2.12,0.68)	Mind+PC				-0.21 (-1.87,1.45)									
0.10 (-0.65,0.85)	-0.03 (-1.86,1.79)	-1.04 (-2.13,0.06)	-0.32 (-1.46,0.83)	BT					-0.19 (-2.03,1.65)	-0.41 (-2.07,1.26)		0.01 (-0.86,0.88)		**-0.98 (-1.77,-0.19)**		
-1.68 (-3.54,0.18)	-1.82 (-4.31,0.68)	**-2.82 (-4.91,-0.73)**	**-2.10 (-4.15,-0.06)**	-1.78 (-3.67,0.10)	Csl					1.55 (-0.08,3.18)						
-0.46 (-1.64,0.72)	-0.60 (-2.64,1.44)	**-1.60 (-3.10,-0.11)**	-0.88 (-2.34,0.57)	-0.57 (-1.74,0.61)	1.22 (-0.83,3.27)	GP care						0.79 (-0.44,2.03)			0.30 (-1.40,2.00)	
0.21 (-0.69,1.11)	0.07 (-1.82,1.96)	-0.93 (-2.33,0.46)	-0.21 (-1.28,0.86)	0.11 (-1.02,1.23)	1.89 (-0.12,3.90)	0.67 (-0.74,2.09)	PE								0.31 (-1.37,1.98)	
0.13 (-0.54,0.79)	-0.01 (-1.80,1.78)	-1.01 (-2.26,0.23)	-0.29 (-1.38,0.79)	0.02 (-0.90,0.95)	1.81 (-0.09,3.70)	0.59 (-0.66,1.84)	-0.08 (-1.14,0.97)	CP+PC							0.14 (-0.83,1.12)	0.93 (-0.73,2.59)
0.04 (-1.21,1.28)	-0.10 (-2.18,1.98)	-1.10 (-2.62,0.41)	-0.38 (-1.90,1.13)	-0.07 (-1.20,1.07)	1.72 (-0.37,3.81)	0.50 (-0.98,1.98)	-0.17 (-1.67,1.32)	-0.09 (-1.43,1.25)	Advice		0.14 (-1.51,1.79)	0.10 (-1.55,1.76)				
-0.13 (-1.03,0.76)	-0.27 (-2.16,1.62)	-1.28 (-2.58,0.03)	-0.56 (-1.79,0.67)	-0.24 (-1.17,0.70)	1.55 (-0.08,3.18)	0.33 (-0.92,1.57)	-0.34 (-1.52,0.83)	-0.26 (-1.22,0.70)	-0.17 (-1.47,1.13)	Usual care	0.44 (-1.22,2.09)	0.34 (-1.32,2.00)			0.08 (-0.87,1.03)	
0.24 (-1.09,1.58)	0.11 (-2.03,2.24)	-0.90 (-2.50,0.71)	-0.18 (-1.76,1.41)	0.14 (-1.15,1.42)	1.92 (-0.16,4.01)	0.71 (-0.84,2.25)	0.03 (-1.53,1.59)	0.12 (-1.30,1.53)	0.21 (-1.04,1.45)	0.38 (-0.92,1.67)	Mindfulness	-0.10 (-1.75,1.56)				
0.18 (-0.58,0.95)	0.05 (-1.79,1.88)	-0.96 (-2.13,0.21)	-0.24 (-1.39,0.91)	0.08 (-0.59,0.75)	1.86 (-0.00,3.73)	0.64 (-0.39,1.67)	-0.03 (-1.15,1.10)	0.05 (-0.86,0.97)	0.14 (-0.95,1.24)	0.32 (-0.59,1.22)	-0.06 (-1.27,1.15)	CBT		-0.66 (-1.53,0.21)		-0.21 (-1.85,1.42)
0.91 (0.35,1.48)	0.78 (-0.98,2.53)	-0.23 (-1.46,1.00)	0.49 (-0.56,1.53)	0.81 (-0.12,1.74)	**2.59 (0.65,4.53)**	**1.37 (0.07,2.68)**	0.70 (-0.36,1.76)	0.78 (-0.08,1.65)	0.87 (-0.49,2.24)	1.05 (-0.01,2.10)	0.67 (-0.78,2.11)	0.73 (-0.21,1.67)	PE+PC			0.06 (-1.64,1.75)
-0.66 (-1.42,0.10)	-0.79 (-2.62,1.04)	**-1.80 (-2.91,-0.68)**	-1.08 (-2.23,0.07)	**-0.76 (-1.45,-0.07)**	1.02 (-0.87,2.92)	-0.20 (-1.37,0.98)	-0.87 (-1.99,0.26)	-0.79 (-1.70,0.13)	-0.70 (-1.91,0.52)	-0.52 (-1.49,0.44)	-0.90 (-2.23,0.42)	**-0.84 (-1.53,-0.15)**	**-1.57 (-2.51,-0.63)**	No intervention	0.71 (-1.10,2.52)	0.11 (-1.53,1.76)
0.12 (-0.66,0.89)	-0.02 (-1.85,1.82)	-1.02 (-2.28,0.23)	-0.30 (-1.44,0.83)	0.01 (-0.88,0.91)	1.80 (-0.01,3.61)	0.58 (-0.56,1.72)	-0.09 (-1.13,0.94)	-0.01 (-0.77,0.75)	0.08 (-1.23,1.38)	0.25 (-0.52,1.03)	-0.13 (-1.48,1.23)	-0.06 (-0.93,0.80)	-0.79 (-1.75,0.16)	0.78 (-0.11,1.66)	CP	
0.91 (0.37,1.46)	0.78 (-0.97,2.53)	-0.23 (-1.41,0.96)	0.49 (-0.54,1.52)	0.81 (-0.05,1.67)	**2.59 (0.69,4.50)**	**1.38 (0.13,2.62)**	0.70 (-0.33,1.74)	**0.79 (0.00,1.57)**	0.88 (-0.43,2.18)	**1.05 (0.06,2.04)**	0.67 (-0.72,2.06)	0.73 (-0.12,1.58)	0.00 (-0.74,0.74)	**1.57 (0.74,2.41)**	0.80 (-0.09,1.68)	CBT+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined physiotherapy approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.11 Pain intensity at post-intervention, only including studies using intention-to-treatment analysis

PC (reference)			**0.86 (0.21,1.51)**	0.22 (-1.20,1.64)		-0.65 (-2.01,0.70)		**1.28 (0.69,1.87)**	0.21 (-0.62,1.04)	1.41 (-0.02,2.83)			-0.25 (-1.63,1.14)	0.38 (-0.68,1.44)	
0.53 (-0.19,1.25)	CP	-0.71 (-2.29,0.87)				-0.08 (-0.88,0.72)			-0.14 (-0.98,0.69)	-0.31 (-1.73,1.12)	-0.30 (-1.75,1.15)				
0.25 (-0.64,1.13)	-0.28 (-1.18,0.61)	No intervention		0.69 (-0.31,1.70)				0.11 (-1.32,1.55)					0.22 (-1.27,1.72)		
0.90 (0.30,1.49)	0.37 (-0.55,1.28)	0.65 (-0.39,1.69)	PE+PC					0.06 (-1.40,1.51)							
0.68 (-0.10,1.46)	0.15 (-0.65,0.95)	0.43 (-0.36,1.22)	-0.22 (-1.18,0.74)	CBT	0.10 (-1.31,1.51)	-0.34 (-1.75,1.07)	-0.10 (-1.52,1.31)	-0.21 (-1.61,1.18)			0.02 (-1.38,1.42)		-0.42 (-1.45,0.62)		
0.72 (-0.51,1.95)	0.19 (-1.02,1.40)	0.47 (-0.80,1.74)	-0.18 (-1.53,1.17)	0.04 (-1.02,1.10)	Mindfulness	-0.44 (-1.85,0.97)	-0.14 (-1.55,1.26)								
0.22 (-0.58,1.03)	-0.31 (-0.97,0.36)	-0.02 (-0.98,0.93)	-0.67 (-1.66,0.32)	-0.45 (-1.26,0.35)	-0.49 (-1.64,0.65)	Usual care						**-1.55 (-2.93,-0.17)**	0.41 (-1.00,1.81)		
0.57 (-0.74,1.89)	0.04 (-1.27,1.36)	0.33 (-1.01,1.67)	-0.32 (-1.75,1.11)	-0.10 (-1.22,1.01)	-0.14 (-1.25,0.97)	0.35 (-0.93,1.64)	Advice								
1.13 (0.63,1.63)	0.60 (-0.19,1.39)	0.88 (-0.00,1.77)	0.23 (-0.49,0.95)	0.45 (-0.36,1.26)	0.41 (-0.85,1.67)	0.90 (0.03,1.78)	0.55 (-0.78,1.89)	CBT+PC	-0.93 (-2.34,0.48)						
0.28 (-0.34,0.91)	-0.25 (-0.92,0.42)	0.04 (-0.92,1.00)	-0.61 (-1.46,0.24)	-0.39 (-1.27,0.48)	-0.43 (-1.71,0.85)	0.06 (-0.79,0.91)	-0.29 (-1.66,1.08)	**-0.84 (-1.56,-0.13)**	CP+PC						
0.64 (-0.28,1.56)	0.11 (-0.87,1.09)	0.40 (-0.80,1.59)	-0.25 (-1.34,0.83)	-0.04 (-1.16,1.09)	-0.08 (-1.54,1.38)	0.42 (-0.69,1.52)	0.07 (-1.47,1.61)	-0.49 (-1.51,0.53)	0.36 (-0.67,1.38)	PE				0.21 (-1.20,1.62)	
0.47 (-0.70,1.65)	-0.06 (-1.13,1.02)	0.23 (-1.01,1.47)	-0.42 (-1.73,0.88)	-0.21 (-1.27,0.86)	-0.24 (-1.70,1.21)	0.25 (-0.93,1.42)	-0.10 (-1.62,1.41)	-0.66 (-1.87,0.56)	0.19 (-1.01,1.39)	-0.17 (-1.56,1.23)	GP care				
-1.32 (-2.92,0.28)	**-1.85 (-3.39,-0.32)**	-1.57 (-3.25,0.11)	**-2.22 (-3.92,-0.52)**	**-2.00 (-3.60,-0.40)**	**-2.04 (-3.83,-0.25)**	**-1.55 (-2.93,-0.17)**	**-1.90 (-3.78,-0.01)**	**-2.45 (-4.09,-0.82)**	-1.61 (-3.23,0.01)	**-1.96 (-3.73,-0.20)**	-1.80 (-3.61,0.02)	Csl			
0.32 (-0.60,1.24)	-0.21 (-1.18,0.75)	0.07 (-0.89,1.03)	-0.58 (-1.66,0.50)	-0.36 (-1.18,0.45)	-0.40 (-1.68,0.88)	0.09 (-0.85,1.04)	-0.26 (-1.61,1.09)	-0.81 (-1.78,0.16)	0.03 (-0.98,1.05)	-0.32 (-1.56,0.91)	-0.16 (-1.43,1.12)	1.64 (-0.03,3.31)	BT		
0.55 (-0.35,1.45)	0.02 (-1.07,1.11)	0.30 (-0.93,1.54)	-0.34 (-1.42,0.73)	-0.13 (-1.29,1.03)	-0.17 (-1.66,1.33)	0.33 (-0.84,1.49)	-0.02 (-1.60,1.55)	-0.58 (-1.60,0.44)	0.27 (-0.80,1.33)	-0.09 (-1.11,0.93)	0.08 (-1.37,1.53)	**1.87 (0.07,3.68)**	0.23 (-1.03,1.50)	Mind+PC	
0.14 (-1.28,1.56)	-0.39 (-1.98,1.20)	-0.11 (-1.78,1.56)	-0.76 (-2.30,0.78)	-0.54 (-2.16,1.08)	-0.58 (-2.46,1.30)	-0.09 (-1.72,1.54)	-0.44 (-2.37,1.50)	-0.99 (-2.50,0.51)	-0.15 (-1.70,1.40)	-0.51 (-2.19,1.18)	-0.34 (-2.18,1.51)	1.46 (-0.68,3.60)	-0.18 (-1.87,1.51)	-0.41 (-2.10,1.27)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.12 Pain intensity at post-intervention, excluding studies published prior to year 1995

PC (reference)																
0.90 (0.32,1.47)	CBT+PC															
0.07 (-0.76,0.90)	-0.82 (-1.75,0.11)	CP														
-0.86 (-1.78,0.07)	**-1.75 (-2.72,-0.79)**	-0.93 (-1.91,0.05)	No intervention													
0.91 (0.32,1.51)	0.01 (-0.77,0.80)	0.84 (-0.18,1.85)	**1.77 (0.68,2.85)**	PE+PC												
0.21 (-0.68,1.10)	-0.68 (-1.63,0.27)	0.14 (-0.81,1.09)	**1.07 (0.21,1.93)**	-0.70 (-1.76,0.36)	CBT											
0.08 (-1.20,1.35)	-0.82 (-2.14,0.50)	0.00 (-1.29,1.29)	0.93 (-0.25,2.11)	-0.83 (-2.24,0.57)	-0.14 (-1.27,0.99)	Mindfulness										
-0.18 (-1.14,0.77)	**-1.08 (-2.12,-0.03)**	-0.26 (-1.07,0.56)	0.67 (-0.39,1.74)	-1.09 (-2.21,0.02)	-0.40 (-1.38,0.59)	-0.26 (-1.51,1.00)	Usual care									
0.02 (-1.52,1.56)	-0.87 (-2.45,0.70)	-0.05 (-1.62,1.51)	0.88 (-0.62,2.37)	-0.89 (-2.53,0.75)	-0.19 (-1.53,1.15)	-0.05 (-1.39,1.28)	0.20 (-1.36,1.76)	Advice								
0.11 (-0.59,0.81)	-0.79 (-1.61,0.04)	0.03 (-0.77,0.84)	0.97 (-0.08,2.01)	-0.80 (-1.71,0.11)	-0.10 (-1.13,0.92)	0.03 (-1.33,1.39)	0.29 (-0.73,1.31)	0.09 (-1.53,1.70)	CP+PC							
0.20 (-0.74,1.14)	-0.70 (-1.78,0.39)	0.12 (-0.97,1.22)	1.05 (-0.20,2.31)	-0.71 (-1.82,0.40)	-0.02 (-1.25,1.22)	0.12 (-1.41,1.65)	0.38 (-0.86,1.62)	0.18 (-1.58,1.93)	0.09 (-1.02,1.20)	PE						
-0.46 (-1.74,0.81)	**-1.36 (-2.69,-0.03)**	-0.54 (-1.74,0.67)	0.39 (-0.90,1.69)	-1.37 (-2.77,0.03)	-0.68 (-1.76,0.41)	-0.54 (-2.04,0.97)	-0.28 (-1.60,1.04)	-0.48 (-2.18,1.22)	-0.57 (-1.90,0.76)	-0.66 (-2.17,0.85)	GP care					
-1.73 (-3.69,0.24)	**-2.62 (-4.64,-0.61)**	-1.80 (-3.71,0.10)	-0.87 (-2.89,1.15)	**-2.64 (-4.69,-0.59)**	-1.94 (-3.93,0.04)	-1.80 (-3.93,0.32)	-1.55 (-3.27,0.17)	-1.75 (-4.07,0.57)	-1.84 (-3.84,0.16)	-1.93 (-4.05,0.19)	-1.27 (-3.43,0.90)	Csl				
0.03 (-0.93,0.99)	-0.87 (-1.91,0.18)	-0.05 (-1.12,1.02)	0.88 (-0.10,1.87)	-0.88 (-2.00,0.24)	-0.19 (-1.11,0.74)	-0.05 (-1.37,1.28)	0.21 (-0.87,1.29)	0.01 (-1.56,1.58)	-0.08 (-1.18,1.02)	-0.17 (-1.47,1.13)	0.49 (-0.86,1.84)	1.76 (-0.27,3.79)	BT			
0.42 (-0.50,1.34)	-0.48 (-1.56,0.60)	0.34 (-0.86,1.54)	1.27 (-0.01,2.56)	-0.49 (-1.59,0.61)	0.20 (-1.06,1.47)	0.34 (-1.22,1.90)	0.60 (-0.70,1.90)	0.40 (-1.38,2.18)	0.31 (-0.83,1.45)	0.22 (-0.90,1.35)	0.88 (-0.67,2.43)	2.15 (-0.01,4.30)	0.39 (-0.93,1.71)	Mind+PC		
1.95 (0.33,3.56)	1.05 (-0.63,2.73)	**1.87 (0.14,3.60)**	**2.80 (1.13,4.48)**	1.04 (-0.68,2.75)	**1.73 (0.03,3.43)**	1.87 (-0.06,3.80)	**2.13 (0.36,3.90)**	1.92 (-0.19,4.04)	**1.84 (0.11,3.56)**	1.75 (-0.10,3.60)	**2.41 (0.46,4.36)**	**3.67 (1.21,6.14)**	**1.92 (0.28,3.55)**	1.53 (-0.33,3.38)	BT+PC	
0.14 (-1.61,1.89)	-0.76 (-2.60,1.08)	0.06 (-1.88,2.00)	0.99 (-0.99,2.97)	-0.77 (-2.62,1.07)	-0.08 (-2.04,1.89)	0.06 (-2.11,2.23)	0.32 (-1.68,2.31)	0.11 (-2.22,2.45)	0.03 (-1.86,1.91)	-0.06 (-2.05,1.93)	0.60 (-1.57,2.76)	1.86 (-0.77,4.50)	0.11 (-1.89,2.10)	-0.28 (-2.26,1.70)	-1.81 (-4.19,0.57)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.13 Pain intensity at post-intervention, excluding studies published prior to year 2000

PC (reference)	**1.14 (0.47,1.82)**		**-4.73 (-6.42,3.04)**	**0.92 (0.27,1.57)**	0.22 (-1.58,2.02)		-0.65 (-2.43,1.12)		0.33 (-0.72,1.37)	0.42 (-0.89,1.72)			-0.63 (-1.88,0.63)	0.42 (-0.64,1.49)	0.55 (-1.12,2.21)	
0.89 (0.31,1.48)	CBT+PC		-0.11 (-1.84,1.61)	-0.06 (-1.87,1.76)	0.21 (-1.54,1.97)				-0.93 (-2.71,0.85)							
0.07 (-0.79,0.93)	-0.83 (-1.78,0.13)	CP	-0.71 (-2.63,1.21)				-0.08 (-1.10,0.94)		-0.14 (-1.19,0.90)	-0.31 (-2.10,1.49)	-0.30 (-2.12,1.51)					
-0.86 (-1.80,0.08)	**-1.76 (-2.74,-0.78)**	-0.93 (-1.93,0.07)	No intervention		0.71 (-0.56,1.98)	0.52 (-1.36,2.40)							**1.67 (0.36,2.98)**		**5.32 (3.56,7.08)**	
0.91 (0.31,1.51)	0.02 (-0.78,0.81)	0.84 (-0.20,1.88)	**1.77 (0.67,2.88)**	PE+PC												
0.21 (-0.70,1.12)	-0.68 (-1.65,0.28)	0.14 (-0.83,1.11)	**1.07 (0.20,1.95)**	-0.70 (-1.78,0.38)	CBT	0.10 (-1.68,1.87)	-0.34 (-2.12,1.44)	-0.10 (-1.88,1.67)			-0.81 (-2.12,0.51)		-0.42 (-1.71,0.86)			
0.07 (-1.23,1.37)	-0.82 (-2.17,0.52)	0.00 (-1.31,1.31)	0.93 (-0.26,2.13)	-0.84 (-2.27,0.58)	-0.14 (-1.29,1.01)	Mindfulness	-0.44 (-2.21,1.34)	-0.14 (-1.92,1.63)								
-0.19 (-1.16,0.79)	**-1.08 (-2.15,-0.02)**	-0.26 (-1.09,0.58)	0.68 (-0.40,1.76)	-1.10 (-2.24,0.04)	-0.40 (-1.40,0.61)	-0.26 (-1.53,1.02)	Usual care					-1.55 (-3.29,0.20)	0.41 (-1.37,2.19)			
0.02 (-1.55,1.58)	-0.88 (-2.48,0.73)	-0.05 (-1.64,1.54)	0.88 (-0.64,2.40)	-0.89 (-2.57,0.78)	-0.19 (-1.56,1.17)	-0.05 (-1.41,1.31)	0.20 (-1.38,1.79)	Advice								
0.10 (-0.68,0.88)	-0.79 (-1.68,0.09)	0.03 (-0.80,0.86)	0.96 (-0.13,2.05)	-0.81 (-1.79,0.16)	-0.11 (-1.17,0.95)	0.03 (-1.37,1.43)	0.29 (-0.76,1.34)	0.08 (-1.57,1.74)	CP+PC							
0.20 (-0.76,1.15)	-0.70 (-1.80,0.40)	0.13 (-0.99,1.25)	1.06 (-0.22,2.34)	-0.71 (-1.84,0.42)	-0.01 (-1.27,1.24)	0.13 (-1.43,1.68)	0.38 (-0.88,1.65)	0.18 (-1.61,1.97)	0.10 (-1.06,1.25)	PE				0.21 (-1.57,1.99)		
-0.47 (-1.77,0.83)	**-1.36 (-2.71,-0.01)**	-0.54 (-1.77,0.69)	0.39 (-0.92,1.71)	-1.38 (-2.80,0.05)	-0.68 (-1.78,0.42)	-0.54 (-2.07,0.99)	-0.28 (-1.62,1.06)	-0.48 (-2.21,1.24)	-0.57 (-1.94,0.80)	-0.66 (-2.20,0.87)	GP care					
-1.73 (-3.74,0.27)	**-2.63 (-4.67,-0.58)**	-1.80 (-3.74,0.13)	-0.87 (-2.92,1.18)	**-2.64 (-4.73,-0.56)**	-1.94 (-3.96,0.07)	-1.80 (-3.97,0.36)	-1.55 (-3.29,0.20)	-1.75 (-4.11,0.61)	-1.83 (-3.87,0.21)	-1.93 (-4.09,0.23)	-1.27 (-3.47,0.94)	Csl				
0.03 (-0.95,1.00)	-0.87 (-1.93,0.19)	-0.04 (-1.13,1.05)	0.89 (-0.11,1.89)	-0.88 (-2.02,0.26)	-0.18 (-1.12,0.75)	-0.04 (-1.39,1.30)	0.21 (-0.89,1.31)	0.01 (-1.59,1.61)	-0.07 (-1.22,1.07)	-0.17 (-1.49,1.15)	0.49 (-0.88,1.87)	1.76 (-0.31,3.83)	BT		1.56 (-0.32,3.45)	
0.42 (-0.52,1.35)	-0.48 (-1.58,0.62)	0.35 (-0.88,1.58)	1.28 (-0.03,2.59)	-0.49 (-1.61,0.62)	0.21 (-1.08,1.49)	0.35 (-1.24,1.94)	0.61 (-0.72,1.93)	0.40 (-1.41,2.21)	0.32 (-0.88,1.52)	0.22 (-0.92,1.37)	0.89 (-0.69,2.47)	2.15 (-0.04,4.35)	0.39 (-0.95,1.73)	Mind+PC		
1.95 (0.31,3.59)	1.06 (-0.65,2.76)	**1.88 (0.12,3.65)**	**2.82 (1.12,4.51)**	1.04 (-0.70,2.78)	**1.74 (0.02,3.47)**	1.88 (-0.07,3.84)	**2.14 (0.34,3.94)**	1.94 (-0.21,4.08)	**1.85 (0.08,3.62)**	1.76 (-0.12,3.63)	**2.42 (0.44,4.40)**	**3.69 (1.18,6.19)**	**1.93 (0.27,3.59)**	**1.53 (-0.35,3.41)**	BT+PC	
0.14 (-1.64,1.91)	-0.76 (-2.63,1.11)	0.07 (-1.91,2.04)	1.00 (-1.01,3.01)	-0.77 (-2.65,1.10)	-0.07 (-2.07,1.92)	0.07 (-2.14,2.27)	0.32 (-1.71,2.35)	0.12 (-2.25,2.49)	0.04 (-1.91,1.98)	-0.06 (-2.08,1.96)	0.60 (-1.60,2.81)	1.87 (-0.81,4.55)	0.11 (-1.92,2.14)	-0.28 (-2.29,1.73)	-1.82 (-4.23,0.60)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.14 Pain intensity at post-intervention, excluding studies published prior to year 2005

PC (reference)																
0.89 (0.31,1.48)	CBT+PC															
0.07 (-0.79,0.93)	-0.83 (-1.78,0.13)	CP														
-0.86 (-1.80,0.08)	**-1.76 (-2.74,-0.78)**	-0.93 (-1.93,0.07)	No intervention													
0.91 (0.31,1.51)	0.02 (-0.78,0.81)	0.84 (-0.20,1.88)	**1.77 (0.67,2.88)**	PE+PC												
0.21 (-0.70,1.12)	-0.68 (-1.65,0.28)	0.14 (-0.83,1.11)	**1.07 (0.20,1.95)**	-0.70 (-1.78,0.38)	CBT											
0.07 (-1.23,1.37)	-0.82 (-2.17,0.52)	0.00 (-1.31,1.31)	0.93 (-0.26,2.13)	-0.84 (-2.27,0.58)	-0.14 (-1.29,1.01)	Mindfulness										
-0.19 (-1.16,0.79)	**-1.08 (-2.15,-0.02)**	-0.26 (-1.09,0.58)	0.68 (-0.40,1.76)	-1.10 (-2.24,0.04)	-0.40 (-1.40,0.61)	-0.26 (-1.53,1.02)	Usual care									
0.02 (-1.55,1.58)	-0.88 (-2.48,0.73)	-0.05 (-1.64,1.54)	0.88 (-0.64,2.40)	-0.89 (-2.57,0.78)	-0.19 (-1.56,1.17)	-0.05 (-1.41,1.31)	0.20 (-1.38,1.79)	Advice								
0.10 (-0.68,0.88)	-0.79 (-1.68,0.09)	0.03 (-0.80,0.86)	0.96 (-0.13,2.05)	-0.81 (-1.79,0.16)	-0.11 (-1.17,0.95)	0.03 (-1.37,1.43)	0.29 (-0.76,1.34)	0.08 (-1.57,1.74)	CP+PC							
0.20 (-0.76,1.15)	-0.70 (-1.80,0.40)	0.13 (-0.99,1.25)	1.06 (-0.22,2.34)	-0.71 (-1.84,0.42)	-0.01 (-1.27,1.24)	0.13 (-1.43,1.68)	0.38 (-0.88,1.65)	0.18 (-1.61,1.97)	0.10 (-1.06,1.25)	PE						
-0.47 (-1.77,0.83)	**-1.36 (-2.71,-0.01)**	-0.54 (-1.77,0.69)	0.39 (-0.92,1.71)	-1.38 (-2.80,0.05)	-0.68 (-1.78,0.42)	-0.54 (-2.07,0.99)	-0.28 (-1.62,1.06)	-0.48 (-2.21,1.24)	-0.57 (-1.94,0.80)	-0.66 (-2.20,0.87)	GP care					
-1.73 (-3.74,0.27)	**-2.63 (-4.67,-0.58)**	-1.80 (-3.74,0.13)	-0.87 (-2.92,1.18)	**-2.64 (-4.73,-0.56)**	-1.94 (-3.96,0.07)	-1.80 (-3.97,0.36)	-1.55 (-3.29,0.20)	-1.75 (-4.11,0.61)	-1.83 (-3.87,0.21)	-1.93 (-4.09,0.23)	-1.27 (-3.47,0.94)	Csl				
0.03 (-0.95,1.00)	-0.87 (-1.93,0.19)	-0.04 (-1.13,1.05)	0.89 (-0.11,1.89)	-0.88 (-2.02,0.26)	-0.18 (-1.12,0.75)	-0.04 (-1.39,1.30)	0.21 (-0.89,1.31)	0.01 (-1.59,1.61)	-0.07 (-1.22,1.07)	-0.17 (-1.49,1.15)	0.49 (-0.88,1.87)	1.76 (-0.31,3.83)	BT			
0.42 (-0.52,1.35)	-0.48 (-1.58,0.62)	0.35 (-0.88,1.58)	1.28 (-0.03,2.59)	-0.49 (-1.61,0.62)	0.21 (-1.08,1.49)	0.35 (-1.24,1.94)	0.61 (-0.72,1.93)	0.40 (-1.41,2.21)	0.32 (-0.88,1.52)	0.22 (-0.92,1.37)	0.89 (-0.69,2.47)	2.15 (-0.04,4.35)	0.39 (-0.95,1.73)	Mind+PC		
1.95 (0.31,3.59)	1.06 (-0.65,2.76)	**1.88 (0.12,3.65)**	**2.82 (1.12,4.51)**	1.04 (-0.70,2.78)	**1.74 (0.02,3.47)**	1.88 (-0.07,3.84)	**2.14 (0.34,3.94)**	1.94 (-0.21,4.08)	**1.85 (0.08,3.62)**	1.76 (-0.12,3.63)	**2.42 (0.44,4.40)**	**3.69 (1.18,6.19)**	**1.93 (0.27,3.59)**	1.53 (-0.35,3.41)	BT+PC	
0.14 (-1.64,1.91)	-0.76 (-2.63,1.11)	0.07 (-1.91,2.04)	1.00 (-1.01,3.01)	-0.77 (-2.65,1.10)	-0.07 (-2.07,1.92)	0.07 (-2.14,2.27)	0.32 (-1.71,2.35)	0.12 (-2.25,2.49)	0.04 (-1.91,1.98)	-0.06 (-2.08,1.96)	0.60 (-1.60,2.81)	1.87 (-0.81,4.55)	0.11 (-1.92,2.14)	-0.28 (-2.29,1.73)	-1.82 (-4.23,0.60)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.15 Pain intensity at post-intervention, excluding studies of patients with leg pain

PC (reference)	**0.71 (0.05,1.38)**		**-1.82 (-2.92,- 0.73)**				-0.65 (-2.05,0.74)		0.30 (-0.53,1.14)	0.43 (-0.62,1.48)			0.63 (-0.25,1.51)	0.56 (-0.48,1.61)	-0.44 (-1.27,0.39)	
0.56 (-0.01,1.12)	CBT+PC		-0.11 (-1.51,1.28)						-0.93 (-2.33,0.47)				0.08 (-1.43,1.59)			
0.08 (-0.65,0.80)	-0.48 (-1.33,0.37)	CP	-0.71 (-2.29,0.88)				-0.08 (-0.88,0.71)		-0.22 (-1.25,0.81)	-0.31 (-1.72,1.11)	-0.30 (-1.76,1.15)					
-0.81 (-1.49,-0.13)	**-1.36 (-2.14,-0.59)**	**-0.88 (-1.65,-0.12)**	No intervention		**0.75 (0.08,1.42)**	0.52 (-1.02,2.05)							**2.33 (1.19,3.48)**		**0.81 (0.19,1.44)**	
1.17 (0.57,1.76)	0.61 (-0.21,1.43)	**1.09 (0.15,2.03)**	**1.98 (1.07,2.88)**	PE+PC												
-0.05 (-0.81,0.72)	-0.60 (-1.46,0.26)	-0.12 (-0.93,0.68)	**0.76 (0.19,1.33)**	**-1.21 (-2.18,-0.25)**	CBT	0.10 (-1.31,1.50)	-0.34 (-1.75,1.07)	-0.10 (-1.51,1.30)			0.02 (-1.38,1.42)				-0.28 (-1.03,0.47)	
-0.05 (-1.08,0.97)	-0.61 (-1.71,0.49)	-0.13 (-1.17,0.91)	0.76 (-0.14,1.65)	**-1.22 (-2.40,-0.04)**	-0.01 (-0.89,0.88)	Mindfulness	-0.44 (-1.84,0.96)	-0.14 (-1.54,1.26)								
-0.25 (-1.04,0.54)	-0.81 (-1.71,0.10)	-0.33 (-0.99,0.34)	0.56 (-0.24,1.35)	**-1.42 (-2.41,-0.43)**	-0.20 (-1.01,0.60)	-0.20 (-1.19,0.80)	Usual care					**-1.55 (-2.92,-0.17)**			0.41 (-1.00,1.81)	
-0.22 (-1.31,0.86)	-0.78 (-1.94,0.38)	-0.30 (-1.42,0.82)	0.58 (-0.40,1.56)	**-1.39 (-2.63,-0.15)**	-0.18 (-1.10,0.74)	-0.17 (-1.16,0.82)	0.03 (-1.08,1.14)	Advice							0.19 (-1.42,1.81)	
0.03 (-0.61,0.68)	-0.52 (-1.28,0.24)	-0.04 (-0.80,0.71)	0.84 (-0.00,1.69)	**-1.13 (-2.01,-0.26)**	0.08 (-0.82,0.98)	0.09 (-1.04,1.22)	0.29 (-0.60,1.17)	0.26 (-0.93,1.45)	CP+PC							
0.23 (-0.55,1.01)	-0.33 (-1.27,0.62)	0.15 (-0.76,1.06)	**1.04 (0.06,2.01)**	-0.94 (-1.92,0.04)	0.27 (-0.76,1.30)	0.28 (-0.95,1.51)	0.48 (-0.54,1.49)	0.45 (-0.84,1.74)	0.19 (-0.77,1.15)	PE				0.21 (-1.20,1.62)		
-0.12 (-1.29,1.05)	-0.68 (-1.92,0.57)	-0.20 (-1.27,0.88)	0.69 (-0.44,1.81)	-1.29 (-2.60,0.03)	-0.08 (-1.14,0.99)	-0.07 (-1.39,1.25)	0.13 (-1.04,1.30)	0.10 (-1.26,1.47)	-0.16 (-1.39,1.08)	-0.35 (-1.68,0.98)	GP care					
-1.80 (-3.38,-0.21)	**-2.35 (-4.00,-0.70)**	**-1.87 (-3.40,-0.35)**	-0.99 (-2.58,0.60)	**-2.97 (-4.66,-1.27)**	**-1.75 (-3.34,-0.16)**	**-1.75 (-3.44,-0.05)**	**-1.55 (-2.92,-0.17)**	-1.57 (-3.34,0.19)	**-1.83 (-3.47,-0.20)**	**-2.02 (-3.73,-0.32)**	-1.68 (-3.48,0.13)	Csl				
0.90 (0.10,1.69)	0.34 (-0.54,1.22)	0.82 (-0.17,1.81)	**1.70 (0.83,2.57)**	-0.27 (-1.26,0.72)	0.94 (-0.00,1.89)	0.95 (-0.23,2.12)	**1.15 (0.12,2.17)**	1.12 (-0.10,2.34)	0.86 (-0.11,1.84)	0.67 (-0.42,1.76)	1.02 (-0.31,2.34)	**2.69 (0.98,4.41)**	BT+PC		-1.06 (-2.14,0.02)	
0.52 (-0.35,1.39)	-0.04 (-1.07,0.99)	0.44 (-0.64,1.53)	**1.33 (0.24,2.41)**	-0.65 (-1.70,0.40)	0.56 (-0.57,1.70)	0.57 (-0.75,1.90)	0.77 (-0.37,1.91)	0.74 (-0.63,2.12)	0.48 (-0.58,1.55)	0.29 (-0.67,1.26)	0.64 (-0.79,2.07)	**2.32 (0.53,4.11)**	-0.38 (-1.55,0.79)	Mind+PC		
-0.17 (-0.85,0.50)	-0.73 (-1.52,0.07)	-0.25 (-1.04,0.55)	**0.64 (0.08,1.20)**	**-1.34 (-2.24,-0.44)**	-0.12 (-0.72,0.47)	-0.12 (-1.06,0.82)	0.08 (-0.71,0.88)	0.05 (-0.90,1.01)	-0.21 (-1.06,0.65)	-0.40 (-1.38,0.58)	-0.05 (-1.19,1.09)	**1.63 (0.04,3.22)**	**-1.07 (-1.92,-0.21)**	-0.69 (-1.77,0.39)	BT	
0.14 (-1.28,1.55)	-0.42 (-1.94,1.10)	0.06 (-1.53,1.65)	0.94 (-0.63,2.51)	-1.03 (-2.57,0.50)	0.18 (-1.43,1.79)	0.19 (-1.56,1.93)	0.39 (-1.23,2.01)	0.36 (-1.42,2.14)	0.10 (-1.45,1.66)	-0.09 (-1.71,1.52)	0.26 (-1.58,2.09)	1.93 (-0.19,4.06)	-0.76 (-2.38,0.86)	-0.38 (-2.04,1.28)	0.31 (-1.26,1.87)	Csl+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.16 Pain intensity at post-intervention, excluding studies involving data imputed from median and interquartile ranges

PC (reference)																
0.14 (-1.47,1.74)	Csl+PC															
1.08 (0.21,1.95)	0.94 (-0.88,2.77)	BT+PC														
0.35 (-0.63,1.34)	0.22 (-1.66,2.10)	-0.73 (-2.04,0.58)	Mind+PC													
0.04 (-0.66,0.74)	-0.10 (-1.85,1.65)	**-1.04 (-1.98,-0.11)**	-0.32 (-1.51,0.88)	BT												
-1.69 (-3.48,0.09)	-1.83 (-4.23,0.57)	**-2.77 (-4.71,-0.84)**	**-2.05 (-4.07,-0.03)**	-1.73 (-3.53,0.07)	Csl											
-0.42 (-1.55,0.71)	-0.56 (-2.52,1.40)	**-1.51 (-2.84,-0.17)**	-0.78 (-2.26,0.70)	-0.46 (-1.57,0.65)	1.27 (-0.70,3.24)	GP care										
0.19 (-0.68,1.07)	0.06 (-1.77,1.88)	-0.89 (-2.10,0.33)	-0.16 (-1.26,0.93)	0.16 (-0.92,1.23)	1.89 (-0.05,3.82)	0.62 (-0.75,1.98)	PE									
0.13 (-0.51,0.77)	-0.01 (-1.73,1.72)	-0.95 (-1.99,0.09)	-0.22 (-1.38,0.93)	0.09 (-0.78,0.96)	**1.82 (0.01,3.64)**	0.55 (-0.64,1.75)	-0.06 (-1.09,0.96)	CP+PC								
0.00 (-1.17,1.17)	-0.13 (-2.12,1.85)	-1.08 (-2.42,0.26)	-0.35 (-1.87,1.17)	-0.04 (-1.10,1.03)	1.70 (-0.30,3.70)	0.43 (-0.98,1.83)	-0.19 (-1.61,1.23)	-0.13 (-1.40,1.14)	Advice							
-0.15 (-1.00,0.70)	-0.28 (-2.10,1.53)	**-1.23 (-2.36,-0.10)**	-0.50 (-1.78,0.77)	-0.18 (-1.07,0.70)	1.55 (-0.02,3.11)	0.28 (-0.92,1.47)	-0.34 (-1.47,0.79)	-0.28 (-1.20,0.64)	-0.15 (-1.39,1.09)	Usual care						
0.14 (-0.96,1.25)	0.01 (-1.94,1.95)	-0.94 (-2.23,0.36)	-0.21 (-1.67,1.26)	0.11 (-0.94,1.15)	1.84 (-0.09,3.76)	0.57 (-0.79,1.93)	-0.05 (-1.41,1.31)	0.02 (-1.18,1.21)	0.14 (-0.98,1.27)	0.29 (-0.83,1.41)	Mindfulness					
0.23 (-0.49,0.94)	0.09 (-1.66,1.85)	-0.85 (-1.84,0.13)	-0.12 (-1.33,1.08)	0.19 (-0.41,0.79)	**1.92 (0.13,3.71)**	0.65 (-0.34,1.65)	0.04 (-1.04,1.12)	0.10 (-0.77,0.97)	0.23 (-0.80,1.26)	0.38 (-0.49,1.24)	0.08 (-0.91,1.08)	CBT				
0.91 (0.37,1.46)	0.78 (-0.92,2.47)	-0.17 (-1.19,0.85)	0.56 (-0.57,1.69)	0.88 (-0.00,1.75)	**2.61 (0.75,4.47)**	**1.34 (0.09,2.59)**	0.72 (-0.31,1.75)	0.78 (-0.05,1.62)	0.91 (-0.37,2.19)	**1.06 (0.06,2.06)**	0.77 (-0.46,1.99)	0.68 (-0.21,1.57)	PE+PC			
-0.62 (-1.32,0.08)	-0.76 (-2.51,0.99)	**-1.70 (-2.65,-0.76)**	-0.98 (-2.17,0.22)	**-0.66 (-1.27,-0.05)**	1.07 (-0.73,2.87)	-0.20 (-1.30,0.90)	-0.82 (-1.89,0.26)	-0.75 (-1.61,0.11)	-0.63 (-1.72,0.47)	-0.48 (-1.37,0.41)	-0.77 (-1.78,0.24)	**-0.85 (-1.45,-0.25)**	**-1.54 (-2.41,-0.66)**	No intervention		
0.12 (-0.63,0.86)	-0.02 (-1.78,1.75)	-0.96 (-2.03,0.11)	-0.23 (-1.43,0.96)	0.08 (-0.77,0.93)	**1.81 (0.08,3.55)**	0.54 (-0.55,1.64)	-0.07 (-1.08,0.93)	-0.01 (-0.74,0.72)	0.12 (-1.12,1.35)	0.27 (-0.48,1.01)	-0.03 (-1.17,1.12)	-0.11 (-0.93,0.71)	-0.79 (-1.71,0.12)	0.74 (-0.08,1.57)	CP	
0.92 (0.42,1.42)	0.79 (-0.89,2.47)	-0.16 (-1.09,0.77)	0.57 (-0.53,1.67)	**0.89 (0.10,1.67)**	**2.62 (0.79,4.44)**	**1.35 (0.17,2.53)**	0.73 (-0.26,1.72)	**0.79 (0.05,1.54)**	0.92 (-0.29,2.14)	**1.07 (0.14,2.00)**	0.78 (-0.37,1.93)	0.69 (-0.09,1.48)	0.01 (-0.69,0.71)	**1.55 (0.79,2.31)**	0.80 (-0.03,1.64)	CBT+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: Mindfulness delivered with physiotherapy care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.17 Pain intensity at short-term treatment sustainability, excluding studies involving data imputed from median and interquartile ranges

PC (reference)													
1.04 (0.17,1.91)	PE+PC												
-0.22 (-1.63,1.18)	-1.26 (-2.88,0.35)	CBT											
-0.36 (-1.85,1.14)	-1.39 (-3.06,0.27)	-0.13 (-1.59,1.32)	Advice										
0.47 (-0.69,1.64)	-0.57 (-1.85,0.72)	0.70 (-0.93,2.33)	0.83 (-0.67,2.33)	CBT+PC									
-0.04 (-1.02,0.95)	-1.08 (-2.35,0.20)	0.19 (-1.39,1.76)	0.32 (-1.29,1.93)	-0.51 (-1.80,0.78)	CP+PC								
0.29 (-1.28,1.87)	-0.74 (-2.53,1.04)	0.52 (-1.39,2.42)	0.65 (-1.32,2.62)	-0.18 (-2.06,1.70)	0.33 (-1.43,2.10)	PE							
0.23 (-1.80,2.26)	-0.81 (-3.02,1.40)	0.45 (-2.02,2.92)	0.59 (-1.94,3.11)	-0.24 (-2.59,2.10)	0.27 (-1.99,2.53)	-0.07 (-2.64,2.51)	Mind+PC						
-0.65 (-1.83,0.53)	**-1.69 (-3.12,-0.26)**	-0.43 (-1.74,0.89)	-0.29 (-1.68,1.10)	-1.12 (-2.58,0.34)	-0.61 (-1.91,0.68)	-0.94 (-2.52,0.63)	-0.88 (-3.23,1.47)	CP					
-2.08 (-3.57,-0.59)	**-3.12 (-4.82,-1.41)**	**-1.85 (-3.24,-0.46)**	-1.72 (-3.44,0.00)	**-2.55 (-4.30,-0.80)**	**-2.04 (-3.70,-0.38)**	**-2.37 (-4.33,-0.41)**	-2.31 (-4.83,0.21)	**-1.43 (-2.81,-0.04)**	No intervention				
-0.47 (-1.81,0.87)	-1.51 (-3.08,0.06)	-0.25 (-1.77,1.27)	-0.12 (-1.75,1.51)	-0.95 (-2.58,0.68)	-0.44 (-1.93,1.06)	-0.77 (-2.56,1.02)	-0.70 (-3.14,1.73)	0.18 (-0.86,1.21)	1.60 (-0.00,3.21)	Usual care			
-1.00 (-2.63,0.63)	**-2.03 (-3.85,-0.22)**	-0.77 (-2.29,0.75)	-0.64 (-2.40,1.12)	-1.47 (-3.31,0.37)	-0.96 (-2.70,0.78)	-1.29 (-3.27,0.69)	-1.23 (-3.83,1.38)	-0.35 (-1.61,0.92)	1.08 (-0.65,2.81)	-0.52 (-2.11,1.07)	GP care		
0.04 (-1.23,1.31)	-1.00 (-2.51,0.52)	0.26 (-0.92,1.45)	0.40 (-1.20,2.00)	-0.43 (-2.03,1.16)	0.08 (-1.42,1.58)	-0.25 (-2.12,1.61)	-0.19 (-2.58,2.21)	0.69 (-0.64,2.03)	**2.12 (0.66,3.58)**	0.51 (-0.92,1.95)	1.04 (-0.63,2.70)	BT	
2.16 (0.23,4.09)	1.12 (-0.98,3.23)	**2.38 (0.29,4.48)**	**2.52 (0.25,4.79)**	1.69 (-0.50,3.88)	**2.20 (0.08,4.31)**	1.87 (-0.54,4.27)	1.93 (-0.87,4.73)	**2.81 (0.74,4.88)**	**4.24 (2.14,6.34)**	**2.63 (0.46,4.80)**	**3.16 (0.83,5.49)**	**2.12 (0.19,4.05)**	BT+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.18 Pain intensity at mid-term treatment sustainability, excluding studies involving data imputed from median and interquartile ranges

PC (reference)															
0.35 (0.04,0.67)	CBT+PC														
0.25 (-0.32,0.83)	-0.10 (-0.66,0.46)	Mindfulness													
-0.06 (-0.59,0.48)	-0.41 (-0.95,0.13)	-0.31 (-0.84,0.22)	Usual care												
0.25 (-0.17,0.66)	-0.11 (-0.52,0.31)	-0.01 (-0.48,0.47)	0.30 (-0.15,0.75)	CBT											
-0.05 (-0.56,0.46)	-0.40 (-0.87,0.07)	-0.30 (-0.78,0.17)	0.01 (-0.55,0.56)	-0.30 (-0.73,0.14)	Advice										
0.17 (-0.20,0.53)	-0.19 (-0.58,0.21)	-0.08 (-0.69,0.52)	0.22 (-0.31,0.76)	-0.08 (-0.55,0.39)	0.22 (-0.33,0.77)	CP+PC									
0.75 (0.16,1.34)	0.40 (-0.27,1.07)	0.50 (-0.32,1.32)	**0.81 (0.01,1.61)**	0.51 (-0.21,1.23)	**0.80 (0.02,1.58)**	0.59 (-0.11,1.28)	PE								
-0.10 (-0.61,0.40)	-0.46 (-1.05,0.14)	-0.36 (-1.12,0.41)	-0.05 (-0.78,0.69)	-0.35 (-1.00,0.30)	-0.05 (-0.77,0.66)	-0.27 (-0.89,0.35)	**-0.86 (-1.63,-0.08)**	Mind+PC							
0.28 (-0.29,0.84)	-0.08 (-0.64,0.49)	0.02 (-0.58,0.63)	0.33 (-0.14,0.81)	0.03 (-0.44,0.49)	0.32 (-0.27,0.92)	0.11 (-0.46,0.67)	-0.48 (-1.29,0.34)	0.38 (-0.38,1.13)	GP care						
0.20 (-0.75,1.15)	-0.16 (-1.11,0.79)	-0.06 (-1.03,0.92)	0.25 (-0.71,1.22)	-0.05 (-0.90,0.80)	0.24 (-0.71,1.20)	0.03 (-0.95,1.00)	-0.56 (-1.68,0.56)	0.30 (-0.77,1.37)	-0.08 (-1.05,0.89)	Csl					
-0.01 (-0.73,0.71)	-0.36 (-1.08,0.35)	-0.26 (-1.01,0.49)	0.05 (-0.69,0.79)	-0.25 (-0.84,0.33)	0.04 (-0.69,0.77)	-0.18 (-0.93,0.57)	-0.76 (-1.69,0.17)	0.10 (-0.78,0.97)	-0.28 (-1.03,0.46)	-0.20 (-0.83,0.42)	No intervention				
0.07 (-0.44,0.58)	-0.28 (-0.80,0.23)	-0.18 (-0.74,0.37)	0.13 (-0.21,0.46)	-0.18 (-0.62,0.27)	0.12 (-0.44,0.68)	-0.10 (-0.58,0.39)	-0.68 (-1.46,0.10)	0.17 (-0.54,0.89)	-0.21 (-0.60,0.18)	-0.13 (-1.09,0.84)	0.08 (-0.66,0.81)	CP			
0.32 (-0.18,0.81)	-0.04 (-0.55,0.47)	0.06 (-0.54,0.67)	0.37 (-0.21,0.95)	0.07 (-0.33,0.47)	0.36 (-0.20,0.93)	0.15 (-0.41,0.70)	-0.44 (-1.21,0.33)	0.42 (-0.29,1.13)	0.04 (-0.56,0.64)	0.12 (-0.82,1.06)	0.32 (-0.38,1.03)	0.25 (-0.32,0.82)	BT		
0.41 (-0.13,0.95)	0.06 (-0.57,0.68)	0.16 (-0.63,0.94)	0.47 (-0.29,1.23)	0.16 (-0.52,0.84)	0.46 (-0.28,1.20)	0.24 (-0.41,0.89)	-0.34 (-0.91,0.23)	0.51 (-0.22,1.25)	0.13 (-0.64,0.91)	0.21 (-0.88,1.31)	0.42 (-0.48,1.32)	0.34 (-0.40,1.08)	0.09 (-0.64,0.82)	PE+PC	
1.03 (0.44,1.63)	**0.68 (0.07,1.29)**	**0.78 (0.02,1.55)**	**1.09 (0.35,1.83)**	**0.79 (0.14,1.43)**	**1.08 (0.36,1.80)**	**0.87 (0.20,1.53)**	0.28 (-0.56,1.12)	**1.14 (0.36,1.92)**	0.76 (-0.00,1.52)	0.84 (-0.23,1.91)	**1.04 (0.17,1.91)**	**0.96 (0.24,1.69)**	**0.72 (0.07,1.37)**	0.62 (-0.18,1.43)	BT+PC

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 14.19 Pain intensity at short-term treatment sustainability, removing portions of the evidence in the network to address inconsistency

PC (reference)	**1.20 (0.68,1.71)**			0.10 (-1.04,1.24)	0.16 (-0.53,0.85)	**1.30 (0.15,2.46)**				-0.24 (-1.38,0.90)		-0.19 (-1.30,0.92)
1.06 (0.56,1.55)	PE+PC			0.32 (-0.83,1.46)								
0.53 (-0.37,1.44)	-0.52 (-1.53,0.49)	CBT	-0.20 (-1.35,0.96)						-0.30 (-1.44,0.84)		**-1.97 (-3.34,-0.59)**	0.00 (-0.87,0.87)
0.24 (-0.63,1.11)	-0.81 (-1.78,0.15)	-0.29 (-1.12,0.54)	Advice	0.37 (-0.80,1.55)				0.09 (-1.05,1.23)				
0.67 (0.01,1.33)	-0.38 (-1.11,0.35)	0.14 (-0.84,1.12)	0.43 (-0.42,1.29)	CBT+PC	-0.48 (-1.64,0.68)							
0.17 (-0.39,0.73)	**-0.88 (-1.61,-0.16)**	-0.36 (-1.32,0.60)	-0.07 (-0.98,0.84)	-0.50 (-1.22,0.22)	CP+PC			0.00 (-1.17,1.17)				
0.70 (-0.21,1.61)	-0.35 (-1.38,0.67)	0.17 (-0.96,1.30)	0.46 (-0.65,1.57)	0.03 (-1.04,1.09)	0.53 (-0.47,1.53)	PE		0.04 (-1.07,1.15)				
0.41 (-0.42,1.23)	-0.65 (-1.61,0.31)	-0.13 (-1.35,1.09)	0.16 (-1.03,1.36)	-0.27 (-1.32,0.79)	0.24 (-0.76,1.23)	-0.30 (-1.52,0.93)	Mind+PC					
0.18 (-0.53,0.90)	**-0.87 (-1.72,-0.03)**	-0.35 (-1.14,0.43)	-0.06 (-0.83,0.71)	-0.49 (-1.33,0.34)	0.01 (-0.74,0.76)	-0.52 (-1.42,0.38)	-0.22 (-1.31,0.87)	CP	0.00 (-1.18,1.18)	0.02 (-0.65,0.69)	-0.28 (-1.35,0.79)	
0.21 (-0.86,1.28)	-0.85 (-2.01,0.31)	-0.33 (-1.20,0.55)	-0.03 (-1.09,1.03)	-0.46 (-1.61,0.68)	0.04 (-1.07,1.15)	-0.49 (-1.73,0.74)	-0.20 (-1.55,1.15)	0.03 (-0.86,0.92)	No intervention			
0.14 (-0.65,0.93)	**-0.91 (-1.83,-0.00)**	-0.39 (-1.27,0.49)	-0.10 (-1.00,0.80)	-0.53 (-1.45,0.39)	-0.03 (-0.88,0.82)	-0.56 (-1.58,0.46)	-0.26 (-1.40,0.87)	-0.04 (-0.62,0.54)	-0.07 (-1.09,0.95)	Usual care		0.05 (-1.11,1.22)
-0.61 (-1.73,0.51)	**-1.67 (-2.88,-0.46)**	**-1.15 (-2.15,-0.14)**	-0.85 (-1.98,0.27)	**-1.29 (-2.48,-0.09)**	-0.78 (-1.94,0.37)	**-1.32 (-2.59,-0.04)**	-1.02 (-2.41,0.37)	-0.80 (-1.73,0.13)	-0.82 (-2.01,0.37)	-0.76 (-1.82,0.31)	GP care	
0.30 (-0.59,1.19)	-0.75 (-1.75,0.25)	-0.23 (-0.97,0.51)	0.06 (-0.90,1.02)	-0.37 (-1.38,0.64)	0.13 (-0.84,1.10)	-0.40 (-1.55,0.75)	-0.10 (-1.31,1.11)	0.12 (-0.73,0.97)	0.09 (-0.96,1.15)	0.16 (-0.71,1.04)	0.92 (-0.22,2.05)	BT

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, Mind+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Final results of global test for inconsistency: $chi^2 = 7.25$, $p = 0.51$. No local inconsistency was detected in the side-splitting approach.

Justification:
To examine the possible cause(s) of inconsistency for pain intensity at short-term treatment sustainability, we first examined the studies contributing to the sides demonstrating $p < 0.05$ from the side-splitting approach. The affected sides were 02 10 (physiotherapy care compared with no intervention), 02 14 (physiotherapy care compared with behavioural therapy delivered with physiotherapy care), 03 10 (cognitive behavioural therapy compared with no intervention), 10 13 (no intervention compared with behavioural therapy), 10 14 (no intervention compared with behavioural therapy delivered with physiotherapy care). We identified that Shariat et al. (2019),[77] was a common article contributing to all affected comparisons. We performed sensitivity analysis excluding this study to examine the impact on the degree of inconsistency. The global inconsistency test returned a result of $chi^2 = 9.38$, $p = 0.31$; however, local inconsistency was still detected in the sides 03 12 (cognitive behavioural therapy compared with general practitioner care) and 09 12 (combined psychological approaches compared with general practitioner care) from the side-splitting approach.

We subsequently visually inspected possible causes of intransitivity across the three studies directly contributing to these comparisons. We identified that Tavafian et al. (2017)[85] was potentially contributing to inconsistency due to intransience related to intervention duration. Intervention duration for the other studies were 2 to 3 weeks[53] and 12 to 24 weeks,[81] whilst Tavafian et al. (2017)[85] involved a one-week intervention post-randomisation with monthly booster counselling sessions between 24 to 30 months post-intervention.[85] We examined the impact of further excluding Tavafian et al. (2017)[85], and found that that global inconsistency ($chi^2 = 7.25$, $p = 0.51$) and local inconsistency were removed entirely.

As seen, the exclusion of Shariat et al. (2019)[77] resulted in behavioural therapy delivered with physiotherapy care (treatment node) becoming disconnected from the network. We recognise that this comparison resulted in statistically important findings from our primary analyses of pain intensity at both post-intervention and short-term treatment sustainability, from which our main conclusions were previously drawn in our initial manuscript submission. However, given that the current sensitivity analysis does not indicate important global or local inconsistency affecting the results, we have revised our discussion accordingly. Further studies should examine the robustness of effect estimates comparing behavioural therapy delivered with physiotherapy care, with physiotherapy care, at short-term treatment sustainability for pain intensity.

Nonetheless, effect estimates for pain education delivered with physiotherapy care compared with physiotherapy care remained very similar to those obtained in the primary analysis in terms of the magnitude of the effect and clinical significance. Also, effect estimates for cognitive behavioural therapy delivered with physiotherapy care remained similar in magnitude to the primary analysis; however, results became statistically significant in the sensitivity analyses, potentially suggesting that the effect of cognitive behavioural therapy delivered with physiotherapy care is sustained at least until short-term follow-up, and findings are not due to chance.

Supplementary O. Assessment of global inconsistency

Results of global inconsistency tests for the primary analysis are presented below in Supplementary Table 15.

Supplementary Table 15. Results of global inconsistency tests for the primary analyses

Time-point	Physical Function	Pain Intensity
Post-intervention	$chi^2 = 6.51$, $p = 0.99$	$chi^2 = 10.07$, $p = 0.97$
Short-term treatment sustainability	$chi^2 = 21.33$, ***p* < 0.001**	$chi^2 = 43.46$, ***p* < 0.001**
Mid-term treatment sustainability	$chi^2 = 28.75$, ***p* < 0.001**	$chi^2 = 11.98$, $p = 0.29$
Long-term treatment sustainability	$chi^2 = 1.18$, $p = 0.28$	$chi^2 = 1.12$, $p = 0.77$

Estimates in bold denote significance at $p<0.05$.

Results of global inconsistency tests for sensitivity analyses conducted to address inconsistency are presented below in Supplementary Table 16.

Supplementary Table 16. Results of global inconsistency tests for the sensitivity analyses conducted to address inconsistency

Time-point	Physical Function	Pain Intensity
Short-term treatment sustainability	$chi^2 = 1.92$, $p = 0.75$	$chi^2 = 7.25$, $p = 0.51$
Mid-term treatment sustainability	$chi^2 = 1.92$, $p = 0.78$	N/A

Estimates in bold denote significance at $p<0.05$.

Supplementary P. Results of side-splitting method for physical function and pain intensity

Supplementary Table 17.1 Physical function at post-intervention

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 03	0.03	0.35	-0.56	0.42	0.28
02 06	-0.78	0.31	-0.07	0.59	0.29
02 08	0.17	0.69	-0.17	0.47	0.68
02 09	-0.13	0.70	-0.49	0.42	0.66
02 12	-0.20	0.51	-0.12	0.45	0.91
02 15	0.18	0.69	-0.16	0.54	0.70
02 16	-0.26	0.75	-0.18	0.78	0.95
02 17	-0.16	0.67	-1.81	0.74	0.10
01 02	1.14	0.25	0.58	0.46	0.28
01 03	0.68	0.69	0.84	0.36	0.85
01 05	0.04	0.70	1.15	0.50	0.20
01 06	0.39	0.71	0.39	0.38	1.00
01 09	-0.12	0.68	0.92	0.44	0.20
03 04	0.03	0.41	-0.40	0.51	0.52
03 11	0.14	0.73	0.42	632.26	1.00
03 12	0.38	0.68	-0.07	0.43	0.57
04 05	0.74	0.77	-0.14	0.49	0.34
04 08	0.21	0.40	0.45	0.58	0.73
04 12	0.36	0.70	0.12	0.47	0.78
04 13	0.14	0.71	0.00	0.80	0.89
05 09	-0.21	0.40	-0.04	0.62	0.82
05 15	0.02	0.73	0.30	0.55	0.77
06 17	-1.06	0.68	0.60	0.73	0.10
07 08	0.37	0.68	0.23	0.85	0.90
07 09	0.01	0.68	-0.05	0.75	0.96
07 10	0.30	0.68	0.41	0.76	0.91
08 09	-0.36	0.68	-0.31	0.48	0.96
08 14	0.20	0.67	0.12	631.65	1.00
08 15	0.01	0.69	0.05	0.59	0.96
09 10	0.04	0.68	0.56	0.54	0.55
09 13	0.06	0.68	0.21	0.82	0.89
09 15	0.35	0.50	0.37	0.55	0.97
10 12	-0.55	0.72	0.20	0.63	0.44
10 15	0.00	0.80	-0.01	0.58	1.00
12 16	-0.04	0.69	-0.11	0.83	0.95

01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care, 03: combined psychological approaches delivered with physiotherapy care, 04: combined psychological approaches, 05: no intervention, 06: pain education delivered with physiotherapy care, 07: mindfulness, 08: usual care, 09: cognitive behavioural therapy, 10: advice, 11: behavioural therapy delivered with physiotherapy care, 12: pain education, 13: general practitioner care, 14: counselling, 15: behavioural therapy, 16: mindfulness delivered with physiotherapy care, 17: counselling delivered with physiotherapy care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 17.2 Physical function at short-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 05	-0.14	0.23	-1.07	0.24	**0.01**
02 06	-0.21	0.23	-0.47	0.30	0.50
02 07	-1.01	0.38	0.06	0.28	**0.02**
02 08	.	.	.	.	.
02 11	0.02	0.39	-0.16	0.39	0.75
02 13	0.11	0.39	-0.24	1.04	0.75
01 02	0.83	0.18	-0.35	0.40	**0.01**
01 05	-0.73	0.36	0.45	0.26	**0.01**
03 04	-0.01	0.39	0.03	0.76	0.97
03 10	0.27	0.37	0.23	0.76	0.97
04 05	-0.33	0.40	-0.29	0.75	0.97
05 06	0.46	0.38	0.19	0.30	0.57
06 07	0.26	0.36	-0.32	0.34	0.24
06 09	0.13	0.39	-0.06	0.34	0.72
07 09	-0.16	0.40	0.27	0.39	0.45
09 10	0.26	0.40	0.30	0.75	0.97
09 11	0.18	0.22	0.36	0.51	0.75
09 12	0.12	0.26	0.56	443.23	1.00
11 13	0.10	0.39	0.45	1.04	0.75

01: pain education delivered with physiotherapy care, 02: physiotherapy care, 03: cognitive behavioural therapy, 04: advice, 05: cognitive behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches delivered with physiotherapy care, 07: pain education, 08: mindfulness delivered with physiotherapy care, 09: combined psychological approaches, 10: no intervention, 11: usual care, 12: general practitioner care, 13: behavioural therapy. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 17.3 Physical function at mid-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 05	-0.11	0.28	-0.22	0.24	0.76
02 07	-0.45	0.19	-0.36	0.20	0.76
02 08	-0.91	0.28	0.04	0.22	**0.01**
02 09	.	.	.	.	.
01 02	0.23	0.10	0.91	0.22	**0.01**
01 05	-0.23	0.25	0.43	0.20	**0.04**
01 06	0.37	0.27	0.15	0.28	0.57
01 07	0.42	0.19	-0.30	0.14	**<0.001**
03 04	0.29	0.25	0.40	0.39	0.82
03 05	-0.01	0.25	0.04	0.30	0.90
03 06	0.14	0.24	0.05	0.30	0.83
04 05	-0.30	0.25	-0.32	0.26	0.96
04 10	-0.31	0.15	-0.26	0.32	0.89
05 06	-0.03	0.25	0.21	0.24	0.48
05 11	0.26	0.25	0.39	0.28	0.72
05 13	0.25	0.21	0.31	279.69	1.00

05 14	0.37	0.30	0.34	620.96	1.00
07 08	0.33	0.19	-0.61	0.31	**0.01**
07 10	0.29	0.18	0.10	0.31	0.61
08 15	-0.31	0.29	0.71	614.07	1.00
10 11	0.34	0.18	0.21	0.32	0.72
12 13	0.22	0.24	0.16	645.50	1.00

01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care, 03: mindfulness, 04: usual care, 05: cognitive behavioural therapy, 06: advice, 07: combined psychological approaches delivered with physiotherapy care, 08: pain education, 09: mindfulness delivered with physiotherapy care, 10: combined psychological approaches, 11: general practitioner care, 12: counselling, 13: no intervention, 14: behavioural therapy, 15: pain education delivered with physiotherapy care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 17.4 Physical function at long-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 03	-1.56	0.85	0.96	258.43	0.99
02 04	-0.09	1.84	-4.58	3.69	0.28
01 02	.	.	.	.	.
03 04	-0.33	1.84	4.16	3.69	0.28
04 05	0.20	1.88	1.55	138.05	0.99
05 10	-0.65	1.88	0.78	153.43	0.99
06 07	0.19	1.88	-2.88	632.64	1.00
07 10	0.00	1.89	-1.81	282.84	1.00
08 09	0.26	1.87	-2.29	632.44	1.00
09 10	-0.30	1.88	-1.84	282.93	1.00

01: combined psychological approaches delivered with physiotherapy care, 02: physiotherapy care, 03: cognitive behavioural therapy delivered with physiotherapy care, 04: cognitive behavioural therapy, 05: general practitioner care, 06: counselling, 07: no intervention, 08: pain education, 09: usual care, 10: combined psychological approaches. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 17.5 Pain intensity at post-intervention

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 04	1.90	0.61	0.01	0.41	**0.01**
02 05	-0.92	0.29	-0.86	0.87	0.95
02 06	-0.22	0.81	-0.23	0.41	0.99
02 08	0.65	0.80	-0.06	0.51	0.45
02 10	-0.28	0.41	0.12	0.53	0.55
02 11	-0.42	0.59	0.04	0.65	0.60
02 14	0.45	0.47	-0.64	0.51	0.12
02 15	-0.42	0.49	-0.42	0.95	1.00
02 16	-0.64	0.49	-2.73	0.97	0.05
02 17	.	.	.	.	.

01 02	1.12	0.29	0.37	0.50	0.20
01 04	0.11	0.80	1.93	0.42	0.05
01 05	0.06	0.82	0.00	0.40	0.95
01 06	-0.21	0.80	0.98	0.45	0.19
01 10	0.93	0.80	0.75	0.43	0.85
01 16	-0.08	0.85	-0.19	0.57	0.92
03 04	0.71	0.88	0.76	0.48	0.96
03 08	0.08	0.46	0.65	0.66	0.48
03 10	0.14	0.47	-0.26	0.61	0.60
03 11	0.31	0.81	-0.34	0.65	0.53
03 12	0.30	0.82	0.75	0.76	0.69
04 06	-0.76	0.38	-1.03	0.52	0.67
04 07	-0.52	0.86	-0.91	0.64	0.72
04 14	-0.84	0.35	-0.07	0.64	0.29
04 16	-2.41	0.63	-0.73	0.73	0.09
06 07	-0.10	0.80	0.21	0.65	0.77
06 08	0.34	0.80	0.39	0.53	0.96
06 09	0.10	0.80	0.32	0.70	0.84
06 12	0.78	0.60	0.33	0.94	0.69
06 14	0.20	0.38	0.18	0.52	0.97
07 08	0.44	0.80	0.14	0.82	0.79
07 09	0.14	0.80	0.15	0.83	1.00
08 13	1.55	0.79	-0.29	628.96	1.00
08 14	-0.41	0.80	-0.08	0.54	0.74
09 14	-0.19	0.90	0.05	0.68	0.83
11 15	-0.21	0.80	-0.21	0.70	1.00
14 16	-1.08	0.60	-0.98	0.76	0.92

01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care, 03: combined psychological approaches, 04: no intervention, 05: pain education delivered with physiotherapy care, 06: cognitive behavioural therapy, 07: mindfulness, 08: usual care, 09: advice, 10:combined psychological approaches delivered with physiotherapy care, 11: pain education, 12: general practitioner care, 13: counselling, 14: behavioural therapy, 15: mindfulness delivered with physiotherapy care, 16: behavioural therapy delivered with physiotherapy care, 17: counselling delivered with physiotherapy care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 17.6 Pain intensity at short-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 05	-0.10	1.04	-0.65	0.72	0.66
02 06	-0.16	0.60	0.48	0.91	0.56
02 07	-1.30	1.00	1.06	1.17	0.12
02 08	.	.	.	.	.
02 10	5.15	0.88	-0.10	0.64	**<0.001**
02 11	0.24	1.04	0.65	0.91	0.77
02 13	0.36	0.73	-1.19	1.23	0.28
02 14	-1.08	0.95	-6.57	1.96	**0.01**
01 02	1.22	0.46	-0.22	1.22	0.27

01 05	-0.32	1.02	1.12	0.81	0.27
03 04	0.20	1.04	0.07	1.06	0.93
03 10	0.30	0.93	3.14	0.89	**0.03**
03 12	1.97	1.07	-0.30	1.00	0.12
03 13	0.00	0.75	-0.73	1.00	0.56
04 05	-0.37	1.04	-1.36	1.12	0.52
04 09	-0.09	1.03	0.64	0.97	0.61
05 06	0.48	1.04	0.53	0.85	0.97
06 09	0.00	1.03	1.02	0.85	0.44
07 09	-0.04	0.99	2.32	1.18	0.12
09 10	0.00	0.97	2.56	0.89	0.05
09 11	-0.02	0.60	-0.70	1.11	0.59
09 12	-0.16	0.69	2.10	1.29	0.12
10 13	-4.44	0.99	-0.46	0.77	**<0.001**
10 14	-6.54	0.89	3.69	1.45	**<0.001**
11 13	-0.05	1.03	-0.97	1.03	0.53
13 14	-1.61	1.07	-4.14	2.12	0.28

01: pain education delivered with physiotherapy care, 02: physiotherapy care, 03: cognitive behavioural therapy, 04: advice, 05: cognitive behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches delivered with physiotherapy care, 07: pain education, 08: mindfulness delivered with physiotherapy care, 09: combined psychological approaches, 10: no intervention, 11: usual care, 12: general practitioner care, 13: behavioural therapy, 14: behavioural therapy delivered with physiotherapy care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 17.7 Pain intensity at mid-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 05	-0.05	0.35	-0.30	0.27	0.58
02 07	-0.35	0.23	0.20	0.29	0.14
02 08	-1.27	0.36	0.06	0.43	**0.02**
02 09	.	.	.	.	.
02 14	-0.02	0.41	-0.45	0.32	0.40
02 15	-0.05	0.28	-1.38	0.48	**0.02**
02 16	-1.01	0.35	-1.00	0.70	0.99
01 02	0.21	0.17	0.57	0.33	0.33
01 05	-0.25	0.34	0.26	0.26	0.24
01 06	0.48	0.35	0.28	0.35	0.68
01 07	0.43	0.32	-0.04	0.25	0.25
01 16	-0.73	0.50	-0.72	0.39	0.98
03 04	0.27	0.33	0.39	0.53	0.85
03 05	-0.03	0.33	0.04	0.39	0.89
03 06	0.35	0.33	0.25	0.40	0.84
04 05	-0.30	0.33	-0.30	0.34	0.99
04 13	-0.13	0.19	-0.09	0.43	0.92
05 06	0.17	0.33	0.43	0.31	0.58
05 10	0.09	0.33	-0.19	0.37	0.57
05 12	0.25	0.30	0.35	280.63	1.00

05 14	-0.13	0.23	0.13	0.45	0.60
07 13	0.00	0.34	0.25	0.39	0.63
08 15	-0.11	0.33	1.22	0.45	**0.02**
10 13	0.27	0.23	-0.01	0.43	0.57
11 12	0.20	0.32	0.10	636.37	1.00
14 16	-0.71	0.42	-0.74	0.56	0.97

01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care, 03: mindfulness, 04: usual care, 05: cognitive behavioural therapy, 06: advice, 07: combined psychological approaches delivered with physiotherapy care, 08: pain education, 09: mindfulness delivered with physiotherapy care, 10: general practitioner care, 11: counselling, 12: no intervention, 13: combined psychological approaches, 14: behavioural therapy, 15: pain education delivered with physiotherapy care, 16: behavioural therapy delivered with physiotherapy care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

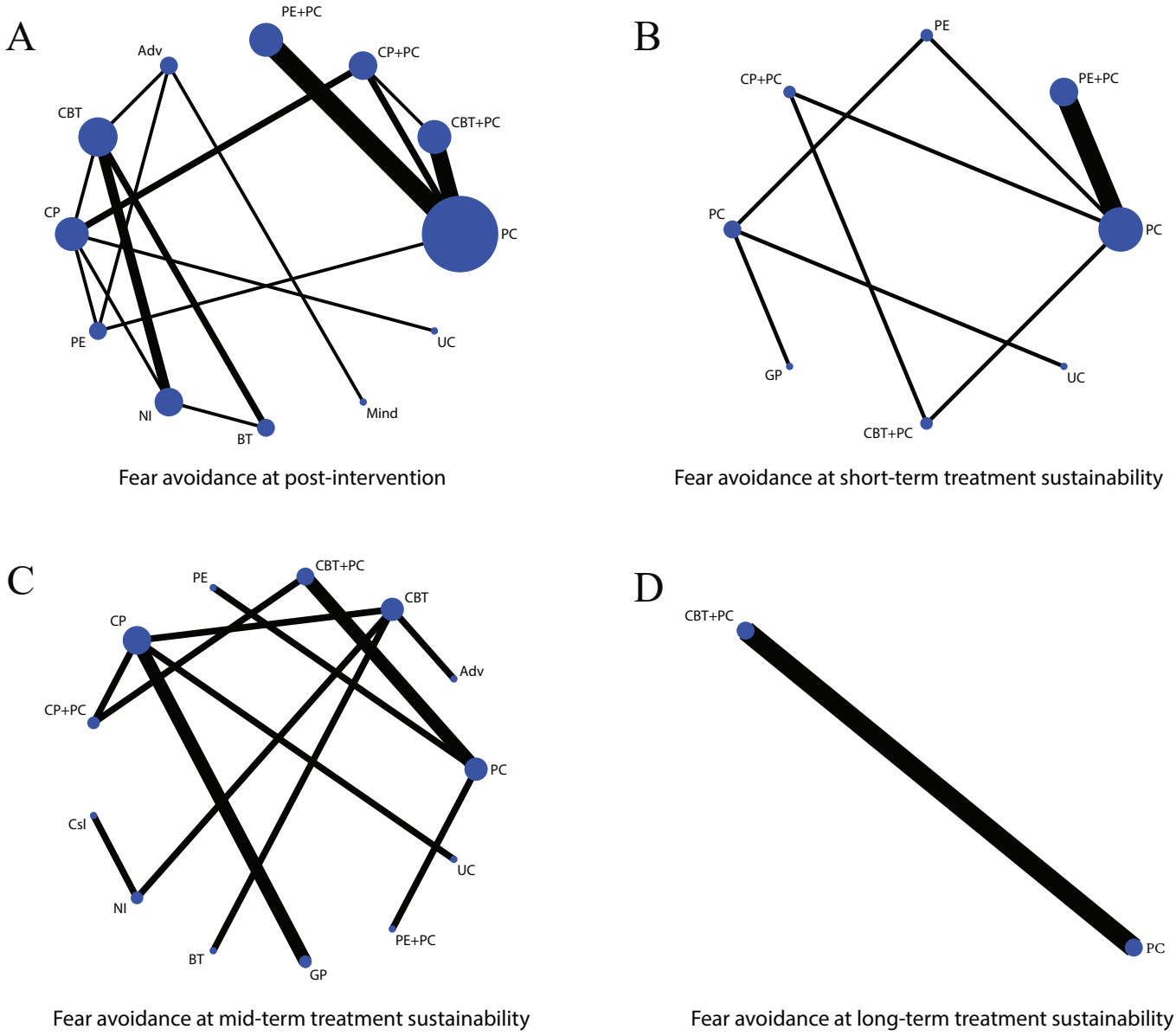
Supplementary Table 17.8 Pain intensity at long-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 03	-0.03	1.43	-3.78	2.86	0.24
02 07	-1.21	0.73	-0.45	4.35	0.86
02 08	-0.77	1.17	-1.56	3.28	0.82
02 10	-0.40	1.63	-1.17	4.10	0.86
01 02	.	.	.	.	.
03 04	0.07	1.47	0.13	175.52	1.00
03 07	0.35	1.43	-3.40	2.86	0.24
04 09	0.92	1.47	0.77	210.87	1.00
05 06	0.18	1.46	0.60	632.28	1.00
06 09	-0.09	1.47	0.17	282.83	1.00
07 08	0.05	1.64	0.64	1.72	0.81
08 10	0.25	1.63	1.02	4.10	0.86

01: combined psychological approaches delivered with physiotherapy care, 02: physiotherapy care, 03: cognitive behavioural therapy, 04: general practitioner care, 05: pain education, 06: usual care, 07: cognitive behavioural therapy delivered with physiotherapy care, 08: behavioural therapy delivered with physiotherapy care, 09: combined psychological approaches, 10: behavioural therapy. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Q. Results from direct and network evidence for fear avoidance and intervention compliance

Supplementary Figure 15. Network plots of fear avoidance at post-intervention, and short, mid, and long-term follow-up



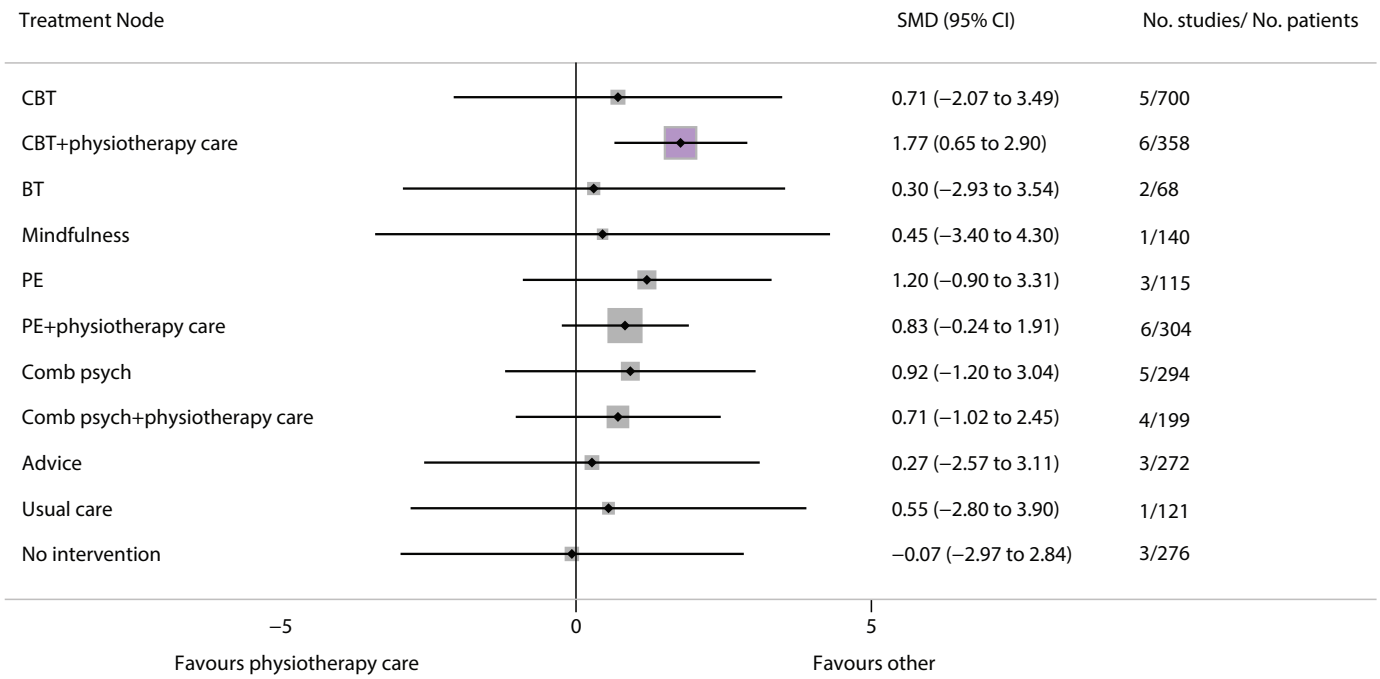
Adv: advice, BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP: general practitioner care, Mind: Mindfulness, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 18.1 Fear avoidance at post-intervention

PC (reference)	**1.93 (0.71,3.14)**					-0.14 (-2.81,2.53)	1.31 (-1.43,4.04)				
1.77 (0.65,2.90)	CBT+PC					-0.33 (-2.98,2.33)					
0.83 (-0.24,1.91)	-0.94 (-2.49,0.62)	PE+PC									
0.27 (-2.57,3.11)	-1.50 (-4.46,1.46)	-0.56 (-3.60,2.47)	Advice	0.13 (-2.55,2.82)			1.25 (-1.48,3.99)			0.18 (-2.41,2.78)	
0.71 (-2.07,3.49)	-1.06 (-3.94,1.82)	-0.12 (-3.10,2.85)	0.44 (-1.76,2.65)	CBT	-0.06 (-2.77,2.64)			-0.84 (-2.41,0.72)	-0.51 (-2.43,1.42)		
0.92 (-1.20,3.04)	-0.85 (-3.08,1.37)	0.08 (-2.29,2.46)	0.65 (-1.80,3.10)	0.21 (-1.87,2.29)	CP	-0.15 (-2.08,1.78)	-0.13 (-2.83,2.56)	-0.79 (-3.51,1.93)			-0.37 (-2.96,2.23)
0.71 (-1.02,2.45)	-1.06 (-2.86,0.74)	-0.12 (-2.16,1.92)	0.44 (-2.33,3.21)	0.00 (-2.57,2.58)	-0.21 (-1.89,1.48)	CP+PC					
1.20 (-0.90,3.31)	-0.57 (-2.85,1.72)	0.37 (-1.99,2.73)	0.93 (-1.30,3.16)	0.49 (-1.93,2.92)	0.28 (-1.65,2.21)	0.49 (-1.69,2.67)	PE				
-0.07 (-2.97,2.84)	-1.84 (-4.83,1.15)	-0.90 (-3.99,2.19)	-0.34 (-2.86,2.19)	-0.78 (-2.24,0.68)	-0.98 (-3.18,1.21)	-0.78 (-3.46,1.91)	-1.27 (-3.87,1.34)	No intervention	0.53 (-2.22,3.27)		
0.30 (-2.93,3.54)	-1.47 (-4.79,1.85)	-0.53 (-3.94,2.87)	0.03 (-2.77,2.83)	-0.41 (-2.18,1.36)	-0.62 (-3.26,2.03)	-0.41 (-3.47,2.64)	-0.90 (-3.85,2.04)	0.37 (-1.65,2.39)	BT		
0.45 (-3.40,4.30)	-1.32 (-5.25,2.62)	-0.38 (-4.38,3.61)	0.18 (-2.41,2.78)	-0.26 (-3.66,3.14)	-0.47 (-4.04,3.10)	-0.26 (-4.06,3.53)	-0.75 (-4.17,2.67)	0.52 (-3.10,4.14)	0.15 (-3.67,3.96)	Mindfulness	
0.55 (-2.80,3.90)	-1.22 (-4.64,2.20)	-0.28 (-3.80,3.24)	0.28 (-3.29,3.85)	-0.16 (-3.49,3.17)	-0.37 (-2.96,2.23)	-0.16 (-3.26,2.93)	-0.65 (-3.89,2.58)	0.62 (-2.78,4.02)	0.25 (-3.46,3.96)	0.10 (-4.31,4.51)	Usual care

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle). Note: Three studies [5, 17, 92] were excluded from the NMA due to using ambiguous methods to score the Fear Avoidance Beliefs Questionnaire which were inconsistent with validated recommendations. The results of these studies have been summarised descriptively in Supplementary E.[17, 92]

Supplementary Figure 16. Forest plots of network results for fear avoidance at post-intervention



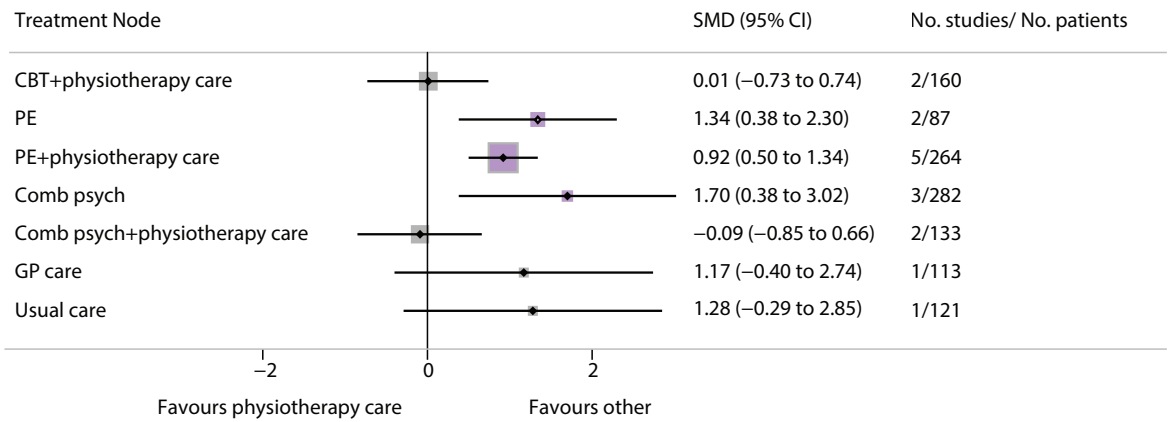
BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 18.2 Fear avoidance at short-term treatment sustainability

PC (reference)		**1.34 (0.38,2.30)**	0.14 (-0.85,1.13)			-0.20 (-1.15,0.74)	
0.92 (0.50,1.34)	PE+PC						
1.34 (0.38,2.30)	0.42 (-0.62,1.47)	PE		0.36 (-0.55,1.27)			
-0.09 (-0.85,0.66)	**-1.01 (-1.87,-0.15)**	**-1.43 (-2.65,-0.21)**	CP+PC			0.30 (-0.61,1.20)	
1.70 (0.38,3.02)	0.78 (-0.60,2.17)	0.36 (-0.55,1.27)	**1.79 (0.28,3.31)**	CP	-0.53 (-1.39,0.33)		-0.42 (-1.27,0.44)
1.17 (-0.40,2.74)	0.25 (-1.37,1.88)	-0.17 (-1.42,1.08)	1.26 (-0.48,3.01)	-0.53 (-1.39,0.33)	GP care		
0.01 (-0.73,0.74)	**-0.91 (-1.76,-0.06)**	**-1.33 (-2.54,-0.12)**	0.10 (-0.62,0.82)	**-1.69 (-3.20,-0.18)**	-1.16 (-2.90,0.57)	CBT+PC	
1.28 (-0.29,2.85)	0.37 (-1.26,1.99)	-0.06 (-1.30,1.19)	1.38 (-0.37,3.12)	-0.42 (-1.27,0.44)	0.11 (-1.10,1.32)	1.27 (-0.46,3.01)	Usual care

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 17. Forest plots of network results for fear avoidance at short-term treatment sustainability



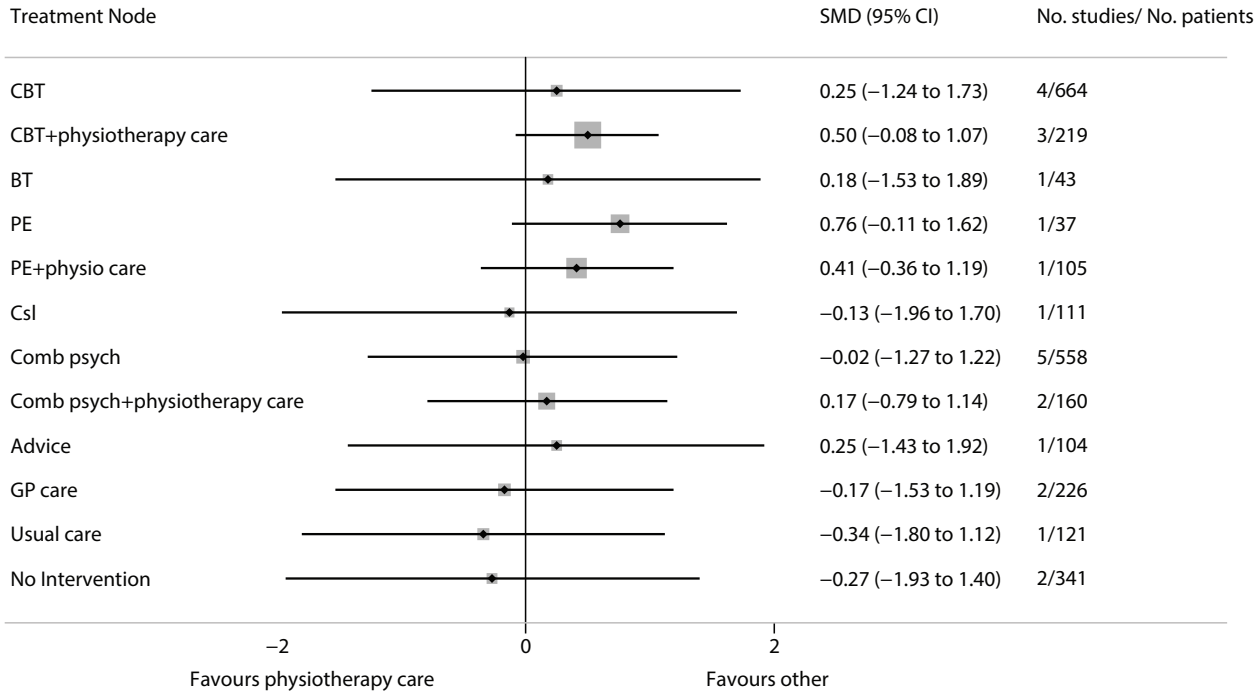
CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary Table 18.3 Fear avoidance at mid-term treatment sustainability

PC (reference)			0.5 (-0.08,1.07)									
0.25 (-1.43,1.92)	Advice	0.00 (-0.78,0.78)										
0.25 (-1.24,1.73)	0.00 (-0.78,0.78)	CBT			-0.27 (-1.08,0.54)			-0.51 (-1.26,0.23)	-0.07 (-0.91,0.77)			
0.50 (-0.08,1.07)	0.25 (-1.33,1.83)	0.25 (-1.12,1.62)	CBT+PC			-0.32 (-1.10,0.45)						
0.76 (-0.11,1.62)	0.51 (-1.38,2.40)	0.51 (-1.21,2.23)	0.26 (-0.78,1.30)	PE								
-0.02 (-1.27,1.22)	-0.27 (-1.39,0.85)	-0.27 (-1.08,0.54)	-0.52 (-1.62,0.58)	-0.78 (-2.30,0.73)	CP	0.20 (-0.59,0.98)				-0.14 (-0.69,0.40)		-0.32 (-1.09,0.45)
0.17 (-0.79,1.14)	-0.07 (-1.44,1.30)	-0.07 (-1.20,1.06)	-0.32 (-1.10,0.45)	-0.58 (-1.88,0.71)	0.20 (-0.59,0.98)	CP+PC						
-0.13 (-1.96,1.70)	-0.38 (-1.70,0.94)	-0.38 (-1.45,0.69)	-0.63 (-2.37,1.11)	-0.89 (-2.92,1.14)	-0.11 (-1.45,1.23)	-0.31 (-1.86,1.25)	Csl	-0.13 (-0.90,0.64)				
-0.27 (-1.93,1.40)	-0.51 (-1.59,0.56)	-0.51 (-1.26,0.23)	-0.76 (-2.32,0.80)	-1.02 (-2.90,0.85)	-0.24 (-1.34,0.86)	-0.44 (-1.79,0.91)	-0.13 (-0.90,0.64)	No Intervention				
0.18 (-1.53,1.89)	-0.07 (-1.21,1.08)	-0.07 (-0.91,0.77)	-0.32 (-1.92,1.29)	-0.58 (-2.49,1.34)	0.20 (-0.97,1.37)	0.01 (-1.40,1.41)	0.31 (-1.05,1.67)	0.45 (-0.68,1.57)	BT			
-0.17 (-1.53,1.19)	-0.41 (-1.66,0.84)	-0.41 (-1.39,0.56)	-0.66 (-1.90,0.57)	-0.93 (-2.54,0.68)	-0.14 (-0.69,0.40)	-0.34 (-1.30,0.61)	-0.04 (-1.49,1.41)	0.10 (-1.13,1.33)	-0.35 (-1.64,0.94)	GP care		
0.41 (-0.36,1.19)	0.16 (-1.68,2.01)	0.16 (-1.51,1.84)	-0.09 (-1.05,0.88)	-0.35 (-1.51,0.81)	0.43 (-1.03,1.90)	0.24 (-1.00,1.48)	0.54 (-1.45,2.53)	0.68 (-1.16,2.51)	0.23 (-1.65,2.11)	0.58 (-0.99,2.14)	PE+PC	
-0.34 (-1.80,1.12)	-0.59 (-1.95,0.78)	-0.59 (-1.70,0.53)	-0.84 (-2.18,0.51)	-1.10 (-2.80,0.60)	-0.32 (-1.09,0.45)	-0.51 (-1.61,0.58)	-0.21 (-1.76,1.34)	-0.07 (-1.42,1.27)	-0.52 (-1.92,0.88)	-0.17 (-1.11,0.77)	-0.75 (-2.41,0.91)	Usual care

Results are presented as standardised mean differences (SMD)and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP care: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

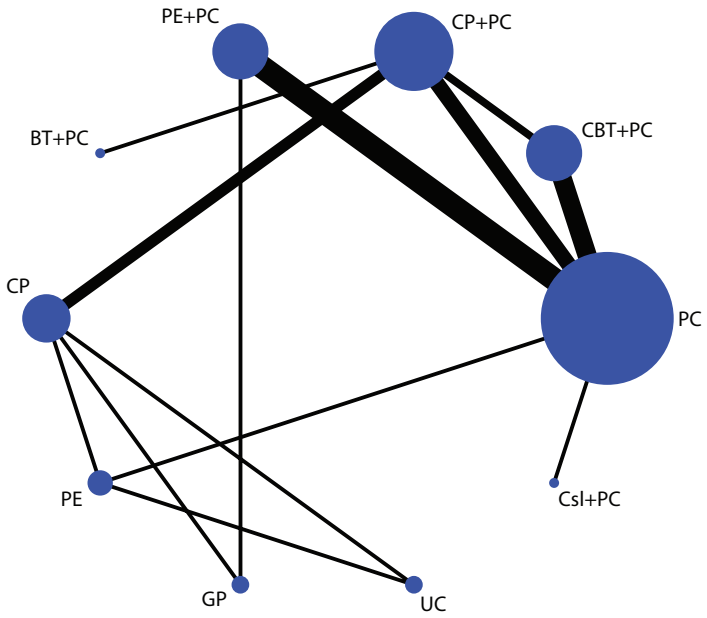
Supplementary Figure 18. Forest plots of network results for fear avoidance at mid-term treatment sustainability



BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Comment. Fear avoidance at long-term treatment sustainability
NMA was not performed at long-term treatment sustainability for fear avoidance as the network became disconnected. Results from pairwise meta-analysis for cognitive behavioural therapy delivered with physiotherapy care (CBT+PC) compared with physiotherapy care (PC): standardised mean difference 3.21 (95% confidence interval 0.00 to 6.41).

Supplementary Figure 19. Network plot for intervention compliance at post-intervention



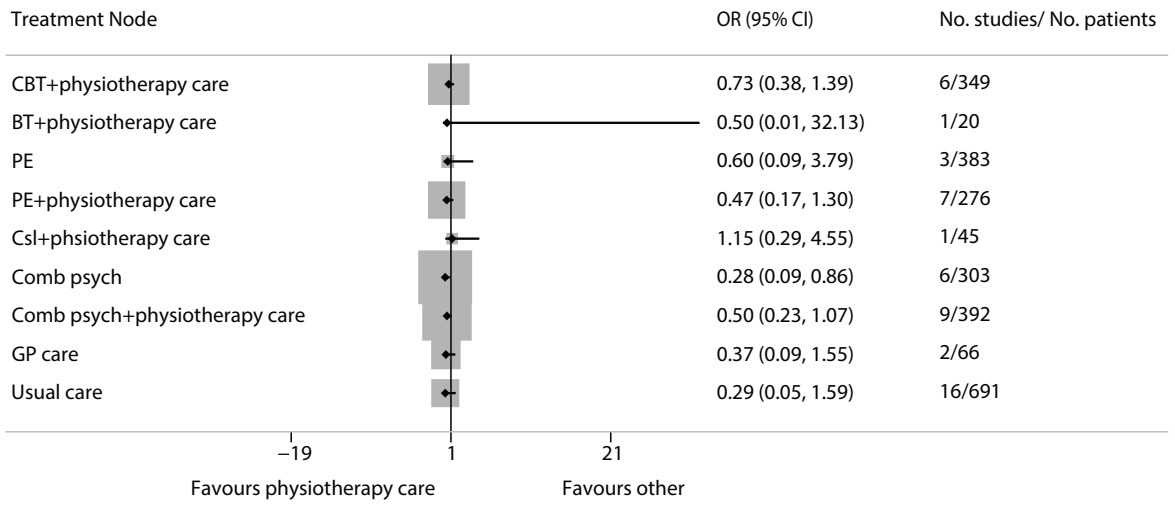
BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 18.4 Intervention compliance at post-intervention

PC (reference)	0.77 (0.36,1.63)	0.40 (0.15,1.06)	0.43 (0.14,1.32)			0.97 (0.02,58.54)			
0.73 (0.38,1.39)	CBT+PC	0.82 (0.31,2.15)							
0.50 (0.23,1.07)	0.68 (0.31,1.49)	CP+PC		1.00 (0.02,60.40)	0.61 (0.22,1.67)				
0.47 (0.17,1.30)	0.65 (0.20,2.13)	0.95 (0.28,3.21)	PE+PC				0.58 (0.09,3.83)		
0.50 (0.01,32.13)	0.68 (0.01,44.29)	1.00 (0.02,60.40)	1.06 (0.01,76.15)	BT+PC					
0.28 (0.09,0.86)	0.39 (0.12,1.24)	0.57 (0.23,1.44)	0.61 (0.16,2.36)	0.57 (0.01,38.41)	CP	3.06 (0.10,89.97)	1.57 (0.33,7.41)	1.40 (0.28,6.95)	
0.60 (0.09,3.79)	0.82 (0.13,5.37)	1.21 (0.21,7.03)	1.27 (0.16,9.83)	1.21 (0.01,104.68)	2.10 (0.43,10.32)	PE		0.41 (0.13,1.27)	
0.37 (0.09,1.55)	0.50 (0.11,2.28)	0.74 (0.18,3.05)	0.78 (0.19,3.26)	0.74 (0.01,56.68)	1.29 (0.36,4.65)	0.61 (0.08,4.63)	GP care		
0.29 (0.05,1.59)	0.40 (0.07,2.27)	0.58 (0.12,2.93)	0.61 (0.09,4.11)	0.58 (0.01,47.71)	1.01 (0.25,4.07)	0.48 (0.17,1.39)	0.79 (0.12,5.12)	Usual care	
1.15 (0.29,4.55)	1.59 (0.35,7.24)	2.33 (0.48,11.22)	2.46 (0.44,13.61)	2.33 (0.03,188.17)	4.05 (0.69,23.63)	1.93 (0.19,19.33)	3.15 (0.43,23.02)	4.01 (0.45,35.99)	Csl+PC

Results are presented as odds ratios (OR) and 95% confidence intervals. BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PC: physiotherapy care. Estimates in bold denote significance at $p<0.05$. OR values less than 1.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Figure 20. Forest plots of network results for intervention compliance at post-intervention



BT: behavioural therapy, CBT: cognitive behavioural therapy, Comb psych: combined psychological approaches, Csl: counselling, GP care: general practitioner care, PE: pain education. Physiotherapy care was considered the reference comparison group.

Supplementary R. CINeMA results for fear avoidance

Judgments of the confidence in cumulative evidence were evaluated using the Confidence in Network Meta-Analysis (CINeMA) framework,[102-104] a web application of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) ratings approach.

In CINeMA, the default confidence rating for each comparison is "high confidence." Confidence ratings per comparison were assessed according to the following steps. First, we assigned a point scale to the domain-level judgments: "no concerns" was 0 points, "some concerns" was 0.5 points, "major concerns" was 1 point. Then, we downgraded the confidence rating, for each comparison, by: (i) one level (i.e., "moderate confidence"), if there was a reduction of ≥1 but <2 points across all domains; two levels (i.e., "low confidence"), if there was a reduction of ≥2 but <3 points across all domains; (ii) three levels (i.e., "very low confidence"), if there was a reduction of ≥3 points across all domains.

Supplementary Table 19.1 Fear avoidance at post-intervention

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:CBT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:Mind	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT	2	Major concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:NI	1	Major concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:NI	3	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PC	5	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:CP+PC	2	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:UC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PC	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
PC:PE	1	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
PC:PE+PC	6	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
Adv:BT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

Adv:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
BT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:Mind	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CP+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
Mind:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

Adv: advice, BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Mind: mindfulness, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 19.2 Fear avoidance at short-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:GP	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:PE	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PC:PE	1	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
PC:PE+PC	5	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CBT+PC:CP	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate

CBT+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CBT+PC:PE	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT+PC:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP:CP+PC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP:PC	0	Some concerns	Undetected	No concerns	No concerns	Some concerns	No concerns	Moderate
CP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
CP+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
CP+PC:PE	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	No concerns	Major concerns	No concerns	Moderate
CP+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:PC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
GP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	No concerns	Moderate
PE:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate
PE+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	No concerns	Moderate

CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Supplementary Table 19.3 Fear avoidance at mid-term treatment sustainability

Comparison	n studies	Within-study bias	Reporting bias	Indirectness	Imprecision	Heterogeneity	Incoherence	Confidence rating
Adv:CBT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:CBT	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:CP	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT:NI	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:CP+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:PC	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low

CP:CP+PC	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:GP	2	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP:UC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Csl:NI	1	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
PC:PE	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
PC:PE+PC	1	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:BT	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:NI	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Adv:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Adv:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:CP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
BT:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:CBT+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:CP+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low

CBT:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:CP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT+PC:GP	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CBT+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CBT+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
CP:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:Csl	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
CP+PC:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
Csl:GP	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
Csl:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:NI	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low

GP:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
GP:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:PE	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
NI:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
PE:PE+PC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low
PE:UC	0	Some concerns	Undetected	No concerns	Some concerns	Some concerns	Major concerns	Low
PE+PC:UC	0	Some concerns	Undetected	No concerns	Major concerns	No concerns	Major concerns	Low

Adv: advice, BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP: general practitioner care, NI: no intervention, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, UC: usual care.

Comment. Fear avoidance at long-term treatment sustainability

At long-term follow-up, the network became disconnected. We were unable to use CINeMA to perform the GRADE assessment.

Supplementary S. Rank results for fear avoidance and intervention compliance

Supplementary Table 20.1 Fear avoidance at post-intervention

Rank	Treatment Node	SUCRA	Mean Rank
1st	CBT+PC	81.8	3
2nd	PE	67.7	4.5
3rd	CBT	59.4	5.5
4th	CP+PC	55.4	5.9
5th	Advice	53.8	6.1
6th	CP	51	6.4
7th	Usual care	47.8	6.7
8th	Mindfulness	46.2	6.9
9th	BT	40.9	7.5
10th	PE+PC	39.1	7.7
11th	No Intervention	29.1	8.8
12th	Physiotherapy care	27.8	8.9

BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.

Supplementary Table 20.2 Fear avoidance at short-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	CP	90.4	1.7
2nd	PE	73	2.9
3rd	Usual care	66.9	3.3
4th	GP care	61.8	3.7
5th	PE+PC	57.6	4
6th	CBT+PC	19.3	6.7
7th	Physiotherapy care	17.4	6.8
8th	CP+PC	13.6	7

CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, GP care: general practitioner care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.

Supplementary Table 20.3 Fear avoidance at mid-term treatment sustainability

Rank	Treatment Node	SUCRA	Mean Rank
1st	PE	80.5	3.3
2nd	CBT+PC	73.2	4.2
3rd	PE+PC	64.5	5.3
4th	CBT	61.3	5.6
5th	Advice	58.7	6
6th	BT	54.6	6.4
7th	CP+PC	54	6.5
8th	CP	42	8
9th	Physiotherapy care	40	8.2
10th	Csl	37.7	8.5
11th	GP care	32.1	9.2
12th	No intervention	27.6	9.7
13th	Usual care	24	10.1

BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, GP care: general practitioner care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.

Comment. Fear avoidance at long-term treatment sustainability

NMA was not performed at long-term treatment sustainability for fear avoidance as the network became disconnected.

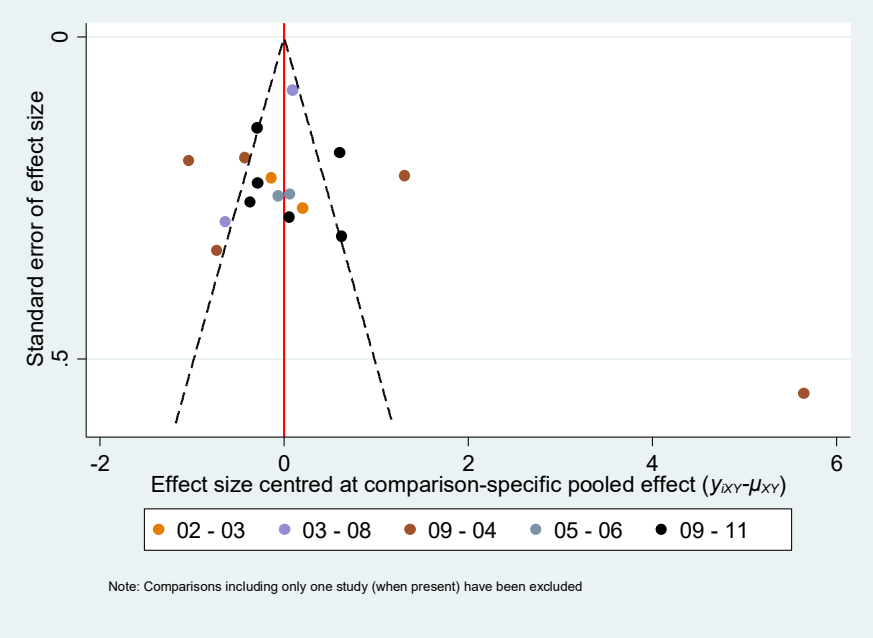
Supplementary Table 20.4 Intervention compliance at post-intervention

Rank	Treatment Node	SUCRA	Mean Rank
1st	CP	78.7	2.9
2nd	Usual care	74.6	3.3
3rd	GP care	64.9	4.2
4th	PE+PC	56.3	4.9
5th	CP+PC	54.6	5.1
6th	BT+PC	51.9	5.3
7th	PE	43.1	6.1
8th	CBT+PC	35.4	6.8
9th	Csl+PC	21.5	8.1
10th	Physiotherapy care	18.9	8.3

BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, PE: pain education, PE+PC: pain education delivered with physiotherapy care.

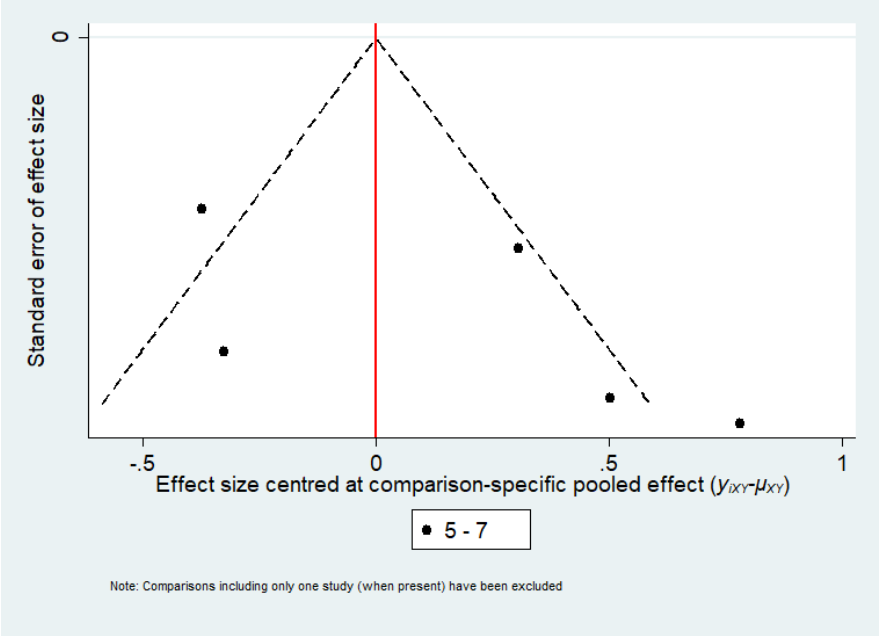
Supplementary T. Comparison-adjusted funnel plots for fear avoidance and intervention compliance

Supplementary Figure 21. Fear avoidance at post-intervention



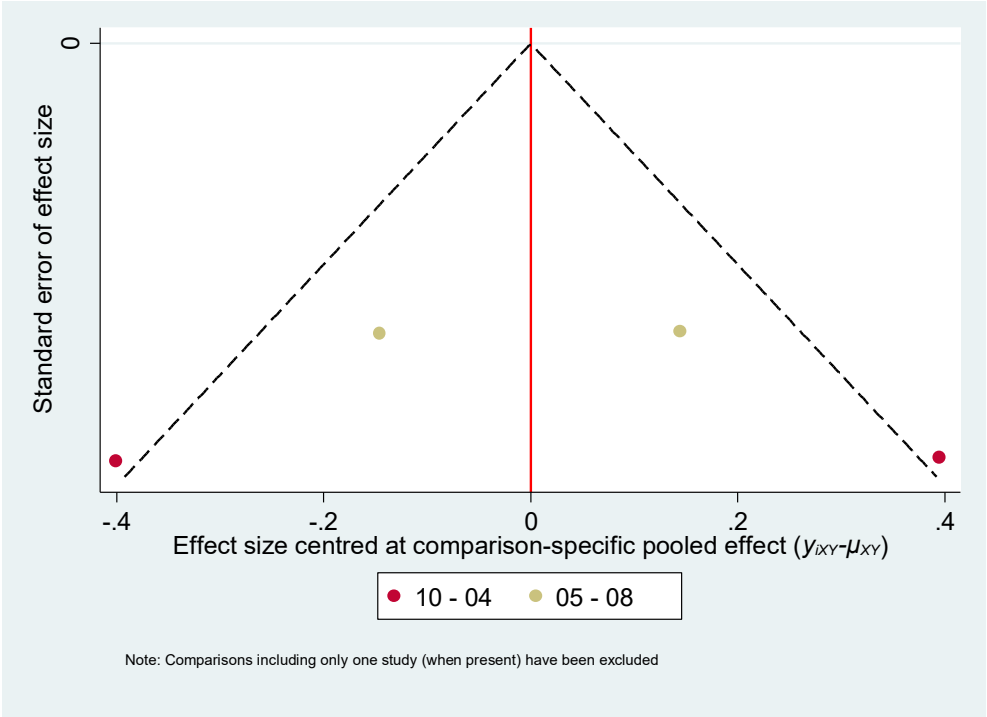
01: advice, 02: behavioural therapy, 03: cognitive behavioural therapy, 04: cognitive behavioural therapy delivered with physiotherapy care, 05: combined psychological approaches, 06: combined psychological approaches delivered with physiotherapy care, 07: mindfulness, 08: no intervention, 09: physiotherapy care, 10: pain education, 11: pain education delivered with physiotherapy care, 12: usual care.

Supplementary Figure 22. Fear avoidance at short-term treatment sustainability



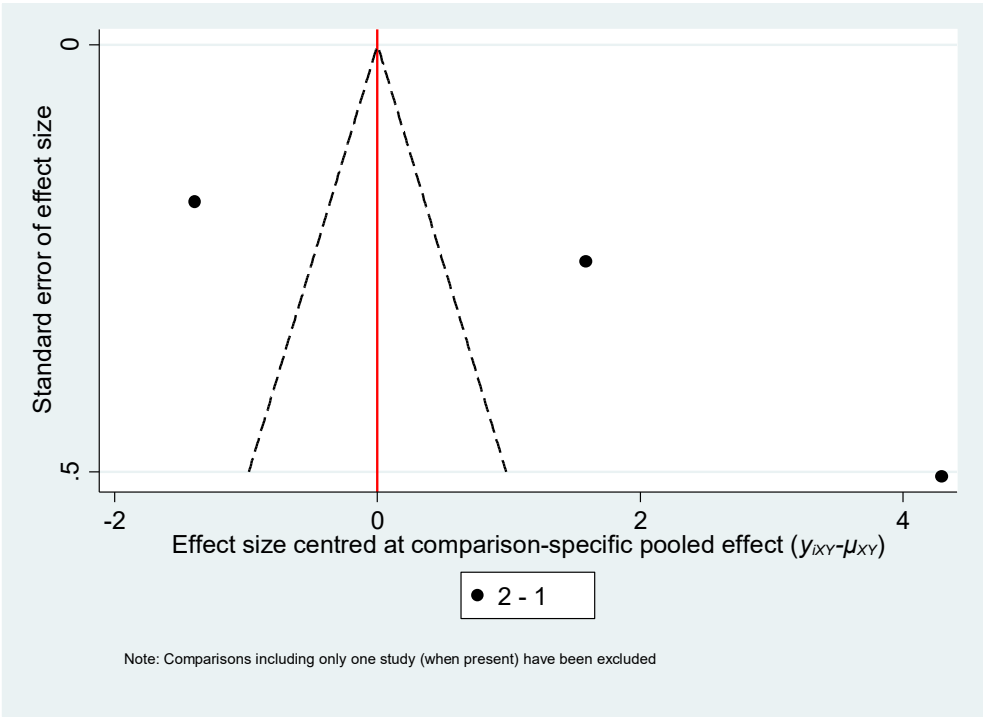
01: cognitive behavioural therapy delivered with physiotherapy care, 02: combined psychological approaches, 03: combined psychological approaches delivered with physiotherapy care, 04: general practitioner care, 05: physiotherapy care, 06: pain education, 07: pain education delivered with physiotherapy care, 08: usual care.

Supplementary Figure 23. Fear avoidance at mid-term treatment sustainability



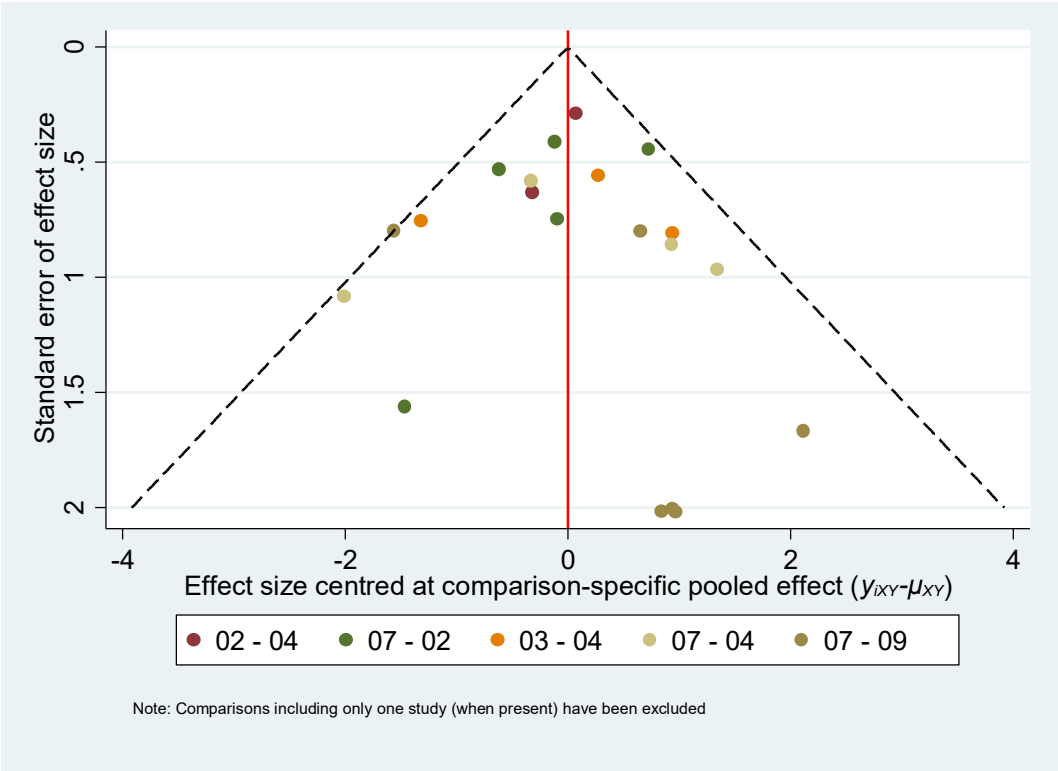
01: advice, 02: behavioural therapy, 03: cognitive behavioural therapy, 04: cognitive behavioural therapy delivered with physiotherapy care, 05: combined psychological approaches, 06: combined psychological approaches delivered with physiotherapy care, 07: counselling, 08: general practitioner care, 09: no intervention, 10: physiotherapy care, 11: pain education, 12: pain education delivered with physiotherapy care, 13: usual care.

Supplementary Figure 24. Fear avoidance at long-term treatment sustainability



01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care.

Supplementary Figure 25. Intervention compliance at post-intervention



01: behavioural therapy delivered with physiotherapy care, 02: cognitive behavioural therapy delivered with physiotherapy care, 03: combined psychological approaches, 04: combined psychological approaches delivered with physiotherapy care, 05: counselling delivered with physiotherapy care, 06: general practitioner care, 07: physiotherapy care, 08: pain education, 09: pain education delivered with physiotherapy care, 10: usual care.

Supplementary U. Summary of health-related quality of life

The following table presents the effect sizes for all studies included in the review which report data on health-related quality of life. The results of the studies involving at least one treatment node classified as physiotherapy care (PC) have been summarised in the main paper.

Supplementary Table 21. Effect sizes for health-related quality of life

Author, Year	Treatment nodes	Outcome	Results[a]
SF-36 physical component summary score provided			
Dufour, 2010[15]	CP+PC vs PC	SF-36 (PCS)	Post-intervention: assessed but between-group differences not analysed Short-term follow-up: ***p* < 0.001 (favouring CP+PC)** Mid-term follow-up: assessed but between-group differences not analysed Long-term follow-up: assessed but between-group differences not analysed
Galan-Martin, 2020[21]	PE+PC vs PC	SF-36 (PCS)	Post-intervention: results of between-group differences were not reported. Short-term follow-up: **12 (9.6 to 14.4), *p* < 0.001 (favouring PE+PC).**
Yao, 2020[98]	Mind+PC vs PC	SF-36 (PCS)	Post-intervention: 3.1 (-1.8 to 8.0), $p > 0.05$.
Saper, 2017[73]	Mind+PC vs PE	SF-36 (PCS)	Post-intervention: 0.62 (-1.6 to 2.9), $p > 0.05$
Fairbank, 2005[16]	CBT+PC vs Surgery (Lumbar Fusion)	SF-36 (PCS)	Post-intervention: between-group differences were not assessed. Long-term follow-up: 2.0 (-1.2 to 5.3), $p > 0.05$.
Cuesta-Vargas, 2011[14]	PE+PC vs PE+PC	SF-36 (PCS)	Post-intervention: Mean difference 5.1, standard deviation 11.2. Results were not statistically significant.
SF-12 physical component summary (PCS) score provided			
Godfrey, 2019[28]	Mind+PC vs PC	SF-12 (PCS)	Post-intervention: between-group differences were not assessed. Short-term follow-up: **mean difference 1.91, standard error 0.89, *p* = 0.032 (favouring Mind+PC).** Mid-term follow-up: Mean difference 0.48, standard error 1.01, $p = 0.637$
Cherkin, 2016[11]	Mind vs UC vs CBT	SF-12 (PCS)	Post-intervention: • Mind vs UC: 1.48 (-0.06 to 3.02), $p > 0.05$ • CBT vs Mind: −0.45 (-1.95 to 1.05), $p > 0.05$ • CBT vs UC: 1.03 (-0.48 to 2.54), $p > 0.05$ Mid-term follow-up: • Mind vs UC: 0.31 (-1.53 to 2.16), $p > 0.05$ • CBT vs Mind: 0.20 (-1.69 to 2.10), $p > 0.05$ • CBT vs UC: 0.52 (-1.19 to 2.22), $p > 0.05$

Lamb, 2010[39]	CBT vs NI	SF-12 (PCS)	Post-intervention: **-2.2 (-3.57 to -0.74), *p* = 0.0031 (favouring CBT).** Short-term follow-up: **-1.8 (-3.25 to -0.37), *p* = 0.0144 (favouring CBT).** Mid-term follow-up: **-4.1 (–5.62 to –2.63), *p* <0·0001 (favouring CBT).**
Macedo, 2012[46]	CP+PC vs CP	SF-12 (PCS)	Post-intervention: -0.2 (-3.7 to 3.2), *p* = 0.89 Short-term follow-up: 1.1 (-2.4 to 4.6), *p* = 0.54 Mid-term follow-up: -0.3 (-3.8 to 3.3), *p* = 0.33
Nguyen, 2017[58]	PE+PC vs PE	SF-12 (PCS)	Post-intervention: between-group differences were not assessed. Mid-term follow-up: -0.3 (-4.5 to 3.9), *p* = 0.89
Tilbrook, 2011[87]	CP+PC vs PE	SF-12 (PCS)	Post-intervention: 1.36 (-0.70 to 3.41), *p* = 0.20 Short-term follow-up: 1.24 (-0.83 to 3.33), *p* = 0.24 Mid-term follow-up: 0.80 (-1.28 to 2.87), *p* = 0.45
SF-36: Scores for all SF-36 sub-scales assessed; however, no physical health or mental health component summary scores provided			
Mehling, 2005[49]	Mind+PC vs PC	SF-36 (all sub-scales)	Post-intervention: *p* > 0.05 for all SF-36 sub-scales. Mid-term follow-up: *p* > 0.05 for all SF-36 sub-scales.
Monticone, 2013[51]	CBT+PC vs PC	SF-36 (all sub-scales)	Post-intervention: results of between-group differences were not reported. Interaction (group x time) assessed at long-term follow-up: ***p* < 0.05 for all SF-36 sub-scales (favouring CBT+PC).**
Monticone, 2016[52]	CBT+PC vs PC	SF-36 (all sub-scales)	Post-intervention: results of between-group differences were not reported. Interaction (group x time) assessed at long-term follow-up: ***p* < 0.05 for all SF-36 sub-scales (favouring CBT+PC).**
Poole, 2007[65]	BT vs PC vs UC	SF-36 (all sub-scales)	Post-intervention: results of between-group differences were not reported. Interaction (group x time) assessed at short-term follow-up: *p* > 0.05 for all SF-36 sub-scales.
Saracoglu, 2020[75]	PE+PC vs PC	SF-36 (all sub-scales)	Post-intervention: • Physical function: **r = -0.35, *p* = 0.04 (favouring PE+PC).** • For all other SF-36 sub-scales, *p* > 0.05
Unal, 2020[92]	PE vs PC	SF-36 (all sub-scales)	Post-intervention: • Physical functioning: ***p* < 0.001 (favouring PC)** • Physical role: ***p* = 0.003 (favouring PC)** • Mental health: ***p* < 0.001(favouring PC)** • For all other SF-36 sub-scales, *p* > 0.05
Tavafian, 2017[85]	CP vs GP	SF-36 (all sub-scales)	Interaction (group x time) assessed at long-term follow-up: • Mental health: ***p* < 0.05 (favouring CP).**

			• For all other SF-36 sub-scales, $p > 0.05$
Michaelson, 2016[50]	PE+PC vs PE+PC	SF-36 (all sub-scales)	Post-intervention: $p > 0.05$ for all SF-36 sub-scales. Mid-term follow-up: $p > 0.05$ for all SF-36 sub-scales.
Luedtke, 2016[43]	CP+PC vs CP+PC	RAND-36 (all sub-scales)	Post-intervention: $p > 0.05$ for all RAND-36 subscales.
SF-36: Only overall score provided. No sub-scale scores or physical health or mental health component summary scores provided			
Gardner, 2019[23]	PE vs PC	SF-36 (overall score)	Post-treatment: **-15.8 (-24.2 to -7.4), $p < 0.05$ (favouring PE).** Short-term follow-up: **-17.7 (-26.0 to -9.5), $p < 0.05$ (favouring PE).** Mid-term follow-up: **-19.5 (-27.9 to -11.0), $p < 0.05$ (favouring PE).**
SF-36 only some components assessed and/or reported			
Magalhaes, 2018[47]	CP+PC vs PC	SF-36 (some sub-scales)	SF-36 sub-scales assessed: physical role, emotional role. Post-intervention: $p > 0.05$ for the SF-36 sub-scales assessed. Short-term follow-up: $p > 0.05$ for the SF-36 sub-scales assessed.
Paolucci, 2017[61]	Mind+PC vs PC	SF-36 (some sub-scales)	SF-36 sub-scales assessed and reported (i.e., between-group data available): vitality, social functioning. Post-intervention: results of between-group differences were not reported. Short-term follow-up: • Vitality: **$p = 0.033$ (favouring PC).** • Social functioning: **$p = 0.022$ (favouring PC).**
Vong, 2011[96]	Csl+PC, PC	SF-36 (some sub-scales)	SF-36 sub-scales assessed: physical functioning, physical role, bodily pain, global health. Post-intervention: • Global health: **$F = 6.21$, $p = 0.015$ (favouring Csl+PC)** • For all other SF-36 sub-scales, $p > 0.05$ for group x time interaction.
Haas, 2005[31]	CP vs NI	SF-36 (some sub-scales)	SF-36 sub-scales assessed: general health, emotional well-being (mental health), and energy-fatigue (vitality). Post-intervention: between-group differences were not assessed. Short-term follow-up: • Mental health: **mean 7.6, SE 3.6, $p = 0.037$ (favouring CP).** • For all other SF-36 sub-scales, $p > 0.05$
Jensen, 2012[33]	Csl vs UC	SF-36 (some sub-scales)	SF-36 sub-scales assessed: physical functioning, bodily pain. Post-intervention: • Physical functioning: **5.60 (1.39 to 9.81), $p < 0.05$ (favouring Csl).**

			• Bodily pain: **6.27 (0.70 to 11.83), $p < 0.05$ (favouring Csl)**
Moore, 2000[53]	CP vs GP	SF-36 (some sub-scales)	SF-36 sub-scales assessed: mental health. Post-intervention: between-group differences were not assessed. Short-term follow-up: $p > 0.05$ Mid-term follow-up: $p > 0.05$
von Korff, 2005[95]	CP vs UC	SF-36 (some sub-scales)	SF-36 sub-scales assessed: social functioning, mental health. Post-intervention: $p > 0.05$ for both SF-36 sub-scales. Short-term follow-up: $p > 0.05$ for both SF-36 sub-scales. Mid-term follow-up: $p > 0.05$ for both SF-36 sub-scales. Long-term follow-up: $p > 0.05$ for both SF-36 sub-scales.
Morone, 2016[54]	Mind vs Adv	RAND-36 (some sub-scales)	RAND-36 composite scores assessed: global health composite, physical health composite. Interaction (group x time) assessed at mid-term follow-up: • Global health composite: **$p = 0.02$ (favouring Mind).** • Physical health composite: **$p = 0.02$ (favouring Mind).**
EuroQoL-5D[b]			
Johnson, 2007[34]	CBT vs GP	EQ-5D	Post-intervention: 0.05 (-0.01 to 0.11), $p > 0.05$ Mid-term follow-up: 0.03 (-0.05 to 0.10), $p > 0.05$ Long-term follow-up: 0.03 (-0.04 to 0.09), $p > 0.05$
Other: Sickness Impact Profile			
Turner, 1990[90]	BT+PC vs BT vs PC vs NI	SIP	Post-intervention: Results of univariate between-group analyses for health-related quality of life were not reported by authors. Descriptive results report there were no statistically significant between-group differences at post-treatment, or mid-term and long-term follow-ups.
Turner, 1982[88]	BT vs CBT vs NI	SIP	Interaction (group x time) assessed at post-intervention: **$F(2, 33) = 8.47$, $p < 0.001$ (favouring CBT).**
Turner, 1988[89]	CBT vs BT vs NI	SIP	Interaction (group x time) assessed at post-intervention (CBT vs BT vs NI): **$F(2, 70) = 4.12$, $p < 0.05$ (favouring BT).** Interaction (group x time) assessed at short-term follow-up (CBT vs BT only): $p > 0.05$ Interaction (group x time) assessed at mid-term follow-up (CBT vs BT only): $p > 0.05$
Turner, 1993[91]	CBT (2 arms) vs BT vs	SIP	Interaction (group x time) assessed at post-intervention: $p > 0.05$

	NI		Interaction (group x time) assessed at short-term follow-up: $p > 0.05$ Interaction (group x time) assessed at mid-term follow-up: $p > 0.05$
Other: Miscellaneous			
Bendix, 2000[8]	CBT+PC vs PC	Investigator-initiated question: "How much has the treatment influenced your quality of life? Has the treatment made it 1 (much better), 2 (better), 3 (unchanged), 4 (worse), or 5 (much worse)."	Post-intervention: between-group differences were not assessed. Mid-term follow-up: ***p* = 0.03 (favouring CBT+PC).**
Shariat, 2019[77]	BT+PC vs BT vs PC vs NI	Quality of Life Scale	Post-intervention: between-group differences were not assessed. Interaction (group x time) assessed at short-term follow-up**:** results not reported clearly.
Bendix, 1998[6] & 1998[7] (Project B)	CP+PC vs CBT+PC vs PC	Investigator-initiated question (scores ranged from 1-5)	Post-intervention: between-group differences were not assessed. Long-term follow-up: • 2-years post-intervention: ***p* = 0.005 (favouring CP+PC).** • 5-year post-intervention: ***p* = 0.004 (favouring CP+PC).**
Bendix, 1998[6] & 1998[7] (Project A)	CP+PC vs NI	Investigator-initiated question (scores ranged from 1-5)	Post-intervention: between-group differences were not assessed. Long-term follow-up: • 2-years post-intervention: $p > 0.05$ • 5-year post-intervention: $p > 0.05$
Sander, 2020[71]	CP vs UC	AQoL-6D	Post-intervention: **-0.25 (-0.42 to -0.08), *p* values not reported (favouring CP).** Short-term follow-up: **-0.24 (-0.42 to -0.05), *p* values not reported (favouring CP).** Mid-term follow-up: **-0.43 (-0.61 to -0.25), *p* values not reported (favouring CP).**
O'Keeffe, 2020[60]	CBT+PC vs CP+PC	General Health (0-13)	Post-intervention: **2.29 (0.33 to 4.24), *p* = 0.022 (favouring CBT+PC).** Mid-term follow-up: 1.91 (0.19 to 4.01), $p = 0.075$
Glombiewski,	CBT vs CBT	Health-Related Life	Post-intervention: results of between-group differences were not reported.

2010[26]		Satisfaction Scale	Descriptive results report no statistically significant difference between groups. Mid-term follow-up: results of between-group differences were not reported. Descriptive results report no statistically significant difference between groups.
Lorig, 2002[44]	PE vs UC	Illness Intrusiveness Scale	Post-intervention: between-group differences were not assessed. Long-term follow-up: ***p* < 0.001 (favouring PE).**

[a] Values are mean difference between groups (95% confidence interval), unless stated otherwise. Estimates in bold denote significance at $p<0.05$.
[b]Results of Reme et al. 2016[68] have not been summarised, as only two of the four study arms were included in our review and only ANOVA results involving all four arms were reported in the original article.

Adv: advice, AQoL: Assessment of Quality of Life Questionnaire, BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+physio care: counselling delivered with physiotherapy care, EuroQoL: European Quality of Life Scale, GP: general practitioner care, Mind: mindfulness, Mind+PC: mindfulness delivered with physiotherapy care, NI: no intervention, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PC: physiotherapy care, SIP: Sickness Impact Profile, SF-12: 12-Item Short-form Survey, SF-36: 36-Item Short-form Survey, UC: usual care.

Supplementary V. Sensitivity analyses for fear avoidance and intervention compliance

Supplementary Table 22.1 Fear avoidance at post-intervention, excluding studies with high risk of bias

PC (reference)	**1.94 (0.63,3.25)**					-0.14 (-3.02,2.74)	1.31 (-1.65,4.26)				
1.79 (0.58,2.99)	CBT+PC					-0.33 (-3.20,2.55)					
0.84 (-0.32,1.99)	-0.95 (-2.62,0.72)	PE+PC									
0.24 (-2.83,3.30)	-1.55 (-4.74,1.64)	-0.60 (-3.88,2.68)	Advice	0.13 (-2.78,3.04)			1.25 (-1.70,4.21)			0.18 (-2.62,2.98)	
0.65 (-2.36,3.67)	-1.13 (-4.25,1.99)	-0.18 (-3.41,3.05)	0.42 (-1.96,2.80)	CBT	-0.06 (-2.98,2.85)			-0.66 (-2.73,1.40)	-0.34 (-3.16,2.48)		
0.93 (-1.35,3.22)	-0.85 (-3.25,1.54)	0.10 (-2.46,2.66)	0.70 (-1.96,3.35)	0.28 (-2.01,2.56)	CP	-0.15 (-2.24,1.93)	-0.13 (-3.05,2.79)	-0.79 (-3.74,2.16)			-0.37 (-3.17,2.43)
0.72 (-1.15,2.59)	-1.06 (-3.00,0.87)	-0.11 (-2.31,2.08)	0.49 (-2.51,3.48)	0.07 (-2.73,2.87)	-0.21 (-2.02,1.60)	CP+PC					
1.20 (-1.07,3.46)	-0.59 (-3.05,1.87)	0.36 (-2.18,2.90)	0.96 (-1.44,3.36)	0.54 (-2.09,3.18)	0.26 (-1.82,2.35)	0.47 (-1.87,2.82)	PE				
0.06 (-3.16,3.27)	-1.73 (-5.03,1.58)	-0.78 (-4.19,2.64)	-0.18 (-3.07,2.72)	-0.59 (-2.54,1.36)	-0.87 (-3.34,1.59)	-0.66 (-3.65,2.32)	-1.14 (-4.06,1.78)	No intervention			
0.32 (-3.81,4.45)	-1.47 (-5.68,2.74)	-0.52 (-4.81,3.77)	0.08 (-3.61,3.77)	-0.34 (-3.16,2.48)	-0.62 (-4.25,3.01)	-0.41 (-4.38,3.57)	-0.88 (-4.74,2.98)	0.26 (-3.17,3.69)	BT		
0.42 (-3.73,4.57)	-1.37 (-5.61,2.88)	-0.42 (-4.73,3.89)	0.18 (-2.62,2.98)	-0.23 (-3.91,3.44)	-0.51 (-4.37,3.34)	-0.30 (-4.40,3.79)	-0.78 (-4.47,2.91)	0.36 (-3.67,4.39)	0.10 (-4.53,4.73)	Mindfulness	
0.56 (-3.05,4.18)	-1.22 (-4.91,2.46)	-0.27 (-4.06,3.52)	0.33 (-3.53,4.19)	-0.09 (-3.70,3.53)	-0.37 (-3.17,2.43)	-0.16 (-3.49,3.18)	-0.63 (-4.12,2.86)	0.51 (-3.22,4.24)	0.25 (-4.33,4.83)	0.15 (-4.62,4.91)	Usual care

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle). Note: Three studies [5, 17, 92] were excluded from the sensitivity analysis due to using ambiguous methods to score the Fear Avoidance Beliefs Questionnaire which were inconsistent with validated recommendations.

Supplementary Table 22.2 Fear avoidance at post-intervention, only including studies using intention-to-treatment analysis

PC (reference)	**2.38 (0.59,4.16)**			-0.14 (-3.65,3.37)	1.31 (-2.34,4.96)	
2.14 (0.53,3.75)	CBT+PC			-0.33 (-3.85,3.19)		
0.78 (-0.93,2.49)	-1.36 (-3.70,0.99)	PE+PC				
1.14 (-1.70,3.98)	-1.00 (-3.98,1.99)	0.36 (-2.95,3.68)	CP	-0.15 (-2.73,2.42)	-0.13 (-3.77,3.50)	-0.37 (-3.76,3.03)
0.92 (-1.39,3.22)	-1.22 (-3.61,1.17)	0.14 (-2.73,3.00)	-0.23 (-2.44,1.98)	CP+PC		
1.16 (-1.65,3.97)	-0.98 (-4.08,2.12)	0.38 (-2.90,3.66)	0.02 (-2.78,2.81)	0.24 (-2.74,3.23)	PE	
0.78 (-3.65,5.20)	-1.36 (-5.89,3.16)	-0.00 (-4.75,4.74)	-0.37 (-3.76,3.03)	-0.14 (-4.19,3.91)	-0.38 (-4.78,4.02)	Usual care

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle). Note: One study [17] was excluded from the sensitivity analysis due to using ambiguous methods to score the Fear Avoidance Beliefs Questionnaire which were inconsistent with validated recommendations.

Comment. Fear avoidance at post-intervention, excluding studies published prior to year 2000.

Sensitivity analysis was not performed, as no studies were excluded (i.e., all included studies were published after year 2004).

Supplementary Table 22.3 Fear avoidance at post-intervention, excluding studies of patients with leg pain.

PC (reference)	0.36 (-0.14,0.86)					-0.14 (-1.00,0.72)	**1.31 (0.50,2.12)**				
0.39 (-0.04,0.82)	CBT+PC					-0.33 (-1.11,0.46)					
1.03 (0.61,1.45)	**0.64 (0.03,1.24)**	PE+PC									
-0.02 (-0.93,0.89)	-0.41 (-1.37,0.55)	**-1.05 (-2.06,-0.04)**	Advice	0.13 (-0.60,0.87)			**1.25 (0.36,2.15)**		0.18 (-0.55,0.91)		
0.32 (-0.55,1.19)	-0.07 (-0.98,0.84)	-0.71 (-1.68,0.26)	0.34 (-0.31,0.99)	CBT	-0.06 (-0.84,0.71)			**-0.79 (-1.24,-0.33)**			-0.68 (-1.53,0.18)
0.48 (-0.19,1.15)	0.09 (-0.62,0.80)	-0.55 (-1.34,0.25)	0.50 (-0.26,1.26)	0.16 (-0.48,0.79)	CP+PC	-0.15 (-0.72,0.41)	-0.13 (-0.77,0.51)	-0.77 (-1.63,0.08)		-0.37 (-1.10,0.37)	
0.14 (-0.41,0.69)	-0.25 (-0.81,0.31)	-0.89 (-1.58,-0.20)	0.16 (-0.72,1.04)	-0.18 (-0.99,0.62)	-0.34 (-0.88,0.20)	CP+PC					
0.92 (0.25,1.60)	0.53 (-0.22,1.28)	-0.11 (-0.90,0.69)	**0.94 (0.21,1.68)**	0.60 (-0.15,1.35)	0.44 (-0.16,1.04)	**0.78 (0.09,1.47)**	PE				
-0.43 (-1.35,0.48)	-0.82 (-1.77,0.13)	**-1.46 (-2.47,-0.45)**	-0.41 (-1.18,0.36)	**-0.75 (-1.21,-0.29)**	**-0.91 (-1.59,-0.23)**	-0.57 (-1.42,0.27)	**-1.35 (-2.17,-0.54)**	No intervention			0.53 (-0.36,1.42)
0.16 (-1.01,1.33)	-0.23 (-1.43,0.97)	-0.87 (-2.11,0.38)	0.18 (-0.55,0.91)	-0.16 (-1.14,0.82)	-0.32 (-1.38,0.74)	0.02 (-1.12,1.16)	-0.76 (-1.80,0.27)	0.59 (-0.47,1.65)	Mindfulness		
0.11 (-0.89,1.11)	-0.28 (-1.30,0.75)	-0.92 (-2.00,0.17)	0.13 (-0.93,1.19)	-0.21 (-1.18,0.76)	-0.37 (-1.10,0.37)	-0.03 (-0.94,0.89)	-0.81 (-1.76,0.14)	0.55 (-0.46,1.55)	-0.05 (-1.34,1.24)	Usual care	
-0.15 (-1.30,1.00)	-0.54 (-1.72,0.64)	-1.18 (-2.40,0.05)	-0.13 (-1.14,0.89)	-0.47 (-1.26,0.32)	-0.63 (-1.61,0.35)	-0.29 (-1.38,0.81)	**-1.07 (-2.14,-0.00)**	0.28 (-0.52,1.09)	-0.31 (-1.56,0.94)	-0.26 (-1.49,0.97)	BT

Results are presented as standardised mean differences (SMD) and 95% confidence intervals. BT: behavioural therapy, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. SMD values less than 0.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle). Note: Three studies [5, 17, 92] were excluded from sensitivity analysis due to using ambiguous methods to score the Fear Avoidance Beliefs Questionnaire which were inconsistent with validated recommendations.

Supplementary Table 22.4 Intervention compliance at post-intervention, excluding studies with high risk of bias

PC (reference)	0.77 (0.36,1.65)	0.40 (0.15,1.07)	0.43 (0.14,1.34)			0.97 (0.02,58.13)			
0.73 (0.38,1.42)	CBT+PC	0.81 (0.30,2.21)							
0.51 (0.23,1.10)	0.69 (0.31,1.53)	CP+PC		1.00 (0.02,60.74)	0.61 (0.22,1.72)				
0.48 (0.17,1.33)	0.65 (0.20,2.16)	0.94 (0.27,3.20)	PE+PC				0.58 (0.09,3.87)		
0.51 (0.01,33.16)	0.69 (0.01,45.36)	1.00 (0.02,60.74)	1.07 (0.01,77.54)	BT+PC					
0.30 (0.10,0.94)	0.41 (0.13,1.34)	0.60 (0.24,1.52)	0.64 (0.16,2.52)	0.60 (0.01,40.39)	CP	0.33 (0.01,9.78)	1.57 (0.33,7.52)		1.40 (0.28,6.95)
0.26 (0.02,3.82)	0.35 (0.02,5.44)	0.51 (0.03,7.54)	0.54 (0.03,9.25)	0.51 (0.00,69.12)	0.85 (0.06,12.01)	PE			
0.38 (0.09,1.64)	0.52 (0.11,2.40)	0.75 (0.18,3.15)	0.81 (0.19,3.41)	0.75 (0.01,58.38)	1.26 (0.34,4.61)	1.49 (0.08,26.82)	GP care		
1.15 (0.29,4.63)	1.57 (0.34,7.32)	2.27 (0.46,11.15)	2.42 (0.43,13.66)	2.27 (0.03,185.82)	3.79 (0.63,22.69)	4.47 (0.22,92.77)	3.01 (0.40,22.52)	Csl+PC	
0.43 (0.06,3.02)	0.58 (0.08,4.22)	0.84 (0.13,5.35)	0.89 (0.11,7.38)	0.84 (0.01,75.90)	1.40 (0.28,6.95)	1.65 (0.07,36.57)	1.11 (0.14,8.74)	0.37 (0.03,4.08)	Usual care

Results are presented as odds ratios (OR) and 95% confidence intervals. BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. OR values less than 1.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 22.5 Intervention compliance at post-intervention, only including studies using intention-to-treatment analysis

PC (reference)	0.80 (0.20,3.15)		1.00 (0.15,6.56)		1.03 (0.02,55.54)			1.32 (0.39,4.45)	
0.98 (0.30,3.17)	PE+PC					0.58 (0.11,3.06)			
1.05 (0.02,65.05)	1.07 (0.02,72.85)	BT+PC	1.00 (0.02,54.49)						
1.05 (0.38,2.92)	1.07 (0.28,4.14)	1.00 (0.02,54.48)	CP+PC	0.60 (0.26,1.38)				1.08 (0.41,2.83)	
0.57 (0.18,1.82)	0.59 (0.15,2.28)	0.55 (0.01,32.20)	0.55 (0.25,1.20)	CP	3.06 (0.12,78.24)	1.57 (0.44,5.60)	1.40 (0.41,4.83)		
1.30 (0.20,8.42)	1.33 (0.18,9.53)	1.24 (0.02,89.56)	1.24 (0.27,5.72)	2.26 (0.56,9.21)	PE		0.41 (0.25,0.67)		
0.77 (0.19,3.03)	0.78 (0.21,2.90)	0.73 (0.01,47.83)	0.73 (0.21,2.50)	1.33 (0.46,3.89)	0.59 (0.10,3.36)	GP care			
0.58 (0.11,2.96)	0.59 (0.10,3.52)	0.55 (0.01,37.71)	0.55 (0.14,2.17)	1.00 (0.31,3.28)	**0.44 (0.21,0.93)**	0.75 (0.16,3.66)	Usual care		
1.23 (0.51,2.96)	1.25 (0.33,4.74)	1.17 (0.02,67.74)	1.17 (0.58,2.35)	2.14 (0.79,5.77)	0.94 (0.18,5.05)	1.61 (0.43,6.05)	2.13 (0.47,9.59)	CBT+PC	
1.15 (0.41,3.22)	1.18 (0.25,5.58)	1.10 (0.02,77.18)	1.10 (0.26,4.67)	2.01 (0.43,9.38)	0.89 (0.11,7.47)	1.51 (0.27,8.39)	2.00 (0.29,13.76)	0.94 (0.24,3.62)	Csl+PC

Results are presented as odds ratios (OR) and 95% confidence intervals. BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, PE: pain education, PE+PC: pain education delivered with physiotherapy care, PC: physiotherapy care. Estimates in bold denote significance at $p<0.05$. OR values less than 1.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 22.6 Intervention compliance at post-intervention, excluding studies published prior to year 2000

PC (reference)	0.89 (0.35,2.30)	0.50 (0.13,1.91)	0.44 (0.13,1.44)			0.97 (0.02,61.83)			
0.81 (0.37,1.78)	CBT+PC	0.93 (0.22,3.94)							
0.58 (0.22,1.49)	0.71 (0.27,1.90)	CP+PC		1.00 (0.02,63.15)	0.61 (0.21,1.79)				
0.49 (0.17,1.42)	0.61 (0.16,2.25)	0.85 (0.22,3.29)	PE+PC				0.58 (0.08,4.24)		
0.58 (0.01,40.53)	0.71 (0.01,50.47)	1.00 (0.02,63.14)	1.18 (0.02,92.33)	BT+PC					
0.33 (0.09,1.13)	0.40 (0.11,1.49)	0.57 (0.21,1.51)	0.67 (0.15,2.92)	0.57 (0.01,40.07)	CP	3.06 (0.10,94.70)	1.57 (0.29,8.40)	1.40 (0.25,7.82)	
0.64 (0.09,4.71)	0.79 (0.10,6.07)	1.11 (0.17,7.25)	1.31 (0.15,11.72)	1.11 (0.01,105.06)	1.96 (0.36,10.76)	PE		0.41 (0.11,1.49)	
0.40 (0.09,1.89)	0.50 (0.10,2.59)	0.70 (0.15,3.20)	0.82 (0.18,3.78)	0.70 (0.01,57.76)	1.23 (0.31,4.90)	0.63 (0.07,5.45)	GP care		
0.32 (0.05,2.04)	0.40 (0.06,2.65)	0.56 (0.10,3.10)	0.65 (0.09,5.02)	0.56 (0.01,49.37)	0.98 (0.22,4.31)	0.50 (0.15,1.66)	0.80 (0.11,5.89)	Usual care	
1.15 (0.26,5.17)	1.43 (0.26,7.77)	2.00 (0.34,11.79)	2.36 (0.37,14.86)	2.00 (0.02,181.69)	3.53 (0.50,24.69)	1.80 (0.15,21.88)	2.87 (0.33,24.80)	3.60 (0.33,38.97)	Csl+PC

Results are presented as odds ratios (OR) and 95% confidence intervals. BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl+PC: counselling delivered with physiotherapy care, GP: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. OR values less than 1.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary Table 22.7 Intervention compliance at post-intervention, excluding studies of patients with leg pain

PC (reference)	0.76 (0.28,2.07)	0.40 (0.14,1.18)	0.42 (0.12,1.45)			0.97 (0.02,63.19)			
0.70 (0.30,1.63)	CBT+PC	0.80 (0.26,2.47)							
0.47 (0.20,1.11)	0.66 (0.27,1.66)	CP+PC		1.00 (0.02,64.78)	0.90 (0.24,3.33)				
0.48 (0.16,1.49)	0.68 (0.17,2.74)	1.03 (0.26,4.01)	PE+PC				0.58 (0.07,4.45)		
0.47 (0.01,32.99)	0.66 (0.01,47.49)	1.00 (0.02,64.77)	0.97 (0.01,77.96)	BT+PC					
0.36 (0.10,1.36)	0.52 (0.13,2.12)	0.78 (0.24,2.49)	0.76 (0.16,3.55)	0.78 (0.01,59.20)	CP	3.06 (0.10,97.62)	1.57 (0.28,8.87)	0.71 (0.12,4.26)	
0.68 (0.09,5.27)	0.97 (0.12,8.02)	1.46 (0.20,10.58)	1.42 (0.15,13.38)	1.46 (0.01,148.06)	1.88 (0.32,10.85)	PE		0.41 (0.10,1.63)	
0.42 (0.08,2.14)	0.60 (0.11,3.44)	0.91 (0.18,4.58)	0.88 (0.18,4.27)	0.91 (0.01,79.63)	1.16 (0.28,4.91)	0.62 (0.07,5.71)	GP care		
0.35 (0.05,2.38)	0.50 (0.07,3.65)	0.75 (0.12,4.73)	0.73 (0.09,5.97)	0.75 (0.01,71.60)	0.96 (0.21,4.43)	0.51 (0.14,1.81)	0.83 (0.10,6.52)	Usual care	
1.15 (0.24,5.54)	1.64 (0.28,9.74)	2.47 (0.41,14.85)	2.40 (0.35,16.61)	2.47 (0.03,231.73)	3.17 (0.41,24.67)	1.69 (0.13,22.24)	2.73 (0.29,26.01)	3.30 (0.28,39.42)	Csl+PC

Results are presented as odds ratios (OR) and 95% confidence intervals. BT+PC: behavioural therapy delivered with physiotherapy care, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, CBT+PC: combined psychological approaches delivered with physiotherapy care, CP: combined psychological approaches, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. Estimates in bold denote significance at $p<0.05$. OR values less than 1.00 favour the column-defining treatment node for the NMA results (lower left triangle) and the row-defining treatment nodes for the pairwise meta-analysis results (upper right triangle).

Supplementary W. Assessment of global inconsistency for fear avoidance and intervention compliance

Supplementary Table 23. Results of global inconsistency tests for fear avoidance and intervention compliance

Time-point	Fear avoidance	Intervention compliance
Post-intervention	$chi^2 = 0.77$, $p = 0.99$	$chi^2 = 1.97$, $p = 0.92$
Short-term Treatment Sustainability	$chi^2 = 0.59$, $p = 0.44$	NMA not performed
Mid-term Treatment Sustainability	No inconsistency detected due to absence of closed loops in the network.	NMA not performed
Long-term Treatment Sustainability	NMA not performed	NMA not performed

NMA: network meta-analysis. Estimates in bold denote significance at $p<0.05$.

Supplementary X. Results of side-splitting method for fear avoidance and intervention compliance

Supplementary Table 24.1 Fear avoidance at post-intervention

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 03	.	.	.	.	.
02 07	0.14	1.36	-1.37	1.20	0.40
02 08	-1.31	1.39	-1.02	1.85	0.90
01 02	1.93	0.62	0.52	1.77	0.45
01 07	0.33	1.35	1.73	1.30	0.45
04 05	-0.13	1.37	-1.23	2.19	0.67
04 08	-1.25	1.39	-0.16	2.17	0.67
04 11	-0.18	1.32	0.54	632.08	1.00
05 06	0.06	1.38	-0.68	1.82	0.74
05 09	0.84	0.80	-0.12	2.99	0.76
05 10	0.51	0.98	-0.55	3.09	0.75
06 07	0.15	0.98	0.44	2.10	0.90
06 08	0.13	1.38	-0.78	1.50	0.66
06 09	0.79	1.39	1.44	2.12	0.80
06 12	0.37	1.32	1.84	632.20	1.00
09 10	-0.53	1.40	-0.15	1.65	0.86

01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care, 03: combined psychological approaches delivered with physiotherapy care, 04: pain education delivered with physiotherapy care, 05: advice, 06: cognitive behavioural therapy, 07: combined psychological approaches, 08: pain education, 09: no intervention, 10: behavioural therapy, 11: mindfulness, 12: usual care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 24.2 Fear avoidance at short-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
2 3	-1.34	0.49	0.14	182.35	0.99
2 4	-0.14	0.51	0.50	0.67	0.44
2 7	0.20	0.48	-0.44	0.69	0.44
1 2	.	.	.	.	.
3 5	-0.36	0.46	1.28	210.37	0.99
4 7	-0.30	0.46	0.35	0.70	0.44
5 6	0.53	0.44	3.40	637.31	1.00
5 8	0.42	0.44	3.40	620.87	1.00

01: pain education delivered with physiotherapy care, 02: physiotherapy care, 03: pain education, 04: combined psychological approaches delivered with physiotherapy care, 05: combined psychological approaches, 06: general practitioner care, 07: cognitive behavioural therapy delivered with physiotherapy care, 08: usual care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Supplementary Table 24.3 Fear avoidance at mid-term treatment sustainability

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
04 05	.	.	.	.	.
04 12	.	.	.	.	.
01 02	0.00	0.40	-0.49	632.44	1.00
02 06	0.27	0.41	0.18	153.77	1.00
02 09	0.51	0.38	0.38	282.34	1.00
02 10	0.07	0.43	0.49	632.38	1.00
03 04	0.50	0.29	0.45	99.76	1.00
03 07	0.32	0.40	0.35	103.60	1.00
06 07	-0.20	0.40	-0.21	110.21	1.00
06 11	0.14	0.28	-0.04	432.16	1.00
06 13	0.32	0.39	-0.05	615.50	1.00
08 09	0.13	0.39	0.54	630.64	1.00

01: advice, 02: cognitive behavioural therapy, 03: cognitive behavioural therapy delivered with physiotherapy care, 04: physiotherapy care, 05: pain education, 06: combined psychological approaches, 07: combined psychological approaches delivered with physiotherapy care, 08: counselling, 09: no intervention, 10: behavioural therapy, 11: general practitioner care, 12: pain education delivered with physiotherapy care, 13: usual care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p<0.05$.

Comment. Fear avoidance at long-term treatment sustainability

NMA was not performed at long-term treatment sustainability for fear avoidance as the network became disconnected.

Supplementary Table 24.4 Intervention compliance at post-intervention

Side	Direct Coef.	SE	Indirect Coef.	SE	*p*
02 03	0.92	0.5	0.35	0.64	0.49
02 04	0.85	0.58	0.12	1.4	0.63
02 07	-0.03	2.09	0.68	1.1	0.77
02 10	.	.	.	.	.
01 02	-0.26	0.38	-0.65	0.87	0.69
01 03	0.2	0.49	0.75	0.71	0.53
03 05	0	2.09	-1.43	4177.09	1.00
03 06	0.5	0.52	0.84	1.28	0.80
04 08	0.55	0.97	-0.18	1.17	0.63
06 07	1.12	1.72	-1.24	0.89	0.22
06 08	-0.45	0.79	0.28	1.3	0.63
06 09	-0.34	0.82	1.05	1.47	0.41
07 09	0.89	0.57	-0.5	1.58	0.41

01: cognitive behavioural therapy delivered with physiotherapy care, 02: physiotherapy care, 03: combined psychological approaches delivered with physiotherapy care, 04: pain education delivered with physiotherapy care, 05: behavioural therapy delivered with physiotherapy care, 06: combined psychological approaches, 07: pain education, 08: general practitioner care, 09: usual care, 10: counselling delivered with physiotherapy care. Direct Coef.: direct coefficient, SE: standard error, Indirect Coef.: indirect coefficient. Estimates in bold denote significance at $p < 0.05$.

Supplementary Y. Results of meta-regression for primary and secondary outcomes

Supplementary Table 25. Results of meta-regression for physical function

Pairwise comparisons for physical function	Post-intervention		Short-term follow-up		Mid-term follow-up		Long- term follow-up	
	Coef. (SE)	*p*	Coef. (SE)	*p*	Coef. (SE)	*p*	Coef. (SE)	*p*
PC vs. CBT								
- Mean age	0.00 (0.14)	0.99	-0.01 (5.69)	1.00	0.08 (0.06)	0.16	0.08 (5.26)	1.00
- Percentage of males	0.00 (0.06)	0.97	-0.01 (5.74)	1.00	0.00 (0.02)	0.94	0.02 (2.28)	1.00
- Sample size	0.00 (0.01)	0.79	0.00 (0.09)	1.00	0.01 (0.01)	0.33	0.01 (0.51)	1.00
- Baseline level of physical function	-0.02 (0.04)	0.72	0.01 (5.27)	1.00	-0.03 (0.03)	0.32	-0.09 (2.51)	0.97
PC vs CBT+PC								
- Mean age	-0.10 (0.06)	0.08	0.00 (0.05)	0.96	-0.01 (0.03)	0.65	-0.26 (0.08)	**0.01**
- Percentage of males	0.02 (0.04)	0.63	0.03 (0.02)	0.23	0.01 (0.01)	0.54	0.27 (0.10)	**0.01**
- Sample size	0.00 (0.00)	0.43	0.00 (0.00)	0.97	0.00 (0.00)	0.58	0.01 (0.03)	0.71
- Baseline level of physical function	-0.03 (0.02)	0.23	0.01 (0.05)	0.75	0.02 (0.01)	**0.02**	-0.03 (0.05)	0.56
PC vs. BT								
- Mean age	-0.20 (0.37)	0.59	N/A	N/A	N/A	N/A	N/A	N/A
- Percentage of males	0.00 (0.08)	0.99	N/A	N/A	N/A	N/A	N/A	N/A
- Sample size	0.00 (0.01)	0.86	N/A	N/A	N/A	N/A	N/A	N/A
- Baseline level of physical function	-0.01 (0.05)	0.78	N/A	N/A	N/A	N/A	N/A	N/A
PC vs. BT+PC								
- Mean age	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Baseline level of physical function	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PC vs. Mindfulness								
- Mean age	-0.32 (0.50)	0.52	N/A	N/A	-0.01 (1.26)	1.00	N/A	N/A
- Percentage of males	0.00 (0.07)	0.96	N/A	N/A	0.01 (0.03)	0.72	N/A	N/A
- Sample size	0.01 (0.03)	0.71	N/A	N/A	0.02 (0.02)	0.20	N/A	N/A
- Baseline level of physical function	0.03 (0.09)	0.71	N/A	N/A	0.01 (0.04)	0.72	N/A	N/A
PC vs. Mindfulness+PC								
- Mean age	0.00 (0.34)	1.00	N/A	N/A	0.22 (0.29)	0.44	N/A	N/A
- Percentage of males	0.00 (0.28)	0.99	N/A	N/A	-0.06 (0.07)	0.40	N/A	N/A
- Sample size	0.00 (0.01)	0.98	N/A	N/A	0.00 (0.00)	0.52	N/A	N/A
- Baseline level of physical function	0.01 (0.07)	0.83	N/A	N/A	-0.09 (0.10)	0.41	N/A	N/A
PC vs. PE								
- Mean age	-0.06 (0.16)	0.70	0.27 (0.19)	0.17	0.61 (0.19)	**<0.01**	N/A	N/A
- Percentage of males	0.01 (0.05)	0.80	-0.08 (0.04)	**0.03**	-0.09 (0.03)	**<0.01**	N/A	N/A
- Sample size	0.00 (0.00)	0.97	0.00 (0.00)	0.31	0.00 (0.00)	**0.03**	N/A	N/A
- Baseline level of physical function	0.01 (0.03)	0.79	-0.01 (0.05)	0.85	-0.10 (0.03)	**<0.01**	N/A	N/A
PC vs. PE+PC								
- Mean age	0.02 (0.10)	0.81	0.05 (0.07)	0.48	N/A	N/A	N/A	N/A
- Percentage of males	0.01 (0.04)	0.79	-0.02 (0.02)	0.26	N/A	N/A	N/A	N/A
- Sample size	-0.01 (0.01)	0.58	-0.01 (0.01)	0.19	N/A	N/A	N/A	N/A
- Baseline level of physical function	0.00 (0.03)	0.91	0.02 (0.04)	0.61	N/A	N/A	N/A	N/A
PC vs. Csl								
- Mean age	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Baseline level of physical function	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PC vs. Csl+PC								
- Mean age	-0.42 (0.33)	0.20	N/A	N/A	N/A	N/A	N/A	N/A
- Percentage of males	-0.08 (0.07)	0.27	N/A	N/A	N/A	N/A	N/A	N/A
- Sample size	0.21 (0.16)	0.18	N/A	N/A	N/A	N/A	N/A	N/A
- Baseline level of physical function	0.39 (0.29)	0.19	N/A	N/A	N/A	N/A	N/A	N/A
PC vs. CP								
- Mean age	-0.11 (0.12)	0.36	0.17 (0.32)	0.57	0.00 (0.07)	0.99	0.07 (11.22)	1.00

- Percentage of males	0.06 (0.04)	0.14	-0.04 (0.04)	0.23	-0.01 (0.02)	0.81	0.01 (2.14)	1.00
- Sample size	0.00 (0.01)	0.72	0.01 (0.01)	0.34	0.01 (0.01)	0.37	0.00 (0.29)	1.00
- Baseline level of physical function	0.00 (0.05)	0.96	-0.03 (0.06)	0.60	-0.03 (0.02)	0.10	0.01 (2.20)	1.00
PC vs. CP+PC								
- Mean age	-0.09 (0.08)	0.26	0.06 (0.08)	0.45	0.07 (0.04)	0.09		N/A
- Percentage of males	0.02 (0.04)	0.56	-0.01 (0.02)	0.57	-0.03 (0.02)	0.09	N/A	N/A
- Sample size	0.00 (0.00)	0.65	0.00 (0.00)	0.80	0.00 (0.00)	0.74	N/A	N/A
- Baseline level of physical function	0.01 (0.04)	0.90	0.02 (0.03)	0.56	-0.01 (0.01)	0.21	N/A	N/A
PC vs. Advice								
- Mean age	-0.28 (0.42)	0.51	N/A	N/A	0.00 (1.12)	1.00	N/A	N/A
- Percentage of males	0.03 (0.12)	0.78	N/A	N/A	-0.05 (0.09)	0.60	N/A	N/A
- Sample size	0.00 (0.01)	0.82	0.00 (0.43)	1.00	0.00 (0.01)	0.75	N/A	N/A
- Baseline level of physical function	0.01 (0.04)	0.70	0.02 (1.79)	0.99	0.01 (0.02)	0.56	N/A	N/A
PC vs. Usual care								
- Mean age	-0.08 (0.18)	0.65	0.21 (0.31)	0.48	-0.03 (0.08)	0.71	0.02 (9.45)	1.00
- Percentage of males	0.00 (0.05)	0.98	-0.06 (0.04)	0.15	0.00 (0.02)	0.92	N/A	N/A
- Sample size	0.00 (0.01)	0.72	0.01 (0.01)	0.28	0.01 (0.01)	0.47	0.00 (0.12)	1.00
- Baseline level of physical function	0.00 (0.05)	0.92	-0.03 (0.06)	0.54	-0.02 (0.02)	0.23	0.02 (2.21)	0.99
PC vs. GP care								
- Mean age	-0.09 (0.17)	0.59	0.24 (0.37)	0.50	-0.10 (0.11)	0.32	-0.13 (23.45)	1.00
- Percentage of males	0.02 (0.05)	0.70	-0.03 (0.04)	0.38	-0.02 (0.02)	0.41	-0.01 (2.13)	1.00
- Sample size	0.00 (0.01)	0.96	0.01 (0.02)	0.54	0.00 (0.01)	0.76	-0.01 (1.00)	1.00
- Baseline level of physical function	0.08 (0.34)	0.80	-0.07 (0.13)	0.60	0.01 (0.04)	0.85	-0.10 (12.00)	0.99
PC vs. No intervention								
- Mean age	0.04 (0.17)	0.83	0.23 (1.42)	0.99	0.33 (13.71)	0.99	0.08 (14.99)	1.00
- Percentage of males	-0.01 (0.07)	0.88	-0.04 (1.29)	0.98	0.00 (0.67)	1.00	0.00 (0.77)	1.00
- Sample size	0.00 (0.01)	0.78	0.00 (0.06)	1.00	0.01 (0.07)	0.99	0.00 (0.32)	1.00
- Baseline level of physical function	-0.05 (0.06)	0.37	-0.04 (6.89)	1.00	-0.28 (18.04)	0.99	-0.01 (2.22)	1.00

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, Coef.: coefficient, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. SE: standard error, vs.: versus (i.e., compared with). Estimates in bold denote significance at $p<0.05$.

Interpretation:
A small number of meta-regression results for comparisons between PC and psychological interventions, delivered with or without PC as a co-intervention (e.g., CBT+PC vs PC and PE vs PC, respectively), demonstrated significance at $p<0.05$. However, for these comparisons, results were only significant at $p<0.05$ at one (majority) to two time points, per potential effect modifier (i.e., results were not consistent across follow-up time points for a given comparison). From a clinical perspective, it is unlikely that a covariate only modifies the effect of treatment at one or two time points, out of four time points in total. Thus, these findings are likely due to type I error.

Conclusion:
We did not find any evidence suggesting that mean age, proportion of males, study sample size, or mean baseline levels of physical function, were effect modifiers.

Supplementary Table 26. Results of meta-regression for pain intensity

Pairwise comparisons for pain intensity	Post-intervention		Short-term follow-up		Mid-term follow-up		Long- term follow-up	
	Coef. (SE)	*p*	Coef. (SE)	*p*	Coef. (SE)	*p*	Coef. (SE)	*p*
PC vs CBT								
- Mean age	-0.21 (0.09)	**0.02**	-0.13 (0.10)	0.20	-0.02 (0.06)	0.75	0.07 (5.32)	1.00
- Percentage of males	0.08 (0.03)	**0.01**	0.07 (0.05)	0.18	0.00 (0.04)	0.97	0.00 (2.28)	1.00
- Sample size	0.00 (0.01)	0.99	-0.02 (0.01)	0.15	0.00 (0.01)	0.55	0.01 (0.50)	1.00
- Baseline level of pain intensity	-0.06 (0.02)	**0.01**	0.03 (0.07)	0.68	0.01 (0.06)	0.87	0.08 (252.91)	1.00
PC vs CBT+PC								
- Mean age	-0.10 (0.05)	**0.04**	0.47 (0.13)	**<0.01**	-0.07 (0.03)	**0.02**	-0.19 (0.16)	0.24
- Percentage of males	0.09 (0.04)	**0.02**	0.03 (0.06)	0.59	-0.01 (0.02)	0.76	0.19 (0.14)	0.16
- Sample size	0.00 (0.01)	0.92	0.01 (0.01)	0.46	0.00 (0.00)	0.97	0.01 (0.02)	0.47
- Baseline level of pain intensity	-0.11 (0.03)	**<0.01**	-0.07 (0.10)	0.49	-0.03 (0.04)	0.41	-0.17 (0.04)	**<0.01**
PC vs. BT								
- Mean age	-0.09 (0.08)	0.23	-0.04 (0.03)	0.26	0.00 (0.12)	0.97	N/A	N/A
- Percentage of males	0.07 (0.03)	**0.03**	0.03 (0.04)	0.50	0.01 (0.05)	0.87	N/A	N/A
- Sample size	0.00 (0.01)	0.86	0.00 (0.01)	0.67	0.00 (0.02)	0.82	N/A	N/A
- Baseline level of pain intensity	-0.05 (0.02)	**0.01**	-0.02 (0.03)	0.38	0.01 (0.06)	0.91	N/A	N/A
PC vs. BT+PC								
- Mean age	0.07 (0.11)	0.50	N/A	N/A	0.06 (0.18)	0.74	-0.03 (0.84)	0.98
- Percentage of males	-0.02 (0.05)	0.63	N/A	N/A	0.09 (0.15)	0.55	0.05 (0.58)	0.94
- Sample size	0.02 (0.03)	0.54	N/A	N/A	0.01 (0.02)	0.41	0.02 (0.07)	0.73
- Baseline level of pain intensity	-0.01 (0.02)	0.76	N/A	N/A	-0.07 (0.08)	0.37	-0.18 (0.06)	**<0.01**
PC vs. Mindfulness								
- Mean age	-0.32 (0.14)	**0.02**	N/A	N/A	0.00 (8.76)	1.00	N/A	N/A
- Percentage of males	0.07 (0.04)	0.10	N/A	N/A	0.01 (0.05)	0.80	N/A	N/A
- Sample size	0.00 (0.01)	0.79	N/A	N/A	0.00 (0.02)	0.93	N/A	N/A
- Baseline level of pain intensity	-0.07 (0.09)	0.41	N/A	N/A	0.03 (0.10)	0.75	N/A	N/A
PC vs. Mindfulness+PC								
- Mean age	0.00 (0.07)	0.98	-0.03 (0.03)	0.25	0.22 (0.28)	0.43	N/A	N/A
- Percentage of males	0.00 (0.05)	0.97	0.02 (0.06)	0.75	-0.06 (0.09)	0.49	N/A	N/A
- Sample size	-0.01 (0.02)	0.63	0.00 (0.01)	0.77	0.00 (0.00)	0.58	N/A	N/A
- Baseline level of pain intensity	0.02 (0.06)	0.71	0.06 (0.15)	0.70	-0.02 (0.04)	0.53	N/A	N/A
PC vs. PE								
- Mean age	-0.15 (0.15)	0.31	0.14 (0.08)	0.08	-1.05 (15.67)	0.95	N/A	N/A
- Percentage of males	0.05 (0.05)	0.31	-0.03 (0.09)	0.75	-0.86 (21.79)	0.97	N/A	N/A
- Sample size	-0.01 (0.02)	0.61	0.20 (0.07)	**<0.01**	0.10 (2.43)	1.00	N/A	N/A
- Baseline level of pain intensity	0.20 (0.24)	0.39	0.16 (0.33)	0.63	-0.22 (5.39)	0.97	N/A	N/A
PC vs. PE+PC								
- Mean age	0.02 (0.04)	0.62	0.07 (0.04)	0.07	-0.49 (4.91)	0.92	N/A	N/A
- Percentage of males	0.01 (0.03)	0.68	0.01 (0.04)	0.78	0.00 (5.07)	1.00	N/A	N/A
- Sample size	0.00 (0.01)	0.99	0.00 (0.01)	0.68	0.00 (0.27)	1.00	N/A	N/A
- Baseline level of pain intensity	-0.03 (0.02)	**0.04**	-0.04 (0.03)	0.15	0.00 (9.11)	1.00	N/A	N/A
PC vs. Csl								
- Mean age	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Baseline level of pain intensity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PC vs. Csl+PC								
- Mean age	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- Baseline level of pain intensity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PC vs. CP								
- Mean age	-0.19 (0.13)	0.13	-0.28 (0.08)	**<0.01**	-0.14 (0.20)	0.49	-0.14 (12.11)	1.00
- Percentage of males	0.06 (0.03)	0.08	0.03 (0.07)	0.66	0.02 (0.04)	0.62	-0.03 (2.44)	1.00
- Sample size	0.00 (0.01)	0.93	-0.03 (0.01)	**0.01**	0.00 (0.01)	0.64	-0.01 (1.04)	1.00

- Baseline level of pain intensity	-0.02 (0.04)	0.53	-0.05 (0.05)	0.30	-0.03 (0.05)	0.62	-0.05 (3.91)	0.99
PC vs. CP+PC								
- Mean age	-0.16 (0.10)	0.11	-0.03 (0.03)	0.40	0.03 (0.04)	0.47	-0.28 (0.74)	0.70
- Percentage of males	0.06 (0.03)	0.08	0.01 (0.05)	0.77	-0.04 (0.03)	0.15	-0.16 (0.40)	0.69
- Sample size	0.00 (0.00)	0.98	0.00 (0.01)	0.82	0.00 (0.00)	0.65	0.00 (0.01)	0.73
- Baseline level of pain intensity	-0.01 (0.03)	0.66	0.00 (0.04)	0.95	0.06 (0.07)	0.40	0.19 (0.19)	0.32
PC vs. Advice								
- Mean age	-0.30 (0.11)	**0.01**	-0.19 (0.08)	**0.02**	0.01 (7.78)	1.00	N/A	N/A
- Percentage of males	0.09 (0.09)	0.31	0.04 (0.08)	0.60	-0.09 (0.15)	0.57	N/A	N/A
- Sample size	0.00 (0.01)	0.92	-0.02 (0.01)	0.09	-0.01 (0.01)	0.58	N/A	N/A
- Baseline level of pain intensity	-0.06 (0.05)	0.19	-0.04 (0.09)	0.66	-0.03 (0.06)	0.58	N/A	N/A
PC vs. Usual care								
- Mean age	-0.24 (0.17)	0.16	-0.24 (0.08)	**<0.01**	-0.11 (0.21)	0.60	-0.01 (10.59)	1.00
- Percentage of males	0.06 (0.04)	0.15	0.01 (0.09)	0.91	0.00 (0.03)	0.92	N/A	N/A
- Sample size	0.00 (0.01)	0.87	-0.03 (0.01)	0.05	0.00 (0.01)	0.82	0.00 (0.13)	1.00
- Baseline level of pain intensity	-0.03 (0.04)	0.39	-0.05 (0.05)	0.32	-0.03 (0.05)	0.61	N/A	N/A
PC vs. GP care								
- Mean age	-0.13 (0.16)	0.44	-0.02 (0.10)	0.82	0.15 (0.22)	0.48	0.26 (24.11)	1.00
- Percentage of males	0.06 (0.04)	0.14	0.03 (0.08)	0.67	0.06 (0.04)	0.14	0.02 (2.13)	1.00
- Sample size	-0.01 (0.01)	0.44	-0.01 (0.01)	0.18	0.02 (0.02)	0.15	0.01 (1.15)	1.00
- Baseline level of pain intensity	-0.15 (0.07)	**0.03**	-0.03 (0.11)	0.78	0.11 (0.07)	0.13	0.18 (34.01)	1.00
PC vs. No intervention								
- Mean age	-0.32 (0.08)	**<0.01**	-0.33 (0.06)	**<0.01**	-0.51 (9.01)	0.96	N/A	N/A
- Percentage of males	0.08 (0.03)	**0.01**	0.12 (0.04)	**0.01**	0.00 (0.67)	1.00	N/A	N/A
- Sample size	0.00 (0.01)	0.85	-0.02 (0.01)	**0.04**	0.00 (0.07)	1.00	N/A	N/A
- Baseline level of pain intensity	-0.09 (0.02)	**<0.01**	-0.12 (0.03)	**<0.01**	-0.08 (44.00)	1.00	N/A	N/A

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, Coef.: coefficient, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. SE: standard error, vs.: versus (i.e., compared with). Estimates in bold denote significance at $p<0.05$.

Interpretation:
Some meta-regression results for comparisons between PC and psychological interventions, delivered with or without PC as a co-intervention, demonstrated significance at $p<0.05$. However, for most affected comparisons, results were only significant at $p<0.05$ at one (majority) to two time points, per potential effect modifier (i.e., results were not consistent across follow-up time points for a given comparison). From a clinical perspective, it is unlikely that a covariate only modifies the effect of treatment at one or two time points, out of four time points in total. Thus, these findings are likely due to type I error.

For CBT+PC vs. PC, meta-regression of mean age demonstrated $p < 0.05$ at three time points (post-intervention, and short and mid-term follow-ups). However, the number of studies available for this comparison at each respective time points was eight, one, and five. In accordance with the pre-specified criteria for performing sub-group analyses (i.e., (i) p value of the regression coefficient was <0.05, (ii) ≥10 studies were available for the relevant comparison), sub-group analyses were not performed. Thus, whilst results suggest that mean age may be a potential effect modifier for pain intensity, insufficient number of studies precludes further investigations to conclude that mean age modifies the effect of CBT+PC compared with PC. Results likely reflect an "absence of evidence."[105]

Conclusions:
We did not find any evidence suggesting that mean age, proportion of males, study sample size, or mean baseline levels of pain intensity were effect modifiers.

Supplementary Table 27. Results of meta-regression for fear avoidance

Pairwise comparisons for fear avoidance	Post-intervention		Short-term follow-up		Mid-term follow-up		Long- term follow-up	
	Coef. (SE)	*p*	Coef. (SE)	*p*	Coef. (SE)	*p*	Coef. (SE)	*p*
PC vs. CBT								
- Mean age	0.56 (4.39)	0.90	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	0.01 (1.89)	1.00	N/A	N/A	Np	Np	N/A	N/A
- Sample size	0.00 (0.08)	0.96	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	-0.02 (0.87)	0.98	N/A	N/A	Np	Np	N/A	N/A
PC vs. CBT+PC								
- Mean age	-0.19 (0.18)	0.29	0.20 (17.93)	1.00	Np	Np	-0.33 (0.42)	0.43
- Percentage of males	0.05 (0.12)	0.68	0.01 (1.33)	1.00	Np	Np	0.39 (0.49)	0.43
- Sample size	-0.01 (0.02)	0.58	0.00 (0.32)	1.00	Np	Np	0.05 (0.08)	0.58
- Baseline level of fear avoidance	0.03 (0.07)	0.65	-0.01 (1.35)	0.99	Np	Np	-0.18 (1.26)	0.89
PC vs. BT								
- Mean age	1.21 (4.88)	0.80	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	-0.05 (1.89)	1.00	N/A	N/A	Np	Np	N/A	N/A
- Sample size	-0.43 (1.33)	0.75	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	-0.01 (0.87)	0.99	N/A	N/A	Np	Np	N/A	N/A
PC vs. BT+PC								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. Mindfulness								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. Mindfulness+PC								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. PE								
- Mean age	0.19 (0.70)	0.79	0.27 (3.92)	0.95	Np	Np	N/A	N/A
- Percentage of males	0.03 (0.25)	0.89	-0.07 (1.33)	0.96	Np	Np	N/A	N/A
- Sample size	-0.01 (0.19)	0.97	0.06 (1.26)	0.96	Np	Np	N/A	N/A
- Baseline level of fear avoidance	0.04 (0.73)	0.96	0.12 (2.31)	0.96	Np	Np	N/A	N/A
PC vs. PE+PC								
- Mean age	0.03 (0.10)	0.74	0.02 (0.07)	0.83	Np	Np	N/A	N/A
- Percentage of males	0.00 (0.07)	0.95	0.00 (0.03)	0.94	Np	Np	N/A	N/A
- Sample size	0.00 (0.02)	0.90	0.00 (0.00)	0.30	Np	Np	N/A	N/A
- Baseline level of fear avoidance	-0.01 (0.05)	0.88	-0.02 (0.02)	0.34	Np	Np	N/A	N/A
PC vs. Csl								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. Csl+PC								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. CP								
- Mean age	0.33 (0.35)	0.34	0.05 (39.35)	1.00	Np	Np	N/A	N/A
- Percentage of males	0.12 (0.13)	0.35	0 (1.69)	1.00	Np	Np	N/A	N/A
- Sample size	0.00 (0.06)	1.00	0.00 (0.29)	1.00	Np	Np	N/A	N/A

- Baseline level of fear avoidance	-0.16 (0.47)	0.74	0.01 (3.87)	1.00	Np	Np	N/A	N/A
PC vs. CP+PC								
- Mean age	0.32 (0.21)	0.14	0.16 (16.73)	1.00	Np	Np	N/A	N/A
- Percentage of males	0.12 (0.09)	0.19	0.30 (31.63)	0.99	Np	Np	N/A	N/A
- Sample size	0.02 (0.12)	0.85	0.00 (0.23)	1.00	Np	Np	N/A	N/A
- Baseline level of fear avoidance	-0.13 (0.26)	0.62	0.03 (3.18)	0.99	Np	Np	N/A	N/A
PC vs. Advice								
- Mean age	-0.01 (9.86)	1.00	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	0.01 (0.91)	1.00	N/A	N/A	Np	Np	N/A	N/A
- Sample size	0.00 (0.01)	0.94	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	0.01 (0.53)	0.99	N/A	N/A	Np	Np	N/A	N/A
PC vs. Usual care								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. GP care								
- Mean age	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Sample size	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	N/A	N/A	N/A	N/A	Np	Np	N/A	N/A
PC vs. No intervention								
- Mean age	0.53 (4.39)	0.90	N/A	N/A	Np	Np	N/A	N/A
- Percentage of males	-0.13 (1.93)	0.95	N/A	N/A	Np	Np	N/A	N/A
- Sample size	0.00 (0.06)	1.00	N/A	N/A	Np	Np	N/A	N/A
- Baseline level of fear avoidance	-0.01 (0.87)	1.00	N/A	N/A	Np	Np	N/A	N/A

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, Coef.: coefficient, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. SE: standard error, vs.: versus (i.e., compared with). Estimates in bold denote significance at $p<0.05$. Np: not performed – meta-regression was unable to be performed due to limitations of the network structure (i.e., limited number of studies).

Interpretation:
No meta-regression results demonstrated significance at $p<0.05$ for any comparisons.

Conclusion:
We did not find any evidence suggesting that mean age, proportion of males, study sample size, or mean baseline levels of fear avoidance, were effect modifiers.

Supplementary Table 28. Results of meta-regression for intervention compliance

Post-intervention					
Pairwise comparisons for intervention compliance	**Coef. (SE)**	***p***	**Pairwise comparisons for intervention compliance**	**Coef. (SE)**	***p***
PC vs. CBT			PC vs. Csl		
- Mean age	N/A	N/A	- Mean age	N/A	N/A
- Percentage of males	N/A	N/A	- Percentage of males	N/A	N/A
- Sample size	N/A	N/A	- Sample size	N/A	N/A
PC vs CBT+PC			PC vs. Csl+PC		
- Mean age	0.14 (0.16)	0.36	- Mean age	N/A	N/A
- Percentage of males	-0.04 (0.03)	0.09	- Percentage of males	N/A	N/A
- Sample size	0.00 (0.01)	0.83	- Sample size	N/A	N/A
PC vs. BT			PC vs. CP		
- Mean age	N/A	N/A	- Mean age	0.08 (0.18)	0.65
- Percentage of males	N/A	N/A	- Percentage of males	0.03 (0.02)	0.23
- Sample size	N/A	N/A	- Sample size	0.01 (0.02)	0.44
PC vs. BT+PC			PC vs. CP+PC		
- Mean age	N/A	N/A	- Mean age	0.09 (0.15)	0.56
- Percentage of males	N/A	N/A	- Percentage of males	0.03 (0.01)	**0.02**
- Sample size	N/A	N/A	- Sample size	0.00 (0.01)	0.98
PC vs. Mindfulness			PC vs. Advice		
- Mean age	N/A	N/A	- Mean age	N/A	N/A
- Percentage of males	N/A	N/A	- Percentage of males	N/A	N/A
- Sample size	N/A	N/A	- Sample size	N/A	N/A
PC vs. Mindfulness+PC			PC vs. Usual care		
- Mean age	N/A	N/A	- Mean age	-0.22 (3.88)	0.95
- Percentage of males	N/A	N/A	- Percentage of males	-0.87 (1.21)	0.47
- Sample size	N/A	N/A	- Sample size	0.07 (0.10)	0.51
PC vs. PE			PC vs. GP care		
- Mean age	0.56 (0.57)	0.33	- Mean age	0.04 (0.17)	0.82
- Percentage of males	-0.10 (0.12)	0.41	- Percentage of males	0.04 (0.03)	0.26
- Sample size	0.06 (0.09)	0.53	- Sample size	-0.06 (0.12)	0.62
PC vs. PE+PC			PC vs. No intervention		
- Mean age	-0.05 (0.11)	0.66	- Mean age	N/A	N/A
- Percentage of males	0.08 (0.07)	0.24	- Percentage of males	N/A	N/A
- Sample size	0.00 (0.02)	0.95	- Sample size	N/A	N/A

BT: behavioural therapy, BT+PC: behavioural therapy delivered with physiotherapy care, CBT: cognitive behavioural therapy, CBT+PC: cognitive behavioural therapy delivered with physiotherapy care, Coef.: coefficient, CP: combined psychological approaches, CP+PC: combined psychological approaches delivered with physiotherapy care, Csl: counselling, Csl+PC: counselling delivered with physiotherapy care, GP care: general practitioner care, Mindfulness+PC: mindfulness delivered with physiotherapy care, PC: physiotherapy care, PE: pain education, PE+PC: pain education delivered with physiotherapy care. SE: standard error, vs.: versus (i.e., compared with). Estimates in bold denote significance at $p<0.05$.

Interpretation:
Meta-regression results demonstrated significance at $p<0.05$ for CP+PC compared with PC for percentage of males, at post-intervention. Only three studies directly compared CP+PC with PC, with sample sizes varying from 45,[5] 66,[47] and 132.[6] In accordance with the pre-specified criteria for performing sub-group analyses (i.e., (i) p value of the regression coefficient was <0.05, (ii) ≥10 studies were available for the relevant comparison), sub-group analyses were not performed.

Conclusion:
We did not find any evidence suggesting that mean age, proportion of males, or study sample size, were effect modifiers.

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PRISMA NMA Checklist of Items to Include When Reporting A Systematic Review Involving a Network Meta-analysis

Section/Topic	Item #	Checklist Item	Reported on Page #
TITLE			
Title	1	Identify the report as a systematic review *incorporating a network meta-analysis (or related form of meta-analysis).*	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: **Background:** main objectives **Methods:** data sources; study eligibility criteria, participants, and interventions; study appraisal; and *synthesis methods, such as network meta-analysis.* **Results:** number of studies and participants identified; summary estimates with corresponding confidence/credible intervals; *treatment rankings may also be discussed. Authors may choose to summarize pairwise comparisons against a chosen treatment included in their analyses for brevity.* **Discussion/Conclusions:** limitations; conclusions and implications of findings. **Other:** primary source of funding; systematic review registration number with registry name.	5
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known*, including mention of why a network meta-analysis has been conducted.*	8-9
Objectives	4	Provide an explicit statement of questions being addressed, with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	9
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists and if and where it can be accessed (e.g., Web address); and, if available, provide registration information, including registration number.	9
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. *Clearly describe eligible treatments included in the treatment network, and note whether any have been clustered or merged into the same node (with justification).*	10-11
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	9
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary A

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	10-11
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	12
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	12
Geometry of the network	**S1**	Describe methods used to explore the geometry of the treatment network under study and potential biases related to it. This should include how the evidence base has been graphically summarized for presentation, and what characteristics were compiled and used to describe the evidence base to readers.	20 Figure 2, 4, 5, 6
Risk of bias within individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	13
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means). *Also describe the use of additional summary measures assessed, such as treatment rankings and surface under the cumulative ranking curve (SUCRA) values, as well as modified approaches used to present summary findings from meta-analyses.*	16
Planned methods of analysis	14	Describe the methods of handling data and combining results of studies for each network meta-analysis. This should include, but not be limited to: • *Handling of multi-arm trials;* • *Selection of variance structure;* • *Selection of prior distributions in Bayesian analyses; and* • *Assessment of model fit.*	16-17
Assessment of Inconsistency	**S2**	Describe the statistical methods used to evaluate the agreement of direct and indirect evidence in the treatment network(s) studied. Describe efforts taken to address its presence when found.	18-19
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	18-19
Additional analyses	16	Describe methods of additional analyses if done, indicating which were pre-specified. This may include, but not be limited to, the following: • Sensitivity or subgroup analyses; • Meta-regression analyses; • *Alternative formulations of the treatment network; and* • *Use of alternative prior distributions for Bayesian analyses (if applicable).*	18-19

RESULTS†			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	20
Presentation of network structure	**S3**	Provide a network graph of the included studies to enable visualization of the geometry of the treatment network.	Figures 2, 3, 4, 5
Summary of network geometry	**S4**	Provide a brief overview of characteristics of the treatment network. This may include commentary on the abundance of trials and randomized patients for the different interventions and pairwise comparisons in the network, gaps of evidence in the treatment network, and potential biases reflected by the network structure.	20-21 Supplementary B
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Supplementary D and E
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment.	26 Supplementary J
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: 1) simple summary data for each intervention group, and 2) effect estimates and confidence intervals. *Modified approaches may be needed to deal with information from larger networks.*	Modified due to large network. 26-33 Supplementary I and Q
Synthesis of results	21	Present results of each meta-analysis done, including confidence/credible intervals. *In larger networks, authors may focus on comparisons versus a particular comparator (e.g. placebo or standard care), with full findings presented in an appendix. League tables and forest plots may be considered to summarize pairwise comparisons.* If additional summary measures were explored (such as treatment rankings), these should also be presented.	26-33 Supplementary I and Q Figure 6, 7, 8, 9
Exploration for inconsistency	**S5**	Describe results from investigations of inconsistency. This may include such information as measures of model fit to compare consistency and inconsistency models, *P* values from statistical tests, or summary of inconsistency estimates from different parts of the treatment network.	26, 29, 31, 33 Supplementary N, O, P Supplementary W and X
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies for the evidence base being studied.	26-33 Supplementary N and V
Results of additional analyses	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression analyses*, alternative network geometries studied, alternative choice of prior distributions for Bayesian analyses,* and so forth).	26-33 Supplementary N and V

DISCUSSION			
Summary of evidence	24	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy-makers).	35-36
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias). *Comment on the validity of the assumptions, such as transitivity and consistency. Comment on any concerns regarding network geometry (e.g., avoidance of certain comparisons).*	37-38
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	45
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. This should also include information regarding whether funding has been received from manufacturers of treatments in the network and/or whether some of the authors are content experts with professional conflicts of interest that could affect use of treatments in the network.	***3***

PICOS = population, intervention, comparators, outcomes, study design.
* Text in italics indicates wording specific to reporting of network meta-analyses that has been added to guidance from the PRISMA statement.
† Authors may wish to plan for use of appendices to present all relevant information in full detail for items in this section.

Box. Terminology: Reviews With Networks of Multiple Treatments

Different terms have been used to identify systematic reviews that incorporate a network of multiple treatment comparisons. A brief overview of common terms follows.

Indirect treatment comparison: Comparison of 2 interventions for which studies against a common comparator, such as placebo or a standard treatment, are available (i.e., indirect information). The direct treatment effects of each intervention against the common comparator (i.e., treatment effects from a comparison of interventions made within a study) may be used to estimate an indirect treatment comparison between the 2 interventions (**Appendix Figure 1, A**). An indirect treatment comparison (ITC) may also involve multiple links. For example, in **Appendix Figure 1, B**, treatments B and D may be compared indirectly on the basis of studies encompassing comparisons of B versus C, A versus C, and A versus D.

Network meta-analysis or *mixed treatment comparison*: These terms, which are often used interchangeably, refer to situations involving the simultaneous comparison of 3 or more interventions. Any network of treatments consisting of strictly unclosed loops can be thought of as a series of ITCs (**Appendix Figure 1, A and B**). In mixed treatment comparisons, both direct and indirect information is available to inform the effect size estimates for at least some of the comparisons; visually, this is shown by closed loops in a network graph (**Appendix Figure 1, C**). Closed loops are not required to be present for every comparison under study. "Network meta-analysis" is an inclusive term that incorporates the scenarios of both indirect and mixed treatment comparisons.

Network geometry evaluation: The description of characteristics of the network of interventions, which may include use of numerical summary statistics. This does not involve quantitative synthesis to compare treatments. This evaluation describes the current evidence available for the competing interventions to identify gaps and potential bias. Network geometry is described further in **Appendix Box 4**.

Appendix Box 1. The Assumption of Transitivity for Network Meta-Analysis

Methods for indirect treatment comparisons and network meta-analysis enable learning about the relative treatment effects of, for example, treatments A and B through use of studies where these interventions are compared against a common therapy, C.

When planning a network meta-analysis, it is important to assess patient and study characteristics across the studies that compare pairs of treatments. These characteristics are commonly referred to as *effect modifiers* and include traits such as average patient age, gender distribution, disease severity, and a wide range of other plausible features.

For network meta-analysis to produce valid results, it is important that the distribution of effect modifiers is similar, for example, across studies of A versus B and A versus C. This balance increases the plausibility of reliable findings from an indirect comparison of B versus C through the common comparator A. When this balance is present, the assumption of transitivity can be judged to hold.

Authors of network meta-analyses should present systematic (and even tabulated) information regarding patient and study characteristics whenever available. This information helps readers to empirically evaluate the validity of the assumption of transitivity by reviewing the distribution of potential effect modifiers across trials.

Appendix Box 2. Differences in Approach to Fitting Network Meta-Analyses

Network meta-analysis can be performed within either a frequentist or a Bayesian framework. Frequentist and Bayesian approaches to statistics differ in their definitions of probability. Thus far, the majority of published network meta-analyses have used a Bayesian approach.

Bayesian analyses return the posterior probability distribution of all the model parameters given the data and prior beliefs (e.g., from external information) about the values of the parameters. They fully encapsulate the uncertainty in the parameter of interest and thus can make direct probability statements about these parameters (e.g., the probability that one intervention is superior to another).

Frequentist analyses calculate the probability that the observed data would have occurred under their sampling distribution for hypothesized values of the parameters. This approach to parameter estimation is more indirect than the Bayesian approach.

Bayesian methods have been criticized for their perceived complexity and the potential for subjectivity to be introduced by choice of a prior distribution that may affect study findings. Others argue that explicit use of a prior distribution makes transparent how individuals can interpret the same data differently. Despite these challenges, Bayesian methods offer considerable flexibility for statistical modeling. In-depth introductions to Bayesian methods and discussion of these and other issues can be found elsewhere.

Appendix Box 3. Network Meta-Analysis and Assessment of Consistency

Network meta-analysis often involves the combination of direct and indirect evidence. In the simplest case, we wish to compare treatments A and B and have 2 sources of information: direct evidence via studies comparing A versus B, and indirect evidence via groups of studies comparing A and B with a common intervention, C. Together, this evidence forms a closed loop, ABC.

Direct and indirect evidence for a comparison of interventions should be combined only when their findings are similar in magnitude and interpretation. For example, for a comparison of mortality rates between A and B, an odds ratio determined from studies of A versus B should be similar to the odds ratio comparing A versus B estimated indirectly based on studies of A versus C and B versus C. This assumption of comparability of direct and indirect evidence is referred to as *consistency* of treatment effects.

When a treatment network contains a closed loop of interventions, it is possible to examine statistically whether there is agreement between the direct and indirect estimates of intervention effect.

Different methods to evaluate potential differences in relative treatment effects estimated by direct and indirect comparisons are grouped as *local approaches* and *global approaches.* Local approaches (e.g., the Bucher method or the node-splitting method) assess the presence of inconsistency for a particular pairwise comparison in the network, whereas global approaches (e.g., inconsistency models, I^2 measure for inconsistency) consider the potential for inconsistency in the network as a whole.

Tests for inconsistency can have limited power to detect a true difference between direct and indirect evidence. When multiple loops are being tested for inconsistency, one or a few may show inconsistency simply by chance. Further discussions of consistency and related concepts are available elsewhere.

Inconsistency in a treatment network can indicate lack of transitivity (see **Appendix Box 1**).

Appendix Box 4. Network Geometry and Considerations for Bias

The term *network geometry* is used to refer to the architecture of the treatment comparisons that have been made for the condition under study. This includes what treatments are involved in the comparisons in a network, in what abundance they are present, the respective numbers of patients randomly assigned to each treatment, and whether particular treatments and comparisons may have been preferred or avoided.

Networks may take on different shapes. Poorly connected networks depend extensively on indirect comparisons. Meta-analyses of such networks may be less reliable than those from networks where most treatments have been compared against each other.

Qualitative description of network geometry should be provided and accompanied by a network graph. Quantitative metrics assessing features of network geometry, such as *diversity* (related to the number of treatments assessed and the balance of evidence among them), *co-occurrence* (related to whether comparisons between certain treatments are more or less common), and *homophily* (related to the extent of comparisons between treatments in the same class versus competing classes), can also be mentioned.

Although common, established steps for reviewing network geometry do not yet exist, however examples of in-depth evaluations have been described related to treatments for tropical diseases and basal cell carcinoma and may be of interest to readers. An example based on 75 trials of treatments for pulmonary arterial hypertension (**Appendix Figure 3**) suggests that head-to-head studies of active therapies may prove useful to further strengthen confidence in interpretation of summary estimates of treatment comparisons.

Appendix Box 5. Probabilities and Rankings in Network Meta-Analysis

Systematic reviews incorporating network meta-analyses can provide information about the hierarchy of competing interventions in terms of treatment rankings.

The term *treatment ranking probabilities* refers to the probabilities estimated for each treatment in a network of achieving a particular placement in an ordering of treatment effects from best to worst. A network of 10 treatments provides a total of 100 ranking probabilities—that is, for each intervention, the chance of being ranked first, second, third, fourth, fifth, and so forth).

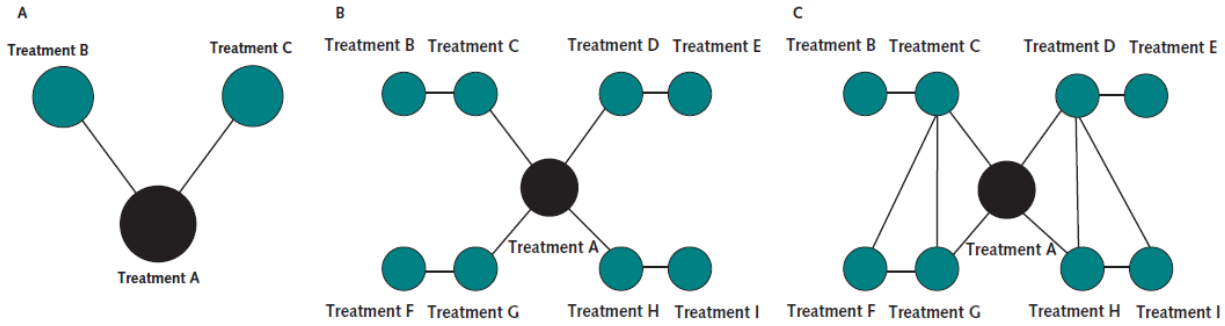
Several techniques are feasible to summarize relative rankings, and include graphical tools as well as different approaches for estimating ranking probabilities. **Appendix Figure 6** shows 2 approaches to presenting such information, on the basis of a comparison of adjuvant interventions for resected pancreatic adenocarcinoma.

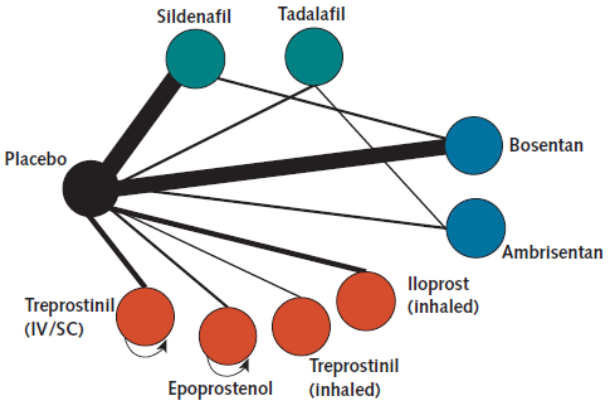
Robust reporting of rankings also includes specifying median ranks with uncertainty intervals, cumulative probability curves, and the surface under the cumulative ranking (SUCRA) curve.

Rankings can be reported along with corresponding estimates of pairwise comparisons between interventions. Rankings should be reported with probability estimates to minimize misinterpretation from focusing too much on the most likely rank.

Rankings may exaggerate small differences in relative effects, especially if they are based on limited information. An objective assessment of the strength of information in the network and the magnitude of absolute benefits should accompany rankings to minimize potential biases.

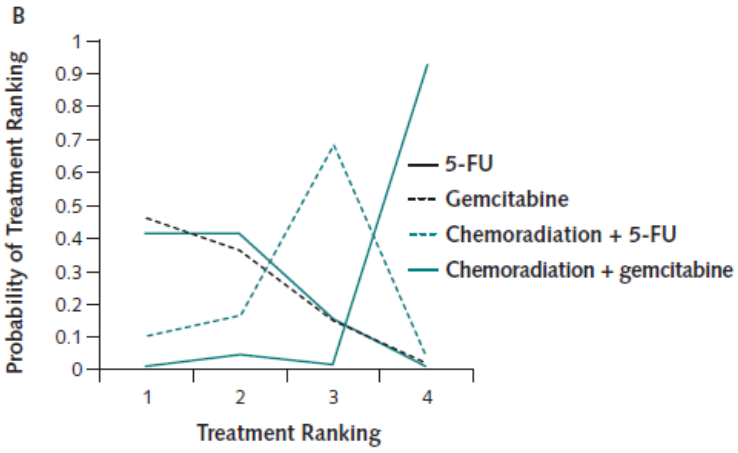
Appendix Figure 1A-1C





Appendix Figure 6

Ranking	Treatment and Cooresponding Ranking Probabilities Grade 3 or 4 Hematologic Toxicity			
	5-FU	Gemcitabine	Chemoradiation + 5-FU	Chemoradiation + gemcitabine
1	0.42	0.42	0.15	0.01
2	0.46	0.36	0.15	0.02
3	0.10	0.17	0.68	0.04
4	0.02	0.05	0.02	0.93



Appendix 4: Supplementary Material for Chapter Six

Registry information

Ethics approval

Published supplementary material

Eligibility and medical clearance screening form

Medical clearance referral form

Materials provided to health coaches

Study advertising materials (hospital sites)

Registry Information

Data category	Information
Registry	Australian New Zealand Clinical Trials Registry
Registration number	ACTRN12620000889954
Date of registration	10/09/2020
Public Title	Comparison of a discharge system and usual care, for supporting people after completing conservative treatment for chronic low back pain: a randomised controlled trial
Scientific Title	A randomised controlled trial investigating the effectiveness, cost-effectiveness, and scalability of a coordinated system, linking people receiving conservative care for chronic low back pain to a public health coaching service (NSW Get Healthy Coaching Service®), at discharge from treatment.
Secondary ID	GNT1180474
Ethics committee name	Western Sydney Local Health District Human Research Ethics Committee
Ethics approval number	2020/ETH00115
Funding sources	National Health and Medical Research Centre Western Sydney Local Health District
Primary sponsor	University of Sydney
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Chronic low back pain
Date of first enrolment (actual)	1/12/2021
Target sample size	374
Recruitment status	Recruiting
Contact for public queries	paulo.ferreira@sydney.edu.au
Contact for scientific queries	paulo.ferreira@sydney.edu.au

Research Office File No: (6348)

Project ID	2020/PID00131
Ethics Ref:	2020/ETH00115
Governance Ref:	2020/STE00154

10 August 2020

Prof Paulo Ferreira
Faculty of Medicine
University of Sydney

Dear Prof Ferreira

Project title: The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 17 July 2020following single ethical review of the above project at its meeting held on 14 July 2020.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice.
This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this research project to be conducted at:

- Westmead Hospital – Principal Investigator Dragana Ceprnja

The following documentation has been reviewed and approved by the HREC:

- HREA 2020/ETH00115 , version 5, dated 20 July 2020
- Protocol, version 4 dated 21 July 2020
- Westmead Hospital - Participant Information Sheet and Consent Form - version 4, dated 21 July 2020
- Participant Withdrawal Form, version 4 dated 21 July 2020
- Eligibility and Medical Clearance Screening Form, version 3 dated 19 June 2020
- Get Back to Healthy Information Pamphlet, version 3 dated 19 June 2020
- 6 and 12 Month Follow-up Questionnaire, version 3 dated 19 June 2020
- Activity Device Instructions and Logbook, version 1 dated 19 June 2020
- Baseline Questionnaire, version 3 dated 19 June 2020
- GetHealthy_Award Letter, dated 8 November 2019
- Fortnightly Follow-up Questionnaire, version 3 dated 19 June 2020
- Weekly Diary, version 1 dated 19 June 2020
- Guideline Script for Study Processes, version 1 dated 19 June 2020

- Medical Clearance Referral Form, version 3 dated 19 June 2020
- Waiting Room Brochure, version 3 dated 19 June 2020
- Waiting Room Poster, version 1 dated 1 April 2020

Please note the following conditions of approval:

- The Coordinating Chief Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project
- For clinical trials of implantable medical devices only – The Coordinating Chief Investigator will confirm to the HREC that a process has been established for tracking the participant, with consent, for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).
- The Coordinating Chief Investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- The Coordinating Chief Investigator will provide to the HREC in the specific format via REGIS, proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project. .
- The Coordinating Chief Investigator must notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Coordinating Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format.
- HREC approval is valid for 5 years contingent upon submission of an annual report via REGIS.
- The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived including
    1. Discussion of relevant aspects of the project with investigators, at any time,
    2. Random inspection of research sites, data or consent documentation,
    3. Interview with research participants or other forms of feedback from them, and
    4. Request and review reports from independent agencies such as a Data Safety Monitoring Board.
- If your research project is an interventional trial, please ensure it is registered on one of the clinical trial registries, eg http://www.actr.org.au.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the Coordinating Chief Investigator.

In all future correspondence concerning this study, please quote Research Office File number ***(6348).***
The HREC wishes you every success in your research.

Yours sincerely

Mrs Patricia Fa
Secretary
WSLHD Human Research Ethics Committee
cc: Research Governance Officer

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4, 10
	2b	All items from the World Health Organization Trial Registration Data Set	4, 10
Protocol version	3	Date and version identifier	31
Funding	4	Sources and types of financial, material, and other support	33
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 33-34
	5b	Name and contact information for the trial sponsor	32
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	33
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	25

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6-10
	6b	Explanation for choice of comparators	7-9
Objectives	7	Specific objectives or hypotheses	10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	10
Methods: Participants, interventions, and outcomes			
Study setting	9	10-11	9-10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11-12
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, 17-20
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	18
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	23
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	17
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12-13, Table 1, Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	26
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	20
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	16
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	16
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	15
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	16
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	25
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-13, 15, 21-23, Table 1, Table 2.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	23-24

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	25
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	26-28
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	27
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	25
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	25
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21-22, 25, Additional File 8 and 9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	20-21, 25
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	32
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	26

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14-15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	28
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	33
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	33
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	22
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	28, 31
	31b	Authorship eligibility guidelines and any intended use of professional writers	28, 33-34
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Additional file 6
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	10	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	7-9,17-19	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	17-20 Table 3	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	17-20 Table 3	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	8, 18, 20	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	18-20	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	18-20	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	18-19	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	19	Table 3
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A – protocol paper	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	N/A – protocol paper.	Plan described on p. 20-21
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A – protocol paper	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BASELINE QUESTIONNAIRE

We expect that this questionnaire will take approximately 35-45 minutes to complete. There is an option to save your responses and return to the questionnaire later if you are unable to complete it immediately.

SECTION 1: IDENTIFICATION

1. Date: ____ / _____/ _____

2. Participant study ID: _____

3. Age: _____ **4.** Sex: ❑ Male ❑ Female

5. Are you of Aboriginal, Torres Strait Islander or Maori origin? ❑ No ❑ Aboriginal ❑ Torres Strait Islander ❑ Maori

SECTION 2: ANTHROPOMETRICS AND DEMOGRAPHICS MEASUREMENT

1. Weight: _____ kg Height: _____ m BMI: _____ kg/m^2

2. Marital Status: ❑ Single ❑ Married or in a domestic partnership ❑ Divorced ❑ Widowed

3.Highest Degree or Schooling Level: ❑ Elementary ❑ High School ❑ Graduate (TAFE, college, or equivalent) ❑ Graduate (Bachelor's, Master's) ❑ Doctorate (PhD)

4. Current employment status:

- ❑ Employed full time (40 or more hours per week)
- ❑ Employed part time (up to 39 hours per week)
- ❑ Unemployed and currently looking for work
- ❑ Unemployed and not currently looking for work
- ❑ Casual
- ❑ Retired
- ❑ Unable to work

5. Occupation (if applicable): _____

6. What is your gross weekly household income (annual income in brackets)?

- ❑ No or negative income
- ❑ $1-$799 ($1-$41,599)
- ❑ $800-$1,999 ($41,600-$103,999)
- ❑ $2,000-$3,999 ($104,000-$207,999)
- ❑ $4,000 or more ($208,000 or more)
- ❑ Prefer not to answer

SECTION 3: MEDICAL HISTORY

Medical History

1. Have you ever experienced any of the following health problems (in the past or currently)? Please tick all the boxes that apply, otherwise please select no. Please answer any relevant questions.

---

a. Cardiovascular conditions:

- ❑ No
- ❑ High blood pressure (hypertension)
- ❑ High cholesterol levels (hypercholesterolemia)
- ❑ High lipid levels (hyperlipidemia)
- ❑ Heart attack
- ❑ Heart murmur
- ❑ Diseases of the arteries
- ❑ Anemia
- ❑ Varicose veins or blood clots
- ❑ Other, please specify _____

---

b. Respiratory conditions:

- ❑ No
- ❑ Asthma
- ❑ Chronic obstructive pulmonary disease (COPD)
- ❑ Pneumonia
- ❑ Bronchitis
- ❑ Emphysema
- ❑ Abnormal chest X-ray
- ❑ Obstructive sleep apnea: **bi.** Do you use a CPAP machine? ❑ No ❑ Yes
- ❑ Other, please specify _____

---

c.	Gastrointestinal conditions:	❑ No ❑ Liver disease ❑ Gall bladder disease ❑ Acid reflux ❑ Other, please specify _____
d.	Musculoskeletal conditions:	❑ No ❑ Lower back pain ❑ Leg pain ❑ Upper or middle back pain ❑ Migraine or recurrent headache ❑ Osteoarthritis, please specify: ❑Hands/wrists ❑Fingers ❑Spine ❑Hip ❑Knees ❑ Osteoporosis ❑ Swollen or painful knees or ankles ❑ Swollen, stiff or painful joints ❑ Pain in your legs after walking short distances ❑ Broken bones, please specify which bone: _____ How many years ago? _____ ❑ Neck pain ❑ Other, please specify _____
e.	Psychological symptoms:	❑ No ❑ Depression or anxiety ❑ Nervous or emotional problems ❑ Other, please specify _____ **ei.** Have you ever received any professional help for it? (e.g. psychologist, GP, psychiatrist, counsellor) ❑ No ❑ Yes **eii.** Do you currently receive any professional help for it? ❑ No ❑ Yes
f.	Neurological conditions:	❑ No ❑ Stroke ❑ Seizures/Epilepsy ❑ Peripheral neuropathy ❑ Other, please specify _____
g.	Sleep-related Problems:	❑ No ❑ Insomnia symptoms (hard to fall asleep, hard to stay asleep) ❑ Snoring ❑ Other, please specific _____
h.	Cancers:	❑ No ❑ Yes, please specify: _____ How many years ago?_____
i.	Any other medical conditions:	❑ No ❑ Yes, please specify _____

Medications

2. Do you currently take medications for any health condition(s) other than low back pain? We will ask you questions about medications for low back pain later in the questionnaire.

❑ No → *Skips to 3*

❑ Yes

2a. Please tick which health conditions you take medications (other than low back pain) for and answer any relevant questions.

i.	Pain (excluding low back pain)	❑ No (skip to ii) ❑ Yes	**a.** Please specify the type/name of the medication _____ **b.** How many tablets do you take daily? _____ **c.** What is the dosage (milligrams per tablet)? _____

ii.	Depression	❑ No (skip to iii) ❑ Yes	**a.** Please specify the type/name_____ **b.** How many tablets do you take daily? _____ **c.** What is the dosage (milligrams per tablet)? _____
iii.	Sleep	❑ No (skip to iv) ❑ Yes	**a.** Please specify the type/name_____ **b**. How many tablets do you take daily? _____ **c.** What is the dosage (milligrams per tablet)? _____
iv.	Cardiovascular disease (e.g. blood pressure, cholesterol)	❑ No (skip to v) ❑ Yes	**a**. Please specify the type/name_____ **b.** How many tablets do you take daily? _____ **c.** What is the dosage (milligrams per tablet)? _____
v.	Diabetes	❑ No (skip to vi) ❑ Yes (tablets) ❑ Yes (insulin)	*[If tablets, the following questions will appear]* **a.** Please specify the type/name_____ **b.** How many tablets do you take daily? _____ **c.** What is the dosage (milligrams per tablet)? _____ *[If insulin, the following questions will appear]* **d.** How often you receive injections? _____ **e.** What is the dosage of your insulin? _____
vi.	Any other health condition	❑ No (skips to 3) ❑ Yes	**a.** How do you use the medication? ❑ Tablet ❑Patch ❑ Injection ❑Other *[If tablets, the following questions will appear]* **b.** What health condition do you use this medication for? _____ **c.** What is the name of the medication?_____ **d.** How many tablets do you take daily? _____ **e.** What is the dosage (milligrams per tablet)? _____ *[If patch, the following questions will appear]* **f.** What health condition do you use this medication for? _____ **g.** What is the name of the patch?_____ **h.** What is the dosage? _____ **i.** How frequently do you wear a patch? _____ *[If injection, the following questions will appear]* **j.** What health condition do you use this medication for? _____ **k.** What is the dosage (if known)? _____ **l.** How frequently do you receive an injection? _____ *[If other, the following questions will appear]* **m.** What health condition do you use this medication for? _____ **n**. How do you use this medication? _____ **o.** What is the name of the medication?_____ **p.** How frequently do you use this medication? _____

Smoking History

3. Have you ever had a history of smoking cigarettes, cigars or a pipe?

- ❑ No, never smoked → *Skips to 4*
- ❑ Occasional smoker
- ❑ Ex-smoker
- ❑ Current Smoker

3a. At what age did you start smoking? _____

3b. How many cigarettes did you previously/do you currently smoke on average per day? _____

3c. How many cigars did you previously/do you currently smoke on average per day? _____

3d. How many pipefuls did you previously/do you currently smoke on average per day? _____

3e. If you are an ex-smoker, when you did you last smoke? ❑ _____ or ❑ N/A (current smoker)

Alcohol Consumption History

4. Have you ever consumed alcohol?

- ❑ No → *Skips to LOW BACK PAIN HISTORY*
- ❑ Yes

4a. In the past, have you ever been a heavy drinker (consumption of more than 5 drinks per day)? ❑ No ❑ Yes

4b. How often do you consume alcohol?

❑ Never	❑ Once a month (approximately)	❑ Sometimes/week
❑ Once a year or less	❑ Sometimes/Month	❑ Daily
❑ Sometimes/year	❑ Once a week	

SECTION 4: LOW BACK PAIN HISTORY

We would like to know about the history of your low back pain symptoms. Please answer the following questions.

1.How long have you experienced low back pain?

- ❑ Less than 6 weeks
- ❑ Between 6-12 weeks
- ❑ Between 12 weeks (3 months) to 1 year
- ❑ More than 1 year: **1b.** How many years _____

2.Regarding your low back pain, which best describes your symptoms?

- ❑ Back pain only
- ❑ Back pain with leg pain
- ❑ Leg pain only

3. Which of the following best describes the pattern of your lower back pain:

- ❑ Constant back pain (always present and never fully recovers)
- ❑ Recurrent back pain (periods of full recovery with no back pain, with intermittent episodes of back pain)

4. Have you ever had surgery for your lower back pain?

- ❑ No → *Skips to LOW BACK PAIN SYMPTOMS*
- ❑ Yes

4a. How many surgeries have you had in your lower back? _____

4b. What year was your most recent lower back surgery? _____

4c. Which type of surgery did you have for your back? ❑ Microdiscectomy ❑ Discectomy ❑ Laminectomy/decompression ❑ Fusion ❑ Unsure ❑ Other, please specify_____

SECTION 5: LOW BACK PAIN SYMPTOMS

We would like to know about the intensity of your low back pain symptoms. Please answer the following questions.

Low Back Pain Intensity (Current)

1. Please rate the intensity of your current low back pain today, where 0 = no pain and 10 = worst possible pain.

0	1	2	3	4	5	6	7	8	9	10
No pain					Moderate Pain					Worst possible Pain

Low Back Pain Intensity (In the Past Week)

2. Please rate the intensity of your average low back pain over the past week, where 0 = no pain and 10 = worst possible pain.

0	1	2	3	4	5	6	7	8	9	10
No pain					Moderate Pain					Worst possible Pain

Low Back Pain Frequency (In the Past Week)

3. Over the last week, how many days did you experience low back pain?_____

Low Back Pain Disability (Roland Morris Disability Questionnaire)

We would like to know about any disability caused by your low back pain. Please answer the following questions.

4. The purpose of the following questions is the understand how much your low back pain interferes with your daily activities. Please select yes or no to the following questions.

a. I stay at home most of the day because of the pain in my back	❑ No	❑ Yes
b. I change position frequently to try and get my back comfortable.	❑ No	❑ Yes
c. I walk more slowly than usual because of the pain in my back.	❑ No	❑ Yes
e. Because of the pain in my back, I am not doing any of the jobs that I usually do around the house.	❑ No	❑ Yes
f. Because of the pain in my back, I use a handrail to climb stairs.	❑ No	❑ Yes
g. Because of the pain in my back, I lie down to rest more often than usual.	❑ No	❑ Yes
h. Because of the pain in my back, I have to hold on to something to get out of a lounge chair.	❑ No	❑ Yes
i. Because of the pain in my back, I ask other people to do things for me.	❑ No	❑ Yes
j. I get dressed more slowly than usual because of the pain in my back.	❑ No	❑ Yes
k. I only stand up for short periods of time because of the pain in my back.	❑ No	❑ Yes
l. Because of the pain in my back, I try not to bend or kneel down.	❑ No	❑ Yes
m. I find it difficult to get out of a dining chair because of the pain in my back.	❑ No	❑ Yes
n. My back is painful most of the time.	❑ No	❑ Yes
o. I find it difficult to turn over in bed because of the pain in my back.	❑ No	❑ Yes
p. I do not feel like eating much because of the pain in my back.	❑ No	❑ Yes
q. I have trouble putting on my socks (or stockings) because of the pain in my back.	❑ No	❑ Yes
r. I only walk short distances because of the pain in my back.	❑ No	❑ Yes
s. I sleep less than usual because of the pain in my back.	❑ No	❑ Yes
t. Because of the pain in my back, I get dressed with help from someone else.	❑ No	❑ Yes
u. I sit down for most of the day because of the pain in my back.	❑ No	❑ Yes
v. I avoid heavy jobs in the house because of the pain in my back.	❑ No	❑ Yes
w. Because of the pain in my back, I am more irritable and bad tempered with people than usual.	❑ No	❑ Yes

x. Because of the pain in my back, I climb stairs more slowly than usual.	❑ No	❑ Yes
y. I stay in bed most of the time because of the pain in my back.	❑ No	❑ Yes

SECTION 6: USE OF CARE AND TREATMENT FOR LOW BACK PAIN

The purpose of this section is to understand what types of care or treatment you have used for your low back pain in the past 3 months. Please answer the following questions.

Emergency Department

1. In the past 3 months, have you visited a hospital emergency department specifically your low back pain?

❑ No → *Skips to 2*

❑ Yes

a. How many separate occasions did you go to the emergency department? _____

b. How many days did you spend at the hospital in total? _____

Imaging

2. In the past 3 months, have you had any of the following imaging or tests specifically for your low back pain?

❑ X-ray ❑ Ultrasound

❑ CT scan ❑ Nerve conduction studies

❑ MRI ❑ Other, please specify _____

Medical and Health Professionals and Services

3. In the past 3 months, have you visited any hospital, medical or health professionals or services specifically for your low back pain (e.g. GP, physiotherapist, specialist clinician, pharmacist)?

❑ No → *Skips to 4*

❑ Yes

a. Please indicate which of the following health professionals or services you visited for your low back pain in the past 3 months. You may be asked additional questions related to travelling time or costs. If you are asked questions about travelling time, please include any time spent on public transport, driving or being driven by someone else, or walking.

❑ General practitioner:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your GP each visit? (HH:MM) _____:_____ iii. On average, how much did each visit cost you (out of pocket)? $_____
❑ Pharmacist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your pharmacist each visit? (HH:MM) _____:_____ iii. On average, how much did each visit cost you (out of pocket)? $_____
❑ Orthopaedic surgeon:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your orthopaedic surgeon each visit? HH:MM) _____:_____ **iii**. On average, how much did each visit cost you (out of pocket)? $_____
❑ Pain physician:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your pain physician each visit? (HH:MM) _____:_____ **iii**. On average, how much did each visit cost you (out of pocket)? $_____
❑ Rheumatologist:	**i.** How many visits/sessions? _____

	ii. On average, how much time did it take for you to travel directly to and from your rheumatologist each visit? (HH:MM) _____:_____ **iii**. On average, how much did each visit cost you (out of pocket)? $_____
❑ Neurologist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your neurologist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Psychiatrist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your psychiatrist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Public Hospital physiotherapist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your hospital physiotherapist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Private Hospital physiotherapist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your hospital physiotherapist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Private clinic physiotherapist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your private clinic physiotherapist each visit? (HH:MM)___:____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Chiropractor:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your chiropractor each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Osteopath:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your osteopath each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Exercise physiologist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your exercise physiologist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Public hospital exercise physiologist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your exercise physiologist each visit? (HH:MM) _____:_____

	iii. On average, how much did each visit cost you (out of pocket)? $_____
❑ Private hospital exercise physiologist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your exercise physiologist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Private clinic exercise physiologist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your exercise physiologist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Massage therapist:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your massage therapist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Public hospital psychiatrist/psychologist/counsellor:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your psychologist/counsellor each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you? $_____
❑ Private hospital psychiatrist/psychologist/counsellor:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your psychologist/counsellor each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Private clinic psychiatrist/psychologist/counsellor:	**i.** How many visits/sessions? _____ **ii**. On average, how much time did it take for you to travel directly to and from your psychologist/counsellor each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Health coach:	**i.** How many visits/sessions? _____ **ii.** On average, how much time did it take for you to travel directly to and from your health coach each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Natural therapist (e.g. acupuncture)	**i.** How many visits/sessions? _____ **ii.** On average, how much time did it take for you to travel directly to and from your natural therapist each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____
❑ Other, please specify: _____	**i.** How many visits/sessions? _____ **ii.** On average, how much time did it take for you to travel directly to and from this health professional each visit? (HH:MM) _____:_____ **iii.** On average, how much did each visit cost you (out of pocket)? $_____

Medications for Low Back Pain

4. In the past 3 months, have you taken any pain medications specifically for your low back pain?

❑ No → *Skips to 5*

❑ Yes

4a. Please indicate which type(s) of pain medications you took and answer any related questions. Please read the questions carefully.

❑ Paracetamol (e.g. Panadol)	**i.** Was this medication prescribed to you by your doctor? ❑ Yes ❑ No **ii.** On average, how many days per week did you take paracetamol for your low back pain? __ **iii.** On the days you took paracetamol for your low back pain, what was the average number of paracetamol tablets you took per day? _____ **iv.** What was the dosage (milligrams per tablet)? _____ v. Where did you source this medication from? ❑ Chemist/Pharmacy ❑ Petrol Station ❑ Supermarket ❑ Online purchase ❑ Other, please specify: _____
❑ NSAIDs (e.g. neurofen, ibuprofen)	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? ❑ Yes ❑ No **ii.** On average, how many days per week did you take NSAIDs for your low back pain? _____ **iii.** On the days you took NSAIDs for your low back pain, what was the average number of NSAID tablets you took per day? _____ **iv.** What was the dosage (milligrams per tablet)? _____ v. Where did you source this medication from? ❑ Chemist/Pharmacy ❑ Petrol Station ❑ Supermarket ❑ Online purchase ❑ Other, please specify: _____
❑ Opioids (e.g. Endone, targin, palexia, panadeine, neurofen Plus, oxycontin)	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? ❑ Yes ❑ No **ii.** On average, how many days per week did you take opioids for your low back pain? _____ **iii.** On the days you took opioids for your low back pain, what was the average number of opioids tablets you took per day? _____ **iv.** What was the dosage (milligrams per tablet)? _____
❑ Other, please specify: _____ _____	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? ❑ Yes ❑ No **ii.** How was the pain medication used? ❑ Tablet ❑ Patch ❑ Other If tablet: **a.** On average, how many days per week did you take this pain medication for your low back pain? _____ **b.** On the days you took this pain medication for your low back pain, what was the average number of tablets you took per day? _____

c. What was the dosage (milligrams per tablet)? _____

If patch:

a. What was the dosage (milligrams per patch)? _____

b. How often did you use a patch (e.g. 1 patch per week)? _____

If other:

a. How did you use the medication (e.g. injection, apply to skin)? _____

b. What was the dosage? _____

c. How often did you use the medication? _____

iii. Where did you source this medication from?

- ❑ Chemist/Pharmacy
- ❑ Petrol Station
- ❑ Supermarket
- ❑ Online purchase
- ❑ Other, please specify: _____

Self-management for Low Back Pain

5. In the past 3 months, have you used any self-management techniques or aids to manage your low back pain?

- ❑ No
- ❑ Massage (i.e., not from a professional)
- ❑ Heat packs or hot shower
- ❑ Brace or support strapping/tape
- ❑ Topical creams/gels (e.g., Voltaren)
- ❑ Physical activity and exercise
- ❑ Relaxation, meditation or mindfulness techniques
- ❑ Walking aids (e.g. crutches, walking stick)
- ❑ Other, please specify _____

SECTION 7: PHYSICAL ACTIVITY LEVELS

Global Physical Activity Questionnaire

We would like to know about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person.

Think first about the time you spend doing work. Think of 'work' as the things that you have to do such as paid or unpaid work, study/training, household chores, seeking employment. In answering the following questions:

- 'Vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate
- 'Moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

Work

1. Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 2*

1a. In a typical week, on how many days do you do vigorous-intensity activities as part of your work?

Number of days _____

1b. How much time do you spend doing vigorous-intensity activities at work on a typical day?

Hours: minutes _____:_____

2. Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 3*

2a. In a typical week, on how many days do you do moderate intensity activities as part of your work?

Number of days _____

2b. How much time do you spend doing moderate-intensity activities at work on a typical day?

Hours: minutes _____:_____

Travel To and From Places

The next questions exclude the physical activities at work that you have already mentioned. Now we would like to ask you about the usual way you travel to and from places. For example, to work, for shopping, to the market, to your place of worship.

3. Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?

❑ Yes ❑ No → *Skips to 4*

3a. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?

Number of days _____

3b. How much time do you spend walking or bicycling for travel on a typical day?

Hours:minutes _____:_____

Recreational Activities

The next questions exclude the work and transport activities that you have already mentioned. Now we would like to ask you about sports, fitness and recreational activities (leisure).

4. Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 5*

4a. In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities?

Number of days _____

4b. How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?

Hours: minutes _____:_____

5. Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 6*

5a. In a typical week, on how many days do you do moderate intensity sports, fitness or recreational (leisure) activities?

Number of days _____

5b. How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?

Hours: minutes_____:_____

Sedentary behaviour

The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include time spent sleeping.

6. How much time do you usually spend sitting or reclining on a typical day?

Hours: minutes _____

SECTION 8: FUNCTION

Patient Specific Functional Scale

The purpose of this questionnaire is to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your low back pain. Please answer the following questions.

Today, are there any activities that you are unable to do or having difficulty with because of your back pain?

Please write three activities in the table below, and score your ability to perform each activity by selecting one number from the following scoring scheme (out of 10):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

Activity	Initial/Baseline
1a.	***1b**. Score:* / 10
2a.	***2b.** Score:* / 10
3a.	***3b.** Score:* / 10

SECTION 9: QUALITY OF LIFE

We would like to know about your quality of life. Please answer the following questions.

Assessment of Quality of Life 8-D Questionnaire (AQOL-8D)

Tick the box that best describes your situation as it has been over the past week:

Q1 How much energy do you have to do the things you want to do?

I am:

- ❑ always full of energy
- ❑ usually full of energy
- ❑ occasionally energetic
- ❑ usually tired and lacking energy
- ❑ always tired and lacking energy.

Q2 How often do you feel socially excluded or left out?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ Always

Q3 How easy or difficult is it for you to get around by yourself outside your place of residence (e.g. to go shopping, visiting)?

- ❑ Getting around is enjoyable and easy
- ❑ I have no difficulty getting around outside my place of residence
- ❑ A little difficulty
- ❑ Moderate difficulty
- ❑ A lot of difficulty
- ❑ I cannot get around unless somebody is there to help me

Q4 Does your health affect your role in your community (e.g. Residential, sporting, church or cultural activities)?

- ❑ My role in the community is unaffected by my health
- ❑ There are some parts of my community role I cannot carry out
- ❑ There are many parts of my community role I cannot carry out
- ❑ I cannot carry out any part of my community role

Q5 How often do you feel sad?

❑ Never ❑ Rarely ❑ Some of the time ❑ Usually ❑ Nearly all the time

Q6 How often do you experience serious pain?

I experience it:

- ❑ Very rarely
- ❑ Less than once a week
- ❑ Once or twice a week
- ❑ Three to four times a week
- ❑ Most of the time

Q7 How much confidence do you have in yourself?

- ❑ Complete confidence
- ❑ A lot
- ❑ A moderate amount
- ❑ A little
- ❑ None at all

Q8 Do you normally feel calm and tranquil or agitated?

I am

- ❑ always calm and tranquil
- ❑ usually calm and tranquil
- ❑ sometimes calm and tranquil, sometimes agitated
- ❑ usually agitated
- ❑ always agitated

Q9 Does your health affect your relationship with your family?

- ❑ My role in the family is unaffected by my health
- ❑ There are some parts of my family role I cannot carry out
- ❑ There are many parts of my family role I cannot carry out
- ❑ I cannot carry out any part of my family role.

Q10 How satisfying are your close relationships (family and friends)?

- ❑ Very satisfying
- ❑ Satisfying
- ❑ Neither satisfying nor dissatisfying
- ❑ Dissatisfying
- ❑ Unpleasant
- ❑ Very unpleasant

Q11 How well do you communicate with others (talking, signing, texting, being understood by others and understanding them)?

- ❑ I have no trouble being understood
- ❑ I have some difficulty being understood by people who do not know me.
- ❑ I am understood only by people who know me.
- ❑ I cannot adequately communicate with others

Q12 How often do you have trouble sleeping?

❑ Never ❑ Almost never ❑ Sometimes ❑ Often ❑ All the time

Q13 How often do you feel worthless?

❑ Never ❑ Almost never ❑ Sometimes ❑ Usually ❑ Always

Q14 How often do you feel angry?

❑ Never ❑ Almost never ❑ Sometimes ❑ Often ❑ All the time

Q15 How easy or difficulty is it for you to move around (using any aids or equipment you need e.g. a wheelchair, frame or stick)?

- ❑ I am very mobile
- ❑ I have no difficulty with mobility
- ❑ I have some difficulty with mobility (for example, going uphill)
- ❑ I have difficulty with mobility, I can go short distances only.
- ❑ I have a lot of difficulty with mobility, I need someone to help me
- ❑ I am bedridden

Q16 Do you ever feel like hurting yourself?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ All the time

Q17 How enthusiastic do you feel?

❑ Extremely ❑ Very ❑ Somewhat ❑ Not much ❑ Not at all

Q18 How often did you feel worried in the last seven days?

❑ Never ❑ Occasionally ❑ Sometimes ❑ Often ❑ All the time

Q19 How difficulty is it for you to wash, toilet, dress yourself, eat or care for your appearance?

- ❑ These things are very easy for me to do
- ❑ I have no real difficulty in doing these things
- ❑ I find some of these things difficult, but I manage to do them on my own
- ❑ Many of these things are difficult, and I need help to do them
- ❑ I cannot do these things by myself at all

Q20 How often do you feel happy?

❑ All the time ❑ Mostly ❑ Sometimes ❑ Almost never ❑ Never

Q21 How much do you feel you can cope with life's problems?

❑ Completely ❑ Mostly ❑ Partly ❑ Very little ❑ Not at all

Q22 How much pain or discomfort do you experience?

- ❑ None at all
- ❑ I have moderate pain
- ❑ I suffer from severe pain
- ❑ I suffer unbearable pain

Q23 How much do you enjoy your close relationships (family and friends)?

❑ Immensely ❑ A lot ❑ A little ❑ Not much ❑ I hate it

Q24 How often does pain interfere with your usual activities?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ Always

Q25 How often do you feel pleasure?

❑ Always ❑ Usually ❑ Sometimes ❑ Almost never ❑ Never

Q26 How much of a burden do you feel you are to other people?

❑ Not at all ❑ A little ❑ A moderate amount ❑ A lot ❑ Totally

Q27 How content are you with your life?

❑ Extremely ❑ Mainly ❑ Moderately ❑ Slightly ❑ Not at all

Q28 How well can you see (using your glasses or contact lenses if they are needed)?

❑ I have excellent sight
❑ I see normally
❑ I have some difficulty seeing things sharply. (e.g. small print, objects in the distance, or watching television)
❑ I have a lot of difficulty seeing sharply.
❑ I only see general shapes.
❑ I am completely blind

Q29 How often do you feel in control of your life?

❑ Always ❑ Mostly ❑ Sometimes ❑ Only occasionally ❑ Never

Q30 How much help do you need with jobs around your place of residence (e.g. preparing food, cleaning

❑ I can do all these tasks very easily without any help
❑ I can do these tasks relatively easily without help
❑ I can do these tasks only very slowly without help
❑ I cannot do most of these tasks unless I have help
❑ I can do none of these tasks by myself

Q31 How often do you feel socially isolated?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ Always

Q32 How well can you hear (using your hearing aid if needed)?

❑ I have excellent hearing
❑ I hear normally
❑ I have some difficulty hearing or I do not hear clearly (e.g. when there is background noise)
❑ I have difficulty hearing things clearly. Often I do not understand what is said. I usually do not take part in conversations because I cannot hear what is said.
❑ I hear very little
❑ I am completely deaf.

Q33 How often do you feel depressed?

❑ Never ❑ Almost never ❑ Sometimes ❑ Often ❑ Very often ❑ All the time

Q34 How happy are you with your close and intimate relationships?

❑ Very happy
❑ Generally happy
❑ Neither happy nor unhappy
❑ Generally unhappy
❑ Very unhappy

Q35 How often did you feel in despair in the last seven days?

❑ Never ❑ Occasionally ❑ Sometimes ❑ Often ❑ All the time

SECTION 10: SLEEP QUALITY

We would like to know about the quality of your sleep. Please answer the following questions.

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night? _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? _____

3. During the past month, what time have you usually gotten up in the morning? _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) _____

5.	During the past month, how often have you had trouble sleeping because you…..	Not during the past month	Less than once a week	Once or twice a week	Three or more time a week
a.	Cannot get to sleep within 30 minutes				
b.	Wake up in the middle of the night or early morning				
c.	Have to get up to use the bathroom				
d.	Cannot breathe comfortably				
e.	Cough or snore loudly				
f.	Feel too cold				
g.	Feel too hot				
h.	Have bad dreams				
i.	Have pain				
j.	Other reasons(s): please describe:				
6.	During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?				
7.	During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				

		No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8.	During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				

		Very good	Fairly good	Fairly bad	Very bad
9.	During the past month, how would you rate your sleep quality overall?				

		No bed partner or room mate	Partner/room mate in other room	Partner in same room but not same bed	Partner in same bed
10.	Do you have a bed partner or room mate?				

	If you have a room mate or bed partner, ask him/her how often in the past month you have had:	Not during the past month	Less than once a week	Once or twice a week	Three or more time a week
a.	Loud snoring				
b.	Long pauses between breaths while asleep				
c.	Legs twitching or jerking while you sleep				
d.	Episodes of disorientation or confusion during sleep				
e.	Other restlessness while you sleep, please describe:				

SECTION 11: BELIEFS ABOUT BACK PAIN

Back Beliefs Questionnaire

We are trying to find out what people think about low back trouble. Please indicate your general views towards back trouble, even if you have never had any.

Please answer ALL statements and indicate whether you agree or disagree with each statement by circling the appropriate number of the scale.

1 2 3 4 5

Completely disagree — Completely agree

Question		Completely disagree				Completely agree
Q1	There is no real treatment for back trouble	1	2	3	4	5
Q2	Back trouble will eventually stop you from working	1	2	3	4	5
Q3	Back trouble means periods of pain for the rest of one's life	1	2	3	4	5
Q4	Doctors cannot do anything for back trouble	1	2	3	4	5
Q5	A bad back should be exercised	1	2	3	4	5
Q6	Back trouble makes everything in life worse	1	2	3	4	5
Q7	Surgery is the most effective way to treat back trouble	1	2	3	4	5
Q8	Back trouble may mean you end up in a wheelchair	1	2	3	4	5
Q9	Alternative treatments are the answer to back trouble	1	2	3	4	5
Q10	Back trouble means long periods of time off work	1	2	3	4	5
Q11	Medication is the only way of relieving back pain	1	2	3	4	5
Q12	Once you have had back trouble there is always a weakness	1	2	3	4	5
Q13	Back trouble must be rested	1	2	3	4	5
Q14	Later in life back trouble gets progressively worse	1	2	3	4	5

SECTION 12: ATTITUDES TOWARDS PAIN MEDICATIONS

We would like to better understand people with low back pain's attitudes towards pain medications. Please answer the following questions.

Pain Medication Attitudes and Questionnaire (PMAQ-14) Short Form

The following statements refer to how you feel about pain medications/painkillers. Please circle the number corresponding to how much you agree with each statement.

		Never true	Almost never true	Seldom true	Often true	Almost always true	Always true
Q1	I am concerned that taking medication for a long time will lead to addiction	0	1	2	3	4	5
Q2	I worry that my pain medication/s will stop working	0	1	2	3	4	5
Q3	I am afraid that stopping my pain medication/s will cause me to feel ill	0	1	2	3	4	5
Q4	I fear that I am becoming an addict	0	1	2	3	4	5
Q5	I would be unwilling to reduce my pain medication/s	0	1	2	3	4	5
Q6	I fear that I will eventually run out of pain medication/s that will help with the pain	0	1	2	3	4	5
Q7	I worry that withdrawal from my pain medication/s will cause me some harm	0	1	2	3	4	5
Q8	I find it hard to put up with the side effects from my pain medication/s	0	1	2	3	4	5
Q9	Needing to take medication for my pain embarrasses me	0	1	2	3	4	5
Q10	I worry what others think about my use of pain medication/s	0	1	2	3	4	5
Q11	I worry about damage to my internal organs from my pain medication/s	0	1	2	3	4	5
Q12	I feel confident about my doctor's management of my pain medication/s	0	1	2	3	4	5
Q13	I depend on my pain medication/s	0	1	2	3	4	5
Q14	I feel satisfied with information with doctor gives me about medication/s	0	1	2	3	4	5

This is the end of the questionnaire, thank you for participating.

6-MONTH AND 12-MONTH FOLLOW-UP QUESTIONNAIRE

We expect that this questionnaire will take approximately 20-30 minutes to complete. There is an option to save your responses and return to the questionnaire later if you are unable to complete immediately.

SECTION 1: IDENTIFICATION

1. Date: ____ / _____/ _____

2. Participant study ID: _____

3. What is your sex? ❑ Male ❑ Female

SECTION 2: LOW BACK PAIN HISTORY

1.In the last 6 months, have you had surgery for your lower back pain?

❑ No → *Skips to LOW BACK PAIN SYMPTOMS*

❑ Yes

2. Which type of surgery? ❑ Microdiscectomy ❑ Discectomy ❑ Laminectomy/decompression

❑ Fusion ❑ Unsure ❑ Other, please specify_____

SECTION 3: LOW BACK PAIN SYMPTOMS

We would like to know about the intensity of your low back pain symptoms. Please answer the following questions.

Low Back Pain Intensity (Current)

1. Please rate the intensity of your current low back pain today, where 0 = no pain and 10 = worst possible pain.

0 1 2 3 4 5 6 7 8 9 10

No pain Moderate Pain Worst possible Pain

Low Back Pain Intensity (In the Past Fortnight)

2. Please rate the intensity of your average low back pain over the past fortnight, where 0 = no pain and 10 = worst possible pain.

0 1 2 3 4 5 6 7 8 9 10

No pain Moderate Pain Worst possible Pain

Low Back Pain Frequency (In the Past Fortnight)

3. Over the last 2 weeks (fortnight), how many days did you experience low back pain?_____

Low Back Pain Disability (Roland Morris Disability Questionnaire)

We would like to know about any disability caused by your low back pain. Please answer the following questions.

4. The purpose of the following questions is the understand how much your low back pain interferes with your daily activities. Please select yes or no to the following questions.

a)	I stay at home most of the day because of the pain in my back	❑ No	❑ Yes
b)	I change position frequently to try and get my back comfortable.	❑ No	❑ Yes
c)	I walk more slowly than usual because of the pain in my back.	❑ No	❑ Yes
d)	Because of the pain in my back, I am not doing any of the jobs that I usually do around the house.	❑ No	❑ Yes
e)	Because of the pain in my back, I use a handrail to climb stairs.	❑ No	❑ Yes
f)	Because of the pain in my back, I lie down to rest more often than usual.	❑ No	❑ Yes
g)	Because of the pain in my back, I have to hold on to something to get out of a lounge chair.	❑ No	❑ Yes
h)	Because of the pain in my back, I ask other people to do things for me.	❑ No	❑ Yes
i)	I get dressed more slowly than usual because of the pain in my back.	❑ No	❑ Yes
j)	I only stand up for short periods of time because of the pain in my back.	❑ No	❑ Yes
k)	Because of the pain in my back, I try not to bend or kneel down.	❑ No	❑ Yes
l)	I find it difficult to get out of a dining chair because of the pain in my back.	❑ No	❑ Yes
m)	My back is painful most of the time.	❑ No	❑ Yes
n)	I find it difficult to turn over in bed because of the pain in my back.	❑ No	❑ Yes
o)	I do not feel like eating much because of the pain in my back.	❑ No	❑ Yes
p)	I have trouble putting on my socks (or stockings) because of the pain in my back.	❑ No	❑ Yes
q)	I only walk short distances because of the pain in my back.	❑ No	❑ Yes
r)	I sleep less than usual because of the pain in my back.	❑ No	❑ Yes
s)	Because of the pain in my back, I get dressed with help from someone else.	❑ No	❑ Yes
t)	I sit down for most of the day because of the pain in my back.	❑ No	❑ Yes
u)	I avoid heavy jobs in the house because of the pain in my back.	❑ No	❑ Yes
v)	Because of the pain in my back, I am more irritable and bad tempered with people than usual.	❑ No	❑ Yes
w)	Because of the pain in my back, I climb stairs more slowly than usual.	❑ No	❑ Yes
x)	I stay in bed most of the time because of the pain in my back.	❑ No	❑ Yes

SECTION 4: PHYSICAL ACTIVITY LEVELS

Global Physical Activity Questionnaire

We would like to know about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person.

Think first about the time you spend doing work. Think of 'work' as the things that you have to do such as paid or unpaid work, study/training, household chores, seeking employment. In answering the following questions:

- 'Vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate
- 'Moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

Work

1. Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 4*

2. In a typical week, on how many days do you do vigorous-intensity activities as part of your work?

Number of days _____

3. How much time do you spend doing vigorous-intensity activities at work on a typical day?

Hours: minutes _____:_____

4. Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 7*

5. In a typical week, on how many days do you do moderate intensity activities as part of your work?

Number of days _____

6. How much time do you spend doing moderate-intensity activities at work on a typical day?

Hours: minutes _____:_____

Travel To and From Places

The next questions exclude the physical activities at work that you have already mentioned. Now we would like to ask you about the usual way you travel to and from places (e.g. to work, for shopping, to market, to place of worship).

7. Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?

❑ Yes ❑ No → *Skips to 10*

8. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?

Number of days _____

9. How much time do you spend walking or bicycling for travel on a typical day?

Hours:minutes _____:_____

Recreational Activities

The next questions exclude the work and transport activities that you have already mentioned. Now we would like to ask you about sports, fitness and recreational activities (leisure).

10. Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 13*

11. In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities?

Number of days _____

12. How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?

Hours: minutes _____:_____

13. Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes continuously?

❑ Yes ❑ No → *Skips to 16*

14. In a typical week, on how many days do you do moderate intensity sports, fitness or recreational (leisure) activities?

Number of days _____

15. How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?

Hours: minutes_____:_____

Sedentary behaviour

The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include time spent sleeping.

16. How much time do you usually spend sitting or reclining on a typical day?

Hours: minutes _____

SECTION 5: FUNCTION

Patient Specific Functional Scale

The purpose of this questionnaire is to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your low back pain.

Please answer the following questions by selecting one number from the following scoring scheme (out of 10):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

When we assessed you at baseline, you indicated that you had difficulty with the following activities.

Today, do you still have difficulty with:

Activity	6-month follow-up	12-month follow-up
1a.	***1b.*** *Score:* / 10	***1c.*** *Score:* / 10
2a.	***2b.*** *Score:* / 10	***2c.*** *Score:* / 10
3a.	***3b.*** *Score:* / 10	***3c.*** *Score:* / 10

SECTION 6: QUALITY OF LIFE

We would like to know about your quality of life. Please answer the following questions.

Assessment of Quality of Life 8-D Questionnaire (AQOL-8D)
Tick the box that best describes your situation as it has been over the past week:

Q1 How much energy do you have to do the things you want to do?
I am:
- ❑ always full of energy
- ❑ usually full of energy
- ❑ occasionally energetic
- ❑ usually tired and lacking energy
- ❑ always tired and lacking energy.

Q2 How often do you feel socially excluded or left out?
❑ Never ❑ Rarely ❑ Sometimes ❑ Often

Q3 How easy or difficult is it for you to get around by yourself outside your place of residence (e.g. to go shopping, visiting)?

- ❑ Getting around is enjoyable and easy
- ❑ I have no difficulty getting around outside my place of residence
- ❑ A little difficulty
- ❑ Moderate difficulty
- ❑ A lot of difficulty
- ❑ I cannot get around unless somebody is there to help me

Q4 Does your health affect your role in your community (eg. Residential, sporting, church or cultural activities)?

- ❑ My role in the community is unaffected by my health
- ❑ There are some parts of my community role I cannot carry out
- ❑ There are many parts of my community role I cannot carry out
- ❑ I cannot carry out any part of my community role

Q5 How often do you feel sad?

❑ Never ❑ Rarely ❑ Some of the time ❑ Usually ❑ Nearly all the time

Q6 How often do you experience serious pain?

I experience it:

- ❑ Very rarely
- ❑ Less than once a week
- ❑ Once or twice a week
- ❑ Three to four times a week
- ❑ Most of the time

Q7 How much confidence do you have in yourself?

- ❑ Complete confidence
- ❑ A lot
- ❑ A moderate amount
- ❑ A little
- ❑ None at all

Q8 Do you normally feel calm and tranquil or agitated? I am:

- ❑ always calm and tranquil
- ❑ usually calm and tranquil
- ❑ sometimes calm and tranquil, sometimes agitated
- ❑ usually agitated
- ❑ always agitated

Q9 Does your health affect your relationship with your family?

- ❑ My role in the family is unaffected by my health
- ❑ There are some parts of my family role I cannot carry out
- ❑ There are many parts of my family role I cannot carry out
- ❑ I cannot carry out any part of my family role.

Q10 How satisfying are your close relationships (family and friends)?

- ❑ Very satisfying
- ❑ Satisfying
- ❑ Neither satisfying nor dissatisfying
- ❑ Dissatisfying
- ❑ Unpleasant
- ❑ Very unpleasant

Q11 How well do you communicate with others (talking, signing, texting, being understood by others and understanding them)?

- ❑ I have no trouble being understood
- ❑ I have some difficulty being understood by people who do not know me.
- ❑ I am understood only by people who know me.
- ❑ I cannot adequately communicate with others

Q12 How often do you have trouble sleeping?

❑ Never ❑ Almost never ❑ Sometimes ❑ Often ❑ All the time

Q13 How often do you feel worthless?

❑ Never ❑ Almost never ❑ Sometimes ❑ Usually ❑ Always

Q14 How often do you feel angry?

❑ Never ❑ Almost never ❑ Sometimes ❑ Often ❑ All the time

Q15 How easy or difficulty is it for you to move around (using any aids or equipment you need e.g. a wheelchair, frame or stick)?

- ❑ I am very mobile
- ❑ I have no difficulty with mobility
- ❑ I have some difficulty with mobility (for example, going uphill)
- ❑ I have difficulty with mobility, I can go short distances only.
- ❑ I have a lot of difficulty with mobility, I need someone to help me
- ❑ I am bedridden

Q16 Do you ever feel like hurting yourself?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ All the time

Q17 How enthusiastic do you feel?

❑ Extremely ❑ Very ❑ Somewhat ❑ Not much ❑ Not at all

Q18 How often did you feel worried in the last seven days?

❑ Never ❑ Occasionally ❑ Sometimes ❑ Often ❑ All the time

Q19 How difficulty is it for you to wash, toilet, dress yourself, eat or care for your appearance?

- ❑ These things are very easy for me to do
- ❑ I have no real difficulty in doing these things
- ❑ I find some of these things difficult, but I manage to do them on my own
- ❑ Many of these things are difficult, and I need help to do them
- ❑ I cannot do these things by myself at all

Q20 How often do you feel happy?

❑ All the time ❑ Mostly ❑ Sometimes ❑ Almost never ❑ Never

Q21 How much do you feel you can cope with life's problems?

❑ Completely ❑ Mostly ❑ Partly ❑ Very little ❑ Not at all

Q22 How much pain or discomfort do you experience?

- ❑ None at all
- ❑ I have moderate pain
- ❑ I suffer from severe pain
- ❑ I suffer unbearable pain

Q23 How much do you enjoy your close relationships (family and friends)?

❑ Immensely ❑ A lot ❑ A little ❑ Not much ❑ I hate it

Q24 How often does pain interfere with your usual activities?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ Always

Q25 How often do you feel pleasure?

❑ Always ❑ Usually ❑ Sometimes ❑ Almost never ❑ Never

Q26 How much of a burden do you feel you are to other people?

❑ Not at all ❑ A little ❑ A moderate amount ❑ A lot ❑ Totally

Q27 How content are you with your life?

❑ Extremely ❑ Mainly ❑ Moderately ❑ Slightly ❑ Not at all

Q28 How well can you see (using your glasses or contact lenses if they are needed)?

❑ I have excellent sight
❑ I see normally
❑ I have some difficulty seeing things sharply. (e.g. small print, objects in the distance, or watching television)
❑ I have a lot of difficulty seeing sharply.
❑ I only see general shapes.
❑ I am completely blind

Q29 How often do you feel in control of your life?

❑ Always ❑ Mostly ❑ Sometimes ❑ Only occasionally ❑ Never

Q30 How much help do you need with jobs around your place of residence (e.g. preparing food, cleaning

❑ I can do all these tasks very easily without any help
❑ I can do these tasks relatively easily without help
❑ I can do these tasks only very slowly without help
❑ I cannot do most of these tasks unless I have help
❑ I can do none of these tasks by myself

Q31 How often do you feel socially isolated?

❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ Always

Q32 How well can you hear (using your hearing aid if needed)?

❑ I have excellent hearing
❑ I hear normally
❑ I have some difficulty hearing or I do not hear clearly (e.g. when there is background noise)
❑ I have difficulty hearing things clearly. Often I do not understand what is said. I usually do not take part in conversations because I cannot hear what is said.
❑ I hear very little
❑ I am completely deaf.

Q33 How often do you feel depressed?

❑ Never ❑ Almost never ❑ Sometimes ❑ Often ❑ Very often ❑ All the time

Q34 How happy are you with your close and intimate relationships?

❑ Very happy
❑ Generally happy
❑ Neither happy nor unhappy
❑ Generally unhappy
❑ Very unhappy

Q35 How often did you feel in despair in the last seven days?

❑ Never ❑ Occasionally ❑ Sometimes ❑ Often ❑ All the time

SECTION 7: SLEEP QUALITY

We would like to know about the quality of your sleep. Please answer the following questions.

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night? _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? _____

3. During the past month, what time have you usually gotten up in the morning? _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) _____

5.	During the past month, how often have you had trouble sleeping because you…..	Not during the past month	Less than once a week	Once or twice a week	Three or more time a week
a.	Cannot get to sleep within 30 minutes				
b.	Wake up in the middle of the night or early morning				
c.	Have to get up to use the bathroom				
d.	Cannot breathe comfortably				
e.	Cough or snore loudly				
f.	Feel too cold				
g.	Feel too hot				
h.	Have bad dreams				
i.	Have pain				
j.	Other reasons(s): please describe:				
6.	During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?				
7.	During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				

		No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8.	During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				

		Very good	Fairly good	Fairly bad	Very bad
9.	During the past month, how would you rate your sleep quality overall?				

		No bed partner or room mate	Partner/room mate in other room	Partner in same room but not same bed	Partner in same bed
10.	Do you have a bed partner or room mate?				

	If you have a room mate or bed partner, ask him/her how often in the past month you have had:	Not during the past month	Less than once a week	Once or twice a week	Three or more time a week
a.	Loud snoring				
b.	Long pauses between breaths while asleep				
c.	Legs twitching or jerking while you sleep				
d.	Episodes of disorientation or confusion during sleep				
e.	Other restlessness while you sleep, please describe:				

SECTION 8: BELIEFS ABOUT BACK PAIN

Back Beliefs Questionnaire

We are trying to find out what people think about low back trouble. Please indicate your general views towards back trouble, even if you have never had any.

Please answer ALL statements and indicate whether you agree or disagree with each statement by circling the appropriate number of the scale.

1 Completely disagree — 2 — 3 — 4 — 5 Completely agree

Question		Completely disagree				Completely agree
Q1	There is no real treatment for back trouble	1	2	3	4	5
Q2	Back trouble will eventually stop you from working	1	2	3	4	5
Q3	Back trouble means periods of pain for the rest of one's life	1	2	3	4	5
Q4	Doctors cannot do anything for back trouble	1	2	3	4	5
Q5	A bad back should be exercised	1	2	3	4	5
Q6	Back trouble makes everything in life worse	1	2	3	4	5
Q7	Surgery is the most effective way to treat back trouble	1	2	3	4	5
Q8	Back trouble may mean you end up in a wheelchair	1	2	3	4	5
Q9	Alternative treatments are the answer to back trouble	1	2	3	4	5
Q10	Back trouble means long periods of time off work	1	2	3	4	5
Q11	Medication is the only way of relieving back pain	1	2	3	4	5
Q12	Once you have had back trouble there is always a weakness	1	2	3	4	5
Q13	Back trouble must be rested	1	2	3	4	5
Q14	Later in life back trouble gets progressively worse	1	2	3	4	5

SECTION 9: ATTITUDES TOWARDS PAIN MEDICATIONS

We would like to better understand people with low back pain's attitudes towards pain medications. Please answer the following questions.

Pain Medication Attitudes and Questionnaire (PMAQ-14) Short Form

The following statements refer to how you feel about pain medications/painkillers.
Please circle the number corresponding to how much you agree with each statement.

		Never true	Almost never true	Seldom true	Often true	Almost always true	Always true
Q1	I am concerned that taking medication for a long time will lead to addiction	0	1	2	3	4	5
Q2	I worry that my pain medication/s will stop working	0	1	2	3	4	5
Q3	I am afraid that stopping my pain medication/s will cause me to feel ill	0	1	2	3	4	5
Q4	I fear that I am becoming an addict	0	1	2	3	4	5
Q5	I would be unwilling to reduce my pain medication/s	0	1	2	3	4	5
Q6	I fear that I will eventually run out of pain medication/s that will help with the pain	0	1	2	3	4	5
Q7	I worry that withdrawal from my pain medication/s will cause me some harm	0	1	2	3	4	5
Q8	I find it hard to put up with the side effects from my pain medication/s	0	1	2	3	4	5
Q9	Needing to take medication for my pain embarrasses me	0	1	2	3	4	5
Q10	I worry what others think about my use of pain medication/s	0	1	2	3	4	5
Q11	I worry about damage to my internal organs from my pain medication/s	0	1	2	3	4	5
Q12	I feel confident about my doctor's management of my pain medication/s	0	1	2	3	4	5
Q13	I depend on my pain medication/s	0	1	2	3	4	5
Q14	I feel satisfied with information with doctor gives me about medication/s	0	1	2	3	4	5

This is the end of the questionnaire, thank you for participating.

FORTNIGHTLY FOLLOW-UP QUESTIONNAIRE

1. Have you experienced low back pain in the last 2 weeks (fortnight)?

❑ No → skips to Q2

❑ Yes

PAIN INTENSITY *(observation: this question will only appear if yes is selected for Q1)*

1a. Over the last 2 weeks (fortnight), what was the average intensity of your low back pain on a scale of 0 (no pain) to 10 (the worst pain imaginable)?

0	1	2	3	4	5	6	7	8	9	10
No pain					Moderate Pain					Worst possible pain

PAIN FREQUENCY *(observation: this question will only appear if yes is selected for Q1)*

1b. Over the last 2 weeks (fortnight), how many days did you experience low back pain?_____

USE OF CARE OF TREATMENTS FOR LOW BACK PAIN

Hospital, Medical and Health Services for Low Back Pain

2. Over the last 2 weeks (fortnight), did you seek care from any medical or health services for your low back pain?

❑ I did not seek care from any health professionals or health services → *skip to Q3*	
❑ Surgery	**i**. What type of surgery? ❑ Microdiscectomy ❑ Discectomy ❑ Laminectomy ❑ Decompression ❑ Fusion ❑ Unsure ❑ Other, please specify **ii**. What type of hospital did you receive treatment? ❑ Private Hospital ❑ Public Hospital **iii**. How much did this surgery cost (out of pocket) in total?
❑ Emergency department visit	**iv**. How many days did you spend at the hospital in total?
❑ Nursing	**v**. Where did you encounter a nurse? ❑ Hospital ❑ GP/medical practice ❑ Other, please specify **vi**. How many visits/sessions? **vii**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Imaging/Scans	**viii**. Please indicate which type(s): ❑ X-ray ❑ Ultrasound ❑ CT scan ❑ Nerve conduction studies ❑ MRI ❑ Other, please specify **iv**. How much did these scans cost (out of pocket) in total over the last 2 weeks?
❑ General practitioner (GP)	**x**. How many visits/sessions? ix. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Pharmacist	**xi**. How many visits to a pharmacist? **xii**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?

❑ Physiotherapist	**xiii**. Where did you visit a physiotherapist? ❑ Public hospital ❑ Private hospital ❑ Private clinic **xiv**. How many visits/sessions? **xv**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Chiropractic	**xvi**. How many visits/sessions? **xvii**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Exercise physiologist	**xviii**. Where did you visit an exercise physiologist? ❑ Public hospital ❑ Private hospital ❑ Private clinic **xix**. How many visits/sessions? **xx**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Massage therapist	**xxi**. How many visits/sessions? **xxii**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Psychiatrist, Psychologist, or Counsellor	**xxiii**. Where did you visit a psychiatrist, psychologist, or counsellor? ❑ Public hospital ❑ Private hospital ❑ Private clinic **xxiv**. How many visits/sessions? **xxv**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Health coaching	**xxvi**. How many visits/sessions? **xxvii**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Natural therapies (e.g. acupuncture)	**xxviii**. How many visits/sessions? **xxvix**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Osteopath	**xxx**. How many visits/sessions? **xxxi**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?
❑ Specialist	**xxxii**. Please indicate which type(s): ❑ Orthopaedic surgeon ❑ Pain physician ❑ Rheumatologist ❑ Neurologist ❑ Other, please specify: *(Observation*: *the following questions will only appear if the participant has selected any of the specialist options.)* **xxxiii**. How many appointments? **xxxiv**. How much did these visits/sessions cost (out of pocket) in total over the last 2 weeks?

❑ Other, please specify: _____	**xxxv.** How many treatment sessions/appointments? **xxix.** In total over the last 2 weeks, how much did these visits/sessions cost you (out of pocket)?

(*Observation*: *this question will only appear if the participant has selected any option except "I did not seek care"*

Traveling Time

2a. In total, how much time in total did you spend travelling to and from all the health professional/services you listed above, in the last 2 weeks (fortnight)? This includes time spent travelling by car, catching public transport or walking etc. _____hours :_____minutes

Prescribed Medications for Low Back Pain

3. Over the last 2 weeks (fortnight), did a medical or health practitioner (e.g., GP, pharmacist, specialist) **prescribe** you any medications for your low back pain?
   - ❑ No
   - ❑ Yes

Medication Use for Low Back Pain

4. Over the last 2 weeks (fortnight), did you **use** any pain medications for low back pain in the last 2 weeks (fortnight)?
   - ❑ No → skips to Q5
   - ❑ Yes

4a. Please indicate which pain medications and answer any relevant questions:

	(Observation: *the following questions in this column will only appear if the participant has selected a given medication)*
❑ Paracetamol (e.g., Panadol)	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? Yes / No **ii.** How many days did you take paracetamol for your low back pain within the last 2 weeks (fortnight)? **iii.** On the days you took paracetamol for your low back pain, what was the average number of tablets you took per day? **iv.** What was the dosage (milligrams per tablet)?
❑ NSAIDs (e.g. neurofen, ibuprofen)	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? Yes / No **ii.** How many days did you take NSAIDs tablets for your low back pain within the last 2 weeks (fortnight)? **iii.** On the days you took NSAIDs for your low back pain, what was the average number of NSAID tablets you took per day? **iv.** What was the dosage (milligrams per tablet)?
❑ Opioids (e.g. codeine, oxycodone, morphine, fentanyl, hydrocodone)	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? Yes / No **ii.** How many days did you take opioid tablets for your low back pain within the last 2 weeks (fortnight)? **iii.** On the days you took opioids for your low back pain, what was the average number of opioid tablets you took per day? **iv.** What was the dosage (milligrams per tablet)?

❑ Other, please specify: _____	**i.** Was this medication prescribed to you by a medical or health practitioner (e.g., GP, pharmacist, specialist)? Yes / No **ii.** How was the pain medication used? ❑ Tablet ❑ Patch ❑ Other If tablet: **iii.** How many days did you take this pain medications for this low back pain within the last 2 weeks (fortnight)? **iv.** On the days you took this pain medication for your low back pain, what was the average number of tablets you took per day? **v.** What was the dosage (milligrams per tablet)? If patch: **vi.** What was the dosage (milligrams per patch)? **vii**. How often did you use a patch (1 patch per week)? If other: **viii.** How did you use the medication (e.g., injection, apply to skin)? **ix.** What was the dosage? **x**. How often did you use the medication?

Other Self-Management Techniques

5. Excluding pain medications, did you use any other self-management behaviours **specifically to manage your low back pain** in the last 2 weeks (fortnight)?

- ❑ No → *end of questionnaire*
- ❑ Massage (i.e., not from a professional)
- ❑ Heat packs or hot shower
- ❑ Brace or support strapping/tape
- ❑ Topical creams/gels (e.g., Voltaren)
- ❑ Physical activity and exercise
- ❑ Relaxation, meditation, or mindfulness techniques
- ❑ Walking aids (e.g., crutches, walking stick)
- ❑ Other, please specify _____

Observation: *the following questions will only appear if the participant has selected any of the options except "no"*

5a. Did you purchase any of the items that you selected in the previous question within the last 2 weeks (fortnight)?

- ❑ No, or not relevant → *end of questionnaire*
- ❑ Yes

5b. Please list which items _____

5c. How much did the item(s) cost you in total?_____

5d. How much time did you spend travelling to and from the store to purchase these items?

(HH:MM) _____hours :_____minutes

Thank you for completing the questionnaire.

You will receive the next questionnaire in approximately 2 weeks.

Participant Information Sheet and Consent Form

Health/Social Science Research

Title	The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability
Short Title	Get Back to Healthy project
Protocol Number	5
Project Sponsor	University of Sydney
Coordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson
Location	Westmead Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research study.

This Participant Information Sheet/Consent Form tells you information about the research project. It explains what taking part in the study involves. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent (given permission) to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research is to test whether a '***back pain support system***' can help people with low back pain maintain improvements in their symptoms and physical activity levels after finishing a course of physiotherapy treatment at Westmead Hospital. The study will also measure whether the ***back pain support system*** changes people's use of hospital, medical and health services for low back pain. The back pain support system will involve a health coaching program delivered over the phone. The program is run by the Get Healthy Service®, which is part of NSW Health. The program will involve having a personal health coach to help support you to achieve healthy lifestyle goals that are important to you. The back pain support system will be compared to the usual care people finishing physiotherapy treatment receive, which may include advice, education and exercises, to see if it better helps and supports you to manage your back pain after finishing physiotherapy treatment at the hospital.

This research has been initiated by the researcher Professor Paulo Ferreira from the University of Sydney. The results of this research will be used by Ms Emma Ho to obtain a Doctor of Philosophy (Health Sciences) degree.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You have been invited because you have low back pain for more than 3 months, you are older than 18 years of age, and you have recently finished (or are close to finishing) physiotherapy treatment for your low back pain at the Outpatient Physiotherapy Department of Westmead Hospital. After reading this information sheet, speak with your physiotherapist or contact the research team if you are interested in the study or have any questions. The study will take one year to complete.

<u>Participation in the research will involve the following:</u>

When you are close to finishing your hospital physiotherapy program, your physiotherapist will introduce the study to you. If you are interested, your physiotherapist will ask for your permission to give your contact details (phone number) to the research team.

The research team will call you to give you more information about the study. You will be given the study information package to read and discuss with your family, friends and GP (if you wish). After approximately one week, the research team will call you again to confirm if you are still interested in the study. You do not have to take part in the study. If you do not wish to participate, your care at the hospital will not be affected.

If you are interested in taking part in the study, the research team will organise a time to discuss the study Participant Information Sheet with you. They will answer any questions you have about the study. If you agree to participate, you will be asked to sign the study consent form. You can choose to sign the consent form online (via an online link) or in person at the hospital. If you choose to sign the consent form online, a research team member will speak with you via phone call or videoconference to give you support. The study consent form must be signed **before** any further study procedures occur. After signing the consent form, you will be immediately assigned a **unique participant study code**. This participant code will be used on all study documents to protect your privacy.

The Participant Information Sheet will clearly explain how and when your contact information will be used. On the consent form, you will be asked to indicate **your preferred method(s)** for the research team to contact you (i.e. phone call, SMS, email, mailing address). You will be asked to provide these contact details on the consent form. Your contact information will be stored in a secure, password-protected server hosted by the University of Sydney. Only the research team will have access to your contact information. A copy of the main study consent form is attached at the end of the Participant Information Sheet.

If you decide to take part in the research project, you will be asked to complete a questionnaire asking about your low back pain and medical history. The questionnaire will assess if you are eligible to take part in the study. Completing the questionnaire will take approximately 5-8 minutes. If the screening questionnaire shows that you meet the requirements, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, the research coordinator will discuss other options with you.

For safety reasons, the research team *may* request you seek approval from your local doctor (GP) before joining the study. If so, you will be given a form for your local doctor to sign. You will need to return the signed form to the research team **before** any further study procedures occur.

Once the research team confirms you are both suitable and safe to join the study, you will be ***enrolled*** into the study.

The research team will request additional permission to access your Medicare (MBS) and Medicine (PBS) data. Medicare collects information on your doctor visits and associated costs. PBS collects information on the prescription medications you purchase at pharmacies. This data will provide valuable information about your use of hospital, medical and health services, and medications. You will receive a **separate** MBS/PBS Information Sheet and Consent Form that explains this information in detail. If you agree, you will be asked to sign a separate MBS/PBS consent form (hard-copy version). You can choose to sign the form in person at the hospital, or you can request for the research team to post the form to your mailing address.

Once you are enrolled in the study, you will be invited to complete an assessment with a member of the research team. You can choose to complete this initial assessment in person at the hospital or online (with phone or videoconference support from the research team).

There are three parts involved in the initial assessment:
1. Completing an electronic questionnaire: You will be asked to complete a **questionnaire** about your height and weight, education levels, medical history, low back pain symptoms, use of treatments, sleep, attitudes towards pain medications and beliefs about back pain. It will take approximately 35 minutes to complete. If you prefer to complete the initial assessment online, you will be emailed a link to the questionnaire.

2. Wearing a physical activity device: You will be asked to wear a **physical activity device**, similar to a Fitbit. The device records information about how active you are (e.g. number of steps). The device will be attached to your right leg using 3 pieces of tape. You will need to wear the device for 7 days in a row. You can continue most of your normal activities during this time.

You will also be given a paper **logbook** to record any physical activity or exercise you complete whilst wearing the device. You will receive reminders (via your preferred contact method) to return the device and logbook back to the research team at the end of 7 days. We will give you a pre-paid envelope to return these items to the research team.

If you complete the initial assessment in person at the hospital, the research team will help you to attach the device to your leg. If you compete initial assessment online, the device and paper logbook will be posted to your mailing address. You will receive instructions on how to attach the device to your leg by yourself or with help from a family/friend. The research team will be available via phone call or video conference to help you if needed.

3. Completing a weekly diary: The research team will also give you a paper **weekly diary** to record any discomfort or incidents that may occur during the study. The research team will explain how to use this diary. The diary will track your safety every week during the first 6 months of the study. You will receive reminders to complete the diary (via your preferred contact method). After 6 months, you will need to return the diary to the research team.

After completing the initial assessment, each participant will be put into a study group by chance (random). There are **two *possible*** study groups involved in this study**.** The groups are either the: (1) Usual Care Control Group or (2) Back Pain Support System Group. The research team will use a computer software program to **randomly select** which study group you will join.

You have a **50% chance** of being put in either of the following two groups:
Usual Care Control Group (Study Group 1):

- If you are randomly put in the usual care group, this means that you will be asked to continue with the **usual care program** that is recommended by your physiotherapist.
- This may include a program of advice, education and exercises to complete at home or in your local community.
- You ***will not*** be asked to participate in the health coaching sessions. However, you will be offered the opportunity to participate in the Get Healthy Service® ***after*** completing your 12-month follow-up assessment.

Back Pain Support System Group (Study Group 2):

- If you are randomly put in the back pain support system group, this means you will be asked to continue with the **usual care program** that is recommended by your physiotherapist. In addition, you will be asked to take part in a **health coaching program.**
- The **health coaching program** will be delivered by the Get Healthy Service®. The research team will need to provide your personal details (name, date of birth, phone number) to the service so they can deliver the health coaching sessions. If you give permission, the research team will also provide the Get Healthy Service® with your email address and postal address. The Get Healthy Service® is funded by the NSW Ministry of Health and will store your personal information securely and confidentially. If you needed additional medical clearance before joining the study, the Get Healthy Service® may ask for a copy of your medical referral form. If so, the research team will send a copy of your form via a secure program used by the NSW Ministry of Health.
- You will receive up to 10 health coaching sessions over 6 months. All sessions will be delivered **over the phone** by a trained health coach. You can decide how often and how many sessions you will take part in.
- In the first session, the health coach will help you set goals to increase your physical activity levels, as well as any other health-related goals if you wish to work on (e.g. improve diet, lose weight, reduce alcohol consumption).
- Your health coach will support you and monitor your progress during the program.
- After completing the program, you have the additional option to enrol into further health coaching sessions or join a free SMS program for another 6 months (called the *Get Healthy Stay Healthy* SMS program). This program will send you automatic SMS messages with tips to stay on track with your goals. If you choose this option, your health coach may contact you periodically to check on your progress.

All participants in both study groups will be asked to take part in the follow-up data collection. Follow-up data collection will continue for **one year** from the start of the study.
It will involve:
1. Completing a fortnightly questionnaire: Every fortnight (2 weeks), you will receive a link to a **brief online questionnaire**. We will send you the link via SMS or email, depending on your preferred contact method. The questionnaire will ask if you experienced low back pain in the past fortnight. You may be asked extra questions related to the pain intensity and whether you used any care or treatment for the pain. It will take roughly 1 minute to complete the questions (maximum 5 minutes). Occasionally, you may receive reminders to complete the questionnaires.

2. Additional assessments at 6 and 12 months:

(1) **An online questionnaire**: At 6 months and 12 months after joining the study, you will be asked to complete an online questionnaire. The questionnaire will be similar to the initial assessment questionnaire, but with less questions. You will receive a link to the online questionnaire (via SMS or email). It will take roughly 25 minutes to complete.

(2) At 6 months after joining the study (not at 12 months), you will also be asked to wear the **physical activity device** and complete the **logbook** again for 7 days. A package containing the device and logbook will be posted to your mailing address. Before sending the package, the research team will contact you (via your preferred contact method) to confirm you are available to receive it (e.g. not away on holidays).

At 3, 6, and 9 months into the study, the research team will also briefly contact you, via your preferred contact method. The research team member will ask if you have any concerns about being in the study. At the end of the study (12 months), you *may* also be asked to take part in an **interview** (approximately one hour). You may be asked questions about your experiences during the study.

4 Other relevant information about the research project

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way. The research project has been designed to prevent study staff or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. If we ask you to take part in the health coaching program, it will be provided to you free of charge.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you decide to take part, you will be given this '**Participant Information and Consent Form'** to sign. You will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Westmead Hospital.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. You can continue with the usual care provided by your physiotherapist, without participating in the study. If you do not wish to take part in the study, your physiotherapist or the research team can discuss other options with you.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include increased support for physical activity participation and reduced pain and disability.

8 What are the possible risks and disadvantages of taking part?

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may just stop the questions. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

There is a small risk of some muscle soreness from participating in the study. If you do experience any muscle soreness during the study, it will most likely be from taking part in new types of activities or exercising more than usual. We expect that any soreness would settle quickly after a few days.

Please take care when doing exercise. If a serious incident occurs, please complete your weekly diary immediately and contact the research team as soon as possible. Please call 000 if it is an emergency.

9 Can I have other treatments during this research period?

Whilst taking part in the study, you will still be able to take all medications or treatments you have been taking for your low back pain or for other reasons.

10 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

11 Could this research project be stopped unexpectedly?

This research project has no reasons to be stopped unexpectedly.

12 What happens when the research project ends?

At the end of the study, the research team will send you a summary of the study findings if you wish. You will be asked to indicate this on the consent form and provide your email address if so.

For participants in the usual care group only: After completing the 12-month assessment, participants in the usual care control group will be contacted by the research team via phone call. The research team will confirm whether you have enrolled into any of the Get Healthy Service® programs and will offer you the opportunity to join any of the Get Healthy Service® health coaching programs if you wish.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you give permission for the research team to collect and use personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and stored securely. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Your personal contact details for the study which will be collected from you via the consent form (e.g. your phone number, email address and mailing address) will only be used for study procedures, such as sending you study documents, equipment and reminders. Any data collected from you that may identify you will be stored on a secure, confidential, password-protected online data collection software called REDCap (hosted by the University of Sydney). Only approved members of the research team will have access to your personal contact details.

To protect your privacy, you will be given a unique participant code so that your name and details are not used on study documents. The research team will collect information about your medical history, symptoms and treatments, and general health (e.g. sleep quality) from questionnaires, diaries and an activity device. Your data will be stored on a secure, password-protected REDCap data collection program. Your data will be stored separate to any personal information about you. No-one can identify you from your data, except for members of the research team who have special approved access.

Only approved members of the research team, the Human Research Ethics Committee (HREC) for monitoring purposes, persons monitoring the conduct of the study on behalf of the Project Sponsor

(i.e. chief principal investigator, principal investigator, clinical trial coordinator, research staff), or regulatory bodies (including the Therapeutic Goods Administration) will have access to your details.

Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. This may include linking to your hospital and Medicare and Prescribed Medicines (MBS/PBS) data. By signing the study consent form and separate MBS/PBS consent form, you give permission for the research team to access your health records and MBS/PBS data, if they are relevant to your participation in this research project.

Your health records and any information collected about you that is relevant to the research project may be reviewed for verifying study procedures and data. This review may be done by the relevant authorities and authorised representatives of the Sponsor (University of Sydney), the institution relevant to this Participant Information Sheet (Western Sydney Local Health District (WSLHD) HREC) or as required by law. By signing both the study and MBS/PBS consent forms, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is expected that the results of this research project will be published and/or presented in a variety of forums and peer reviewed journals. The results may also be used in a PhD thesis at the University of Sydney. You will not be able to be identified in any publications and/or presentations, except with your permission. Your data may be used for extended (related) research projects. Separately, your MBS/PBS data will be stored on a secure, confidential, password protected network server hosted by the University of Sydney. Once the research team links your study data to your MBS/PBS data, the research team will remove any identifying information (e.g. personal details) from your MBS/PBS data. Your MBS/PBS data will not be used in any future or unspecified research outside of the approved study.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

After removing any identifying information from the data, the research team will keep your study data archived on the secure University of Sydney's server for 5 years. This is consistent with clinical trial recommendations outlined in section 2.1.1 of the National Health and Medical Research Council's "Australian Code for the Responsible Conduct of Research". Your MBS/PBS will undergo a different process. According to the requirements of Services Australia, your MBS/PBS data will be destroyed 5 years after results of the project are published.

14 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible and you will be assisted with arranging appropriate medical treatment. In the event of loss or injury, there will be no special compensation agreements. In the event of loss or injury due to someone's negligence, you may have grounds for legal action but may have to pay for the expenses. If you wish you complain or have concerns about any aspects of how you have been treated during the study, you are advised to contact the WSLHD HREC. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

15 Who is organising and funding the research?

This research project is being conducted by the University of Sydney and will be led by Professor Paulo Ferreira. Associated researchers are from WSLHD and The University of Sydney and have experience in conducting research projects. The project also involves a partnership with the Get Healthy Service®, which is funded and managed by the NSW Government (Ministry of Health) and is free of charge to participants. This project is funded by an Allied Health Kickstarter Grant from WSLHD and a Partnership Grant from the National Health and Medical Research Council.

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of WSLHD. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor (Lead Investigator) or any of the following people:

Lead Investigator Contact Details

Name	Professor Paulo Ferreira
Position	Chief investigator
Telephone	<Insert contact number>
Email	paulo.ferreira@sydney.edu.au

Central Research Team Contact Details

Name	Ms Emma Ho
Position	Central research team staff member
Telephone	02 9114 4808
Email	getbacktohealthy.study@sydney.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Westmead Hospital Patient Representative
Position	Westmead Hospital Patient Advice and Liaison Service
Telephone	(02) 8890 7014
Email	wslhd-pals-mail@health.nsw.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you can contact:

Reviewing HREC approving this research

Reviewing HREC	WSLHD Human Research Ethics Committee
Telephone	(02) 8890 9007
Email	Wslhd-researchoffice@health.nsw.gov.au

Local HREC Office contact

Position	Research Governance Manager
Telephone	(02) 8890 9007
Email	wslhd-researchoffice@health.nsw.gov.au

Participant Consent Form

Title	*The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability*
Short Title	Get Back to Healthy project
Protocol Number	5
Project Sponsor	University of Sydney
Co-ordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson
Location	Westmead Hospital

Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

2. I understand the purposes, procedures and risks of the research described in the project.

3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

4. I give permission for my doctors, other health professionals, or hospitals outside this hospital to release information to the University of Sydney concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

5. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

6. I acknowledge that regulatory authorities may have access to my medical records specifically related to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

7. I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

8. I give permission for the research team to use and confidentially store my personal contact information, specifically for the purposes of conducting study procedures.

9. I understand that if I am put in the back pain support group, my personal details (name, date of birth, phone number) and medical referral form (if required) will be sent securely to the Get Healthy Service®, who will store my information confidentially.

10. I understand that I will be given a signed copy of this document to keep.

My best contact details are (please also tick your preferred contact method(s)):

☐ Mobile phone number: _____ (mobile)

☐ Home phone number: _____(home)

☐ Email address: _____

☐ Mailing address: _____

Please indicate: ☐ I wish to receive feedback from my participation at the end of the study;

☐ I wish to receive a summary of the study findings at the end of the study.

Name of Participant (PRINT) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (PRINT) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

Title	*The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability*
Short Title	Get Back to Healthy project
Protocol Number	5
Project Sponsor	University of Sydney
Co-ordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson
Location	Westmead Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project. I understand that:

1. withdrawal will not affect my routine care, or my relationships with the researchers or Westmead Hospital;
2. no further information about me will be collected for the study from the withdrawal date;
3. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the withdrawal of participation must date their own signature.

This form should be forwarded by email to: getbacktohealthy.study@sydney.edu.au

Alternatively, this form can be posted to: Professor Paulo Ferreira, School of Physiotherapy, Level 7, Western Avenue, D18 – Susan Wakil Health Building, The University of Sydney, NSW, 2006.

ACTIVITY DEVICE INSTRUCTIONS

Thank you for participating in the study. At the start, and at 6 months into the study, we would like you to **wear an activity device** (similar to a Fitbit) for **7 days in a row**. The device measures how active you are. During the 7 days, **please also complete a logbook entry every day (page 3).**
If you need help to wear the device, you can ask a family member or friend. The research team can also help you via phone call or video conference.

Please contact the research team if you need help, or have any problems with the device or logbook:
Phone: 02 9114 4808 or Email: **getbacktohealthy.study@sydney.edu.au**

Equipment

You will receive **3 different sizes** of tape (including spares). Each tape is labelled with a number.

- Tape 1: 1cm x 2cm, smallest size, double-sided white colour.
- Tape 2: 3cm x 5cm, medium size, white colour.
- Tape 3: 8cm x 10cm, largest size, clear colour.

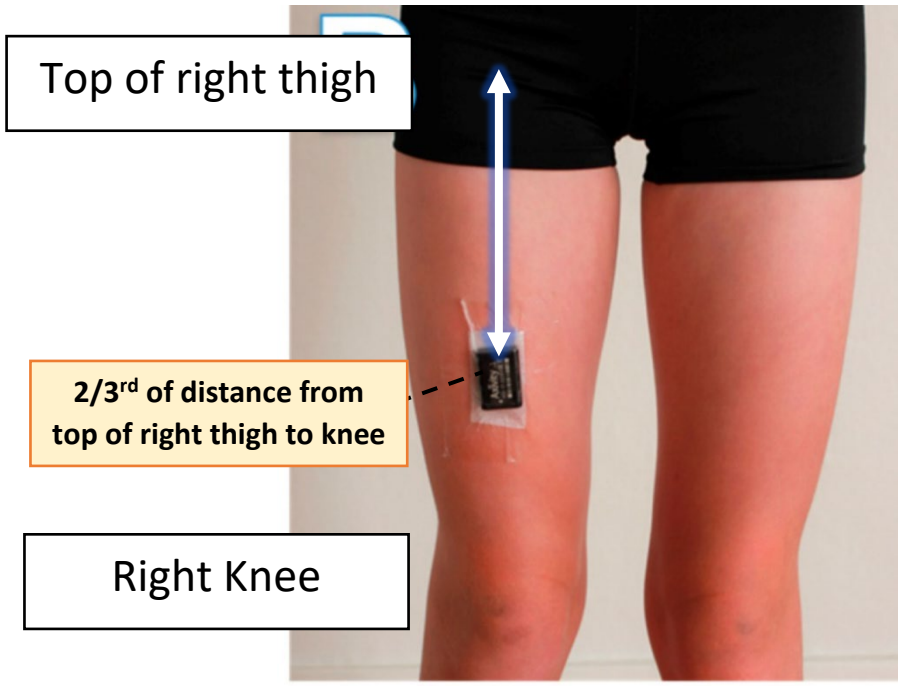
We have also given you an alcohol wipe to clean your skin.

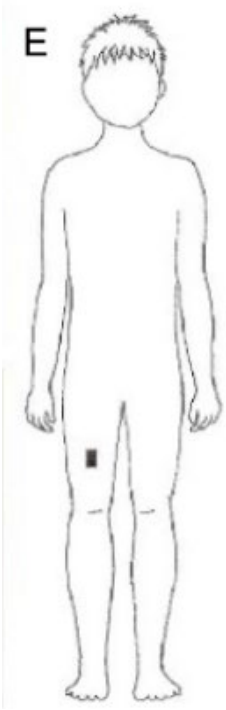
What can (or can't) I do whilst wearing the activity device?

- You can continue your normal daily activities, such as working, exercise (including walking and water sports), and showering, whilst wearing the activity device.
- The activity device is waterproof to 1.5 meters, so you can swim or exercise in the water while having it on your thigh. However, **you cannot dive deeper than 1.5 meters**.
- **Please do not wear it in the ocean** in case if falls off.
- Also, **please take care of the tape** and do not rub it strongly with a towel after taking a shower. If you need to change the tape, please follow the instructions on page 1.

Where will the activity device be attached?

The activity device will be attached to your **RIGHT thigh**. The device should be roughly **2/3rd** of the distance from your right thigh to your knee (e.g. closer to your knee).





How to wear the device

Find where to attach the device:

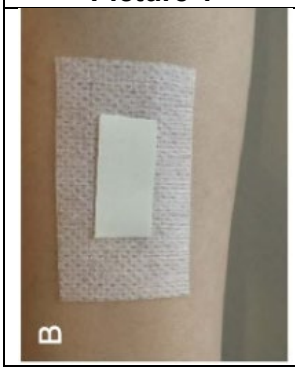
1. Sit down on a chair so that your feet are flat on the ground.
2. Looking at the pictures on page 1, find the top of your right thigh and your right knee.
3. Measure 2/3rd of the distance between your right thigh and knee. This is where the device will be attached onto your skin. It should be slightly closer to your knee.

Prepare your skin:

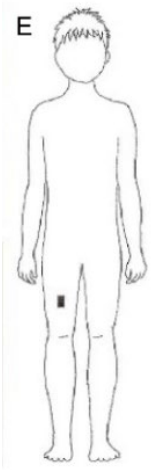
4. Carefully shave the area where the device will be attached if needed.
5. Clean the area with the alcohol wipe. Let the area dry for a few seconds.

Attach the device:

6. Stick **Tape 2** directly onto the shaved area of your thigh (see **big white tape** in Picture 1).
7. Next, stick **Tape 1** on the middle of **Tape 2** (see **smaller white tape** in Picture 1).
8. Next, stick the **device** on top of **Tape 1**. Make sure the white arrow on the device points down towards your knees (see Picture 2).
9. Next, place **Tape 3** so it covers the device completely (see **big clear tape** in Picture 3).
10. Starting from the middle, press **Tape 3** firmly down onto the device.
11. Then, slowly flatten (smooth) the tape against your skin as you move out towards the edges.
12. Try to flatten air bubbles or wrinkles if you can. This helps protect the device from water or dust.
13. Make sure the device is firmly attached to your thigh.

Picture 1	Picture 2	Picture 3
		

The **arrow** on the device should **point DOWN towards your knee**



What if the tape peels off?

- If the tape peels off, please remove it carefully and replace it with the spare tape provided to you. Make sure your skin and the device are clean and dry before attaching the new spare tape.

When and how do I remove the tape and activity device?

- You should remove the tape after wearing the activity device for 7 days. For example, if you started wearing the device on Monday morning, remove it on the following Monday morning.
- To remove the tape, hold down your skin and start by slowly peeling one edge of the tape. Continue to pull the tape gently in the direction towards your knee. Avoid peeling the tape without holding down your skin first, to prevent stretching or injuring your skin.
- For sensitive skin, apply a **small** amount of sensitive lotions or oil on the tape before trying to remove the tape. Throw away the used tape only. **Do not** throw away the activity device.

If you experience skin irritation (e.g. redness, itchiness)

- Skin irritations due to the tape may occur. If this happens, clearly remove the tape and device from your right leg and attach it to your left leg following the instructions on page 1. If you continue to experience irritation, remove the device completely and contact the research team.

Returning the equipment to the research team

- After wearing the device for 7 days, remove the device from your leg (see instructions above). Follow the instructions (and checklist) on **page 4** of this booklet to return the device, logbook and study documents to the research team. You will receive reminders to wear and return the device.

Participant ID: _____ Time (please circle)**: Baseline / 6 months**

DAILY LOGBOOK

STEP 1: Please write the date, day and time that you put the activity device onto your right leg:

DATE: _____/_____/____ **DAY:** _____ **TIME** (HH:MM)**:** _____

STEP 2: Every day, please write the date, time you woke up, any physical activities you completed (e.g. walking, exercise), and time you went to bed/sleep.

Day 1 Date:	• Wake up time (HH:MM) *(e.g. 08:00, or 8:00am)* • Physical activity/exercise: *(e.g. walking 30 minutes, exercise program 30 minutes)* • Sleep time (HH:MM) *(e.g. 21:00, or 9:00pm)*
Day 2 Date:	• Wake up time (HH:MM) • Physical activity/exercise: • Sleep time (HH:MM)
Day 3 Date:	• Wake up time (HH:MM) • Physical activity/exercise: • Sleep time (HH:MM)
Day 4 Date:	• Wake up time (HH:MM) • Physical activity/exercise: • Sleep time (HH:MM)
Day 5 Date:	• Wake up time (HH:MM) • Physical activity/exercise: • Sleep time (HH:MM)
Day 6 Date:	• Wake up time (HH:MM) • Physical activity/exercise: • Sleep time (HH:MM)
Day 7 Date:	• Wake up time (HH:MM) • Physical activity/exercise: • Sleep time (HH:MM)

Participant ID: _____

This is your initial / 6-month assessment.

This device was sent by the research team on: ____/ _____/ ____

RETURNING ITEMS TO THE RESEARCH TEAM:

To return the items to the research team:

1. Carefully remove the activity device, following the instructions written on page 2.
2. Carefully remove the logbook sheet (page 3 & 4) from the booklet (i.e. this page).
3. Place the items listed below into the pre-paid reply envelop given to you. The return address has already been written on the envelope.
4. Post the envelope back to the research team at your nearest post office or post box.

CHECKLIST: This is a checklist of the items to return to the research team

Please return the following items:	Please tick the items you have included in this return package:
☐ Activity device	☐
☐ Daily Logbook sheet (page 3 & 4)	☐
☐ Weekly Diary (at **6-month only**)	☐

QUESTIONS?

If you are unsure how to return the equipment to the research team, please contact us:

Central Research Team
Phone: 02 9114 4808
Email: **getbacktohealthy.study@sydney.edu.au**

Weekly Diary

The 'Get Back to Healthy' project

Participant Initials: _____

Participant ID: _____

Date (baseline): ___ /___ /___

Date (6-months): ___ /___ /___

PURPOSE OF THE WEEKLY DIARY

- Completing the weekly diary will help us monitor your safety.
- The diary will record any discomfort or incidents that may occur during the treatment period (6 months from joining the study).
- The research team will send you reminders to complete the diary.
- Please return this diary after 6 months (see page 3).

INSTRUCTIONS: HOW TO COMPLETE AN ENTRY

- Start from Week 1 (page 5). Please complete an entry **every week.**
- Please write the date at the start of each week.
- Tick any boxes which may apply to you (example on page 4). If no boxes apply to you, there is no need for further action.
- Examples of discomfort that often occur from participating in exercise include:
    - Flare-ups of back pain (i.e., increased back pain) that can be self-managed
    - Muscle soreness, swelling, or muscle cramps related to commencement of unaccustomed exercise
    - Trips and/or falls, that have not resulted in an injury.

  These events usually resolve after a few days and are often self-managed without the need for additional medical attention.

If a serious incident occurs:

- **Call 000 if it is an emergency.**
- **Let the research team know** as soon as possible on 02 9114 4808.
- **Record the event** in your diary entry and **email a copy of the entry** to the research team as soon as possible (detailed instructions on page 17-18 of this booklet).

RETURNING THE DIARY

- Please keep this diary safe and do not lose it!
- **After 6-months**, please return the diary to the research team.
- **At 6 months**, we will send a package to you containing a pre-paid reply envelope. Please use the envelope the return this diary.

EXAMPLE ENTRY

Below is an example of how you can complete the diary.

Week 1: (Date: 13/01/2020)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

- ☑ Increased back pain
- ☑ Pain elsewhere
- ☑ Muscle soreness
- ☐ Swelling
- ☐ Muscle cramp
- ☐ Trip/fall
- ☐ Emotional distress
- ☐ Serious event
- ☐ Other symptoms, please specify_____
  _____

Did any of the above last more than 24 hours? ☑ No ☐ Yes

Did you require medical attention? ☑ No ☐ Yes

Note: It can be easy to lose track of the week number. Please write the date at the start of each week to help you keep track (e.g. each Monday).

QUESTIONS

- If you have concerns about your participation in the study, please **contact the central research team** at 02 9114 4808 or getbacktohealthy.study@sydney.edu.au

Diary entries start on the next page.

Weekly Diary

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 1: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Muscle cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 2: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 3: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain	☐ Trip/fall
☐ Pain elsewhere	☐ Emotional distress
☐ Muscle soreness	☐ Serious event
☐ Swelling	☐ Other symptoms, please describe
☐ Muscle cramp	_____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 4: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain	☐ Trip/fall
☐ Pain elsewhere	☐ Emotional distress
☐ Muscle soreness	☐ Serious event
☐ Swelling	☐ Other symptoms, please describe
☐ Cramp	_____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 5: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 6: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 7: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 8: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 9: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain	☐ Trip/fall
☐ Pain elsewhere	☐ Emotional distress
☐ Muscle soreness	☐ Serious event
☐ Swelling	☐ Other symptoms, please describe
☐ Cramp	_____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 10: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain	☐ Trip/fall
☐ Pain elsewhere	☐ Emotional distress
☐ Muscle soreness	☐ Serious event
☐ Swelling	☐ Other symptoms, please describe
☐ Cramp	_____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 11: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 12: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 13: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 14: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 15: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 16: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 17: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes
Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 18: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes
Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 19: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 20: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 21: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 22: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 23: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 24: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

If you ticked **any** of the boxes below, please **email** a copy of this page to **getbacktohealthy.study@sydney.edu.au** (instructions on page 17-18).

Week 25: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Week 26: (Date / /)

Please add a tick (✓) to as many as appropriate:

Did you experience any of the following this week?

☐ Increased back pain ☐ Trip/fall
☐ Pain elsewhere ☐ Emotional distress
☐ Muscle soreness ☐ Serious event
☐ Swelling ☐ Other symptoms, please describe
☐ Cramp _____

Did any of the above last more than 24 hours? ☐ No ☐ Yes

Did you require medical attention? ☐ No ☐ Yes

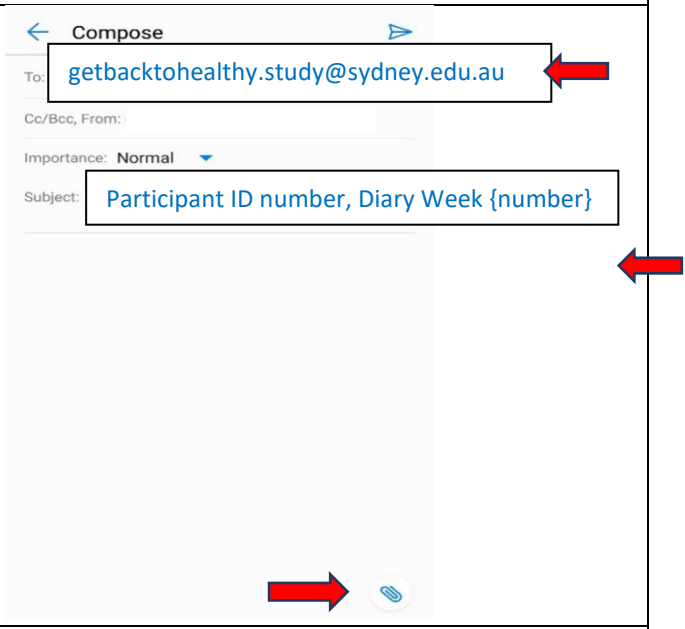
If you feel that taking part in the study has caused these symptoms or you are concerned, please contact the central study team on 02 9114 4808. Call 000 if it is an emergency.

Instructions for sending a diary entry via email:

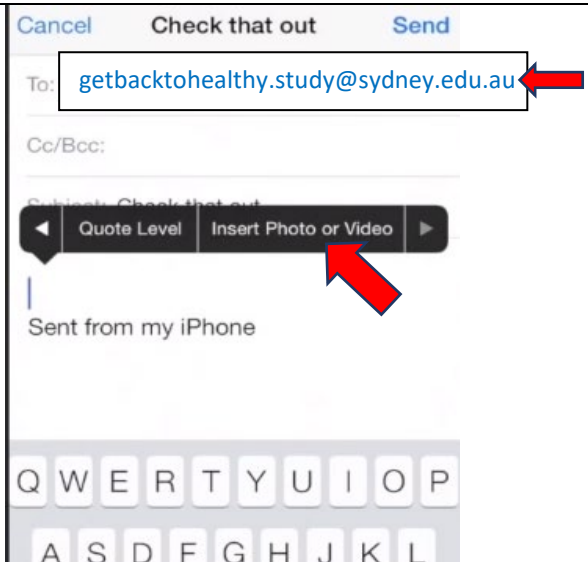
1. If discomfort or an incident has occurred, please complete a detailed diary entry for that week.
2. Write **your participant ID number** at the top of the page (your ID number can be found on the front of this booklet).
3. Open the camera application on your phone/tablet.
4. Take a clear picture of the whole page.
5. On your phone/tablet, open your mail account (Gmail, Outlook, Mail etc.)
6. Click on compose an email (this could be the '**+**' symbol on your screen)
7. '**To'**: **getbacktohealthy.study@sydney.edu.au**
8. '**Subject'**: Write your participant ID number, and the week number of the entry you are sending us. *Example: Participant 001-001, Diary Week 1*
9. If you use Android: Tap on the button attach a file (paper clip symbol).
    a. Click "Attach File".
    b. The" Mail" app will redirect you to your Photos/Files.
    c. Tap the picture of the diary page that you just took.
10. If you use iPhone: Double-tap the text field of the email message.
    a. The stripe with extra options appears. Tap the little triangle on the right of the stripe to invoke extra options.
    b. Tap "Insert Photo or Video".
    c. The" Mail" app will redirect you to your Photos.
    d. Tap the album containing the picture you just took. Then, tap the picture of the diary page that you just took.
11. You will return to your unfinished email. Tap **"Send".**

If you are unsure, please contact the research team if you need any help

Android



iPhone



Thank you for completing the weekly diary!

Clinical Escalation Pathway for Health Coaches

Indicators for Clinical Escalation

Red Flags for LBP requiring clinical escalation:

- Major trauma, minor trauma in elderly or osteo-porotic patient
- Fever, chills, night sweats, unexplained weight loss, immuno-compromised
- Night pain, non-mechanical pain, unremitting pain even at rest
- Severe or progressive sensory alteration or weakness
- Bladder or bowel dysfunction
- History of Cancer
- Intravenous drug use, steroid use

Procedures for Clinical Escalation

If a health coach identifies any red flags requiring clinical escalation during the health coaching sessions, the health coach will follow Get Healthy Service's® Clinical Escalation Policy according to whether urgent emergency response or urgent medical review is required. If emergency response is necessitated, this may involve the health coach completing a warm transfer to 000 (Australian national emergency phone number). If urgent medical review is required, this may involve the health coach contacting the participant's medical practitioner, as appropriate. In addition, the health coach will also prompt the participant to complete their weekly diary and contact the research team as soon as possible. In accordance with standard Get Healthy Service® procedures, the health coach may re-screen participants prior to continuing further health coaching sessions in the event clinical escalation is required. If there are any concerns, the Get Healthy Service® may contact the study team. If a participant is discharged from the Service (i.e., the study intervention), the study team will be notified of the participant's withdrawal from the intervention.

If an adverse event occurs, other than red flag indicators or events warranting emergency response or urgent medical review, the health coach will prompt the participant to complete their weekly diary and contact the research team as soon as possible. The research team will follow-up the adverse event until resolution.

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ELIGIBILITY AND MEDICAL CLEARANCE SCREENING FORM

Participant Study ID: _____

Participant Initials: _____

Date of Screening: _____ /_____ /_____

INFORMED CONSENT

- Study Consent Form version and version date: Version ____ date ____ / ____ / _____
- Date informed consent signed by subject: ____ / ____ / _____
- Has the participant signed the **study consent form** prior to any study procedures being conducted? Yes / No
- Has the participant been provided with a **copy** of the signed consent form for the study? Yes / No
- Name of study staff obtaining consent from subject: _____
- Has the study been thoroughly discussed with the participant and all questions have been answered? Yes / No
- Has the participant agreed to contact the research team in case of an early termination? Yes / No
- Notes/Comments: _____

INCLUSION CRITERIA:

Age older than 18 years old	Yes	No
Presents with a diagnosis of non-specific LBP for at least 12 weeks, with or without leg pain, but without radicular symptoms (e.g. reflex changes, motor loss)	Yes	No
Recently discharged (<4 weeks), or within 2 weeks of potential discharge from chronic low back pain treatment from the Outpatient Physiotherapy Department of a participating hospital site, **OR:**	Yes	No
Discharged from treatment for chronic low back pain by a physiotherapist, chiropractor, or general practitioner within <6 months in either private or public setting.	Yes	No
Adequate hearing and eyesight to participate safely in physical activity	Yes	No
Independent ambulatory status (with or without a gait aid)	Yes	No
Regularly accesses and uses a computer or mobile phone device connected to the internet	Yes	No

EXCLUSION CRITERIA

Presents with any of the following symptoms:			
- Unexplained weight loss associated with the back pain	Yes	No	Unsure
- Fever associated with the back pain or recent infection	Yes	No	Unsure
- History of osteoporosis or corticosteroid use	Yes	No	Unsure
Spinal surgery within the last 12 months	Yes	No	Unsure
Presents with any of the following symptoms:			
- Sharp pain in the back radiating into the foot?	Yes	No	Unsure
- Numbness, tingling or changes in sensation in your back or leg?	Yes	No	Unsure
- Significant weakness in the leg or foot?	Yes	No	Unsure
- Severe pain in *both* legs?	Yes	No	Unsure

- Loss of urinary and bowel control (incontinence)?	Yes	No	Unsure
- Difficulty co-ordinating movement of your legs?	Yes	No	Unsure
- Change or loss in sensation in the saddle region? 	Yes	No	Unsure
Diagnosis of severe spinal stenosis by a medical doctor	Yes	No	Unsure
Experiences pain, numbness and/or fatigue in the leg that is worse in standing or walking and improves during sitting/flexion	Yes	No	Unsure
Low back pain caused by involvement in a road traffic accident in the past 12 months or currently receiving ongoing compensation	Yes	No	Unsure
Diagnosis of fibromyalgia or a systemic/ inflammatory disorder (e.g. rheumatoid arthritis)	Yes	No	Unsure
Received a corticosteroid injection in the spine in the past 4 weeks	Yes	No	Unsure
(Women only): Currently pregnant or plan to fall pregnant over the duration of the study (e.g. the next 12 months)	Yes	No	N/A

ADDITIONAL MEDICAL CLEARANCE SCREENING			
Presence of co-morbid health condition(s) that may require clearance by a medical practitioner prior to participating in exercise or physical activity	Yes	No	Unsure
Presents with any of the following symptoms:			
- Trouble breathing or feel out of breath sitting still, sleeping or walking short distances	Yes	No	Unsure
- Uncontrolled asthma	Yes	No	Unsure
- Unstable or uncontrolled COPD	Yes	No	Unsure
- Unstable hypertension (resting systolic BP>180 or diastolic BP>100)	Yes	No	Unsure
- History of surgery in the past 3 months (for example: cardiac surgery, joint replacement, wound healing)	Yes	No	Unsure
- Unstable angina/chest pain	Yes	No	Unsure
- Decompensated heart failure	Yes	No	Unsure
- Unexplained weight loss (>5% of your body weight) in the last 6 months	Yes	No	Unsure
History of an abnormal ECG or EKG reading, showing signs of an irregular heart rhythm, coronary disease or heart attack, as informed by a medical doctor.	Yes	No	Unsure
History of experiencing unexplained chest pain or discomfort at rest or during physical activity/exercise	Yes	No	Unsure

Following review of the inclusion and exclusion criteria using the current available data, is the patient still eligible for the trial?

❑ **Yes** ❑ **No** ❑ **Requires additional medical clearance before eligible**

If not eligible, screen failure date: _____ / _____ / _____

Research Investigator name (PRINT) _____ signature _____

Date: _____ / _____ / _____

GET BACK TO HEALTHY STUDY

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Medical Clearance Referral Form

INSTRUCTIONS

The research team has identified that you may require approval from your medical doctor to ensure you are safe to participate in the study.

1. Please visit your preferred medical practitioner (e.g. your local GP) and give them this form.
2. Your medical practitioner will need to complete and sign the form. Bring the form home with you.
3. You will need to show the research team the signed form **before** you can join the study.

HOW TO RETURN THE FORM TO THE RESEARCH TEAM

Return the form in person: Please return the completed form to _____

_____

OR

Return the form via email: You can return a copy of the form to the research team via email.

1. Take a clear picture OR scan **PAGE 2** of this booklet using your camera, printer or scanner**.**
2. Open your preferred mail account (Gmail, Outlook etc.) on your computer/phone/tablet.
3. Click on compose an email. This could be the '**+**' symbol on your phone/tablet screen).
4. '**To'**: getbacktohealthy.study@sydney.edu.au
5. '**Subject'**: [Insert your initials], Medical Clearance Form. *Example: AB, Medical Clearance Form*
6. Attach the scan/picture of **page 2** to the email.
    i. If you are using your computer: Click 'Attach File' and select the scanned image.
    ii. If you are using an Android phone:
        1. Tap on the button attach a file (paper clip symbol).
        2. Click "Attach File". The" Mail" app will redirect you to your Photos/Files.
        3. Tap the picture you took of page 2.
    iii. If you are using an iPhone:
        1. Double-tap the text field of the email message. The stripe with extra options appears.
        2. Tap the little triangle on the right of the stripe to see extra options.
        ii. Tap "Insert Photo or Video". The" Mail" app will redirect you to your Photos.
        iii. Tap the album with the photo of page 2. Tap the picture you took of page 2.
7. The screen will return to your unfinished email. Tap "**Send**".

If you need help to return the signed form, please contact the research team at
02 9114 4808 **or** getbacktohealthy.study@sydney.edu.au

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{Insert site/LHD logo}

Dear Medical Practitioner,

Re: *Medical clearance for your patient to participate in the Get Back to Healthy research study.*

Your patient wishes to partake in the *'Get Back to Healthy'* research study conducted by the University of Sydney. The study involves adults with chronic low back pain who recently completed a course of treatment for their low back pain at their physiotherapist, chiropractor, or general practitioner (GP).

Participants will be randomised to either a usual care control group, or a support system group. Participants in the support system group will be asked to take part in a health coaching program run by the Get Healthy Service®. The health coaching program involves participating in exercises or physical activity. More information about the program is included in the attached information sheet.

Your patient has indicated they experience or suffer from the following:

- ❑ Uncontrolled asthma
- ❑ Unstable/uncontrolled COPD
- ❑ Post-surgery under 3 months
- ❑ High blood pressure (resting BP: systolic > 180 or diastolic >100)
- ❑ Unexplained chest pain or discomfort at rest or during physical activity/exercise
- ❑ Unstable angina/chest pain
- ❑ Decompensated heart failure
- ❑ Unexplained weight loss (>5% in 6 months)
- ❑ History of abnormal electrocardiogram reading
- ❑ Have a health condition that may require clearance by a medical practitioner: _____

_____

For your patient's safety to participate in the study, please provide your medical recommendations below.

PHYSICIAN RECOMMENDATIONS: *Please complete all sections below.*

I, the Medical Practitioner, confirm that the patient is fit to participate in the Get Healthy Information and Standard Coaching Service, including taking part in an exercise and physical activity program.

❑ Yes, fit to participate

❑ No, fit to participate, reason _____

_____

PHYSICIAN DETAILS:

Physician specialty _____ Date: _____/_____/_____

Physician name (*print*) _____ Physician signature _____

Practice Name/Address _____ Phone _____

(Please tick if this applies):

❑ I would like to receive email feedback and program updates from the Get Healthy Program about my patient. Please provide your email:_____

Please return this form to your patient

Get Healthy Information & Coaching Service

Information for General Practice and Health Professionals

WHAT IS THE GET HEALTHY SERVICE?

The Get Healthy Information and Coaching Service® (Get Healthy Service) is a FREE telephone service staffed by university qualified health coaches aimed at supporting adults to make lifestyle changes regarding:

- Healthy eating
- Physical activity
- Alcohol reduction
- How to reach and maintain a healthy weight and
- Healthy weight gain during pregnancy

The Service offers participants:

- Their own personal health coach
- 10 free coaching calls (additional calls for Aboriginal participants and for people at risk of Type 2 Diabetes)
- Support to make changes over 6 months
- An information booklet that provides additional information to support participants to achieve their goals
- A coaching journal to record goals and actions

After completing the coaching program, participants are welcome to re-enrol. The Service includes free interpreters for people who do not speak fluent English and services for people who are deaf, hearing impaired or speech impaired.

WHO CAN JOIN THE GET HEALTHY SERVICE?

Anyone over the age of 16 years living in NSW can join the Get Healthy Service.

The Service is targeting individuals at risk of developing chronic disease due to having one or more of the following risk factors:

- not meeting healthy eating guidelines;
- inadequate physical activity; and

IS THE GET HEALTHY SERVICE EFFECTIVE?

Independent evaluation of the Service shows that participants who successfully complete the 6 month program lose 3.8kg and reduce their waist circumference by 5.1cm. Findings show 56% of participants who complete the 6 month coaching program lose between 2.5-10% of their original body weight.

WHY SHOULD I REFER PATIENTS TO THE GET HEALTHY SERVICE?

- GPs and Health Professionals are well placed to reach those in the community who are most at need of the assistance that the Get Healthy Service can offer, both in terms of a client's socio-demographic profile but also their risk factor profile.
- The Get Healthy Service is an effective service that can complement patient care provided by GPs and other Health Professionals.
- Retention of participants is greater when referred by a GP or Health Professional.
- The Get Healthy Service can provide you with participant updates at baseline, mid-point and when a participant graduates (with participant's consent).

HOW DO I REFER PATIENTS TO THE GET HEALTHY SERVICE?

- Referral forms for General Practitioners and Health Professionals can be found at

  www.gethealthynsw.com.au /refer-your-patients

- Download the form, complete for each patient and send to the Get Healthy Service.
- Referral forms can be emailed to

  contact@gethealthynsw.com.au
  or faxed to 1300 013 242.

  Alternatively, you can post referrals to

  Get Healthy Information & Coaching Service
  PO Box 63, North Ryde BC NSW 1670.

- Referral forms are also available on Medical Director and Best Practice software

WHY IS MEDICAL CLEARANCE REQUIRED FOR SOME PARTICIPANTS?

While the Get Healthy Service is suitable for most people, participants who have a medical condition that is not stable or is not being managed by an appropriate Health Professional may be asked to see their doctor to get medical clearance before participating.

ADDITIONAL SUPPORT

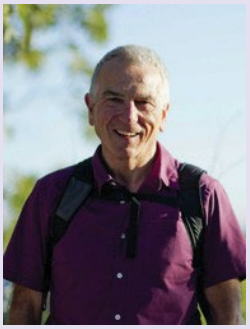
- General Practitioners and Health Professionals can earn points toward their ongoing Health Professional development by participating in a ThinkGP educational activity that supports doctors and Health Professionals to encourage healthy lifestyle changes in their patients.

thinkgp.com.au/education/managing-patients-lifestyle-get-healthy-information-and-coaching

- A range of resources have been developed to assist General Practitioners and Health Professionals promote the Get Healthy Service.

www.gethealthynsw.com.au/professionals-resources

GET HEALTHY SERVICE PARTICIPANT



Name: Ian
Age: 61 years

Prior to the program Ian was eating unhealthy food, sugary drinks and hardly any fruit and vegetables.

Ian set a goal with his coach to be more active and improve his eating habits – *'I have gone from being an overweight guy who didn't exercise, to now considering myself as very fit, very healthy. This has turned my life around!'*

Ian now bushwalks regularly and has competed in his first Oxfam Trail Walk.

After 6 months he had lost 22.6kg and 27cm off his waist.

'I don't see this as a diet that I have been on; I see this as a lifestyle change as I have changed how I go about my life. It is not a diet, it is my life.'

GET HEALTHY SERVICE REFERRER

Name: Denise Barwick

Denise Barwick is currently an Aboriginal Youth Health Worker working at the Aboriginal Corporation Health Service in Wellington NSW and a referrer to the Get Healthy Service.

Denise is aware of many clients that have lost a lot of weight by participating in the Get Healthy Service. She also enjoys trying to help clients maintain the effort and changes they made by participating in Get Healthy.

'The Get Healthy Service gives clients the opportunity to set goals and track their achievements. A lot of the participants have said it's great to have the same coach all the time; the coach isn't changing every time you answer a call.

I find the process of referring is easy – you just fill a form out. Some clients may need a medical clearance – and we arrange for them to visit the doctor to get checked out.

I have clients who are really benefiting from the program and getting good advice. They have given high ratings of the program. I like that there is a mentor coaching clients on the phone and also providing support'.

Get Back to Healthy Study
(University of Sydney)

Handout – Updated March 2022
Mark Halliday and Emma Ho

Overview of Trial
The trial involves a randomised controlled trial comparing a discharge support system group (incorporating the Get Healthy Service®) to a usual care control group.

Study population: (* ≥ 12 weeks duration)
- People recently discharged from hospital outpatient physiotherapy treatment for chronic* low back pain, *OR*
- People discharged <6 months ago from regular weekly treatments for chronic* LBP from a GP, physiotherapist, or chiropractor from private settings.

Inclusion criteria: Diagnosis of non-specific LBP of at least 12-weeks duration, with or without leg pain, but without radicular (e.g., reflex changes, motor loss) symptoms.

Note: If required, the trial team will have obtained a completed medical clearance form *prior* to a participant being referred to the GHS. This form will be emailed to GHS/Remedy.

Interventions:
Usual care: Both groups continue with the usual care provided to them by their treating health care professional before inclusion in the study. This may include advice, exercise, or passive therapies.

Discharge support group: In addition, the discharge support system group is also referred for enrolment into the **Standard Coaching module** with support to achieve **physical activity goals** and any other personal health goals.

Outcomes:
Main outcome: use of health services for LBP (e.g., hospital, medical, health services).

Main secondary outcomes include pain, disability, physical activity levels, quality of life, use of self-management techniques, and medication use.

STUDY TEAM CONTACT

Escalation or queries (Emma Ho – trial co-ordinator)
Contact: 02 9114 4808 | 0434 596 855
Email: GetBacktoHealthy.study@sydney.edu.au

Study Chief Investigator (Prof Paulo Ferreira)
Contact: 02 8627 7062

Role of Remedy/Health coaches
- Intake specialist: During the registration call, please confirm the main goal of the health coaching program (for the purposes of the trial) is to support participants with **physical activity**
- Health Coaches provide *the Standard Coaching Module*, primarily focused on **physical activity goals** and other personal health goals.
- Provide health coaching support tailored for people with chronic low back pain (see below & appendix)
- Provide the referring health care practitioner (on the referral form) with updates on the participant's progress (get-back-to-healthy.referral@sydney.edu.au)
- Escalate if red flags identified
- At the completion of the program, offer participants the option to re-enrol or opt into the *Get Healthy Stay Healthy* SMS program per usual practice.

Red flags for low back pain requiring escalation:
- Major trauma, minor trauma in elderly or osteo-porotic patient
- Fever, chills, night sweats, unexplained weight loss, immuno-compromised
- Night pain, non-mechanical pain, unremitting pain even at rest
- Severe or progressive sensory alteration or weakness of the back or legs
- Recent onset of bladder or bowel dysfunction
- History of cancer
- Intravenous drug use, steroid use

Best current evidence for treating low back pain:
- Avoid bed rest +++
- Remain active +++
- Modify activity - such as sustained repetitive postures and activities (e.g., excessive loads when sitting, bending and twisting)
- Use pacing techniques - Vary with participants physical capacity and goals
- Exercise tailored to the patient's physical capacity, goals and beliefs

Common psychological factors in this population:
- Fear avoidance
- Catastrophizing
- Familial and social stress
- Work pressures
- Financial pressure

Strategies for addressing these factors:
- Build rapport, trust, commonality
- Understand the patients' beliefs about back pain
- De-escalate potential perceived threats
- Involve patient in problem solving & decision-making
- Ask simple and unambiguous questions
- Keep things positive and supportive
- Avoid using threatening/catastrophising terms (e.g., bulging or crumbling discs, degenerated discs) when discussing their pain
- Focus on function, what they can do, and what they are willing to try.

Table 3 Tailored health coaching content for chronic LBP

Tailored health coaching content for chronic LBP
Goal-setting:
• Mutually establish a physical activity goal with the participant at commencement of the health coaching program. Where relevant, this will include ongoing adherence to the exercise program prescribed by their hospital physiotherapist prior to discharge from treatment.
• Establish other health-related goals that are meaningful to the participant (i.e., reducing weight, achieving a healthy diet, reducing alcohol consumption).
Promotion of exercise and physical activity:
• Explore barriers to exercise and physical activity participation (e.g., time, access, financial resources, social comfort).
• Promote participant-led problem-solving skills to encourage overcoming perceived and real barriers to exercise or physical activity participation.
Support:
• Empower patients to foster self-efficacy and take charge of their own health, including monitoring their own symptoms and capacity to adhere to goals.
• Encourage involvement of family members, partners, or friends for social support with achieving goals.
• Provide continual motivation, encouragement, and support for the use of positive self-management strategies (e.g., physical activity, exercise).
Interpersonal skills:
• Build report, trust, and commonality with the participant.
• Directly involve the participant in the problem-solving and decision-making processes.
• *Educate and advise participants that the presence of pain does not always equal to harm.*
Education:
• *Educate and advise participants that many findings on imaging are common and do not necessarily identify the exact cause of pain. Further, imaging should only be carried out when consideration of serious pathology is clinically indicated.*
• Identify and address unhelpful beliefs about their condition or progress.
• *Educate and advise participants on the benefits of exercise and the consequences of inactivity such as prolonged bed rest (*i.e.*, muscle weakness).*
• *Assist participants in navigating decision-making processes surrounding whether additional care from hospital, medical, or health services for LBP is necessary.*
Pacing and activity modification:
• *Encourage participants to maintain engagement in usual activities (*e.g.*, occupational, leisure).*
• *Promote activity modification when required (*i.e.*, regress the difficulty of an exercise or activity, perform alternative exercises or tasks that do not elicit painful symptoms, minimise sustained repetitive postures and activities, minimise excessive loads when sitting, bending, or twisting).*
• Educate and advise participants on incidental opportunities to increase physical activity levels when exercise may not be feasible (e.g., use public transportation, walk to the shops, stand at work, spend less time sitting at home).
• *Encourage activity pacing when required, according to the participant's physical capacity and goals.*
Identifying and addressing psychological factors:
• *Screen and address common psychological factors in chronic LBP populations (*e.g.*, fear avoidance, catastrophising, familial and social stress, work pressures, financial pressures).*
• De-escalate potential perceived threats.
• Ask simple and unambiguous questions.
• *Avoid using catastrophising terms when discussing pain (*e.g.*, bulging disc, crumbling discs, degenerated discs).*
• Use positive, supportive, and empathetic language.
Reframing:
• Focus problem-solving on the participant's functional ability (i.e., improved ability to complete certain tasks or activities), instead of drawing attention to their pain.
• Focus on activities that the participant can perform and what they are willing to try.
• *Encourage participants to continue safe participation in exercise, even in the presence of acute symptoms (*i.e.*, flare-ups of LBP).*
• Focus on activities that the participant has been able to perform successfully and provide ongoing encouragement for future success.

Items in italics indicate content which has been tailored specifically for chronic LBP

(This Table has been extracted from the published trial protocol, and can only be shared within the health coaching team for the purposes of the trial. The published protocol can be viewed here: https://doi.org/10.1186/s12891-021-04479-z)

DO YOU SUFFER FROM LOW BACK PAIN?

Almost finishing treatment
& looking for MORE SUPPORT?

Join a university research study involving a

BACK PAIN SUPPORT PROGRAM

Find out more!

Read the brochure & speak to your physiotherapist for more information

THE UNIVERSITY OF SYDNEY

<insert hospital logo>

NSW GOVERNMENT Health Western Sydney Local Health District

This study has been approved by the Western Sydney Local Health District Human Research Ethics Committee (2020/ETH00115)
MASTER Version 1 dated 08/07/2021

What does health coaching involve?

If you are in back pain support group:

You will receive up to 10 health coaching sessions, delivered over the phone by the Get Healthy Service®.

Your health coach will ***motivate & support you to keep physically active*** and better manage your pain.

They will also help you ***achieve personal health goals.***

All sessions will be delivered **via phone call**, so there's no need to go into the hospital

This research is approved by:

THE UNIVERSITY OF SYDNEY

NSW GOVERNMENT Health Western Sydney Local Health District

I AM INTERESTED! HOW DO I GET INVOLVED?

If you are interested in participating:

- Ask your physiotherapist for the *Get Back to Healthy* information pack

FOR MORE INFORMATION

Contact the Chief Principal Investigator:

Professor Paulo Ferreira
paulo.ferreira@sydney.edu.au
Ph: (02) 8627 7062

Or, contact the Study Team:

Get Back to Healthy Central Study Team
getbacktohealthy.study@sydney.edu.au
Ph: 02 9114 4808

This study has been approved by the Western Sydney Local Health District Human Research Ethics Committee (2020/ETH00115)
MASTER Version 1 dated 08/07/2021

DO YOU HAVE LOW BACK PAIN?

Need MORE SUPPORT to manage your symptoms?

Join a research study!

BACK PAIN SUPPORT PROGRAM
(WITH HEALTH COACHING)

<insert hospital logo>

LOW BACK PAIN

affects 4 million people in Australia

MOST IMPROVE WITH PHYSIOTHERAPY

Most people make **good recovery** from low back pain after physiotherapy treatment.

HOWEVER...

After finishing treatment, some people:

- feel **unsupported**
- **find it hard** to continue their exercises or keep active
- experience **back pain again**
- Seek **more treatment.**

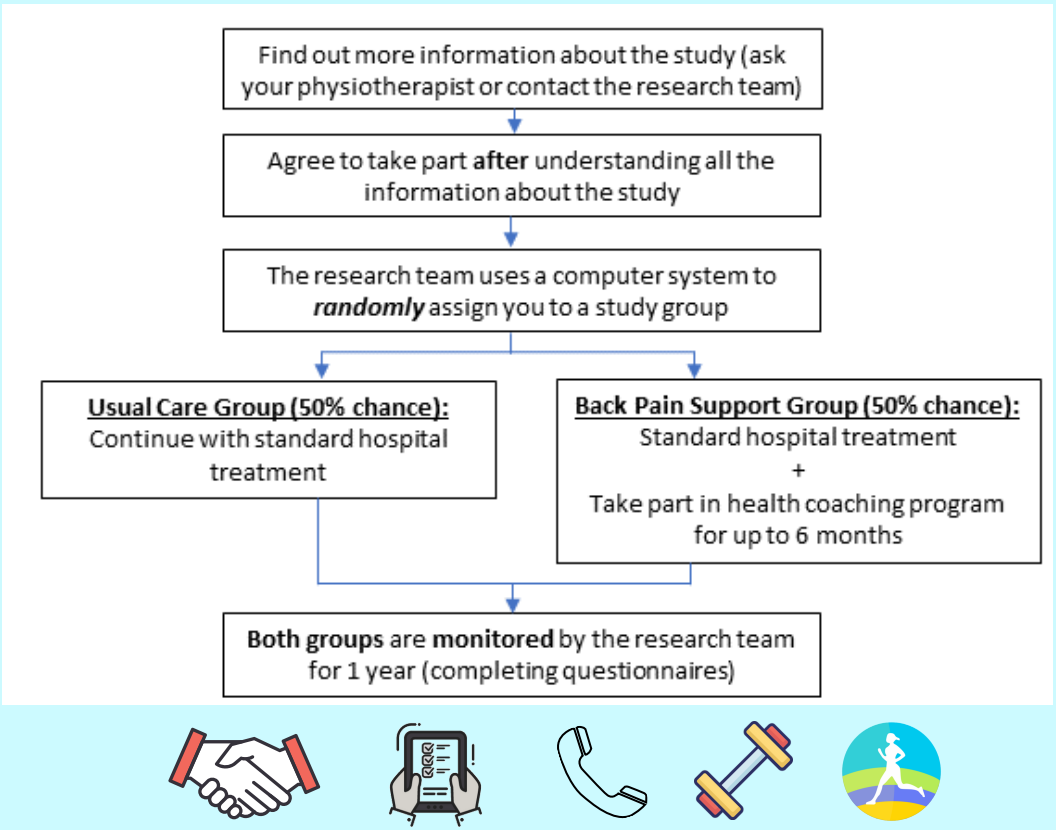
THE SOLUTION?

BACK PAIN SUPPORT PROGRAM (WITH HEALTH COACHING)

We are testing whether a **back pain support program** can help people *maintain improvements* in their **pain, disability and physical activity levels** after finishing hospital physiotherapy treatment.

We also want to measure if the **back pain support program** will change peoples' use of hospital, medical & health services for low back pain.

How does the study work?



This study has been approved by the Western Sydney Local Health District Human Research Ethics Committee (2020/ETH00115) MASTER Version 1 dated 08/07/2021

Appendix 5: Supplementary Material for Chapter Seven

Supplementary material

Master participant information sheet and consent form

General community participant information sheet and consent form

General community pre-screening questionnaire

Study advertising materials (general community)

THE UNIVERSITY OF SYDNEY

{Insert LHD logo}

Participant Information Sheet and Consent Form

Health/Social Science Research

Title	The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability
Short Title	Get Back to Healthy study
Coordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson, Ms Katharine Roberts.
Location	{Insert Hospital}

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research study.

This Participant Information Sheet/Consent Form tells you information about the research project. It explains what taking part in the study involves. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent (given permission) to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research is to test whether a '***back pain support system***' can help people with low back pain maintain improvements in their symptoms and physical activity levels after finishing a course of physiotherapy treatment at {Insert Hospital}. The study will also measure whether the ***back pain support system*** changes people's use of hospital, medical and health services for low back pain. The back pain support system will involve a health coaching program delivered over the phone. The program is run by the Get Healthy Service®, which is part of NSW Health. The program will involve having a personal health coach to help support you to achieve healthy lifestyle goals that are important to you. The back pain support system will be compared to the usual care people finishing physiotherapy treatment receive, which may include advice, education and exercises, to see if it better helps and supports you to manage your back pain after finishing physiotherapy treatment at the hospital.

This research has been initiated by the researcher Professor Paulo Ferreira from the University of Sydney. The results of this research will be used by Ms Emma Ho and Ms Katharine Roberts to obtain a Doctor of Philosophy (Health Sciences) degree.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You have been invited because you have low back pain for more than 3 months, you are older than 18 years of age, and you have recently finished (or are close to finishing) physiotherapy treatment for your low back pain at the Outpatient Physiotherapy Department of {Insert Hospital}. After reading this information sheet, speak with your physiotherapist or contact the research team if you are interested in the study or have any questions. The study will take one year to complete.

<u>Participation in the research will involve the following:</u>

When you are close to finishing your hospital physiotherapy program, your physiotherapist will introduce the study to you. If you are interested, your physiotherapist will ask for your permission to give your contact details (phone number) to the research team.

The research team will call you to give you more information about the study. You will be given the study information package to read and discuss with your family, friends and GP (if you wish). After approximately one week, the research team will call you again to confirm if you are still interested in the study. You do not have to take part in the study. If you do not wish to participate, your care at the hospital will not be affected.

If you are interested in taking part in the study, the research team will organise a time to discuss the study Participant Information Sheet with you. They will answer any questions you have about the study. If you agree to participate, you will be asked to sign the study consent form. You can choose to sign the consent form online (via an online link) or in person at the hospital. If you choose to sign the consent form online, a research team member will speak with you via phone call or videoconference to give you support. The study consent form must be signed **before** any further study procedures occur. After signing the consent form, you will be immediately assigned a **unique participant study code**. This participant code will be used on all study documents to protect your privacy.

The Participant Information Sheet will clearly explain how and when your contact information will be used. On the consent form, you will be asked to indicate **your preferred method(s)** for the research team to contact you (i.e. phone call, SMS, email, mailing address). You will be asked to provide these contact details on the consent form. Your contact information will be stored in a secure, password-protected server hosted by the University of Sydney. Only the research team will have access to your contact information. A copy of the main study consent form is attached at the end of the Participant Information Sheet.

If you decide to take part in the research project, you will be asked to complete a questionnaire asking about your low back pain and medical history. The questionnaire will assess if you are eligible to take part in the study. Completing the questionnaire will take approximately 5-8 minutes. If the screening questionnaire shows that you meet the requirements, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, the research coordinator will discuss other options with you.

For safety reasons, the research team *may* request you seek approval from your local doctor (GP) before joining the study. If so, you will be given a form for your local doctor to sign. You will need to return the signed form to the research team **before** any further study procedures occur.

Once the research team confirms you are both suitable and safe to join the study, you will be ***enrolled*** into the study.

The research team will request additional permission to access your Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data. Medicare collects information on your doctor visits and associated costs. PBS collects information on the prescription medications you purchase at pharmacies. This data will provide valuable information about your use of hospital, medical and health services, and medications. You will receive a **separate** MBS/PBS Information Sheet and Consent Form that explains this information in detail. If you agree, you will be asked to sign a separate MBS/PBS consent form (hard-copy version). You can choose to sign the form in person at the hospital, or you can request for the research team to post the form to your mailing address.

Once you are enrolled in the study, you will be invited to complete an assessment with a member of the research team. You can choose to complete this initial assessment in person at the hospital or online (with phone or videoconference support from the research team).

There are three parts involved in the initial assessment:
1. Completing an electronic questionnaire: You will be asked to complete a **questionnaire** about your height and weight, education levels, medical history, low back pain symptoms, use of treatments, sleep, attitudes towards pain medications and beliefs about back pain. It will take approximately 35 minutes to complete. If you prefer to complete the initial assessment online, you will be emailed a link to the questionnaire.

2. Wearing a physical activity device: You will be asked to wear a **physical activity device**, similar to a Fitbit. The device records information about how active you are (e.g. number of steps). The device will be attached to your right leg using 3 pieces of tape. You will need to wear the device for 7 days in a row. You can continue most of your normal activities during this time.

You will also be given a paper **logbook** to record any physical activity or exercise you complete whilst wearing the device. You will receive reminders (via your preferred contact method) to return the device and logbook back to the research team at the end of 7 days. We will give you a pre-paid envelope to return these items to the research team.

If you complete the initial assessment in person at the hospital, the research team will help you to attach the device to your leg. If you compete initial assessment online, the device and paper logbook will be posted to your mailing address. You will receive instructions on how to attach the device to your leg by yourself or with help from a family/friend. The research team will be available via phone call or video conference to help you if needed.

3. Completing a weekly diary: The research team will also give you a paper **weekly diary** to record any discomfort or incidents that may occur during the study. The research team will explain how to use this diary. The diary will track your safety every week during the first 6 months of the study. You will receive reminders to complete the diary (via your preferred contact method). After 6 months, you will need to return the diary to the research team.

After completing the initial assessment, each participant will be put into a study group by chance (random). There are **two *possible*** study groups involved in this study**.** The groups are either the: (1) Usual Care Control Group or (2) Back Pain Support System Group. The research team will use a computer software program to **randomly select** which study group you will join.

You have a **50% chance** of being put in either of the following two groups:
Usual Care Control Group (Study Group 1):

- If you are randomly put in the usual care group, this means that you will be asked to continue with the **usual care program** that is recommended by your physiotherapist.
- This may include a program of advice, education and exercises to complete at home or in your local community.
- You ***will not*** be asked to participate in the health coaching sessions. However, you will be offered the opportunity to participate in the Get Healthy Service® ***after*** completing your 12-month follow-up assessment.

Back Pain Support System Group (Study Group 2):

- If you are randomly put in the back pain support system group, this means you will be asked to continue with the **usual care program** that is recommended by your physiotherapist. In addition, you will be asked to take part in a **health coaching program.**
- The **health coaching program** will be delivered by the Get Healthy Service®. The research team will need to provide your personal details (name, date of birth, phone number) to the service so they can deliver the health coaching sessions. If you give permission, the research team will also provide the Get Healthy Service® with your email address and postal address. The Get Healthy Service® is funded by the NSW Ministry of Health and will store your personal information securely and confidentially. If you needed additional medical clearance before joining the study, the Get Healthy Service® may ask for a copy of your medical referral form. If so, the research team will send a copy of your form via a secure program used by the NSW Ministry of Health.
- You will receive up to 10 health coaching sessions over 6 months. All sessions will be delivered **over the phone** by a trained health coach. You can decide how often and how many sessions you will take part in.
- In the first session, the health coach will help you set goals to increase your physical activity levels, as well as any other health-related goals if you wish to work on (e.g. improve diet, lose weight, reduce alcohol consumption).
- Your health coach will support you and monitor your progress during the program.
- After completing the program, you have the additional option to enrol into further health coaching sessions or join a free SMS program for another 6 months (called the *Get Healthy Stay Healthy* SMS program). This program will send you automatic SMS messages with tips to stay on track with your goals. If you choose this option, your health coach may contact you periodically to check on your progress.

All participants in both study groups will be asked to take part in the follow-up data collection. Follow-up data collection will continue for **one year** from the start of the study.
It will involve:
1. Completing a fortnightly questionnaire: Every fortnight (2 weeks), you will receive a link to a **brief online questionnaire**. We will send you the link via SMS or email, depending on your preferred contact method. The questionnaire will ask if you experienced low back pain in the past fortnight. You may be asked extra questions related to the pain intensity and whether you used any care or treatment for the pain. It will take roughly 1 minute to complete the questions (maximum 5 minutes). Occasionally, you may receive reminders to complete the questionnaires.

2. Additional assessments at 6 and 12 months:

(1) **An online questionnaire**: At 6 months and 12 months after joining the study, you will be asked to complete an online questionnaire. The questionnaire will be similar to the initial assessment questionnaire, but with less questions. You will receive a link to the online questionnaire (via SMS or email). It will take roughly 25 minutes to complete.

(2) At 6 months after joining the study (not at 12 months), you will also be asked to wear the **physical activity device** and complete the **logbook** again for 7 days. A package containing the device and logbook will be posted to your mailing address. Before sending the package, the research team will contact you (via your preferred contact method) to confirm you are available to receive it (e.g. not away on holidays).

At 3, 6, and 9 months into the study, the research team will also briefly contact you, via your preferred contact method. The research team member will ask if you have any concerns about being in the study. At the end of the study (12 months), you *may* also be asked to take part in an **interview** (approximately one hour). You may be asked questions about your experiences during the study.

4 Other relevant information about the research project

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way. The research project has been designed to prevent study staff or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. If we ask you to take part in the health coaching program, it will be provided to you free of charge.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you decide to take part, you will be given this '**Participant Information and Consent Form'** to sign. You will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with {Insert Hospital}.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. You can continue with the usual care provided by your physiotherapist, without participating in the study. If you do not wish to take part in the study, your physiotherapist or the research team can discuss other options with you.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include increased support for physical activity participation and reduced pain and disability.

8 What are the possible risks and disadvantages of taking part?

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may just stop the questions. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

There is a small risk of some muscle soreness from participating in the study. If you do experience any muscle soreness during the study, it will most likely be from taking part in new types of activities or exercising more than usual. We expect that any soreness would settle quickly after a few days.

Please take care when doing exercise. If a serious incident occurs, please complete your weekly diary immediately and contact the research team as soon as possible. Please call 000 if it is an emergency.

9 Can I have other treatments during this research period?

Whilst taking part in the study, you will still be able to take all medications or treatments you have been taking for your low back pain or for other reasons.

10 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

11 Could this research project be stopped unexpectedly?

This research project has no reasons to be stopped unexpectedly.

12 What happens when the research project ends?

At the end of the study, the research team will send you a summary of the study findings if you wish. You will be asked to indicate this on the consent form and provide your email address if so.

For participants in the usual care group only: After completing the 12-month assessment, participants in the usual care control group will be contacted by the research team via phone call. The research team will confirm whether you have enrolled into any of the Get Healthy Service® programs and will offer you the opportunity to join any of the Get Healthy Service® health coaching programs if you wish.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you give permission for the research team to collect and use personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and stored securely. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Your personal contact details for the study which will be collected from you via the consent form (e.g. your phone number, email address and mailing address) will only be used for study procedures, such as sending you study documents, equipment and reminders. Any data collected from you that may identify you will be stored on a secure, confidential, password-protected online data collection software called REDCap (hosted by the University of Sydney). Only approved members of the research team will have access to your personal contact details.

To protect your privacy, you will be given a unique participant code so that your name and details are not used on study documents. The research team will collect information about your medical history, symptoms and treatments, and general health (e.g., sleep quality) from questionnaires, diaries and an activity device. Your data will be stored on a secure, password-protected REDCap data collection program. Your data will be stored separate to any personal information about you. No-one can identify you from your data, except for members of the research team who have special approved access.

Only approved members of the research team, the Human Research Ethics Committee (HREC) for monitoring purposes, persons monitoring the conduct of the study on behalf of the Project Sponsor

(i.e. chief principal investigator, principal investigator, clinical trial coordinator, research staff), or regulatory bodies (including the Therapeutic Goods Administration) will have access to your details.

Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. This may include linking to your hospital and Medicare and prescribed medicines (MBS/PBS) data. By signing the study consent form and separate MBS/PBS consent form, you give permission for the research team to access your health records and MBS/PBS data, if they are relevant to your participation in this research project.

Your health records and any information collected about you that is relevant to the research project may be reviewed for verifying study procedures and data. This review may be done by the relevant authorities and authorised representatives of the Sponsor (University of Sydney), the institution relevant to this Participant Information Sheet (Western Sydney Local Health District (WSLHD) HREC) or as required by law. By signing both the study and MBS/PBS consent forms, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is expected that the results of this research project will be published and/or presented in a variety of forums and peer reviewed journals. The results may also be used in a PhD thesis at the University of Sydney. You will not be able to be identified in any publications and/or presentations, except with your permission. Your data may be used for extended (related) research projects. Separately, your MBS/PBS data will be stored on a secure, confidential, password protected network server hosted by the University of Sydney. Once the research team links your study data to your MBS/PBS data, the research team will remove any identifying information (e.g. personal details) from your MBS/PBS data. Your MBS/PBS data will not be used in any future or unspecified research outside of the approved study.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

After removing any identifying information from the data, the research team will keep your study data archived on the secure University of Sydney's server for 15 years. This is consistent with clinical trial recommendations outlined in section 2.1.1 of the National Health and Medical Research Council's "Australian Code for the Responsible Conduct of Research". Your MBS/PBS will undergo a different process. According to the requirements of Services Australia, your MBS/PBS data will be destroyed 15 years after results of the project are published.

14 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible and you will be assisted with arranging appropriate medical treatment. In the event of loss or injury, there will be no special compensation agreements. In the event of loss or injury due to someone's negligence, you may have grounds for legal action but may have to pay for the expenses. If you wish you complain or have concerns about any aspects of how you have been treated during the study, you are advised to contact the WSLHD HREC. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

15 Who is organising and funding the research?

This research project is being conducted by the University of Sydney and will be led by Professor Paulo Ferreira. Associated researchers are from The University of Sydney and Western Sydney, Sydney, and South Western Sydney LHD, and have experience in conducting research projects. The project also involves a partnership with the Get Healthy Service®, which is funded and managed by the NSW Government (Ministry of Health) and is free of charge to participants. This project is funded

by an Allied Health Kickstarter Grant from WSLHD and a Partnership Grant from the National Health and Medical Research Council.

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of WSLHD. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor (Lead Investigator) or any of the following people:

Lead Investigator Contact Details

Name	Professor Paulo Ferreira
Position	Chief investigator
Telephone	(02) 8627 7062
Email	paulo.ferreira@sydney.edu.au

Central Research Team Contact Details

Name	Ms Emma Ho
Position	Central research team staff member
Telephone	02 9114 4808
Email	getbacktohealthy.study@sydney.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Patient Experience Unit
Position	Patient Experience Unit
Telephone	{Insert LHD reviewing office email}.
Email	{Insert Hospital feedback email address}

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you can contact:

Reviewing HREC approving this research

Reviewing HREC	WSLHD Human Research Ethics Committee
Telephone	(02) 8890 9007
Email	Wslhd-researchoffice@health.nsw.gov.au

Local HREC Office contact

Position	Research Governance Manager
Telephone	{Insert phone number}.
Email	{Insert email}.

If you have a privacy complaint in relation to the use of your MBS/PBS data, you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

THE UNIVERSITY OF SYDNEY

{Insert site/LHD logo}

Participant Consent Form

Title	*The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability*
Short Title	Get Back to Healthy study
Co-ordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson, Ms Katharine Roberts.
Location	<Insert site name>

Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

2. I understand the purposes, procedures and risks of the research described in the project.

3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

4. I give permission for my doctors, other health professionals, or hospitals outside this hospital to release information to the University of Sydney concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

5. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

6. I acknowledge that regulatory authorities may have access to my medical records specifically related to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

7. I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

8. I give permission for the research team to use and confidentially store my personal contact information, specifically for the purposes of conducting study procedures.

9. I understand that if I am put in the back pain support group, my personal details (name, date of birth, phone number) and medical referral form (if required) will be sent securely to the Get Healthy Service®, who will store my information confidentially.

10. I understand that I will be given a signed copy of this document to keep.

My best contact details are (please also tick your preferred contact method(s)):

☐ Mobile phone number: _____ (mobile)

☐ Home phone number: _____(home)

☐ Email address: _____

☐ Mailing address: _____

Please indicate: ☐ I wish to receive feedback from my participation at the end of the study;

☐ I wish to receive a summary of the study findings at the end of the study.

Name of Participant (PRINT) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (PRINT) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

THE UNIVERSITY OF SYDNEY

{Insert site/LHD logo}

Form for Withdrawal of Participation

Title	*The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability*
Short Title	Get Back to Healthy study
Co-ordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson, Ms Katharine Roberts.
Location	<insert site name>

Declaration by Participant

I wish to withdraw from participation in the above research project. I understand that:

1. Withdrawal will not affect my routine care, or my relationships with the researchers or <insert Hospital name> (or) my treating physiotherapist, chiropractor, or general practitioner (GP);
2. no further information about me will be collected for the study from the withdrawal date;
3. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the withdrawal of participation must date their own signature.

This form should be forwarded by email to: getbacktohealthy.study@sydney.edu.au

Alternatively, this form can be posted to: Professor Paulo Ferreira, School of Physiotherapy, Level 7, Western Avenue, D18 – Susan Wakil Health Building, The University of Sydney, NSW, 2006.

Participant Information Sheet and Consent Form

Health/Social Science Research

Title	The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability
Short Title	Get Back to Healthy study
Coordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson, Ms Katharine Roberts
Location	General Community

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research study.

This Participant Information Sheet/Consent Form tells you information about the research project. It explains what taking part in the study involves. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent (given permission) to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research is to test whether a '***back pain support system***' can help people with low back pain maintain improvements in their symptoms and physical activity levels after finishing a course of treatment with their outpatient physiotherapist at a hospital or treatment with their physiotherapist, chiropractor, or general practitioner (GP) in a public or private practice. The study will also measure whether the ***back pain support system*** changes people's use of hospital, medical and health services for low back pain. The back pain support system will involve a health coaching program delivered over the phone. The program is run by the Get Healthy Service®, which is part of NSW Health. The program will involve having a personal health coach to help support you to achieve healthy lifestyle goals that are important to you. The back pain support system will be compared to the usual care people finishing physiotherapy treatment receive, which may include advice, education and exercises, to see if it better helps and supports you to manage your back pain after finishing physiotherapy treatment at the hospital.

This research has been initiated by the researcher Professor Paulo Ferreira from the University of Sydney. The results of this research will be used by Ms Emma Ho and Ms Katharine Roberts to obtain a Doctor of Philosophy (Health Sciences) degree.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You have been invited because you have had low back pain for more than 3 months, you are older than 18 years of age, and you have recently finished (or are close to finishing) treatment for your low back pain. You may have received treatment from an outpatient physiotherapist at a hospital or you may have received treatment from your physiotherapist, chiropractor, or GP in a public or private practice. After reading this information sheet, speak with your treating practitioner or contact the research team if you are interested in the study or have any questions. The study will take one year to complete.

<u>Participation in the research will involve the following:</u>

When you are close to finishing your treatment program, your physiotherapist, chiropractor, or GP will introduce the study to you. Alternatively, you may have seen our posters and pamphlets on social media, on public noticeboards or in a newsletter. If you are interested, you can complete an online pre-screening form which will ask you brief questions about the treatment you recently received for your back pain, and your best contact details (phone number or email address).

The research team will call you to give you more information about the study. You will be given the study information package to read and discuss with your family, friends and GP (if you wish). After approximately one week, the research team will call you again to confirm if you are still interested in the study. You do not have to take part in the study. If you do not wish to participate, your care at the hospital will not be affected.

If you are interested in taking part in the study, the research team will organise a time to discuss the study Participant Information Sheet with you. They will answer any questions you have about the study. If you agree to participate, you will be asked to sign the study consent form. You can choose to sign the consent form online (via an online link) or in person at the hospital. If you choose to sign the consent form online, a research team member will speak with you via phone call or videoconference to give you support. The study consent form must be signed **before** any further study procedures occur. After signing the consent form, you will be immediately assigned a **unique participant study code**. This participant code will be used on all study documents to protect your privacy.

The Participant Information Sheet will clearly explain how and when your contact information will be used. On the consent form, you will be asked to indicate **your preferred method(s)** for the research team to contact you (i.e. phone call, SMS, email, mailing address). You will be asked to provide these

contact details on the consent form. Your contact information will be stored in a secure, password-protected server hosted by the University of Sydney. Only the research team will have access to your contact information. A copy of the main study consent form is attached at the end of the Participant Information Sheet.
If you decide to take part in the research project, you will be asked to complete a questionnaire asking about your low back pain and medical history. The questionnaire will assess if you are eligible to take part in the study. Completing the questionnaire will take approximately 5-8 minutes. If the screening questionnaire shows that you meet the requirements, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, the research coordinator will discuss other options with you.

For safety reasons, the research team *may* request you seek approval from your local doctor (GP) before joining the study. If so, you will be given a form for your local doctor to sign. You will need to return the signed form to the research team **before** any further study procedures occur.

Once the research team confirms you are both suitable and safe to join the study, you will be ***enrolled*** into the study.

The research team will request additional permission to access your Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data. Medicare collects information on your doctor visits and associated costs. PBS collects information on the prescription medications you purchase at pharmacies. This data will provide valuable information about your use of hospital, medical and health services, and medications. You will receive a **separate** MBS/PBS Information Sheet and Consent Form that explains this information in detail. If you agree, you will be asked to sign a separate MBS/PBS consent form (hard-copy version). You can choose to sign the form in person at the hospital, or you can request for the research team to post the form to your mailing address.

Once you are enrolled in the study, you will be invited to complete an assessment with a member of the research team. You can choose to complete this initial assessment in person at the hospital or online (with phone or videoconference support from the research team).

There are three parts involved in the initial assessment:
1. Completing an electronic questionnaire: You will be asked to complete a **questionnaire** about your height and weight, education levels, medical history, low back pain symptoms, use of treatments, sleep, attitudes towards pain medications and beliefs about back pain. It will take approximately 35 minutes to complete. If you prefer to complete the initial assessment online, you will be emailed a link to the questionnaire.

2. Wearing a physical activity device: You will be asked to wear a **physical activity device**, similar to a Fitbit. The device records information about how active you are (e.g. number of steps). The device will be attached to your right leg using 3 pieces of tape. You will need to wear the device for 7 days in a row. You can continue most of your normal activities during this time.

You will also be given a paper **logbook** to record any physical activity or exercise you complete whilst wearing the device. You will receive reminders (via your preferred contact method) to return the device and logbook back to the research team at the end of 7 days. We will give you a pre-paid envelope to return these items to the research team.

After you have completed your online initial assessment, the device and paper logbook will be posted to your mailing address. You will receive instructions on how to attach the device to your leg by yourself or with help from a family/friend. The research team will be available via phone call or video conference to help you if needed.

3. Completing a weekly diary: The research team will also give you a paper **weekly diary** to record any discomfort or incidents that may occur during the study. The research team will explain how to use this diary. The diary will track your safety every week during the first 6 months of the study. You will receive reminders to complete the diary (via your preferred contact method). After 6 months, you will need to return the diary to the research team.

After completing the initial assessment, each participant will be put into a study group by chance (random). There are **two *possible*** study groups involved in this study**.** The groups are either the: (1) Usual Care Control Group or (2) Back Pain Support System Group. The research team will use a computer software program to **randomly select** which study group you will join.

You have a **50% chance** of being put in either of the following two groups:
Usual Care Control Group (Study Group 1):

- If you are randomly put in the usual care group, this means that you will be asked to continue with the **usual care program** that is recommended by your physiotherapist.
- This may include a program of advice, education and exercises to complete at home or in your local community.
- You ***will not*** be asked to participate in the health coaching sessions. However, you will be offered the opportunity to participate in the Get Healthy Service® ***after*** completing your 12-month follow-up assessment.

Back Pain Support System Group (Study Group 2):

- If you are randomly put in the back pain support system group, this means you will be asked to continue with the **usual care program** that is recommended by your physiotherapist, chiropractor or GP. In addition, you will be asked to take part in a **health coaching program.**
- The **health coaching program** will be delivered by the Get Healthy Service®. The research team will need to provide your personal details (name, date of birth, phone number) to the service so they can deliver the health coaching sessions. If you give permission, the research team will also provide the Get Healthy Service® with your email address and postal address. The Get Healthy Service® is funded by the NSW Ministry of Health and will store your personal information securely and confidentially. If you needed additional medical clearance before joining the study, the Get Healthy Service® may ask for a copy of your medical referral form. If so, the research team will send a copy of your form via a secure program used by the NSW Ministry of Health.
- You will receive up to 10 health coaching sessions over 6 months. All sessions will be delivered **over the phone** by a trained health coach. You can decide how often and how many sessions you will take part in.
- In the first session, the health coach will help you set goals to increase your physical activity levels, as well as any other health-related goals if you wish to work on (e.g. improve diet, lose weight, reduce alcohol consumption).
- Your health coach will support you and monitor your progress during the program.
- After completing the program, you have the additional option to enrol into further health coaching sessions or join a free SMS program for another 6 months (called the *Get Healthy Stay Healthy* SMS program). This program will send you automatic SMS messages with tips to stay on track with your goals. If you choose this option, your health coach may contact you periodically to check on your progress.

All participants in both study groups will be asked to take part in the follow-up data collection. Follow-up data collection will continue for **one year** from the start of the study.
It will involve:
1. Completing a fortnightly questionnaire: Every fortnight (2 weeks), you will receive a link to a **brief online questionnaire**. We will send you the link via SMS or email, depending on your preferred contact method. The questionnaire will ask if you experienced low back pain in the past fortnight. You may be asked extra questions related to the pain intensity and whether you used any care or treatment for the pain. It will take roughly 1 minute to complete the questions (maximum 5 minutes). Occasionally, you may receive reminders to complete the questionnaires.

2. Additional assessments at 6 and 12 months:

(1) **An online questionnaire**: At 6 months and 12 months after joining the study, you will be asked to complete an online questionnaire. The questionnaire will be similar to the initial assessment questionnaire, but with less questions. You will receive a link to the online questionnaire (via SMS or email). It will take roughly 25 minutes to complete.

(2) At 6 months after joining the study (not at 12 months), you will also be asked to wear the **physical activity device** and complete the **logbook** again for 7 days. A package containing the device and logbook will be posted to your mailing address. Before sending the package, the research team will contact you (via your preferred contact method) to confirm you are available to receive it (e.g. not away on holidays).

At 3, 6, and 9 months into the study, the research team will also briefly contact you, via your preferred contact method. The research team member will ask if you have any concerns about being in the study. At the end of the study (12 months), you *may* also be asked to take part in an **interview** (approximately one hour). You may be asked questions about your experiences during the study.

4 Other relevant information about the research project

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way. The research project has been designed to prevent study staff or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. If we ask you to take part in the health coaching program, it will be provided to you free of charge.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you decide to take part, you will be given this '**Participant Information and Consent Form'** to sign. You will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, or your relationship with those treating you.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. You can continue with the usual care provided by your physiotherapist, chiropractor, or GP without participating in the study. If you do not wish to take part in the study, the research team can discuss other options with you.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include increased support for physical activity participation and reduced pain and disability.

8 What are the possible risks and disadvantages of taking part?

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may just stop the questions. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

There is a small risk of some muscle soreness from participating in the study. If you do experience any muscle soreness during the study, it will most likely be from taking part in new types of activities or exercising more than usual. We expect that any soreness would settle quickly after a few days.

Please take care when doing exercise. If a serious incident occurs, please complete your weekly diary immediately and contact the research team as soon as possible. Please call 000 if it is an emergency.

9 Can I have other treatments during this research period?

Whilst taking part in the study, you will still be able to take all medications or treatments you have been taking for your low back pain or for other reasons.

10 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

11 Could this research project be stopped unexpectedly?

This research project has no reasons to be stopped unexpectedly.

12 What happens when the research project ends?

At the end of the study, the research team will send you a summary of the study findings if you wish. You will be asked to indicate this on the consent form and provide your email address if so.

For participants in the usual care group only: After completing the 12-month assessment, participants in the usual care control group will be contacted by the research team via phone call. The research team will confirm whether you have enrolled into any of the Get Healthy Service® programs and will offer you the opportunity to join any of the Get Healthy Service® health coaching programs if you wish.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you give permission for the research team to collect and use personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and stored securely. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Your personal contact details for the study which will be collected from you via the consent form (e.g. your phone number, email address and mailing address) will only be used for study procedures, such as sending you study documents, equipment and reminders. Any data collected from you that may identify you will be stored on a secure, confidential, password-protected online data collection software called REDCap (hosted by the University of Sydney). Only approved members of the research team will have access to your personal contact details.

To protect your privacy, you will be given a unique participant code so that your name and details are not used on study documents. The research team will collect information about your medical history, symptoms and treatments, and general health (e.g., sleep quality) from questionnaires, diaries and an activity device. Your data will be stored on a secure, password-protected REDCap data collection program. Your data will be stored separate to any personal information about you. No-one can identify you from your data, except for members of the research team who have special approved access.

Only approved members of the research team, the Human Research Ethics Committee (HREC) for monitoring purposes, persons monitoring the conduct of the study on behalf of the Project Sponsor

(i.e. chief principal investigator, principal investigator, clinical trial coordinator, research staff), or regulatory bodies (including the Therapeutic Goods Administration) will have access to your details.

Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. This may include linking to your hospital and Medicare and prescribed medicines (MBS/PBS) data. By signing the study consent form and separate MBS/PBS consent form, you give permission for the research team to access your health records and MBS/PBS data, if they are relevant to your participation in this research project.

Your health records and any information collected about you that is relevant to the research project may be reviewed for verifying study procedures and data. This review may be done by the relevant authorities and authorised representatives of the Sponsor (University of Sydney), the institution relevant to this Participant Information Sheet (Western Sydney Local Health District (WSLHD) HREC) or as required by law. By signing both the study and MBS/PBS consent forms, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is expected that the results of this research project will be published and/or presented in a variety of forums and peer reviewed journals. The results may also be used in a PhD thesis at the University of Sydney. You will not be able to be identified in any publications and/or presentations, except with your permission. Your data may be used for extended (related) research projects. Separately, your MBS/PBS data will be stored on a secure, confidential, password protected network server hosted by the University of Sydney. Once the research team links your study data to your MBS/PBS data, the research team will remove any identifying information (e.g. personal details) from your MBS/PBS data. Your MBS/PBS data will not be used in any future or unspecified research outside of the approved study.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

After removing any identifying information from the data, the research team will keep your study data archived on the secure University of Sydney's server for 15 years. This is consistent with clinical trial recommendations outlined in section 2.1.1 of the National Health and Medical Research Council's "Australian Code for the Responsible Conduct of Research". Your MBS/PBS will undergo a different process. According to the requirements of Services Australia, your MBS/PBS data will be destroyed 15 years after results of the project are published.

14 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible and you will be assisted with arranging appropriate medical treatment. In the event of loss or injury, there will be no special compensation agreements. In the event of loss or injury due to someone's negligence, you may have grounds for legal action but may have to pay for the expenses. If you wish you complain or have concerns about any aspects of how you have been treated during the study, you are advised to contact the WSLHD HREC. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

15 Who is organising and funding the research?

This research project is being conducted by the University of Sydney and will be led by Professor Paulo Ferreira. Associated researchers are from The University of Sydney and Western Sydney, Sydney, and South Western Sydney LHD, and have experience in conducting research projects. The project also involves a partnership with the Get Healthy Service®, which is funded and managed by the NSW Government (Ministry of Health) and is free of charge to participants. This project is funded

by an Allied Health Kickstarter Grant from WSLHD and a Partnership Grant from the National Health and Medical Research Council.

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of WSLHD. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor (Lead Investigator) or any of the following people:

Lead Investigator Contact Details

Name	Professor Paulo Ferreira
Position	Chief investigator
Telephone	(02) 8627 7062
Email	paulo.ferreira@sydney.edu.au

Central Research Team Contact Details

Name	Ms Emma Ho
Position	Central research team staff member
Telephone	02 9114 4808
Email	getbacktohealthy.study@sydney.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you can contact:

Reviewing HREC approving this research

Reviewing HREC	WSLHD Human Research Ethics Committee
Telephone	(02) 8890 9007
Email	Wslhd-researchoffice@health.nsw.gov.au

Local HREC Office contact

Position	Research Governance Manager
Telephone	(02) 8890 9007
Email	Wslhd-researchoffice@health.nsw.gov.au

If you have a privacy complaint in relation to the use of your MBS/PBS data, you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

Participant Consent Form

Title	*The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability*
Short Title	Get Back to Healthy study
Co-ordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson, Ms Katharine Roberts
Location	General Community

Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

2. I understand the purposes, procedures and risks of the research described in the project.

3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

4. I give permission for my doctors, other health professionals, or hospitals outside this hospital to release information to the University of Sydney concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

5. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

6. I acknowledge that regulatory authorities may have access to my medical records specifically related to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

7. I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

8. I give permission for the research team to use and confidentially store my personal contact information, specifically for the purposes of conducting study procedures.

9. I understand that if I am put in the back pain support group, my personal details (name, date of birth, phone number) and medical referral form (if required) will be sent securely to the Get Healthy Service®, who will store my information confidentially.

10. I understand that I will be given a signed copy of this document to keep.

My best contact details are (please also tick your preferred contact method(s)):

☐ Mobile phone number: _____ (mobile)

☐ Home phone number: _____(home)

☐ Email address: _____

☐ Mailing address: _____

Please indicate: ☐ I wish to receive feedback from my participation at the end of the study;

☐ I wish to receive a summary of the study findings at the end of the study.

Name of Participant (PRINT) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (PRINT) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

Title	*The Get Healthy Coaching Service® to reduce the burden of low back pain: effectiveness, cost effectiveness, and scalability*
Short Title	Get Back to Healthy study
Co-ordinating Principal Investigator	Professor Paulo Ferreira
Investigator(s)	Prof Manuela Ferreira, A/Prof Milena Simic, Ms Dragana Ceprnja, Ms Katherine Maka, Dr Mark Halliday, Ms Emma Ho, Mr Thomas Patterson, Ms Katharine Roberts
Location	General Community

Declaration by Participant

I wish to withdraw from participation in the above research project. I understand that:

1. withdrawal will not affect my routine care, or my relationships with the researchers or my treating physiotherapist, chiropractor, or general practitioner (GP);
2. no further information about me will be collected for the study from the withdrawal date;
3. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the withdrawal of participation must date their own signature.

This form should be forwarded by email to: getbacktohealthy.study@sydney.edu.au

Alternatively, this form can be posted to: Professor Paulo Ferreira, School of Physiotherapy, Level 7, Western Avenue, D18 – Susan Wakil Health Building, The University of Sydney, NSW, 2006.

Pre-Screening Questionnaire for the Get Back to Healthy study

Thank you for interest in the Get Back to Healthy study. Please complete the brief pre-screening questionnaire to help the research team determine if you are potentially suitable to join the study.

Please answer all of the following questions.

1. How did you hear about this study?
   - ☐ My therapist (physiotherapist, general practitioner (GP), chiropractor)
   - ☐ My physiotherapist at the hospital
   - ☐ Social media (e.g., facebook, instagram, twitter)
   - ☐ Printed poster
   - ☐ Word of mouth
   - ☐ Newsletter
   - ☐ Other (please specify) _____

Eligibility Criteria

2. Are you 18 years old or over?
   ☐ Yes ☐ No

3. Have you had non-specific low back pain for at least 12 weeks?
   ☐ Yes ☐ No

4. Have you recently received treatment for low back pain from your local hospital?
   ☐ Yes ☐ No

   4b. If yes, are you currently receiving treatment for low back pain from your local hospital, or have you recently been discharged from treatment in the past 4 weeks?
   - ☐ Yes, currently receiving treatment
   - ☐ Yes, recently discharge (finished treatment) in the past 4 weeks
   - ☐ No, I finished treatment more than 4 weeks ago

5. Within the last 6 months, have you received treatment for low back pain from a physiotherapist, general practiticoner (GP), or chiropractor in a public or private clinic setting? Please tick all that apply.
   - ☐ Yes, from a physiotherapist
   - ☐ Yes, from a general practitioner (GP)
   - ☐ Yes, from a chiropractor
   - ☐ No

   5b. If yes, are you still having regular weekly treatment for your low back pain from your physiotherapist, general practitioner (GP), or chiropractor?
   ☐ Yes ☐ No

6. Do you have adequate hearing and eyesight to exercise safely?
   ☐ Yes ☐ No

7. Can you walk independently (with or without a walking aid)?
   ☐ Yes ☐ No

Personal Contact Details

8. What is your name? _____

9. Do you agree to be contacted by the research team?

☐ Yes ☐ No

9c. How would you prefer to be contacted by the research team (please tick all that apply)?

☐ Phone ☐ Email

Observation: 9d and 9e only appear as indicated from responses to 9c.

9d. Please provide your phone number: _____

9e. Please provide your email address: _____

9f. What time would you prefer we contact you?

☐ Early morning
☐ Late morning
☐ Middle of the day
☐ Early afternoon
☐ Late afternoon

Thank you for taking the time to complete this short survey!

A member of the research team will review your responses and be in touch with you within 5 days.

THE UNIVERSITY OF SYDNEY AND NSW GET HEALTHY SERVICE®

GET BACK TO HEALTHY STUDY

DO YOU HAVE LOW BACK PAIN?

Would you like to participate in an exciting study of low back pain care?
Would you be interested in joining a back pain support group?
Do you think being part of a study might help you follow the advice given to you by your treating therapist?

WHAT WILL WE ASK YOU TO DO

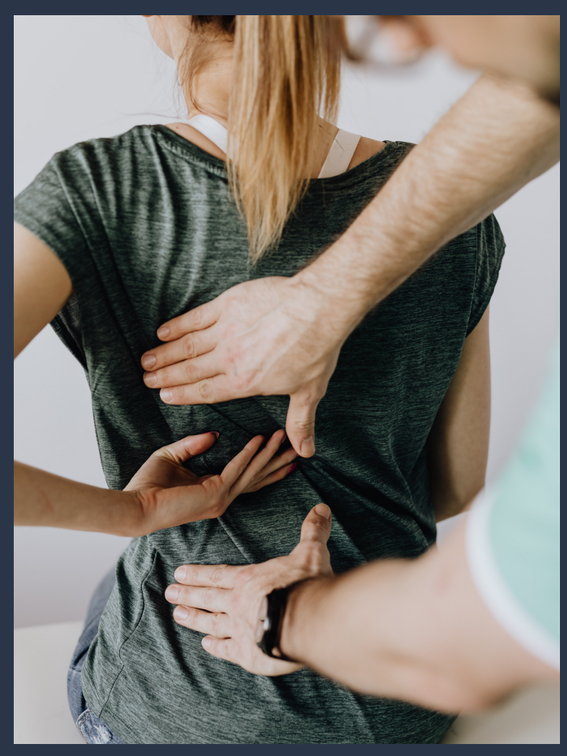
- *Fill in some forms for us*
- *Keep and activity diary*
- *Wear an activity monitor for one week*
- *Continue to follow the advice of your treating therapist*

HEALTH COACHING GROUP

If you are in the health coaching group you will receive ten health coaching sessions, over the phone with NSW Get Healthy Service®. The health coach will help you to increase your physical activity, stay motivated and set realistic goals

WOULD YOU LIKE TO KNOW MORE?

If you would like to know more, contact the Study team at getbacktohealthy.study@sydney.edu.au or you can fill-in a prescreening form by following the QR code below and the study team will contact you.



GET BACK TO HEALTHY STUDY

This study is approved by Western Sydney Local Health District Human Research Ethics Committee (2020/ETH00115) and Sponsored by the University of Sydney version 2 dated 2 Feb 2022

DO YOU HAVE LOW BACK PAIN?

Do you think being part of a study might help you to follow the advice given to you by your treating therapist?

Join the Get Back to Healthy Study

What will we ask you to do?

Fill in some forms
Keep an activity diary
Wear an activity tracker for one week
Keep following the advice of your treating therapist

Get Back to Healthy

You will be asked to follow the advice given to you by your therapist and keep track of your activity levels and pain.

You may also receive up to 10 health coaching sessions over the phone to:
motivate you, support you and help you to set achievable goals

Would you like to know more?

contact the Get Back to Healthy Study Team
getbacktohealthy.study@sydney.edu.au

or scan this QR code to fill in a pre-screening form and the Study Team will contact you

This study is approved by Western Sydney Local Health District Human Research Ethics Committee (2020/ETH00115) and Sponsored by the University of Sydney version 2 dated 2 Feb 2022

Appendix 6: Supplementary Material for Chapter Eight

Supplementary material

Supplementary A. Modifications to the trial protocol and inclusion criteria

Due to the impact of the COVID-19 pandemic on clinical services for our target population at our recruiting hospital sites (i.e., suspension of treatment of patients with chronic non-specific LBP), pragmatic modifications were made to the trial protocol to increase recruitment rates and to ensure timely study completion to meet funding deadlines. The changes primarily involved expanding recruitment to people in the general community who were recently discharged from treatment for chronic non-specific LBP from public or private physiotherapists, chiropractors, or general practitioners. The amendments were approved by the reviewing ethics committee on 9 February 2022 and were accompanied by a revision of the primary aims and eligibility criteria of the trial as follows (Supplementary Tables 1 and 2).

Supplementary Table 1. Previous and revised primary aims for the Get Back to Healthy trial

Previous primary aims	Revised primary aims
1. To determine the effectiveness and cost-effectiveness of a discharge support system (incorporating referral to the Get Healthy Service®) for improving pain, disability, and physical activity levels, in people recently discharged from hospital outpatient physiotherapy treatment for chronic LBP. 2. To investigate the effect of a discharge support system (incorporating referral to the Get Healthy Service®) on the future use of hospital, medical and health services for LBP, in people recently discharged from hospital outpatient physiotherapy treatment for chronic LBP.	1. To determine the effectiveness and cost-effectiveness of a discharge support system (incorporating referral to the Get Healthy Service®) for improving pain, disability, and physical activity levels, in people recently discharged from hospital outpatient physiotherapy treatment, *or from public or private physiotherapy, chiropractic or general practitioner care for chronic LBP.* 2. To investigate the effect of a discharge support system (incorporating referral to the Get Healthy Service®) on the future use of hospital, medical and health services for LBP, in people recently discharged from hospital outpatient physiotherapy treatment, *or from public or private physiotherapy, chiropractic or general practitioner care,* for chronic LBP.

Changes in the primary aims have been highlighted in italics.

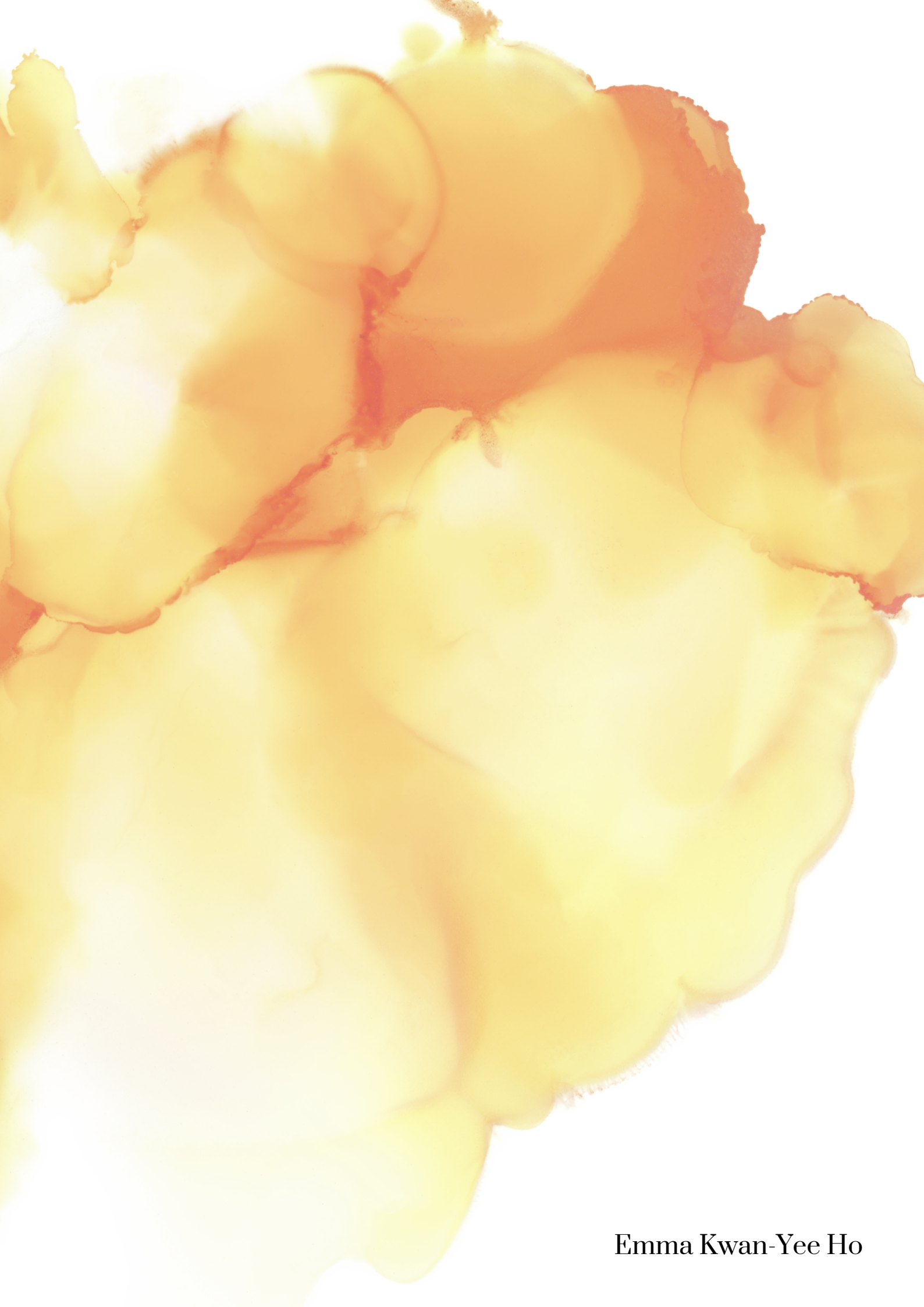
Supplementary Table 2. Previous and revised eligibility criteria for the Get Back to Healthy trial

Previous eligibility criteria	Revised eligibility criteria
Inclusion criteria: Potential participants will need to meet all the following inclusion criteria: 1. 18 years of age or older; 2. presentation of non-specific LBP of at least 12-week duration, with or without leg pain but without radicular (e.g., reflex changes, motor loss) symptoms. Non-specific LBP will be defined as LBP without diagnosis of a specific cause, and the absence of serious spinal pathology or indicators of potentially serious conditions using 'red' flags; 3. recently discharged (< 4 weeks post-treatment) from outpatient physiotherapy treatment from a participating hospital site. This includes discharge from one-to-one physiotherapy care directly into the community, or from supervised group exercise programs offered by the outpatient physiotherapy department; 4. have adequate hearing and eyesight to participate safely in physical activity; 5. independent ambulatory status, with or without a gait aid. **Exclusion criteria** Potential participants will be excluded if they have any of the following: 1. known or suspected serious spinal pathology (e.g., fracture, inflammatory disorder); diagnosis of specific LBP (e.g., sciatica, spinal stenosis grade 3 to 4); 2. co-morbid health condition(s) diagnosed by a medical practitioner that would prevent participation in physical activity or exercise programs; 3. fibromyalgia or systemic/inflammatory condition; 4. currently pregnant or planning to become pregnant over the study duration; 5. inadequate English to complete outcome measures or participate in the health coaching intervention; 6. spinal surgery in the past 12 months; 7. LBP caused by involvement in a road traffic crash in the last 12 months or ongoing compensation.	**Inclusion Criteria** To be included, they will need to meet all the following inclusion criteria: 1. 18 years of age or older; 2. present with a diagnosis of non-specific LBP of at least 12-week duration, with or without leg pain but without radicular (e.g., reflex changes, motor loss) symptoms. Non-specific LBP will be defined after screening for serious spinal pathology and indicators of potentially serious conditions using 'red' flags; 3. have been recently discharged (<4 weeks post-treatment) from physiotherapy treatment from outpatient physiotherapy departments at the participating hospital sites; *OR* *have been recently discharged (<6 months post-regular treatment) from a course of treatment by their physiotherapist, chiropractor, or general practitioner in either private or public practices (including hospitals). For participants recruited from the general community, the definition of a course of treatment will be at least one attendance to a physiotherapist, chiropractor, or general practitioner, which may include a clinical examination, provision of manual therapy, a home exercise program, back care education or medication. Discharge from regular treatment describes people who are no longer receiving weekly treatment from their health care professional for their LBP.* 4. have adequate hearing and eyesight to participate safely in physical activity; 5. independent ambulatory status, with or without gait aid. **Exclusion Criteria** Potential participants will be excluded if they have any of the following: 1. known or suspected serious spinal pathology (fracture, inflammatory disorder); 2. diagnosis of specific LBP, e.g. sciatica, spinal stenosis (grade 3 to 4); 3. co-morbid health condition(s) preventing participation in physical activity or exercise programs as diagnosed by a medical practitioner; 4. fibromyalgia or systemic/inflammatory condition; 5. currently pregnant or planning to become pregnant over the study duration; 6. inadequate English to complete outcome measures or participate in the health coaching intervention; 7. spinal surgery in the past 12 months; 8. LBP caused by involvement in a road traffic accident in the last 12 months or ongoing compensation; 9. *currently enrolled in the Get Healthy Service® Standard Coaching module.*

Changes in the eligibility criteria have been highlighted in italics.

Supplementary B. Feasibility, site initiation, and site monitoring visits

Feasibility visits ensure that prior to the initiation of recruitment, a given site is adequately staffed with qualified personnel to support recruitment (e.g., identify potentially eligible participants) and maintain accurate participant documentation and records. Feasibility visits also ensure that sufficient budget and equipment for the trial (e.g., printers, Axivity accelerometers for baseline assessment) are available. Site initiation visits involve formal confirmation that a site has been assessed for feasibility and has received all necessary authorisation to commence recruitment (e.g., all personnel are trained; ethical, governance, and sponsor approvals are obtained; agreements and contracts are established). Site monitoring visits involve a formal review of items, including: (i) site enrolment status (e.g., number of participants randomised, number of withdrawals), (ii) informed consent (e.g., completion and storage of valid consent forms), (iii) data collection (e.g., accurate completion of questionnaires), (iv) safety reporting (e.g., occurrence of unreported serious adverse events, follow-up of serious adverse events), (v) trial conduct (e.g., compliance with trial protocol and good clinical practice standards), (vi) site personnel, facilities and equipment (e.g., adequate access to printing, equipment, and supervision, (vii) essential documentation (e.g., maintenance of updated study documents, ethical approvals, and contracts), (viii) other potential risks or concerns identified. Inability to perform these assessments and visits can potentially compromise the integrity and rigour of a trial, and participant safety.



Emma Kwan-Yee Ho