# Innovative, Scalable and Affordable Interventions for the Treatment of Low Back Pain

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BPhty (Hons), MSc

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# Candidate's statement

This thesis is submitted to The University of Sydney in fulfilment of the requirements for the Degree of Doctor of Philosophy.

I, Carolina Gassen Fritsch, hereby declare that this manuscript is my own work and that it contains no material previously published or written by another person except where acknowledged in the text. Nor does it contain material which has been submitted, either in full or in part, for a degree at this or any other institution.

I, Carolina Gassen Fritsch, understand that if I am awarded a higher degree for my thesis entitled "Innovative, scalable, and affordable interventions for the management of low back pain" being lodged herewith for examination, the thesis will be lodged in the University Library.

_____ Date: 16/09/2022

Carolina Gassen Fritsch

# Supervisors' statement

As supervisors of Carolina Gassen Fritsch's doctoral work, we certify that we consider her thesis "Innovative, scalable and affordable interventions for the management of low back pain" to be suitable for examination.

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# TABLE OF CONTENTS

# PUBLICATIONS AND PRESENTATIONS

Parts of the work presented in this thesis have been published and/or presented in the following forms:

**Publications in peer-reviewed journals**

1. **Fritsch CG**, Ferreira PH, Prior JL, McLachlan AJ, Ferreira ML. Effects of using text messages in the treatment of musculoskeletal pain: a systematic review. PAIN. 2020;161(11):2462-2475. doi: 10.1097/j.pain.0000000000001958.
2. **Fritsch CG**, Ferreira ML, da Silva AKF, Simic M, Dunn KM, Campbell P, Foster NE, Ferreira PH. Family-based Interventions Benefit Individuals With Musculoskeletal Pain in the Short-term but not in the Long-Term: A Systematic Review and Meta-Analysis. Clin J Pain. 2021;37(2):140-157. doi: 10.1097/AJP.0000000000000897.
3. **Fritsch CG**, Ferreira PH, Prior JL, Clavisi O, Chow CK , Redfern J, Thiagalingam A, Lung T, McLachlan AJ, Ferreira ML. TEXT4myBACK - A Text Message Intervention to Improve Function in People With Low Back Pain: Protocol of a Randomized Controlled Trial. Phys Ther 2021 Mar 24;pzab100. doi: 10.1093/ptj/pzab100.
4. **Fritsch CG**, Ferreira PH, Prior JL, Vesentini GV, Schlotfeldt P, Eyles J, Robbins S, Yu S, Mills K, Taylor DA, Lambert TE, Clavisi O, Bywaters L, Chow CK, Redfern J, McLachlan AJ, Ferreira ML. TEXT4myBACK – The Development Process of a Self-Management Intervention Delivered Via Text Message for Low Back Pain. Arch Rehabil Res Clin Transl 2021 27;3(2):100128. doi: 10.1016/j.arrct.2021.100128.
5. **Fritsch CG**, Duong V, Chen L, Hunter DJ, McLachlan AJ, Ferreira PH, Ferreira ML. Use of Online Information in Musculoskeletal Conditions: An Analysis of Google Trends Data. J Clin Rheumatol. 2022 1;28(3):1620169. doi: 10.1097/RHU.0000000000001820

**Manuscripts submitted for publication**

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4. *Oral presentation* - **Fritsch CG**, Ferreira PH, Prior JL, McLachlan AJ, Chow C, Redfern J, Ferreira ML. 'TEXT4myBACK' – A text message intervention to improve function of people with low back pain. ACI MSK Network Forum, Sydney, Australia, 2020.
5. *Oral presentation* - **Fritsch CG**, Ferreira PH, Prior JL, McLachlan AJ, Ferreira ML. Effects of using text messages in the treatment of musculoskeletal pain: a systematic review. Annual Scientific Meeting Musculoskeletal Health Alliance, Sydney, Australia, 2020.
6. *Oral presentation* - **Fritsch CG**. Innovative, scalable and affordable interventions for low back pain. eHealth and Healthcare Delivery Research Theme Showcase, Sydney, Australia, 2019.
7. *Oral presentation* - **Fritsch CG**, Ferreira PH, Prior JL, McLachlan AJ, Chow C, Redfern J, Ferreira ML. 'TEXT4myBACK' – The development process of a self-

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| APC | Annual percentage change |
| BMI | Body mass index |
| BP | Breusch-Pagan |
| CG | Control group |
| CI | Confidence interval |
| CLBP | Chronic low back pain |
| CAPES | Coordenação de Aperfeiçoamento de Pessoal de Nível Superior |
| CONSERVE | CONSORT and SPIRIT Extensions for Randomised Controlled Trials Revised in Extenuating Circumstances |
| CONSORT | Consolidated standards of reporting trials |
| COREQ | Consolidated criteria for reporting qualitative studies checklist |
| COVID-19 | Coronavirus disease-19 |
| CQR-19 | Compliance Questionnaire Rheumatology |
| DALY | Disability-adjusted life years |
| GBD | Global Burden of Disease |
| GRADE | Grading of Recommendations Assessment, Development and Evaluation |
| HIV | Human immunodeficiency virus |
| IG | Intervention group |
| IQR | Interquartile range |
| JAMA | Journal of American Medical Association |
| LBP | Low back pain |
| MAMS | Multiarm, multistage |
| MCID | Minimal clinically important difference |
| MD | Mean difference |
| MRI | Magnetic resonance imaging |
| NHMRC | National Health and Medical Research Council |
| NSW | New South Wales |
| OA | Osteoarthritis |
| OR | Odds ratio |
| PA | Physical activity |
| PSFS | Patient-Specific Functional Scale |
| RCT | Randomised controlled trial |
| REDCap | Research eletronic data capture |
| RMDQ | Roland and Morris Disability Questionnaire |
| RSV | Relative search volumes |
| SD | Standard deviation |
| SDI | Sociodemographic index |
| SF-12 | 12-Iteam Short Form Health Survey |
| SPIRIT | Standard protocol items: recommendations for interventional trials |
| TIDieR | Template for intervention description and replication |
| UI | Uncertainty interval |
| USD | United States Dollar |
| VAS | Visual analogue scale |
| YLD | Years lived with disability |

# PREFACE

This thesis includes ten chapters comprising innovative interventions for the management of low back pain that can be read independently. The University of Sydney allows published papers that arose from the candidature to be included in the thesis. Chapters **Two, Three, Four, Five** and **Eight** are the PDF files of the publications, while chapters **Six, Seven** and **Nine** are submitted manuscripts.

**Chapter One** introduces the thesis and provides an overview of low back pain, its prevalence and burden, and its management, including innovative approaches such as text messages and health coaching interventions.

**Chapter Two** is a study conducted with Google Trends data that investigated the online interest for the most disabling musculoskeletal conditions (i.e., gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis) between 2004 and 2020. The study is presented as published in the *Journal of Clinical Rheumatology*.

**Chapter Three** is a systematic review that appraised the use of text messages in the management of musculoskeletal pain. The review is presented as published in the *PAIN* journal.

**Chapters Four**, **Five**, **Six** and **Seven** are a series of related chapters. **Chapter Four** describes the development process of TEXT4myBACK, a self-management text message intervention to support recovery of low back pain and is presented as published in the *Archives of Rehabilitation Research and Clinical Translation*. **Chapter Five** describes the protocol of the randomised controlled trial being conducted to assess the effectiveness of the TEXT4myBACK intervention compared to control on function of people with non-specific, non-persistent low back pain. It is presented as published in the *Physical Therapy & Rehabilitation Journal*. **Chapter Six** is a qualitative assessment of the TEXT4myBACK intervention and is presented in the format required by *Pain Medicine* journal, where it is currently under review. **Chapter Seven** is a cross-sectional analysis of baseline data from 212 participants of the TEXT4myBACK randomised controlled trial that estimated the smallest worthwhile change needed for a self-management

intervention consisting of text messages to be considered worthwhile. It is presented in the format required by the *Patient Education and Counseling*, where it is currently under review.

**Chapter Eight** is a systematic review and meta-analysis summarising the effects of family-based interventions on pain intensity and disability of people with musculoskeletal pain compared with individual-focused interventions and usual care. The review is presented as published in the *Clinical Journal of Pain* journal.

**Chapter Nine** explores the feasibility of a health coaching intervention with or without the support of exercise buddies versus usual discharge care for people with low back pain recently discharged from treatment as well as recruitment and data collection approaches through a pilot and feasibility randomised controlled trial. It is presented in the format required by the journal of *Pilot and Feasibility Studies*.

**Chapter Ten** summarises the key findings of the thesis, and discusses the limitations and implications for future research and clinical practice.

# ABSTRACT

The overall aim of the thesis was to investigate innovative, scalable and affordable interventions for the management of low back pain. **Chapter Two** shows an increasing online public interest in musculoskeletal conditions from 2008, with low back and neck pain being the ones with the highest annual increase (nearly 7%). **Chapter Three** reviews the use of text messages in the management of musculoskeletal pain. Text messages improved medication adherence compared to usual care and pain, function, quality of life and treatment adherence when added to comprehensive interventions and compared to control. **Chapter Four** describes the development process of the TEXT4myBACK intervention, which is a self-management text message intervention for people with low back pain. **Chapter Five** presents the protocol of the randomised controlled trial assessing the effect of the TEXT4myBACK intervention on function of people with low back pain compared to control. **Chapter Six** explores participants' experience with the TEXT4myBACK intervention, including its acceptance, usefulness and behaviour-change ability. **Chapter Seven** proposes a methodology to aid the interpretation of the clinical significance of the TEXT4myBACK trial's findings. It shows that people need to improve at least 9.4 points on a 0-30 function scale to consider self-management worthwhile. As pain management is complex and influenced by several factors including families, **Chapter Eight** reviews the effects of family-based interventions on health outcomes of people with musculoskeletal pain. It found that family-based interventions improve pain and disability compared to individual-focused interventions and pain compared to usual care. **Chapter Nine** explores the feasibility of a telephone health coaching intervention with or without an exercise buddy for people with low back pain compared to usual care and data collection approaches through a pilot and feasibility study. The thesis findings may be used to 1) guide the development of educational and text message interventions for musculoskeletal pain; 2) aid the interpretation of the clinical relevance of the TEXT4myBACK intervention's effects through a responder analysis; 3) optimise the approaches of future randomised controlled trials including family members or exercise buddies for low back pain.

# CHAPTER ONE

## Introduction

## 1.1 Musculoskeletal conditions

According to the World Health Organisation, musculoskeletal conditions 'comprise more than 150 conditions that affect the locomotor system of individuals'. [1] Musculoskeletal conditions may affect the spine (e.g., neck pain, lower back pain), peripheral joints (e.g., osteoarthritis, rheumatoid arthritis, gout), bones (e.g., fractures, osteoporosis), muscles (e.g., sarcopenia), or various body structures simultaneously (e.g., widespread pain disorders). [1] These conditions are vastly prevalent and are estimated to affect between 20% and 30% of the global population. [2-5]

The Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) is a tool that provides worldwide comprehensive epidemiological data and reports on the incidence, prevalence, mortality and burden of an extensive list of diseases and injuries, including musculoskeletal conditions. [2] The GBD report concerns a systematic scientific assessment of epidemiological data from multiple sources (either published, publicly available or contributed data, such as censuses, health service use, disease registries and notifications, among others). [2] The most recent GBD report estimated that the prevalence rate of musculoskeletal conditions per 100,000 population peaks at 50 to 54 years of age when the prevalence rate is approximately 36,651 (95% Uncertainty Interval [UI] 32,000 to 41,000) among men and 45,475 (95% UI 40,000 to 50,300) among women. [3] The difference in the prevalence rate of musculoskeletal conditions between sexes became significant in the age group of 60 to 64 years when it was approximately 31,490 (95% UI 28,000 to 35,160) among men and 39,600 (95% UI 35,560 to 43,800) among women. [3] The difference between the musculoskeletal conditions prevalence rate among men and women increases with age. [3] For example, between 80 and 84 years of age, the prevalence rate of musculoskeletal conditions was approximately 8,960 (95% UI 8,140 to 9,770) among men and 14,120 (95% UI 12,900 to 15,200) among women. [3] The higher prevalence rate of musculoskeletal conditions among women may be related to their body anatomy (e.g., shorter height, lower muscle mass, lower bone mineral density) and better perception of their physical health. [4]

Musculoskeletal conditions may lead to pain and impairments in physical function, [1] ability to work, [5-7] quality of life [8,9] and social relationships. [9,10] Therefore, they cause a great burden to both individuals and society and are leading causes of disability

worldwide measured as years lived with disability (YLD). [11-13] According to the most recent GBD report (2019), low back pain is the number one cause of YLD, whilst neck pain and osteoarthritis are the 7th and 15th causes, respectively. [11] The 2019 GBD report also estimated that musculoskeletal conditions (i.e., gout, low back pain, neck pain, osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions) accounted for approximately 2.9 billion YLD worldwide in 2017. [11] Furthermore, musculoskeletal conditions reduce people's capacity to engage in physical activity, [14,15] contribute to obesity, [7,16] depression, [17,18] and cardiovascular diseases [19,20] and can lead to death. [21,22] Due to the growing population, the number of people affected by these health problems as well as their burden are expected to soar. [12,23]

Musculoskeletal conditions are the main reason for pursuing care at rehabilitation services worldwide. [12] They are also common reasons for seeking primary health care. [24-26] For instance, people with musculoskeletal conditions represented 21% of patients who sought care from general practitioners in the United Kingdom in 2018. [24] Musculoskeletal complaints represented 14% of primary health care consultations in Israel in 2014 [25] and were among the top ten reasons for Emergency Department presentations in Australia between 2017 and 2018. [26]

The high prevalence of health care use will consequently contribute to high costs. [27] In fact, musculoskeletal conditions were the health conditions with the highest health care expenditure in the United States amid the 154 health conditions assessed in 2016 and were responsible for approximately 264.3 billion American dollars spent on health care. [27] Similarly, the Australian Burden of Disease Study evidenced that musculoskeletal conditions were the disease group with the highest direct health care expenditure by the public sector between 2018 and 2019, accounting for 14 billion Australian dollars spent. [28] Musculoskeletal conditions are also associated with a long-term increase in primary, secondary and tertiary health care use, [29] which aggravates the impact on health care services.

Besides the enormous health care impact, musculoskeletal conditions impose a massive indirect economic burden because of work absenteeism and impaired efficiency. In Europe, musculoskeletal conditions are the leading cause of work absenteeism and loss of productivity. [30] The loss of productivity due to musculoskeletal conditions among

adults of working age has been estimated to represent around 2% of the European gross domestic product. [30] In the United Kingdom, musculoskeletal conditions represent more than 50% of work-related illnesses and around 12% of the reasons for sick leave. [31] A similar scenario is found in countries with lower sociodemographic index (SDI). In Chile, the economic burden of loss of productivity due to musculoskeletal conditions was over 19 million American dollars between 2014 and 2015, although these figures were likely underestimated due to the inclusion of data from the private health care sector only and the assumption of its equivalence with the public health care sector data. [32] Musculoskeletal conditions were the main reason and accounted for 19% of the sick leave benefits granted by the Brazilian government in 2014. [33]

Besides being a significant cause of sick leave, musculoskeletal conditions can also lead to early retirement and negatively impact personal savings and the government budget. A cross-sectional, population-based study from Portugal including 1286 adults between 50 and 64 years of age showed that people with knee osteoarthritis have greater chances of early retirement compared to those without (odds ratio [OR] 2.25, 95% confidence interval [CI] 1.42 to 3.59). [34] The annual cost of early retirement has been estimated to be 656 million Euros when considering the costs for patients, employers and the government. [34] Australians who leave the labour force due to arthritis have on average one-fifth of the income of those who continue in the workforce [35] and early retirement due to arthritis can lead to a loss of 9.4 billion Australian dollars in gross domestic product. [36]

## 1.2 Low back pain

Low back pain is a symptom rather than a disease that is usually defined as pain between the lower rib margins and the buttocks. [6,37] Low back pain can be classified as specific or non-specific, the latter being more common and estimated to represent 90% or more of the cases. [37,38] Specific low back pain refers to when the pain is arising from specific spinal disorders, such as radiculopathy (low back pain associated with leg pain in a nerve root distribution associated with sensory loss, weakness or reduced reflex), spinal stenosis (low back pain and bilateral buttock, thigh or leg pain associated with claudication) or disorders beyond the spine (such as leaking aortic aneurysm). [37] Low back pain can also result from serious spinal pathologies, including vertebral fractures, malignancy and infections. [37] Non-specific low back pain refers to when no pathoanatomical source of

pain can be defined, [37] although several innervated structures in the lumbar region could be causing pain, such as intervertebral discs, facet joints, and vertebral endplates. [6] Low back pain can also be classified according to the duration of the pain episode, being those episodes of less than six weeks duration classified as acute and those with more than 12 weeks duration as chronic or persistent. [39]

The occurrence of low back pain has been associated with various risk factors. Occupational factors (e.g., lifting, awkward postures), psychological factors (e.g., fatigue, distraction during a task) or a combination of both have been evidenced as risk factors for the occurrence of a new episode of low back pain in prospective studies. [40] A case cross-over study with 999 participants with a new episode of low back pain has confirmed that both occupational and psychological factors are associated with an increased risk of developing a new episode of low back pain, such as carrying heavy loads (OR 5.0, 95%CI 3.3 to 7.4), assuming awkward postures (OR 8.0, 95%CI 5.5 to 11.8), being tired (OR 3.7, 95%CI 2.2 to 6.3) and being distracted during a task (OR 25.0, 95%CI 3.4 to 184.5). [41] A previous cross-sectional study questioning clinicians to nominate exposure factors that were most likely to trigger a new episode of low back pain found similar results and evidenced that clinicians could accurately identify risk factors for a new episode. [42] Clinicians also nominated occupational and psychological risk factors, along with individual factors (such as physical inactivity and obesity) and genetic factors. [42]

A meta-analysis of 33 cohort studies including data on over 11,000 people evidenced that most people experiencing a non-persistent episode of low back pain (i.e., less than 12 weeks duration) have a favourable prognosis. [43] Most people will recover from the episode of pain within six weeks and report very low pain intensity after one year. [43] Nonetheless, one-third of those who recover from the episode report experiencing a new recurrent pain within a year. [44] Those who report higher levels of pain, [45] presence of leg pain, [45] depressive symptoms, [46] or pain catastrophizing (i.e., an exaggerated negative reaction to a painful experience) [47] are at greater risks of developing persistent low back pain.

### 1.2.1 Prevalence and burden

Low back pain is an extremely common condition and between 40% and 84% of people are expected to experience low back pain in their lifetime. [48,49] It might occur at any time

across the lifespan, from childhood to older age, despite being more common at the later stages of life. [50] An analysis of the GBD data has evidenced an increased point prevalence of low back pain with the increasing age, ranging from less than 5% in adolescents and peaking at approximately 20% in people 80 to 90 years old. [50] However, there is high variability in the reported prevalence of low back pain across different studies possibly due to varying methodologies and population characteristics. For instance, a previous systematic review and meta-analysis including 59 longitudinal or cross-sectional studies of moderate methodological quality estimated that the point prevalence of low back pain in children and/or adolescents (age range: 9 to 18 years) is approximately 12%. [51] Likewise, a systematic review including 35 cross-sectional and/or longitudinal studies with people older than 60 years of age estimated that the prevalence of low back pain in the older population may vary from 21% to 75%. [52] Due to the high prevalence of low back pain added to its peak in older age, the number of people suffering from this condition is expected to rise with the growing and aging global population. [6,53]

Besides being a common condition, low back pain is also extremely burdensome. Low back pain has been the leading cause of YLD worldwide since 1990. [2] Data from the GBD study estimated that low back pain was responsible for 63.7 million YLD worldwide in 2017. [11] Despite low back pain being the leading cause of YLD in most countries around the globe, its burden is greater in high-income countries (such as the United States of America, Canada and most Western European countries) than in middle- and low-income countries. [11,50] For instance, the age-standardised YLD rate per 100,000 population in Western Europe was estimated to be 1,356 whilst it was estimated to be 688 in Southern Sub-Saharan Africa in 2017. [50] However, these estimates should be interpreted with caution since approximately 61% of the prevalence data included in the GBD analysis are from high-income countries. [54]

Due to both the high prevalence and disability caused by low back pain, the condition also poses a great financial burden to both patients and society. It is the sixth most common reason that Australians [55] and South Africans [56] present to primary care. Low back pain also represents 3% of all Emergency Department presentations in Canada [57] and the United States [58] and approximately 1% in Australia. [26,59] Highly costly care is provided to patients seeking treatment for their low back pain, leading to enormous health care costs. In the United States, low back and neck pain together represented the

conditions with the highest health care expenditure in 2016, which was estimated at around 134.5 billion dollars. [27] For comparison, the cost of diabetes was approximately 111.2 billion dollars whilst ischemic heart disease accounted for 89.3 billion dollars. [27] Astonishingly, this indicates that spinal conditions were estimated to cost 21% and 51% more than diabetes and heart disease, respectively. [27] Whilst low back pain represents a smaller proportion of the total health care expenditure, the condition also causes a great financial burden in other countries, such as Australia and Brazil. In Australia, low back pain-related health care costs were approximately 2.8 billion Australian dollars and represented 2.4% of the total national health system expenditure between 2015 and 2016. [60] In Brazil, the condition was estimated to cost more than 70.5 million American dollars from the public health care sector only in the same year. [61]

Despite the increasing prevalence of low back pain with older age, low back pain-related disability peaks at an earlier age (between 45 to 54 years), impacting those of working age the most. [11] Consequently, the condition also causes enormous indirect costs, which are associated with lost or reduced productivity caused by the condition. [62] Data from high-income countries evidence that indirect health care costs represent the vast majority of the low back pain-related costs. [62] To illustrate, a recent study with data from national and regional registries in Sweden estimated that sick leave and early retirement due to low back pain accounted for 67% of the total low back pain-related costs, whilst direct health care costs accounted only for 33%. [63] A similar situation might be found in mid-income countries. Brazilian data evidenced that the loss of productivity due to low back pain accounted for 85% of the total costs related to the condition in the country between 2012 and 2016, representing around 1.8 billion American dollars. [61]

The work-related disability caused by low back pain causes a great financial burden to individuals as well. Low back pain, along with other spinal conditions, is the number one reason for early retirement in Australia, followed by arthritis and mental disorders. [64] Indeed, scientific evidence shows that spinal conditions are driving more people out of the workforce than cardiovascular diseases, diabetes, cancer and asthma combined. [65] Early retirement due to spinal conditions negatively impacts personal savings. It is estimated that Australians who retire early due to back problems have a median accumulated wealth varying from 3,708 to 20,064 Australian dollars, approximately, at the age of 65 years. [66] On the other hand, Australians who continue working full time and

do not have any health condition have a median accumulated wealth varying from 214,432 to 339,121 Australian dollars at the same age. [66] Although these results were based on modelling data from 671 Australians and should be interpreted with caution, they were estimated to represent 474,000 Australians aged between 45 and 64 years and highlight the significant impact of disabling spinal conditions on personal finance.

Low back pain also negatively impairs other aspects of life, such as physical activity participation, familial relationships, and daily activities, leading to decreased quality of life. [67-69] A systematic review published in 2014 including 42 qualitative studies identified that people with low back pain report a high impact of pain on domestic chores (such as shopping, gardening, housework), recreational activities (i.e., activities people enjoyed doing are impacted or no longer possible to do) and ability to plan ahead, impairing decision-making processes. [67] The review also showed that the relationships with the closest ones are impacted by low back pain, leading to issues in social and family interactions, impaired sexual relations and feelings of isolation. [67] People with low back pain also feel that they are no longer trusted by their family members, friends, work colleagues and health care providers, leading to the delegitimisation of their pain and inability to meet expectations. [67]

### 1.2.2 Management of low back pain

Despite the low prevalence of low back pain due to serious pathologies (e.g., cancer, infection, or fracture), clinical practice guidelines recommend health care practitioners to initially assess and identify whether symptoms indicate the presence of these pathologies. [70,71] The screening via various red flags has been endorsed, despite the limited evidence on the accuracy of recommended red flags. [72,73] For example, asking for recent major trauma and/or use of steroids or immunosuppressors to screen for a spinal fracture, and a history of cancer and/or unintended weight loss to screen for malignancy has been recommended. [72] If there is a suspicion of serious spinal pathology, the use of imaging exams is endorsed. [39,70,71]

When low back pain is believed to be non-specific (i.e., when no pathoanatomical source of pain can be defined), [37] the use of imaging is discouraged, [39,70] as there are no clear associations between radiological findings and clinical symptoms, [74] matching treatments, [75] prognosis [76] or risk of future episodes of low back pain. [77] In fact, recent

evidence has shown that people who are prescribed imaging exams present a worse prognosis than those who are not. [78] A recent systematic review including seven prospective and retrospective observational studies evidenced that people with acute low back pain without suspicion of a serious spinal pathology who undergo magnetic resonance imaging (MRI) have a higher number of days of continued paid indemnity (ranging from nine to 14 extra days) than those who do not. [78] Imaging exams have also been associated with increased health care utilisation and costs. [79] For example, a previous analysis of propensity-matched groups of 203 patients undergoing imaging exams and 203 patients undergoing physiotherapy as first-line care has evidenced that those who received imaging exams had higher odds of undergoing future surgery (OR 5.47, 95%CI 2.22 to 13.49) and spinal injections (OR 3.67, 95%CI 2.20 to 6.), and visiting spinal surgeons (OR 4.01, 95%CI 2.26 to 7.11), spinal specialists (OR 4.58, 95%CI 2.95 to 7.11) and Emergency Departments (OR 3.81, 95%CI 1.05 to 13.90). [80] A previous randomised controlled trial including 421 patients with low back pain compared usual care with and without X-rays and found that those who received X-rays had a higher health-care expenditure of £93. [81] Nonetheless, the aforementioned studies are of limited methodological quality and future high-quality studies should be conducted to support these findings.

Despite the evidence-based recommendations, clinicians from high-, mid- and low-income countries continue to prescribe imaging exams to their patients. [82-84] In Sweden, 40% of people with low back pain presenting to general practitioners are prescribed imaging exams, [82] whilst up to 50% of people with low back pain are prescribed an X-ray in the United States. [83] A cross-sectional study conducted in Nepal also suggests a high prevalence of imaging exams being prescribed to those seeking care for low back pain, with over 720 MRIs being prescribed over three months in 2012. [84] A cross-sectional study conducted in Cameroon assessing the reasons and body parts undergoing computed tomography exams evidenced that the lumbar spine was the second most commonly scanned body part, with pain in the lower back with or without concurrent leg pain being the most common reason for undergoing the exam (without a history of trauma or other serious disease suspicions). [85] Besides health care professionals' beliefs regarding the importance of imaging tests to identify the location of pain, [86] people with non-specific low back pain also desire imaging exams for diagnostic purposes and legitimation of their

pain. [86,87] Therefore, multiple interventions have been developed to educate clinicians and patients to decrease the prescription of imaging, and the results have been positive. [88-91]

Evidence shows that people with low back pain are frequently prescribed pharmaceutical treatment, such as over-the-counter analgesics (e.g., paracetamol), non-steroidal inflammatory drugs, muscle relaxants, or opioids. [92] A recent systematic review published in 2020, which aimed to describe usual care for low back pain, summarised the findings from 26 prospective or retrospective studies which included data on approximately 195,000 patients from seven different countries. [92] The review identified that between 6% and 18% of patients seeking care at family practices for their low back pain are prescribed paracetamol. [92] Additionally, approximately 36% of them are prescribed non-steroid anti-inflammatory drugs, between 1% and 8% are prescribed muscle relaxants and between 5% and 31% are prescribed opioids. [92] Nonetheless, clinical practice guidelines and scientific evidence recommend against the use of these medications due to their lack of effectiveness and possible harms. [39,70,71] There is high-quality evidence that paracetamol is no better than a placebo to improve pain and function of patients and might lead to adverse events, like liver impairments. [93,94] The consumption of non-steroid anti-inflammatory drugs and muscle relaxants leads to small and non-clinically relevant reductions in pain intensity (approximately 7 points on a 0-100 scale) and disability (between 3 and 8 points on a 0-100 scale) when compared to placebo. [95-98] Similarly, opioids have a small and non-clinically relevant effect on both pain and function of people with low back pain and their consumption is associated with adverse events, such as headache, constipation, and vomiting. [99]

When the initial treatment has failed, many patients are prescribed more invasive procedures, such as spinal injections and surgery. However, clinical guidelines do not recommend spinal injections due to their lack of effectiveness and spinal surgeries due to insufficient evidence of effects on the treatment of non-specific low back pain. [39,71] An abridged Cochrane review including 25 randomised clinical trials with a total of 2,470 patients with low back pain has found very low to moderate quality evidence that epidural corticosteroid injections have small effects on disability (mean difference [MD] -4.18 on a 0-100 scale, 95%CI -6.04 to -2.17), leg pain (MD -4.93 points on a 0-100 scale, 95%CI -8.77 to -1.09) and overall pain (MD -9.35 points on a 0-100 scale, 95%CI -14.05 to -4.65) only in the short-term when compared to placebo. [100] Similarly, the available

evidence does not support the benefit of spinal fusion compared to conservative treatment for low back pain. [101] A meta-analysis including three studies and 399 patients comparing spinal fusion with exercise and cognitive behavioural therapy for the treatment of chronic low back pain found no between-group difference in disability (MD 1.17 on a 0-100 scale, 95%CI -5.73 to 2.31). [102] Nonetheless, the rate of these procedures has been increasing globally. To illustrate, a retrospective analysis of American Medicare beneficiaries evidenced an annual increase in epidural spinal injections from a total number of 839,474 annual injections (or 2,118 injections per 100,000 Medicare enrollees) in the year 2000 to a total of 2,255,668 injections (or 4,216 injections per 100,000 Medicare enrollees) in 2014, representing an increase of 99% in the number of injections per 100,000 Medicare enrollees within 14 years. [103] There has also been a high increase in the cases of spinal fusion in the United States, with numbers ranging from a total number of 122,679 surgical procedures (or 60.4 per 100,000 population) annually in 2004 to 199,140 (or 79.8 per 100,000) procedures in 2015, representing an increase of 62%. [104] The number and costs of spinal surgeries have also increased exponentially in other countries. In Brazil, the number of spinal surgical procedures has increased by an astonishing 226%, whilst their costs have increased by 540% considering only public health care system data between 1995 to 2014. [105] Regardless of scientific recommendations against the use of imaging, medication, injections and surgeries for low back pain, many people with this condition still receive low-value care that is not relieving their symptoms and may even be causing them harm.

Scientific evidence and clinical practice guidelines endorse the provision of education and self-management strategies to people with low back pain. [39,71] Current guidelines recommend clinicians to inform and educate their patients about the nature of low back pain and its prognosis (e.g., reassurance of back pain not being a serious illness despite the intensity and duration of the symptoms, and the favourable prognosis), provide them with advice (e.g., to avoid bed rest, stay active and continue to work), and empower them to self-manage their condition. [39,71] However, clinicians often fail to do so. Cross-sectional and longitudinal studies from Australia have shown that only around 20% of patients seeking care from general practitioners received education and advice from 290,000 encounters analysed [106] and around 60% of 203 physiotherapists surveyed reported providing advice to patients to remain active. [107] An analysis of Canadian data has shown that only around 3% of a random sample of 325 patients with low back pain

seeking care at one Emergency Department received documented advice to remain active, whilst 10% were advised to rest. [108] Different health care professionals have described barriers to provide education, advice and self-management strategies to patients with low back pain. General practitioners have reported multiple barriers to provide advice to patients to remain active, including a lack of knowledge on how, why, and when patients should exercise, as well as what activity to recommend based on individuals' circumstances, conflict with and lack of skills to negotiate with patients' beliefs that bed rest was better than keeping active, as well as lack of time. [109] Physiotherapists have also reported barriers to providing self-management strategies to patients, including how to integrate self-management with patients' expectations and their treatment and the lack of tools for patients to use to empower their self-management. [110] Thus, it is clear that new strategies to educate and change patients' beliefs about low back pain and its prognosis, support and motivate them to become more physically active and empower them to self-manage their condition are urgently needed.

Exercise is also endorsed as first-line care for patients with persistent non-specific low back pain. [39,111] Exercise has a positive effect on both pain and function of people with low back pain. [112,113] The most recent network meta-analysis including 217 randomised controlled trials with almost 21,000 participants has evidenced that Pilates, McKenzie therapy and functional restoration are the most effective exercise modalities to improve pain and disability of people with chronic low back pain. [112] Nonetheless, since most exercise modalities investigated (e.g., aerobic exercise, Yoga, Tai-Chi) were more effective than minimal treatment, patients should be encouraged to find an enjoyable exercise and adhere to it, which will improve not only their low back pain symptoms but also their general health. [112]

However, people with low back pain often face multiple barriers when trying to become and keep active. Although pain seems to be the greatest barrier preventing people with low back pain from being active, various other factors do also impose challenges, such as other comorbidities, lack of motivation and will to exercise, kinesiophobia (i.e., fear of movement due to concerns of vulnerability to pain from an injury or reinjury) [114] as well as false beliefs that physical activity is not beneficial for their recovery. [115] Socio-environmental factors have also been reported as barriers to becoming active, like work (e.g., dissatisfaction with work or exhaustion after work), lack of time and health care

professionals' advice to rest. [115] Familial environment may be a barrier as well since many relatives recommend their loved ones in pain to rest and act in a paternalistic and protective way (e.g., telling people in pain not to do or go easy with an activity otherwise the low back pain will get worse or doing activities for them) leading those with pain into a vicious cycle of inactivity. [115]

Given that multiple factors influence the physical activity participation of people with low back pain, various strategies might be needed to help them to become active, ranging from education on the importance of exercise to encouragement from health care professionals, along with social and family support. People with low back pain value social support to exercise, coming either from an exercise group, a work colleague or a family member. [115] Other strategies, such as digital interventions, could also provide additional assistance. [115]

## 1.3 eHealth interventions

### 1.3.1 The use of the Internet as a source of health information

The internet has been increasingly used by the public to search for information about innumerous topics, including health conditions. [116] Data from the International Telecommunication Union and the World Telecommunication Database evidence an exponential increase in the use of the Internet in high, mid and low-income countries. [117] In 2000, 30.5%, 1.5%, and 0.1% of the population of high, mid, and low-income countries used the Internet, respectively. These proportions rose to 85.8%, 40.5% and 14% by 2017. [117]

Besides the increase in Internet use by the public, people have also been progressively using the Internet as a source of health information. [116] Data from the United Kingdom and the European Union demonstrate the change in online health information-seeking behaviour. In 2007, only 18% of the population of the United Kingdom sought health information online, whilst in 2020 the proportion escalated to 60%. [116] Similarly, data from the European Union show that one in two Europeans sought health information online in 2020, representing a 34% increase since 2010. [118]

People might conduct online searches on different web search engines, such as *Google*, *Yahoo*, *Bing*, and *Ask*, among others. However, *Google* is by far the most frequently utilised search engine, being used in 70% of the searches conducted on desktops or laptops and in 94% of the ones conducted on mobiles. [119] *Google Trends* is a web search data analytic tool that provides information on online searches conducted on *Google* search engine since 2004. [120] *Google Trends* provides archived and real-time data on any search term, time and global region conducted on *Google* search engine. [120,121] The data are free and available worldwide. [120] For that reason, *Google Trends* has been increasingly used by health researchers for various research purposes, ranging from monitoring disease outbreaks and pandemics (such as the coronavirus disease-19 [COVID-19] pandemic), [122] to assessing the impact of a celebrity's death from a health condition, [123] public health media campaigns, [124] and policy changes [125] on the online public interest.

Studies conducted with *Google Trends* data have also illustrated this increase in online interest in numerous health conditions. [126-130] Previous studies conducted on breast cancer and cardiovascular diseases have shown that the online interest in these conditions has increased. [129,130] Within the musculoskeletal research field, some previous studies have been conducted, which also indicated an increase in the online interest in musculoskeletal conditions within the past years. [126-128] For example, Ciaffi et al. evidenced an increase in the online interest for three search terms related to low back pain in Italy between 2010 and 2020. [126] Jellison et al. showed an increase in the global online interest in osteoarthritis from 2014 onwards, [127] whilst Kardes found an increase in the interest in gout between 2008 and 2018 in five English-speaking countries. [128] Moreover, previous studies have also investigated the seasonality pattern of the online interest in musculoskeletal conditions, such as gout, knee injuries and low back pain. [126,128,131] They identified that the peak in online interest in gout occurred in late spring to early summer, whilst the interest in knee injuries peaked in spring and low back pain peaked in winter. [126,128,131] Nonetheless, there was a lack of information regarding the worldwide online interest for the most disabling musculoskeletal conditions and the information related to the conditions that people were looking for when conducting the online searches. Therefore, **Chapter Two** of the thesis presents a study conducted with *Google Trends* data investigating the worldwide online public interest for the most disabling musculoskeletal conditions, which are gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis. The study investigated changes in the online interest for the five

conditions over time, compared changes in the interest for each musculoskeletal condition accross countries with different SDIs, and assessed the queries and topics searched for (e.g., treatment options, causes, symptoms, diagnosis).

Despite being used by many people, health-related information available online might not be reliable and present low credibility according to the Journal of the American Medical Association benchmark (which addresses the currency of information, the declaration of authorship, availability of reference list, and conflict of interest/ funding/ sponsorship declaration). [132-134] A 2022 cross-sectional study systematically appraised the quality of 127 websites about pulmonary arterial hypertension.[134] It evidenced that the websites did not provide credible information according to the JAMA benchmark and did not meet the readability criteria of the American Medical Association (which is to present fifth- to sixth-grade readability levels). [134] Similarly, a cross-sectional assessment of 26 breast cancer websites evidenced that only seven met all JAMA credibility benchmarks. [133]

Unfortunately, previous studies conducted on low back pain have presented comparable findings. A recent systematic review has assessed 79 websites (from government and nongovernmental organisations, hospitals, professional societies, universities and consumer organisations) from English-speaking countries providing information on low back pain and identified on *Google*. [132] The study found that only 43% of the websites' treatment recommendations were accurate according to clinical practice guidelines (i.e., the 2016 National Institute for Health and Care Excellence and the 2017 American Colleges of Physicians guidelines). [132] Most websites were also not credible following the JAMA benchmarks, as only 54% disclosed the date of creation or update, 31% were updated after the publication of the latest National Institute for Health and Care Excellence guidelines, 22% declared authorship and only 26% disclosed a reference list. [132] Moreover, a recent cross-sectional study assessing the 200 most-watched videos on *YouTube* using the term 'low back pain' reported that only 30% of the videos presented at least one diagnostic recommendation endorsed by clinical guidelines and 50% provided a treatment recommendation. [135] Besides the lack of accurate, high-quality online information on health conditions and low back pain, the information available online is not tailored to individual expectations and necessities. Therefore, educational interventions that are evidence-based, and focused on patients' needs might be needed.

### 1.3.2 Text message interventions

eHealth interventions might represent a good opportunity to provide evidence-based educational interventions. eHealth interventions have been described in over 50 different ways. [136] However, following the World Health Organisation, eHealth means "the use of information and technologies for health". [137] Multiple modalities of eHealth interventions are available, such as teleconsultations, video consultations, mobile apps, and text messages. Text messages are messages with up to 160 characters that can be sent to mobile phones via other mobile phones or a computer. [138] They are still the most widely used and least costly function of mobile phones. [138] Text messages represent a promising eHealth intervention modality since they are scalable and affordable. [138-140] They also have a low development cost and do not depend on Internet connection, which facilitates the dissemination of the intervention to the most disadvantaged populations. [138] Text messages are simple and delivered to individuals without any personal effort. [138] These characteristics represent advantages over alternative digital interventions, such as mobile apps, which require active participation from users, who need to download the apps, open them, actively engage with them (e.g., to provide some information), and may end up turning some functions off, as notifications and reminders. [138]

For these reasons, text messages have been vastly investigated as a strategy to provide educational and self-management interventions to help people to improve healthy behaviours as well as manage numerous chronic health conditions. [138-140] Text messages represent effective strategies to help people to stop smoking, [141] lose and maintain weight loss, [142,143] and increase the number of daily steps. [144] Systematic reviews have evidenced the efficacy of text messages to support self-management of chronic health conditions, such as diabetes (leading to improvements in glycemic management), [145] and cardiovascular diseases (improving medication adherence and reducing systolic blood pressure). [146,147] Text messages can act by reminding people to take their medications and empowering them to better manage their conditions. [140,147-149] Text messages can also be used to provide education, motivation and behaviour change techniques, which support people to make healthier choices and adopt healthier behaviour, leading to better health outcomes.[143,150,151]

Text messages can support behaviour change through multiple techniques, such as the Information-Motivation-Behaviour Skills Theoretical Model, [152] Social-Cognitive

Theory, [153] and Classical Conditioning theoretical framework. [154] The Information-Motivation-Behaviour Skills Theoretical Model states that people are more likely to start and maintain a healthy behaviour when they are well-informed, motivated, confident and skilled to act. [152] The Social-Cognitive Theory proposes that a combination of cognitive, personal and environmental factors influence human behaviour. [153] It means that the behaviour is influenced by an interaction between thought, affect, self-perception and aims. [155] Meanwhile, the Classical Conditioning theoretical framework suggests that people respond to and learn with repeated stimuli rather than one individual stimulus. [154] All these factors may be embedded into text message interventions, which may inform, motivate and empower people to change or better manage their condition. [156] Text message interventions also provide frequent stimuli and information that may lead to an overall improvement in healthy behaviour. [156] All these theoretical models support and explain how text messages can help people to improve their health or better manage their chronic conditions.

Despite the large number of studies conducted on some chronic conditions (e.g. hypertension), [147] there is still limited evidence on the benefits of text messages for other health conditions, like cancer-supportive care [157] and chronic kidney disease. [158] The effects of text message interventions in the management of musculoskeletal conditions have also been less studied in comparison with other chronic conditions. **Chapter Three** of this thesis presents a systematic review that investigated the effects of text message interventions on the management of musculoskeletal pain. Four databases were searched, and 9,604 unique titles and abstracts were screened. However, only 11 studies met the inclusion criteria and were included in the review. Heterogeneity among the studies' designs and clinical characteristics of studies' participants was found, preventing a meta-analysis of the data. Surprisingly, none of the included studies was conducted with people with low back pain, which is the most prevalent and disabling musculoskeletal condition. [11]

Text messages represent a promising intervention to provide education and self-management strategies (which are recommended as first-line care) [39] to those suffering from low back pain. They also represent a scalable and affordable solution to the high prevalence and costs associated with the condition. Given the lack of studies in the field and the potential benefits of a text message intervention for people with low back pain,

the development of an evidence-based text message intervention is highly needed. Evidence suggests that text message interventions should be developed through an iterative process, involving consumers, clinicians and researchers to increase the likelihood of clinical effectiveness. [159-162] Researchers have recommended frameworks to be followed when developing text message interventions, which include the following steps: i) consumers and their health behaviour or needs should be understood; ii) the goal of the text message program should be established as well as its framework (i.e., the timing and frequency of the messages, the nature and language/ style of communication, the duration as well as the degree of tailoring of the program) and then the text message library should be developed; iii) the text message intervention should be revised by experts in the field (i.e., clinicians and/or researchers) as well as consumers before being pretested; iv) the text message program should be amended according to the results of the previous phase. [159,160] Experts also highlight that the development process of text message interventions should be published to enhance the transparency of the process as well as to inform future research and implementation of the interventions into clinical practice. [160,162]

**Chapter Four** of this thesis describes the iterative co-design development process of TEXT4myBACK – a self-management text message intervention for low back pain. TEXT4myBACK was developed following the recommendations of the Medical Research Council framework for the development of complex interventions, which involves the following steps: i) identifying existing evidence; ii) identifying and developing a theory; iii) modelling process and outcomes. [163] The Medical Research Council framework was followed as it is largely accepted and represents the framework recommended by experts for the development of text message interventions for health described above. [163] The text messages were developed with support from clinicians, researchers, consumer representatives and people with low back pain according to the framework described. 82 text messages were developed to provide information, education, and change behaviour across six domains: exercise, education, mood, sleep, use of care and medication.

Before a new intervention can be implemented into clinical practice, the effectiveness and the cost-effectiveness of the intervention should be investigated. **Chapter Five** presents the protocol of the TEXT4myBACK randomised controlled trial. The exceptional

challenges imposed by the COVID-19 pandemic have delayed the recruitment of participants into the trial, which is still being conducted. The TEXT4myBACK randomised controlled trial aims to assess the effectiveness of a self-management text message intervention to a control intervention (one-off text message with a link to an online information package about low back pain and healthy diet) on the improvement of function in people with non-specific non-persistent low back pain. A parallel economic analysis will also be conducted to investigate if the text message intervention is cost-effective.

*Qualitative assessment of a self-management text message intervention*

Complex interventions are described as interventions that encompass multiple interacting components. [164] Complex interventions might also require several behaviours or actions from their recipients, and may present a certain level of flexibility and tailoring within them. [164] Considering the aforementioned definition, text messages may be considered complex interventions, since they present multiple components, are expected to lead to behaviour change and offer a degree of flexibility within their format (such as the frequency and timing of the messages) and tailoring (such as delivering smoking cessation messages to smokers and not delivering meat-related diet messages to vegetarians; [161] or tailoring sleep and medication-related messages to people who report sleep issues or taking medication). [165] Due to the elaboration and multi-components of complex interventions, solely investigating their efficacy or effectiveness in randomised controlled trials might not be sufficient. [164,166] The Medical Research Council guidance recommends further assessments of complex interventions, including qualitative or mixed methods assessments, to gain insights into the possible causal mechanisms of the effects or lack of effects of the intervention, the contextual factors associated with outcomes, and their possible future implementation. [164,166]

Qualitative methodology is suggested by the Medical Research Council to gain a deeper understanding of patients' experiences in receiving the intervention and unanticipated or complex causal pathways, as well as to aid the quantitative data analysis, providing insights into the findings. [166] Qualitative information can appraise the reason why an intervention was effective or not, why it impacted patients or not, and how and in which context the impact occurred. [167] Qualitative methodology is a scientific method that extends over various disciplines, areas and topics and comprises various approaches. [167]

Examples of qualitative approaches include in-depth interviews, focus groups, observations, and document reviews. [167] In-depth interviews are one-to-one interviews that allow researchers to discuss individual perceptions and experiences in detail with only one participant, whilst focus groups comprise researcher-guided discussions with small groups of participants to gain insights into shared or alternative experiences. [167] In observational approaches, researchers watch participants in a systematic and structured way to learn about their behaviours and interactions in their natural settings. [167] Whereas, during document reviews, researchers analyse written communication to identify and label patterns, and infer the communication background and effects, among others. [167]

Unlike quantitative studies, the data collection and analysis of qualitative studies occur in an iterative way to allow new inquiries when additional data is gathered. [167] Qualitative data may be analysed through diverse strategies, such as the inductive approaches and framework analysis. [168] Through inductive approaches, the research is an iterative process that progresses in response to the information acquired and the continuous analysis. [168] In the framework analysis, the information is managed and analysed in a more systematic way, allowing researchers to study the information in depth whilst maintaining an efficient and clear record of the analytical process and the study findings. [168] Because of that, the framework analysis has become more popular over the past decades and is more frequently used by researchers conducting qualitative assessments. [168]

**Chapter Six** describes a qualitative study conducted with participants randomised to the intervention group of the TEXT4myBACK randomised controlled trial. The initial 42% of participants who received the TEXT4myBACK intervention and completed their participation in the trial were invited to focus group sessions to discuss their experiences in receiving the text messages, the perceived usefulness, impact, delivery, ability to lead to behavioural change and potential for the TEXT4myBACK text message intervention to be scaled up. It was found that the TEXT4myBACK intervention was well-accepted by participants, and provided reminders, reassurance and support to increase physical activity and focus on better health. Nonetheless, there were mixed feelings regarding the effects of the intervention.

*Smallest worthwhile change of a self-management text message intervention*

Randomised controlled trials are conducted to estimate the magnitude of the clinical effects of certain interventions. [169] Nonetheless, even though a difference in outcomes between groups might be statistically significant, it might not be clinically meaningful to patients. [169] Various methods have been described in the literature to define a threshold for clinical significance of treatment effects. [169] Consensus methods, anchor-based approaches and distributional methods are frequently used to determine the clinical importance of interventions' effects, despite having been greatly criticised. [170-172]

Consensus methods define the minimal clinically important difference (MCID) (also commonly referred to as minimal important difference, minimal clinically important improvement, among others), [170] which is the minimal difference in an outcome that is believed to be meaningful to patients, based on an expert panel decision. [170] In the consensus methods, also known as Delphi methods, experts are asked to independently appraise and estimate the MCID of an outcome or intervention on behalf of patients. [170] Changes to the value of the MCID are made by panel members until a consensus is reached. [170] Thus, this method does not include patients' opinions and concerns regarding interventions and the smallest effects needed so that the interventions can be considered worthwhile.

Anchor-based approaches define the MCID by anchoring a change in an outcome to other subjective assessments of improvement, often the global rating scale. [170,172] Global rating scales are frequently used in clinical practice to quantify the improvement or deterioration over time in an outcome of interest. [173] There is some variability in the way they are presented to patients, which might be on an 11-point scale (i.e., ranging from -5 to 5, where -5 means 'much worse', 0 means 'unchanged' and 5 means 'completely recovered'), 3-point Likert scale (i.e., 'worse', 'unchanged', 'better') or 5-point Likert scale (i.e., 'much worse', 'a bit worse', 'unchanged', 'somewhat better', 'much better'). [173] For instance, patients might be asked if they feel 'much worse', 'a bit worse', 'about the same', 'somewhat better', or 'much better' after receiving treatment. To define the MCID, these categorical answers are compared with a health outcome of interest (e.g., pain intensity) and used as a threshold that is believed to be meaningful to patients. [170,172] Nonetheless, the decision of which threshold or anchor value to use (e.g., 'somewhat better' or 'much better') is frequently determined by researchers and does not consider patients' opinions and interventions' characteristics. [170,172]

Distribution methods do not involve either the experts' or the patients' opinions. [170,172] Distribution methods determine the magnitude of change of an outcome that is greater than chance. [170,172] These methods use the clinimetric properties of the outcome, such as the standard error or the minimum detectable change of an outcome measure. [172] An outcome measurement should provide similar results when people answer it multiple times and do not present changes in their clinical characteristics (e.g., test-retest of people who present unchanged pain intensity). [174] Small errors are needed so that researchers and clinicians can distinguish relevant changes from measurement errors. [174] The standard errors and the minimum detectable change can be calculated to estimate the measurement errors and the minimal change needed in an outcome measure so that it can be considered relevant and not a measurement error. [174] Therefore, distribution methods assess the clinimetric properties of outcome measures and do not include patients' perspectives and interventions' characteristics. [172] Thus, they should not be used to define the effects of interventions that are believed to be meaningful to patients. [172]

The three aforementioned methods have been criticised for not including consumers' perspectives and not considering the risks, costs and inconveniences of the intervention in question. [172,175] To establish the clinical significance of an intervention, the smallest worthwhile effect should be defined. [172,175] The smallest worthwhile effect represents 'the smallest beneficial effect of an intervention that justifies the costs, risks, and inconveniences of that intervention'. [172,175] It should be intervention-specific, defined by health care consumers and appraised based on the difference between outcomes of the intervention of interest compared with a control intervention. [172,175] The benefit-harm trade-off and the discrete choice experiments are methods that can be used to estimate the smallest worthwhile effect of interventions. [172] The benefit-harm trade-off method concerns describing evidence-based treatment scenarios to patients, including the expected benefits, costs, harms and inconveniences. [175] Participants are asked if they would like to undergo this treatment or not. [175] Then, when holding everything constant, the benefit/improvement in the outcome measure is changed whilst maintaining the costs, harms and inconveniences constant. [175] This process might be repeated multiple times until participants indicate they would like to undergo the treatment given a certain improvement in the outcome measure would be achieved in comparison to no treatment or other intervention. [175] This improvement represents the smallest worthwhile effect.

[172,175] The discrete-choice experiment is a method commonly used to investigate the value or the preference for different characteristics (attributes) of health care services or interventions without directly asking participants about their preferences. [176] Despite these methods being discussed in the literature for more than ten years, little research has been done to assess the smallest worthwhile effect of interventions for low back pain. [177-179]

Previous research has shown that 50% of people with chronic low back pain would need to see an improvement of approximately 20% in pain and disability total scores to consider physiotherapy intervention (i.e., manual therapy and exercise) to be worthwhile compared with no intervention. [177,178] Similar estimates have been shown for anti-inflammatory pills. [177] People with low back pain would need to see a decrease of at least 30% in pain and an improvement of 20% in disability to consider anti-inflammatory medication to be worthwhile. [177] Interestingly, although self-management intervention is recommended as first-line care to people with low back pain, [39] the smallest worthwhile effect of self-management for low back pain has not yet been investigated. As the smallest worthwhile effects are specific to each health care intervention, they should not be used for other interventions. [172,175] For instance, people might need to see a greater effect of physiotherapy than self-management intervention to consider physiotherapy to be worthwhile. This may be because physiotherapy care requires more time commitment and inconveniences than a self-management intervention.

Unfortunately, there are limited options to interpret the clinical meaning of findings from a randomised controlled trial when the smallest worthwhile effect is unknown. Ideally, a benefit-harm trade-off or discrete-choice methods study should be conducted before running a clinical trial to estimate the hypothetical smallest worthwhile effect of the intervention in question. Yet, these studies require time and resource commitment and a large number of participants. For instance, the aforementioned studies have involved 102 and 160 participants. [177,178] Thus, these options are not always feasible within a randomised trial context. A second option would be to incorporate the smallest worthwhile questionnaire into the baseline survey of a clinical trial. If incorporating the benefit-harm trade-off method question, researchers would initially explain the characteristics of the intervention being investigated and how it is usually administered, including its inconveniences, costs and potential harms. Then, they would describe the

natural history of the condition (including how much improvement is expected without any treatment and the time frame). Finally, they would ask participants how much further improvement (compared with the natural history of the condition) they would need to see after the proposed intervention to consider it worthwhile. If incorporating the discrete-choice methods, researchers would present participants with various scenarios with different treatment characteristics. This could lead to further time requirements and extra burden on participants completing the initial survey. For instance, a previous systematic review of 34 studies using discrete-choice experiments has evidenced that the time required to complete the discrete-choice surveys about health care programs (e.g., insurance plans, economic evaluations) might range from between 10 and 15 minutes up to one to two hours. [180]

An alternative approach could be to add a simpler and shorter question to the baseline survey asking participants about the smallest worthwhile change or improvement they would like to achieve after an intervention to consider its costs, inconveniences and harms to be worthwhile. This question would allow researchers to elicit the smallest worthwhile change in the trial's primary outcome based on participants' perspectives and the characteristics of the intervention being investigated. For example, researchers could provide a brief description of the intervention being investigated (including its characteristics, costs, harms and inconveniences) and ask participants to indicate the smallest improvement they would need to achieve at the trial's primary outcome (e.g., pain or function) at end of the intervention to consider it worthwhile. The result could then be used in a later responder analysis, which allows the estimation of the proportion of participants who achieve a pre-defined improvement on an outcome (which would be the participants' individual smallest worthwhile change scores) at a defined time point (which would be post-intervention). [181] Consequently, researchers could use the smallest worthwhile change score of each participant to compare the differences between groups in the number of participants reaching their own worthwhile score as well as the number needed to treat. This would improve the understanding of the clinical meaning of findings from the randomised controlled trials.

**Chapter Seven** of this thesis is the first study to incorporate the smallest worthwhile question into a randomised controlled trial within the low back pain field. It estimated the smallest worthwhile change in function that people with non-persistent, non-specific low

back pain would need to achieve at the end of a self-management text message intervention consider it worthwhile. It is a cross-sectional analysis of data from 212 participants from the TEXT4myBACK randomised controlled trial. The study presents the estimates of the smallest change in function people would need to reach at the end of that self-management intervention to consider it is worth the costs, inconveniences and harms. Predictors of the smallest worthwhile change, such as participants' demographic characteristics, comorbidities, lifestyle behaviour, and low back pain clinical profile, have also been investigated.

## 1.4 Family-based interventions

Since familial environment can significantly influence health and behaviour, [182-184] researchers have been increasingly interested in the influence of family members and familial dynamics on healthy lifestyle behaviour and management of chronic diseases. Evidence suggests that family members can positively or negatively encourage each other's health and behaviour, depending on how they interact. [185-187] While providing support and autonomy appears to have positive effects on partners' and children's health behaviours, imposing pressure on each other and being overprotective, controlling, critic, hostile or an unhealthy model may have negative effects. [185-187] However, when families interpret an illness as a common problem and provide a supportive environment, healthier behaviours and better disease management are achieved. [188]

The beneficial effects of including family members in interventions to manage chronic conditions have been previously reported. For example, involving family members in educational and self-management diabetes programs lead to better control of glucose markers (HbA1c) compared to usual care in patients with poorly controlled diabetes. [189] Family-based interventions (where patients and family members participated in educational and motivational sessions on diet and physical activity participation) are also effective in reducing body mass index, cholesterol and fast-food consumption of primary health care patients compared to usual care. [190] Furthermore, greater engagement in physical activity has been observed in patients with coronary artery disease [191] and obesity [192] when participating in family-assisted interventions compared to individual-only interventions.

### 1.4.1 Family-based interventions for the management of musculoskeletal pain

Various studies have shown that family members play an important role in the management of musculoskeletal pain. [184,186,193] Burns and colleagues conducted a laboratory experiment with 71 patients with pain and their partners to investigate if the partners' behaviour influenced the pain behaviour and intensity of patients. [186] They found that greater spouse criticism and hostility during a discussion between patients and their partners lead to increased pain behaviour and intensity during daily activities. [186] Scientific evidence also shows that relationship quality, such as cohesion, consensus and satisfaction, impacts pain and disability of adults with low back pain and depression. [194] Similarly, spouses' autonomy, physical activity participation and support positively impact the number of daily steps of people with knee osteoarthritis. [193] Taken together, these findings indicate that involving family members in the treatment of musculoskeletal pain could potentially be beneficial and help patients and family members to better cope with pain and improve healthy behaviours, such as physical activity, which are important in the management of musculoskeletal conditions. [112,195]

The first randomised controlled trial investigating the effects of family-based interventions for people with musculoskeletal pain was conducted by Moore and colleagues in 1985. [196] A total of 43 people with chronic pain were randomised either to a usual care group, patient-focused group (i.e., group sessions of pain education, goal-setting and problem-solving, relaxation techniques, and pain coping skills), or family-based group (i.e., same as a patient-focused group but delivered for patients and spouses). [196] Although no differences between patient-focused and family-based treatment groups were found for any studied outcomes (including pain intensity, spouse-observed pain behaviour, somatization, and spouse communication), both groups showed better improvements than the usual care group. [196] Since then, multiple studies have been performed to assess the effects of involving family members in the treatment of chronic musculoskeletal conditions, including low back pain. [197-200]

Given the promising results of family-based interventions in the management of chronic conditions, systematic reviews have been conducted to appraise and summarise the evidence of family-based interventions in the management of chronic health conditions. [201,202] The reviews found that family-based interventions (i.e., interventions involving spouses or family members of patients) lead to improvements in various health outcomes,

such as depressive and distress symptoms, marital functioning and communication, and pain. [201,202] However, both reviews investigated the effects of family-based interventions on various chronic health conditions (such as cardiovascular diseases, diabetes, cancer and acquired immunodeficiency syndrome [AIDS]), and did not summarise the effects on people with musculoskeletal pain only. [201,202] Due to the increasing number of studies in the field and their diverging findings, a systematic review to appraise and summarise the evidence of family-based interventions in the management of musculoskeletal pain was required.

**Chapter Eight** presents a systematic review and meta-analysis investigating the effects of family-based interventions (i.e., interventions including active participation of patients and family members or a significant other) compared to individual-focused interventions (i.e., interventions with similar characteristics to the family-based intervention but including the patient only) or usual care in the management of musculoskeletal. Eight databases were searched and 1,223 unique records were found. 18 articles representing 15 unique studies were included in the qualitative synthesis and 10 studies were included in the meta-analysis. Family-based interventions led to greater improvements in pain (MD -3.55 on a 0-100 scale, 95%CI -4.03 to -3.06) and disability (MD -1.51 on a 0-100 scale, 95%CI -1.98 to -1.05) than individual-focused interventions at short-term only. Family-based interventions led to greater reductions in pain (MD -6.05 on a 0-100 scale, 95%CI -6.78 to -5.33) compared with usual care only at the short-term as well. No effects were found on other outcomes and time-points in both comparisons.

### 1.4.2 Buddy support to increase physical activity participation of people with low back pain

Interestingly, no study included in the aforementioned systematic review investigated if the support of a family member or an exercise buddy can assist people with low back pain to increase their physical activity levels. [203] Despite the benefits of exercise for low back pain intensity and disability as well as activity limitation and medicine consumption, [112,204] people with low back pain experience significant barriers to becoming active or adhering to an exercise regime. [115] People with low back pain often encounter challenges such as lack of motivation, kinesiophobia and false beliefs (such as the thought that physical activity is not vital for low back pain management), lack of perceived benefits and time as well as family overprotection. [115] On the other hand, the desire to recover,

regular monitoring of physical activity practice, and exercising within a group or with family members have been reported as facilitators of physical activity. [115] Thus, it has been previously suggested that accounting for barriers and emphasising facilitators of physical activity could support exercise practice of people with low back pain. [115]

Health coaching programs are motivating interventions that meet some of the barriers and facilitators of physical activity named by people with low back pain. Although the definition of health coaching may vary, it is classified as a patient-centred intervention that facilitates healthy behaviour change through techniques such as motivational interviewing, education, stage-based motivational counselling, facilitative counselling approaches and goal setting. [205,206] Health coaching programs are affordable, scalable and can be delivered at a low cost. For instance, in Australia, The Get Healthy® program is provided by the New South Wales Ministry of Health for free to anyone who resides in the states of New South Wales or South Australia and would like to self-enrol in the program or is referred by a health care professional. [207] The Get Healthy® program offers up to 10 telephone-based coaching sessions (formerly it was up to 13 sessions) for up to six months and allows people to choose which healthy behaviour they would like to improve (e.g., increase physical activity participation, improve diet, reduce alcohol consumption). [207]

Health coaching has been increasingly investigated over the last years as a strategy to help people to change behaviours, manage their health conditions and achieve healthier lifestyles. [205,206,208,209] It helps to improve the quality of life of patients with diabetes and cardiovascular diseases, [208] physical activity of older people, [210] as well as pain and disability of people with low back pain. [211] A recently published systematic review with meta-analyses summarised the effects of the addition of health coaching to physiotherapy on pain, disability and other health outcomes of people with low back pain compared with physiotherapy alone. [211] Due to the heterogeneity of physical activity assessments, a meta-analysis of the effects of health coaching intervention on physical activity participation could not be conducted. [211] However, meta-analyses were conducted to summarise the effects of the intervention on pain intensity and disability. Pooled data of two randomised controlled trials with 219 participants showed a significant effect of the intervention on pain intensity (MD -7.57 on a 0-100 scale, 95%CI -10.08 to -5.07) at the mid-term. [211] Additionally, results from four studies with 446 participants evidenced improvements in

disability in the short-term (standardised mean difference [SMD] -0.22, 95%CI -0.41 to -0.03) and from three studies with 376 participants at the mid-term follow-up (SMD -0.42, 95%CI -0.75 to -0.09). [211] Despite the positive effects on pain and disability, the lack of effects of health coaching on physical activity might be related to the lack of social support whilst exercising, which is valued by people with low back pain and perceived as an exercise enabler. [115,212]

Previous qualitative studies have evidenced the importance of the social environment in the health behaviour change process of both adults and older people. [202,213,214] The support, motivation and regulation from partners aid people in successfully achieving a health behaviour change. [213,215] Evidence from both qualitative and longitudinal studies suggests that the way partners influence each other's physical activity participation varies according to their health behaviours. [214,216] For instance, spouses' support and their physical activity level are associated with greater physical activity levels of their spouses, [214,216] and having an active partner increases the likelihood of the other being physically active. [183,216] However, having an inactive partner who became active has a substantially greater likelihood of positively influencing the other partner to become active as well. [183,216]

In spite of the benefits and scalability of health coaching interventions and the effect of partners or buddies on each other's physical activity participation, the benefits of combining both interventions to help people with low back pain to become active as well as the feasibility of a randomised controlled trial design remain unknown. The Medical Research Council has recommended the assessment of the feasibility of a complex intervention after its development. [120] A process evaluation, where the mechanisms of impact and context of the intervention are assessed, are vital for understanding and enhancing the feasibility and assessment of the intervention and the research design. [166] **Chapter Nine** is a pilot randomised controlled trial investigating the feasibility of a free health coaching intervention with or without the support of an exercise buddy and exploring the potential effects on physical activity participation and health care utilisation of people with low back pain recently discharged from treatment compared to usual care. A total of 30 people recently discharged from treatment for chronic low back pain were enrolled. Although the data collection and follow-up rates were not successful (i.e., were lower than 70%), the recruitment rate was acceptable (i.e., higher than 70%) and indicated

people's interest in the trial. Additionally, 70% of participants from the Buddy-Assisted Health Coaching Group were satisfied with the health coaching intervention received and 85% of them believed that their buddies' support helped them to increase their physical activity participation.

## 1.5 Objectives of the thesis

The broad aim of this thesis was to investigate innovative, scalable and affordable interventions for the treatment of non-specific low back pain. This thesis reports on a series of studies that were conducted to address this aim.

The specific aims were to:

1. Investigate the general public interest for online information in the five most disabling musculoskeletal conditions **(Chapter Two)**
2. Appraise the evidence on the effectiveness of text message interventions in the treatment of musculoskeletal pain **(Chapter Three)**
3. Develop and evaluate the acceptability of a self-management text message intervention to improve function of people with low back pain **(Chapters Four, Five, Six)**
4. Estimate the average smallest worthwhile change that people with low back pain need to experience to consider a self-management text message intervention worthwhile **(Seven)**
5. Summarise the effects of family-based interventions on pain and disability in people with musculoskeletal pain **(Chapter Eight)**
6. Assess the feasibility of a health coaching intervention with or without the support of an exercise buddy and explore the potential effects on physical activity participation and health care utilisation of people with low back pain compared to usual care **(Chapter Nine)**

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# CHAPTER TWO

## Use of Online Information in Musculoskeletal Conditions: An Analysis of Google Trends Data

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## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper *"**Fritsch CG**, Duong V, Chen L, Hunter DJ, McLachlan AJ, Ferreira PH, Ferreira ML. Use of Online Information in Musculoskeletal Conditions: An Analysis of Google Trends Data. J Clin Rheumatol. 2022 1;28(3):1620169. doi: 10.1097/RHU.0000000000001820"* confirm that Carolina G Fritsch 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

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

# Use of Online Information in Musculoskeletal Conditions

## *An Analysis of Google Trends Data*

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**Background/Objective:** We aimed to investigate the yearly online public interest for gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis, the most popular topics searched for these conditions, and the association between the change in their interest over time and the sociodemographic index of the search location.

**Methods:** We conducted online searches in Google Trends for the aforementioned conditions between 2004 and 2020. The search volumes for each condition (relative to all searches conducted in the period) and the top and rising related queries and topics were downloaded and summarized.

**Results:** There was a rise in the online interest for musculoskeletal conditions between 2008 and 2020, with low back pain (annual percent change, 7.4; 95% confidence interval [CI], 7.1–7.7) and neck pain (annual percent change, 7.2; 95% CI, 6.9–7.5) presenting the highest increases. There was a negative, statistically significant, but small association between change in online interest and the country's sociodemographic index for low back pain (−0.007; 95% CI, −0.011 to−0.003), neck pain (−0.005; 95% CI, 0.009 to −0.001), and rheumatoid arthritis (−0.009; 95% CI, −0.017 to −0.001) between 2013 and 2020. The interest for the cause and symptoms of the selected conditions increased over time, except for gout. The proportion of queries and topics related to treatment of all conditions decreased over time.

**Conclusions:** The worldwide interest in musculoskeletal conditions increased between 2008 and 2020. The public seems more interested in understanding what musculoskeletal conditions are and less interested in which treatment options are available. The results can guide the development of educational campaigns for musculoskeletal conditions.

**Key Words:** musculoskeletal disease, rheumatology, big data

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Musculoskeletal conditions are highly prevalent, affecting approximately 20% to 30% of the world population,[1–4] and are among the leading causes of disability globally.[3–5] According to the most recent Global Burden of Disease report, low back pain, neck pain, and osteoarthritis are among the top 15 causes of years lived with disability.[5] Along with rheumatoid arthritis and gout, these health conditions were responsible for approximately 147 million years lived with disability worldwide in 2019.[5] Because of the growing population, the burden of musculoskeletal conditions is expected to escalate as well as the number of people affected by these health problems.[3,6]

A range of online sources of information are currently available, such as social media, websites from consumer or professional organizations, governments or universities, and web-based search engines. Although the exact topics of interest may vary, a better understanding of the trends in interest and behavior toward online information seeking may assist in the development of targeted educational resources. This would be essential to empower patients to better manage their conditions as well as to address common misconceptions regarding the treatment and prevention of musculoskeletal conditions, for example, keeping active and keeping at work.[7,8]

Social media and search engine data analytics can be used to assess the public interest for different health conditions.[9] Google Trends is one of the online sources being increasingly used in health research.[9] This web search data analytic tool provides information via the Google search engine and has been widely used to investigate the online interest for multiple health conditions.[10] Google Trends data represent an opportunity to explore real-time and archived data on worldwide interest in specific terms and topics.[9,10] Google Trends presents the online interest for a time series in any selected term and any selected region or period.[10] One of the main advantages of using Google Trends is that, different to consumer surveys that provide stated preferences regarding a topic, the trends data give us information on the real topics of interest among consumers.[9] Previous studies have investigated the online interest for gout,[11] low back pain,[12] osteoarthritis,[13] and rheumatoid arthritis[14] over time and their seasonality. However, the type of information people are interested in, i.e., diagnosis, symptoms, and treatment, is still unknown. Moreover, given that the access to information either online or from health care providers is different in high- and low-income countries,[15,16] it is still unclear whether the change in online interest of musculoskeletal conditions over time is different in countries of lower socioeconomic levels compared with those of higher levels.

Thus, the current study aimed to (1) investigate the yearly online public interest for the most disabling musculoskeletal conditions (i.e., gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis) between 2004 and 2020; (2) compare the change in the relative interest for each musculoskeletal condition in countries with different socioeconomic levels between 2004 and 2012 and 2012 and 2020; and (3) assess the top yearly topics of interest (e.g., classification, cause, symptoms, treatment options).

## METHODS

The web-based data analytics tool Google Trends was used to investigate the worldwide interest for various topics related to gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis on Google from January 1, 2004 (inception) to December 31, 2020. The study was conducted according to the framework proposed by Nuti and colleagues.[17] These health conditions were selected because they represent the individual musculoskeletal conditions studied in the Global Burden of Disease studies and

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some of the most significant causes of disability worldwide.[5] Different search terms were combined on Google Trends using MeSH terms for each condition to ensure a standardize search strategy.[18] The combination with the greatest relative interest was selected to conduct the searches, which are detailed on Supplemental Digital Content 1 (http://links.lww.com/RHU/A412). Google Trends provides the option to analyze the terms of interest based on a selected category, which can be used when words with different meanings are searched for.[9] All categories were selected in Google Trends, and the search was conducted worldwide. Data were accessed and downloaded on January 21, 2021.

Google Trends provides data on the online interest as relative search volumes as search results are normalized and adjusted to the time and location of the search strategy.[9] Relative search volume is presented on a 0–100 scale, where 100 represents peak popularity.[9] The worldwide RSV of the musculoskeletal conditions (i.e., low back pain, neck pain, osteoarthritis, rheumatoid arthritis, and gout) and the yearly interest by region, including low search volume regions (i.e., regions associated with very little search traffic on Google), for each musculoskeletal condition were downloaded as .csv files. Data including low search volume regions were downloaded as more countries are considered in the analysis by Google Trends.

As the search included terms in English only and the terms are not automatically translated into multiple languages,[19] only countries where English is the official language were searched and included in the sociodemographic analysis. The list of countries included in the analysis of each condition (some were not included due to RSV being too low to generate data) is presented in Supplemental Digital Content 2 (http://links.lww.com/RHU/A413).

The "related queries" and "related topics" related to gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis were also assessed. They represent the queries and topics searched along with the musculoskeletal conditions terms (e.g., yoga for low back pain, gout diet, rheumatoid arthritis treatment). The top "related queries" and "related topics" are the most frequently searched queries and topics related to the terms of interest, whereas the rising "related queries" and "related topics" are the ones with the most significant rise in volume in the requested period. Up to 25 results are provided by Google Trends.

## Data Analysis

The Joinpoint Trend Analysis Software (version 4.9)[20] was used to calculate the annual percentage change (APC) and 95% confidence interval (CI) in the relative interest for each musculoskeletal disorder over each year (2004 to 2020). The APC was calculated with a log regression to characterize a trend over time.[21] Joinpoint trend analysis is also used to assess if a segmented line is significantly better than a straight line to fit the temporal trend. The segments in the line are named joinpoints, and up to 5 joinpoints can be determined.[21] As there were clear trends in the data, 1 joinpoint was considered in the analysis of each condition, and the APC (±95% CI) was calculated for the 2 periods. We also calculated the relative interest for each musculoskeletal condition relative to each other.

To compare the relative change in interest in countries with different sociodemographic levels between the early and late years of the data, the APC (±95% CI) in the relative interest for each musculoskeletal condition and each country's sociodemographic level between 2004 and 2012 and 2013 and 2020 were calculated using the Joinpoint Trend Analysis Software. The cutoff point was selected as it represents the midpoint between 2004 and 2020. When the RSV for a musculoskeletal condition was reported as <1 for a country, it was included in the analysis as 0.5 to differentiate from the countries where the RSV was 0 (which indicates no sufficient search volumes to be included in Google Trends analysis). We used the same approach described in the Global Burden of Disease Study to classify countries into different sociodemographic index (SDI) regions.[22] The SDI is a composite score of the development status of countries and territories strongly correlated with health outcomes. It is the geometric mean of 0 to 1 indices of total fertility rate younger than 25 years, mean education for those aged 15 years and older, and lag distributed income per capita.[22] It ranges from 0 to 1 (0 = theoretical minimum level of development relevant to health, 1 = theoretical maximum level of development relevant to health).[22] The country's mean SDI between the periods was considered for the analyses. Linear regression was used to investigate the association between SDI and the mean change in interest for each condition over time.

The top and rising related queries and topics related to each condition were classified by 2 researchers (C.G.F. and V.D.) using thematic analysis to show the most common themes searched with each musculoskeletal condition. The queries and topics were classified into the following themes: (1) classification-related; (2) symptom-related; (3) cause-related; (4) interfering/risk factors; (5) treatment-related; (6) related to another related condition/disorder; (7) prevention-related; (8) commonly affected structures; and (9) other nonrelated queries or topics. The "treatment-related" theme was further classified into the following subthemes: (1) general treatment inquiry (e.g., "treatment for osteoarthritis"); (2) pharmacological treatment; (3) supplement; (4) diet; (5) exercise and physical activity; (6) biomechanical interventions (e.g., braces); (7) physiotherapy, chiropractic, and osteopath; (8) surgery; (9) acupuncture, homeopathy, and alternative/natural medicine; and (10) self-management and educational consumer-focused sources (e.g., Arthritis Australia, Arthritis Foundation, WebMD). Moreover, the theme "related to another related condition/disorder" was further classified into (1) differential diagnosis and (2) disorder/condition associated with the musculoskeletal condition (e.g., low back pain and pregnancy, kidney disease, and gout). A detailed description of the classification of the queries and topics is described in Supplemental Digital Content 3 (http://links.lww.com/RHU/A414). Any conflicts about the classification of queries and topics were resolved through discussions, and a third researcher (M.L.F.) was consulted when necessary. The main analysis was conducted with the top queries and topics data, whereas a secondary analysis was done with the rising queries and topics data. The annual proportion of the searches of each theme in relation to all queries and topics was calculated for each musculoskeletal condition. The APC ± 95% CI of the top interest for each theme in relation to each musculoskeletal condition was calculated with the Joinpoint Trend Analysis Software. Similarly, the APC ± 95% CI top treatment-related subthemes' queries and topics for each musculoskeletal condition was calculated. The yearly relative popularity of the top topics and queries' themes for each musculoskeletal condition between 2004 and 2020 is presented in the Supplemental Digital Content 4 (http://links.lww.com/RHU/A415). In a secondary analysis, the changes in the trending themes and treatment subthemes were calculated and presented as appendices (Supplemental Digital Content 5 and 6, http://links.lww.com/RHU/A416, http://links.lww.com/RHU/A417).

# RESULTS

Between 2004 and 2020, low back pain was the most commonly searched condition, followed by neck pain, rheumatoid arthritis, osteoarthritis, and gout. The interest for the five musculoskeletal conditions relative to each other is presented in Figure 1. We have identified two periods with marked differences in relative interest for online information on musculoskeletal conditions.

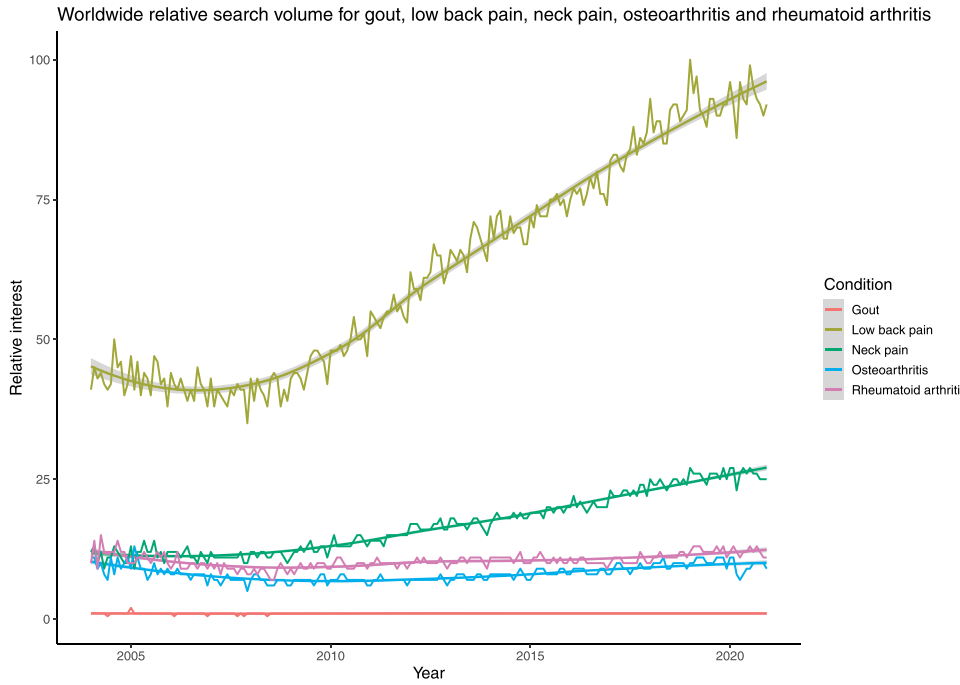


**FIGURE 1.** Worldwide RSV for gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis from 2004 to 2020. Image presents the relative interest for all five conditions relative to each other between 2004 and 2020. Color online-figure is available at http://www.jclinrheum.com.

Between 2004 and 2008, the interest for low back pain and neck pain remained stable, whereas the online interest for gout, osteoarthritis, and rheumatoid arthritis decreased (Fig. 2). However, between 2008 and 2020, the interest for all musculoskeletal conditions increased, with low back pain (APC, 7.4; 95% CI, 7.1–7.7) and neck pain (APC, 7.2; 95% CI, 6.9–7.5) presenting the highest increases.

As seen in Table 1, there was a negative, statistically significant, and small association between the SDI and change in relative interest for low back pain (−0.007; 95% CI, −0.011 to −0.003), neck pain (−0.005; 95% CI, 0.009 to −0.001), and rheumatoid arthritis (−0.009; 95% CI, −0.017 to −0.001) ($p < 0.05$), suggesting a greater increase in relative interest for these conditions in countries of lower SDI. These were only observed between 2013 and 2020.

The changes in the relative popularity of the top topics and queries' themes for each musculoskeletal condition are presented in Figure 3. The yearly change in the themes' popularity is presented in Supplemental Digital Content 4 (http://links.lww.com/RHU/A415). Although being one of the least popular themes, the interest for the cause of all conditions significantly increased over time (APC ranged between 8% for low back pain and 53% for osteoarthritis). Searches on the symptoms of all conditions, except for gout, also increased between 2004 and 2020. Conversely, the interest in treatment options for all conditions decreased over time, and there were no top queries and topics related to their prevention. There were no observed trending queries and topics related to the treatment of gout, neck pain, osteoarthritis, or rheumatoid

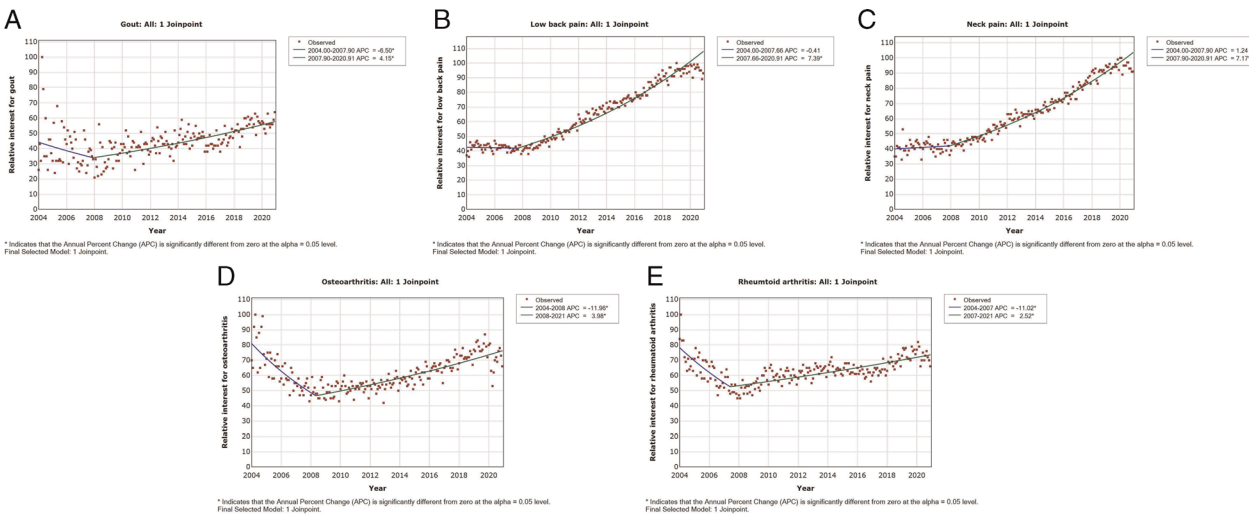


**FIGURE 2.** Relative interest for gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis from 2004 to 2020. Image presents the relative interest for each condition individually between 2004 and 2020. Color online-figure is available at http://www.jclinrheum.com.

**TABLE.** Association Between the Mean APC in the Relative Search Volume for Gout, Low Back Pain, Neck Pain, Osteoarthritis, and Rheumatoid Arthritis and the SDI of English-Speaking Countries

| | 2004–2012 | | 2013–2020 | |
|---|---|---|---|---|
| **Musculoskeletal Condition** | **Estimate (95% CI)** | ***p* value** | **Estimate (95% CI)** | ***p* value** |
| Gout | 0.0063 (0.0004; 0.0122) | 0.05 | −0.0019 (−0.0074; 0.0036) | >0.05 |
| Low back pain | 0.0000 (−0.0022; 0.0022) | >0.05 | −0.0072 (−0.0111; −0.0033) | <0.05 |
| Neck pain | 0.0016 (−0.0009; 0.0041) | >0.05 | −0.0048 (−0.0087; −0.0009) | <0.05 |
| Osteoarthritis | −0.0004 (−0.0043; 0.0035) | >0.05 | −0.0062 (−0.0138; 0.0014) | >0.05 |
| Rheumatoid arthritis | −0.0008 (−0.0037; 0.0021) | >0.05 | −0.0093 (−0.0171; −0.0015) | <0.05 |

arthritis between 2004 and 2020. However, there was a significant increase in the online interest for treatments among the low back pain rising queries and topics over time (Supplemental Digital Content 5, http://links.lww.com/RHU/A416).

Figure 4 shows the interest in treatment options for musculoskeletal conditions over time. Top treatment-related searches for osteoarthritis and rheumatoid arthritis were the most heterogeneous and included seven different treatment subthemes. The interest in pharmacological approaches for the treatment of gout increased over time, whereas it decreased for osteoarthritis and rheumatoid arthritis. The proportion of general treatment queries and topics for osteoarthritis increased over time as well as the proportion of diet queries and topics for rheumatoid arthritis. The trending queries and topics related to the treatment of musculoskeletal conditions are presented in Supplemental Digital Content 6 (http://links.lww.com/RHU/A417). The interest in conventional pharmacological treatments for gout was the only treatment modality that increased among the trending queries and topics, whereas the interest in neck surgery and for physiotherapy/chiropractic/osteopathy/acupuncture to treat low back pain decreased over time.

## DISCUSSION

The current study investigated the online interest for the most disabling musculoskeletal conditions from the inception of Google Trends data until December 2020. The main findings of the current study were as follows: (1) there were two distinct periods with marked differences in the online interest in musculoskeletal conditions; (2) low back pain and neck pain were the conditions with the greatest rises in popularity between 2008 and 2020; (3) there was a small negative association between the change in the interest for low back pain, neck pain, and rheumatoid arthritis and the SDI of English-speaking countries between 2013 and 2020; (4) the relative interest in the cause of all conditions significantly increased over time, whereas the interest in their treatment decreased; and (5) there was a decrease in the interest of pharmacological treatment for rheumatoid arthritis and an increase in the interest of pharmacological treatment for gout, the general treatment for osteoarthritis, and diet for rheumatoid arthritis.

To the best of our knowledge, this is the first study to conduct a comprehensive worldwide search strategy and analysis of the online interest for the most disabling musculoskeletal disorders. We used data from Google Trends, which is the preferred search engine and used in approximately 80% of online searches.[23] We combined different search terms based on the MeSH terms of each condition and have chosen the ones which resulted in the greater RSV. Nonetheless, search terms are not automatically translated into all languages by Google,[9] and the results might not represent the international interest despite the worldwide search strategy. Moreover, the search did not include lay terms as "knee pain" or "hip pain" as they are nonspecific symptoms that could have led to mixed results and a greater number of queries and topics unrelated to the conditions of interest. The analysis of the association between SDI and change in the interest for the conditions over time was limited to English-speaking countries, and findings should not be extrapolated to non–English-speaking countries. Besides, the results obtained in countries where English is the official language but not the local or native language might not represent the real online interest of the population.

Overall, there was a nonlinear increase in the online interest for musculoskeletal conditions, which presented two clear stages. The interest for musculoskeletal conditions remained stable or decreased between 2004 and 2008, whereas it increased between 2008 and 2020. Similar to the results of the current study, Ciaffi et al[12] showed a nonlinear significant increase in the online interest for three low back pain search terms throughout the years in Italy. Jellison et al[13] also reported a U-shaped worldwide online interest for osteoarthritis with greater interest observed in 2004, followed by a decrease and another increase from 2014 onwards. Kardes[11] showed that the online interest for gout in five English-speaking countries was stable between 2004 and 2008 and increased between 2008 and 2018. The significant increase in the online interest for musculoskeletal conditions from 2008 onward might be related to the overall increased use of the Internet to seek health-related information.[24] As an example, data from the United Kingdom indicate that the proportion of people seeking health information online increased from 18% in 2007 to 60% in 2020.[24] The increase in the online interest for gout, osteoarthritis, and rheumatoid arthritis could also be related to rises in the global prevalence of these conditions.[25–27]

Low back pain and neck pain were the most popular terms and presented the greatest increases in interest over time. These findings may reflect the high prevalence of these two conditions—there are approximately 568 million and 223 million people around the world currently experiencing low back pain and neck pain, respectively.[5] The online interest for osteoarthritis was, however, lower in comparison to the other conditions, despite it being the second most prevalent musculoskeletal condition worldwide.[5] We acknowledge that a possible explanation for the relatively low online interest for osteoarthritis could be related to the search terms used (such as "osteoarthritis," "osteoarthrosis"). An increase in the popularity of topics such as "knee injury," "knee pain," "wrist pain," and "podalgia" over the years has been observed,[28,29] and it is likely that these searches could also be related to osteoarthritis. However, these terms could not be included in the current search strategy as they are nonspecific symptoms related to multiple musculoskeletal conditions.

We found that countries with lower SDI had a greater increase in the interest for low back pain, neck pain, and rheumatoid arthritis between 2013 and 2020. This could be related to limited health care access[16,30] and limited health educational campaigns[31] in middle and low SDI countries. As an example, a recent systematic review evaluated the effectiveness of mass media campaigns for the management of low back pain, and all included studies were conducted in high SDI countries.[31] Nonetheless, the estimate

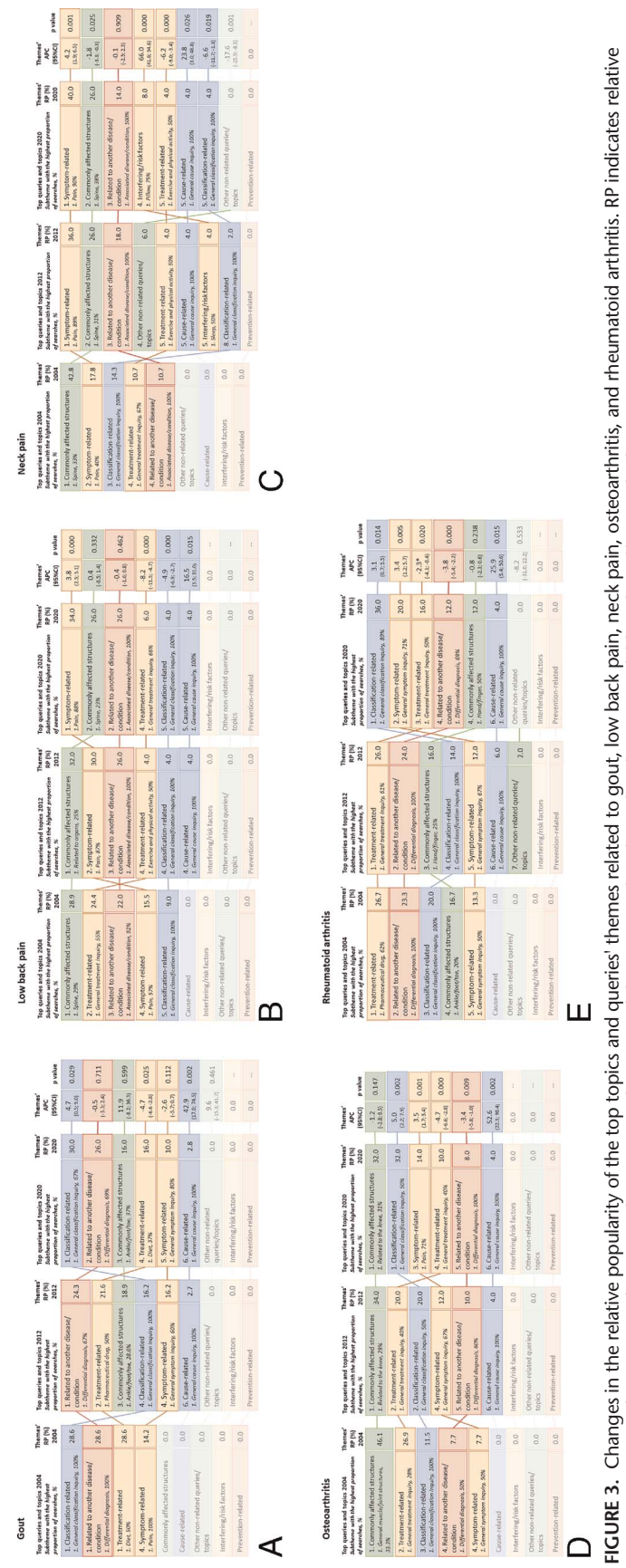


**FIGURE 3.** Changes in the relative popularity of the top topics and queries' themes related to gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis. RP indicates relative proportion; APC indicates Annual Percent Change; CI indicates Confidence Interval. Color online-figure is available at http://www.jclinrheum.com.

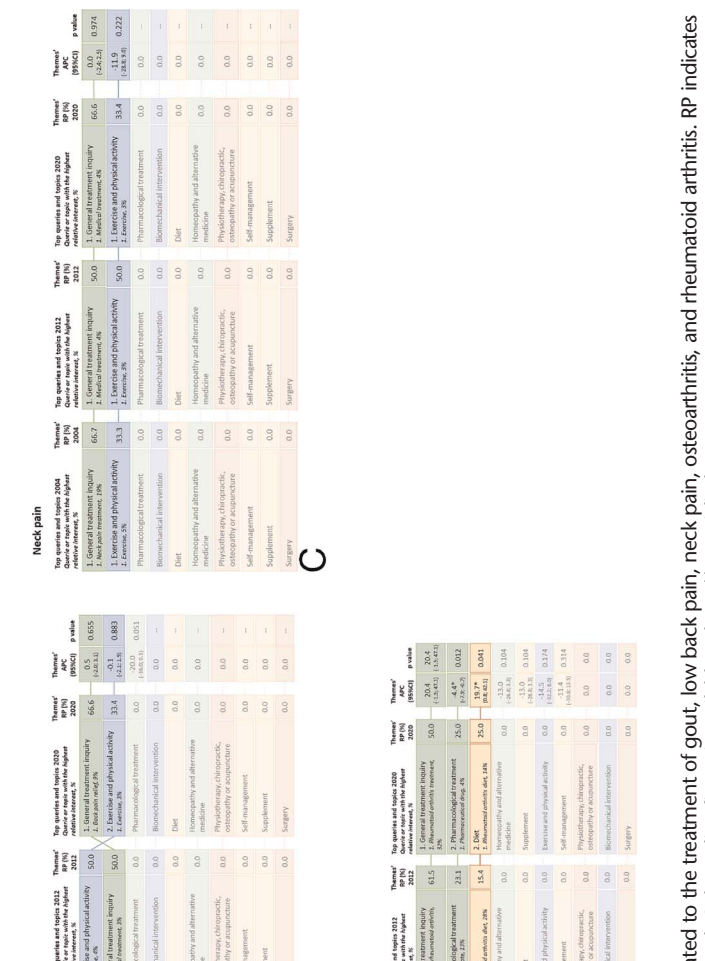


**FIGURE 4.** Changes in the relative popularity of the top topics and queries' themes related to the treatment of gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis. RP indicates relative proportion; APC indicates Annual Percent Change; CI indicates Confidence Interval. Color online-figure is available at http://www.jclinrheum.com.

of associations between countries' SDI and the change in interest for low back pain, neck pain, and rheumatoid arthritis found in the current study are small and perhaps irrelevant.

The results of the queries and topics searched along with the musculoskeletal conditions provide important information that may assist the development of targeted and consumer-relevant educational resources. People seem to be more curious about how to classify/diagnose gout, osteoarthritis, and rheumatoid arthritis, how to make differential diagnoses of gout and rheumatoid arthritis, and to know which body structures (like joints, ligaments, muscles, etc) are commonly affected by the musculoskeletal conditions. Interestingly, there was no public interest in the prevention of any musculoskeletal condition among the top 25 results provided by Google Trends. Although there was little or no demonstrated online interest in preventative strategies for any of the musculoskeletal conditions analyzed, we did observe an increased interest on the potential causes of these diseases. It is possible that people were seeking information on potential causes as a way of avoiding or preventing these conditions.

Results also showed a high public interest in exercise and only a small interest in pharmacological treatments for the management of low back pain and neck pain. Exercise was also among the most searched treatment for osteoarthritis. However, people also frequently sought pharmacological treatments for osteoarthritis, despite the lack of evidence about their benefits for this condition.[7] Furthermore, there was a high interest in diet therapy for gout and rheumatoid arthritis, regardless of the limited evidence of its effects on disease activity and symptoms of both conditions.[32,33] These results may suggest that people may be relating lifestyle behaviors, as exercise and diet, to musculoskeletal conditions. Nonetheless, educational interventions may be needed to reinforce the specific roles of exercise, medications, and diet for the prevention and optimal management of musculoskeletal conditions.

Some limitations of using Google Trends data to investigate the public interest in health conditions include that it does not provide the number of searches for the conditions, information about the characteristics of people conducting the searches, their intentions, and reasons for conducting the searches. Moreover, the results might underrepresent the interest of the population of low-income countries due to limited access to the Internet. As an example, 86% of the population from high-income countries had Internet access compared with 14% of the population from low-income in 2017.[15] Results might also not reflect the interest of people who do not use Google as their search engine, older people, or people with limited technology-related knowledge. Differences in the main interests of people from different countries and social backgrounds were not studied. Finally, our search strategy included terms related to musculoskeletal conditions and not their symptoms or general terms, which might be more frequently used by the public. Other lay terms, such as "arthritis," were also not included as they could lead to mixed results (e.g., arthritis is a term that could lead to results related to gout, rheumatoid arthritis, and osteoarthritis).

## CONCLUSIONS

This study showed a rise in the worldwide online interest in gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis, between 2008 and 2020. There was a small negative association between the change in the interest for low back pain, neck pain, and rheumatoid arthritis and the SDI of English-speaking countries between 2013 and 2020. The public seems uninterested in the prevention of musculoskeletal conditions while being increasingly interested in the causes of the conditions over the years and less concerned about their treatment. The proportion of general treatment, pharmacological treatment, and diet treatment subthemes varied significantly throughout the years. The results of the current study might be used to inform the development of educational interventions for the general public or people with musculoskeletal conditions so that the interventions provide consumer-relevant information.

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# CHAPTER THREE

## Effects of Using Text Message Interventions for the Management of Musculoskeletal Pain: A Systematic Review

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## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper "***Fritsch CG**, Ferreira PH, Prior JL, McLachlan AJ, Ferreira ML. Effects of using text messages in the treatment of musculoskeletal pain: a systematic review. PAIN. 2020;161(11):2462-2475. doi: 10.1097/j.pain.0000000000001958*" confirm that Carolina G Fritsch 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

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

Systematic Review and Meta-Analysis

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# Effects of using text message interventions for the management of musculoskeletal pain: a systematic review

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**Abstract**

Musculoskeletal pain is the greatest cause of disability worldwide. Owing to its increasing prevalence and burden, the importance of affordable treatments has been highlighted. Text message interventions are accessible, low cost, and effective in promoting healthy behaviour and managing chronic diseases. However, little is known about their role in musculoskeletal pain. This systematic review was conducted to appraise the literature on the effects of text messages (as an intervention or a component of an intervention) compared with any control on pain and function in people with musculoskeletal pain (PROSPERO: CRD42018117371). MEDLINE, EMBASE, CINAHL, Cochrane, and PEDro databases were searched from inception to April 2020. Keywords relating to musculoskeletal pain, text messages, and randomised controlled trials were combined. Methodological quality was assessed using the PEDro score. Of the 12,022 studies identified, 11 were included, with a mean PEDro score of 5.4/10 points (SD 1.3). Pooled analyses were not performed because of heterogeneity of interventions and clinical characteristics. When text messages were added to and compared with usual care, some positive effects were found only on treatment adherence. Although small and inconsistent, some positive effects were reported for pain intensity, function, care-seeking behaviour, adherence, and quality of life when text messages were added to multicomponent interventions. Moreover, text message and telephone counselling interventions had similar effects on function. Overall included studies were of limited methodological quality and heterogeneous. However, our results indicate potential benefits of text messages in the treatment of musculoskeletal pain, which need to be confirmed in future trials.

**Keywords:** Musculoskeletal disorder, SMS, Text messaging, Mobile health, Systematic review

## 1. Introduction

Musculoskeletal pain is a common condition worldwide[21,35] defined as "pain that arises as part of a disease process directly affecting bones, joints, muscles, or related soft tissues."[53] Its prevalence in adults may vary from 18% to 70%, with studies showing a higher prevalence for lower back and neck pain.[21,27] Low back pain, neck pain, and osteoarthritis are leading causes of years lived with disability worldwide.[17,25] Furthermore, the burden of these conditions (measured as the number of years lived with disability) has increased by 20% in the past 10 years.[17]

Research has emphasised the impact of musculoskeletal conditions because of their rising prevalence and burden and their association with the modern world trending phenomena of ageing and obesity.[4,17,14,28,39] Health costs related to musculoskeletal care are significant and estimated to represent up to 19% of all healthcare expenditure.[3] Moreover, musculoskeletal pain is also a main cause of loss of work productivity,[28,39] what further increases its personal and societal burden.[3,39]

As the burden of musculoskeletal pain is expected to grow, the importance of affordable and accessible treatments has been highlighted.[39] Although pharmacological treatments, injections, and surgical procedures have been shown to have limited use to most musculoskeletal pain conditions, advice, education, and self-management approaches have been emphasised in the literature.[16,25] Numerous technology-based interventions have been proposed to provide better access to evidence-based care,[44,54] reliable and effective self-management strategies,[10,54] and patient-centred behaviour-change interventions,[1] or to empower patients to perform shared healthcare decision-making.[29,54] These interventions may include self-management web sites,[10,54] mobile device applications,[29] telephone-based interventions,[44] and combined technology approaches.[1]

Technology-based interventions may also include provision of text messages, which may be delivered alone or as a component of a comprehensive intervention.[2,13,20] Text message–based interventions are both effective and cost-effective in improving chronic disease care, such as diabetes, cardiovascular diseases, and medication adherence.[6,13,20,47,50,56] They are also effective health promotion strategies supporting smoking cessation,

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weight loss, and improvements in physical activity participation.[2,13,20,22] Nevertheless, evidence of the effectiveness of text message interventions for managing musculoskeletal pain is still conflicting.

Although some studies report significant effects of text messages on pain reduction,[52,55] function,[34,52] and care-seeking behaviour[7] improvements in people living with musculoskeletal pain, other studies report no effect on the same outcomes.[5,9,32,45] Given the scalability of text message interventions, their minimal costs, low technology–related knowledge requirements, and wide utilisation,[13,20,40] it is essential to assess their use and effects on health-related outcomes in people with musculoskeletal pain. Therefore, this systematic review was conducted to appraise the literature on the effects of text message as a sole intervention or as part of an intervention and compared with any control in reducing pain and improving function in people with acute or chronic musculoskeletal pain.

## 2. Methods

### 2.1. Data sources and searches

We have prospectively registered the review protocol on the International Prospective Register of Systematic Reviews (protocol number CRD42018117371) and present the current report according to the 2009 PRISMA Statement.[42] The electronic search was conducted on MEDLINE through Ovid, Embase through Ovid, CINAHL through EBSCOhost, Cochrane, and PEDro databases from inception to April 2020. The search strategy was developed by a research librarian and contained both controlled vocabulary and free text terms related to musculoskeletal pain (eg, musculoskeletal pain, back pain, and osteoarthritis), text message interventions (eg, text message and telephone), and study design (eg, randomised clinical trial) (Supplemental Table 1, available at http://links.lww.com/PAIN/B75). In addition, citation tracking of included studies and relevant systematic reviews as well as search for ongoing and possibly unpublished trials in www.ClinicalTrials.gov, BioMed Central, (http://www.isrctn.com), and Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au) were performed. No date restrictions were applied.

### 2.2. Study selection

Two independent reviewers (C.G.F. and J.L.P.) screened titles and abstracts and read full articles for final selection. Any disagreements were resolved with a third reviewer (M.L.F.). Eligible studies were published or unpublished randomised controlled trials, which investigated the use of text message interventions for adults with acute or chronic musculoskeletal pain, such as, but not limited to, knee or hip osteoarthritis, low back pain, chronic widespread pain, and shoulder pain. Studies including people with and without musculoskeletal pain were included if they reported separate data for the subgroup of people with musculoskeletal pain. Text message interventions could have been applied as an independent or additional intervention to any type of treatment (eg, cognitive behavioural therapy, exercise, or medication) and needed to have been compared with any control intervention (eg, sham, no treatment, cognitive behavioural therapy, exercise, medication, or usual care). Nonrandomised trials and studies including participants younger than 18 years and/or with neuropathic or nonmusculoskeletal pain were excluded.

### 2.3. Data extraction

Two independent reviewers (C.G.F. and J.L.P.) performed data extraction using a standardised form and resolved any disagreements with a third reviewer (M.L.F.). For each study, summary data were obtained on year of publication, study design, geographic location, sample size and characteristics, follow-up rates and duration, pain and clinical outcomes, and adverse events. A narrative synthesis of descriptive data of text message characteristics and frequency and participants' feedback were also extracted. Measures of central tendency (eg, mean or median) and variability (eg, SD or 95% confidence intervals [95% CIs]) were extracted for primary outcomes (ie, pain and function) and other studied outcomes (eg, care-seeking behaviour, physical activity, and quality of life). The authors were contacted when there were insufficient data reported.

### 2.4. Risk of bias assessment

Two reviewers assessed the methodological quality of included studies according to the PEDro scale.[38] Three of the reviewers are certified PEDro ratters (C.G.F., P.H.F., and M.L.F.). Reviewers confirmed the scores at PEDro web site (http://www.pedro.org.au) for studies whose scores were available. Methodological quality was classified as excellent (9-10 points), good (6-8 points), fair (4-5 points), and poor (<4 points).[24] PEDro scale has good reliability (interclass correlation coefficient: 0.58-0.91)[15,38] and convergent validity (correlation: 0.31-0.88).[37,57] The overall risk of bias was assessed with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach[19] for narrative synthesis.[43]

### 2.5. Analyses

The studies were grouped according to the interventions provided: effects of text messages added to usual care and compared with usual care alone; effects of text messages as a component of a comprehensive intervention compared with any other intervention; and effects of text messages compared with telephone counselling. A meta-analysis could not be performed because of between-study heterogeneity in terms of group comparisons and clinical characteristics. The mean difference (MD) between groups and standard errors was used to calculate treatment effects and 95% confidence intervals (CI) with Review Manager Version 5.3.5. The scores from different function (Patient-Specific Functional Scale,[34] Activities of Daily Living Scale,[45] and Health Assessment Questionnaire[52]) and adherence (Visual Analogue Scale[34] and Compliance Questionnaire Rheumatology [CQR-19][41]) questionnaires were converted to a 0 to 100 scale based on the proportion to the original scale to be presented in **Figure 2**. SDs were calculated as suggested by the Cochrane Handbook[23] for studies that reported 95% CIs or interquartile range. When the study had 3 or more intervention groups (IGs), we considered the usual care group as the comparator to decrease the variability between comparisons and IGs and to add to the understanding of the effect of addition of text messages to usual care.

## 3. Results

### 3.1. Study selection

Our search identified a total of 12,022 titles. After removing duplicates and screening titles and abstracts, 26 full-text articles were assessed. Fifteen studies were further excluded because

they did not use text message interventions (n = 7), were not randomised clinical trials (n = 2), did not include patients with musculoskeletal conditions (n = 1), or were conference abstracts (n = 5). Twelve articles representing 11 studies were included in the review (**Fig. 1**). Two articles reported the postintervention and 5-month follow-up results[31] as well as the 11-month follow-up results[30] of the same trial. The study with postintervention and short-term follow-up results was used as a reference and was included in **Figure 2**.[31] The overall characteristics of included studies are detailed in **Table 1**.

### 3.2. Participants

Studies included participants with rheumatoid arthritis (n = 3),[32,41,52] chronic widespread pain (n = 1),[31] upper or lower limb musculoskeletal injuries or conditions (n = 1),[34] frozen shoulder (n = 1),[9] or undergoing knee arthroscopy (n = 1),[5] total joint arthroplasty surgery (n = 2),[7,45] and hand surgery due to trauma (n = 1)[49] or knee pain (n = 1).[55] Four studies[31,34,41,52] included participants with chronic (more than 3 months of duration)[12] conditions and reported mean symptom duration ranging from 4.5 months[34] to 15 years.[31] The mean age of participants ranged from 39 (SD 7.1)[55] to 61 (SD 8.2) years.[7] Studies recruited participants from different settings, including hospitals (n = 5),[5,7,34,45,49] orthopaedic or rheumatological centres/clinics (n = 3),[9,32,41] multidisciplinary pain clinics (n = 1),[31] national arthritis registries (n = 1),[52] and general community (n = 1).[55]

### 3.3. Text message intervention

Text message interventions varied in characteristics and duration across studies. One study compared a text message intervention with telephone counselling.[45] Five studies investigated the effect of a text message intervention as a support tool to usual care.[5,9,32,41,49] In the remaining studies (n = 5), text messages were a component of a comprehensive intervention (ie, were not the only difference between the investigated interventions). In one study, text messages to instruct and encourage patients to participate in the rehabilitation program after total joint arthroplasty were added to personalised and instructional therapy videos and compared with usual care.[7] In another trial, text messages were delivered in addition to a mobile app–based intervention and compared with usual care.[34] Kristjansdottir et al. added text messages to a smartphone-based intervention (web-based diaries with feedback from health professionals) compared with inpatient rehabilitation.[31] Thomsen et al.[52] added text

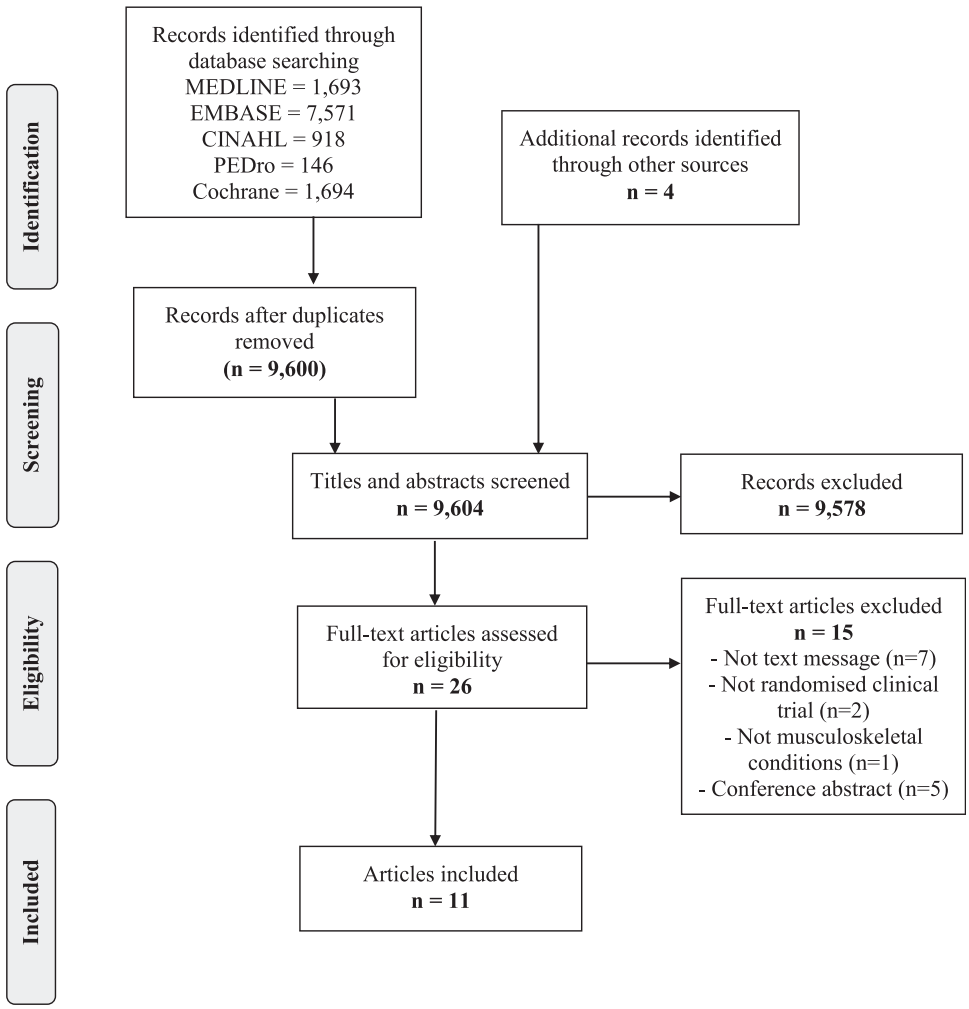


**Figure 1.** Flowchart of included studies.

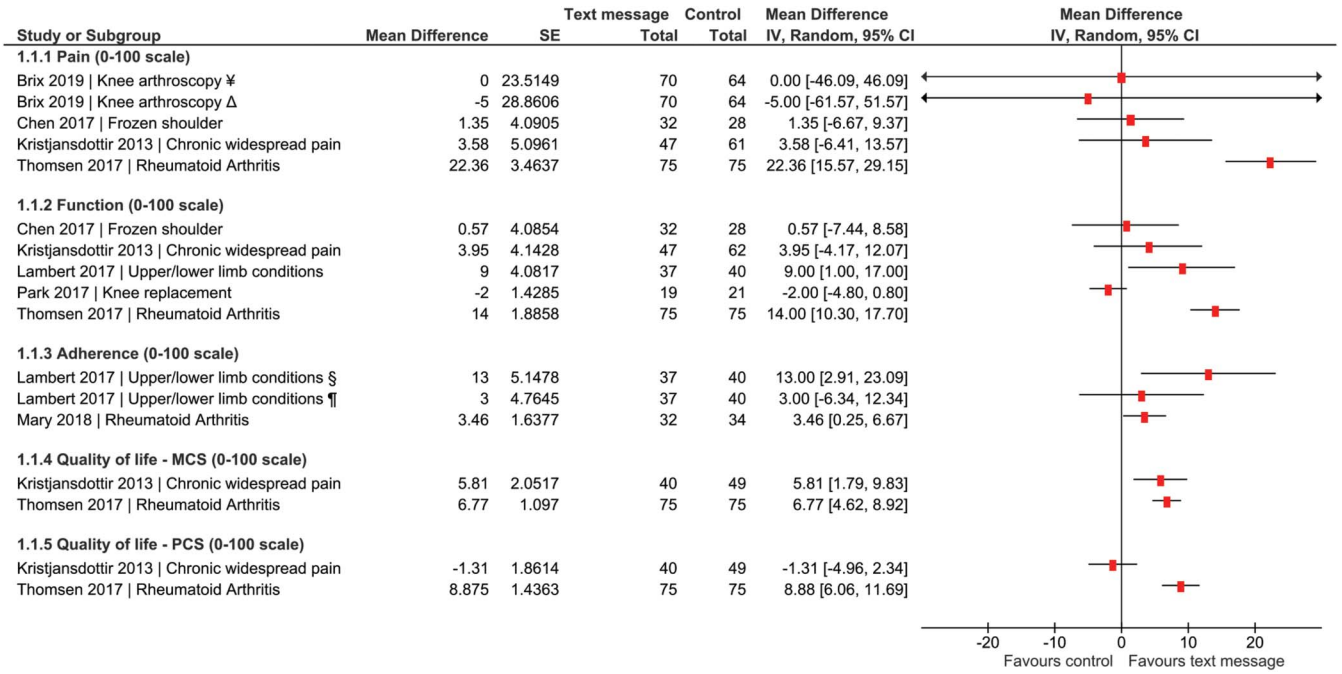


**Figure 2.** Forest plot of the most frequently reported outcomes. MCS, Mental Component Scale; PCS, Physical Component Scale; ¥pain at rest; Δpain when walking; §self-reported adherence; ¶assessor-reported adherence.

messages to health counselling compared with usual care, and Wang et al.[55] associated text messages with individualised counselling, group session, and a printed manual and compared it with group session alone (**Table 1**). For these studies, the specific added contribution of the text messages cannot be identified due to the presence of the additional interventions (ie, difference between interventions across groups was not only the provision of text messages).

The frequency of messages delivered varied from once monthly[55] up to 3 or more text messages daily,[5,31] and they were often sent through a software (n = 3) or a server (n = 3) [7,9,31,32,49,55] (**Table 2**). Only 5 studies included a clear statement that some characteristics of the messages were personalised. Participants could have received extra information based on questions about specific feedback,[7] could have received the messages at their preferred time,[9,55] could have received messages with details about the surgery they would undergo,[49] or could have received messages based on their individual health-related goals with their names and on their preferred frequency and time.[52] Approximately 30% of the studies clearly reported whether participants were allowed to reply to the text messages (n = 3)[7,31,41] or that the messages were 2-way (ie, the sender delivers a message and expects a reply from the receiver) (n = 1).[32] In addition, one study stated that patients were not encouraged to respond to the messages, but they could reply with predefined keywords (such as pain or shower) and obtain additional automated responses.[7]

None of the studies reported whether the content development of the messages was informed by a theoretical framework. The content of the text messages was educational (n = 1),[49] motivational (n = 1),[34] or a combination of educational and motivational (n = 2).[7,45] In 5 studies, text messages were used as reminders to complete online diaries,[31] to take medication,[5,41] to increase physical activity,[52] and of healthy behaviours.[55] Text messages were also used in combination with reminders to perform exercises with motivational and educational content (n = 1)[9] or reminders to take medication and questions about rheumatic disease activity and adverse events (n = 1).[32] Some studies provided examples of the text messages as presented in **Table 2**.

### 3.4. Risk of bias

The overall methodological quality of the included studies was fair (PEDro score of 4-5 points)[24] (**Table 3**). The mean PEDro score was of 5.4/10 points (SD 1.13). Five studies[32,34,41,45,52] had a PEDro score of ≥6/10 points (ie, good methodological quality). Only one study reported concealed allocation[34] and 3 studies reported follow-up rates <85%.[5,31,55] No study reported blinding of participants and 1 study reported blinding of therapists.[5]

### 3.5. Outcomes

Results from studies that added text messages to and compared with usual care[5,9,32,41] are presented in **Table 4**. Results from studies that combined text messages with other interventions[8,31,34,52,55] and a study that compared a text message with telephone health coaching[45] are presented in **Table 5**. The calculated effect sizes and 95% CIs of the more frequently assessed outcomes are presented in **Figures 2 and 3**. The overall quality of evidence for the outcomes of pain and function was low (Supplemental Table 2, available at http://links.lww.com/PAIN/B75).

### 3.6. Effects of text messages added to and compared with usual care alone

#### 3.6.1. Pain

Compared with usual care alone, adding a text message intervention to usual care did not significantly improve pain in

**Table 1**

**Characteristics of included RCTs**

| Author, y | Condition | Symptom duration (y) | Sample size (% females) | Age (mean ± SD) | Outcome measures | Intervention characteristics and contents | Intervention and follow-up duration | Country |
|---|---|---|---|---|---|---|---|---|
| Brix, 2019[5] | Post knee arthroscopy | NR | CG: 64 (62%)<br>IG: 70 (49%) | CG: 46.6 ± 12.8<br>IG: 47.5 ± 16.5 | Adherence to medication (number of missed doses)<br>Pain at rest (NRS)<br>Pain during walking (NRS)<br>No of unscheduled contact with healthcare providers | CG: UC (written and oral instructions about medication)<br>IG: UC + 10 TM reminders | Intervention: 4 d<br>Follow-up: 4 d | Denmark |
| Campbell, 2019[7] | Post primary total hip or knee arthroplasty | NR | CG: 83 (43%)<br>IG: 76 (46%) | CG: 59.5 ± 8.0<br>IG: 61.0 ± 8.2 | Adherence to exercise (min/d doing home-based exercise)<br>No. of calls to the surgeon's office<br>No. of patients presenting to the ED<br>Mood state (VAS)<br>Days taking narcotics<br>Knee ROM (degrees) | CG: UC (perioperative education)<br>IG: UC + TM and video messages | Intervention: 6 wk<br>Follow-up: 6 wk | USA |
| Chen, 2017[9] | Frozen shoulder | NR | CG: 33 (61%)<br>IG: 33 (62%) | CG: 59.0 ± 9.4<br>IG: 56.1 ± 7.5 | Pain (VAS)<br>Adherence to exercise (self-reported)<br>Function (SST)<br>Active shoulder ROM (degrees) | CG: UC (corticosteroid injection + exercise instructions + printed exercise pamphlet)<br>IG: UC + TM | Intervention: 2 wk<br>Follow-up: 2 wk | Taiwan |
| Kristjansdottir, 2013[a, b][30,31] | Chronic widespread pain | CG: 15.5 ± 12.1<br>IG: 13.1 ± 8.8 | CG: 66 (100%)<br>IG: 69 (100%) | CG: 43.8 ± 11.2<br>IG: 44.6 ± 11.1 | Pain (VAS)<br>Function (FIQ)<br>Quality of life (SF-8)<br>Pain catastrophizing (PCS)<br>Pain acceptance (CPAQ)<br>General health (GHQ)<br>Pain values (CPVI)<br>Fatigue (VAS)<br>Sleep disturbance levels (VAS) | CG: 4-wk multidisciplinary inpatient rehabilitation for chronic pain (CBT, motivational interviewing, and exercise) + myofascial pain treatment and medication as needed + self-management web site<br>IG: Same as the CG; smartphone rehabilitation (1 educational face-to-face session + 3 web-based diaries/day with personalised feedback + TM reminders to complete diary + guided mindfulness audio files) | Intervention: 4-wk multidisciplinary rehabilitation + 4-wk smartphone intervention after discharge for the IG<br>Follow-up: 8, 28, and 48 wk | Norway |
| Kuusalo, 2020[32] | Rheumatoid arthritis | NR | CG: 82 (70%)<br>IG: 84 (71%) | CG: 59.0 ± 14.0<br>IG: 54.0 ± 13.0 | Quality of life (SF-36)<br>No. of visits to doctors<br>No. of calls to doctors<br>No. of calls to nurses<br>No. of visits to nurses<br>Disease activity (Boolean remission and DAS28)<br>Confidence to treatment (VAS) | CG: UC (medical visits at 0, 3, and 6 mo and phone calls if needed)<br>IG: Same UC + TM | Intervention: 24 wk<br>Follow-up: 24 and 52 wk | Finland |
| Lambert, 2017[34] | Upper or lower limb MSK injuries or conditions | CG: 5.3 (2.0-6.3)*†<br>IG: 4.5 (3.3-7.9)*† | CG: 40 (63%)<br>IG: 40 (68%) | CG: 47 (35-48)*<br>IG: 56 (24-59)* | Self-reported adherence (NRS)<br>Assessor-reported adherence (NRS)<br>Function (PSFS)<br>Disability (WHODAS 2.0)<br>Perceived global impression of change (GCS)<br>Satisfaction with healthcare service (NRS) | CG: UC (paper-based home exercise program)<br>IG: Home exercise program prescribed on an app + phone call at 2 wk (and at 1 and/or 3 wk if they had not log any activity on the app for 7 d) + TM | Intervention: 4 wk<br>Follow-up: 4 wk | Australia |

(*continued on next page*)

Table 1 (*continued*)

| Author, y | Condition | Symptom duration (y) | Sample size (% females) | Age (mean ± SD) | Outcome measures | Intervention characteristics and contents | Intervention and follow-up duration | Country |
|---|---|---|---|---|---|---|---|---|
| Mary, 2018[41] | Rheumatoid arthritis | Overall: 12.0 ± 11.0 | CG: 38 (79%)<br>IG1: 37 (73%)<br>IG2: 37 (81%) | CG: 58.2 ± 8.8<br>IG1: 56.3 ± 10.6<br>IG2: 59.1 ± 14.4 | Function (HAQ)<br>Adherence to medication (CQR-19 and Girerd score)<br>Disease activity (DAS28)<br>Erythrocyte sedimentation rate<br>Serum C-reactive protein levels | CG: UC (standard advice by the medical doctor and pharmacist)<br>IG1: UC + pharmacist counselling on medication + advices sheet<br>IG2: UC + TM | Intervention: 24 wk<br>Follow-up: 24 wk | France |
| Park, 2017[45] | Post total knee replacement | NR | CG: 21 (95%)<br>IG: 19 (89%) | 50-80 | Knee function (total WOMAC score)<br>Function (ADL scale)<br>Life satisfaction (Kang scale) | CG: Fortnightly telephone counselling (questions about the patient's general condition, daily activities, and inflammatory status; encouragement to exercise and reminder of the next session)<br>IG: Fortnightly TM | Intervention: 11 wk<br>Follow-up: 11 wk | South Korea |
| Smith, 2018[49] | Post hand surgery due to trauma | NR | CG: 20 (% NR)<br>IG: 20 (% NR) | NR | Hospital attendance (PROMs)<br>Time of surgery (PROMs)<br>Overall hospital experience (PROMs) | CG: UC (verbal and written information about the surgery)<br>IG: UC + TM | Intervention: 2 d<br>Follow-up: 3 d | United Kingdom |
| Thomsen, 2017[52] | Rheumatoid arthritis | CG: 11.0 (7.0-20.0)<br>IG: 12.00 (8.0-20.0) | CG: 75 (80%)<br>IG: 75 (81%) | CG: 59.5 ± 12.7<br>IG: 59.7 ± 10.7 | Pain (VAS)<br>Function (HAQ)<br>Quality of life (SF-36)<br>Daily sitting time (h/d)<br>Daily standing time (hrs/d)<br>Daily stepping time (h/d)<br>Breaks up of daily sitting time (numbers/d)<br>Sitting time at work (h/d)<br>Sitting time in leisure (hrs/d)<br>Fatigue (VAS and MFI)<br>Self-efficacy (GSES)<br>Anthropometric and cardiometabolic biomarkers (weight, waist circumference, waist–hip ratio, body mass index, blood pressure, and lipids) | CG: UC<br>IG: 3 individual motivational counselling sessions + TM | Intervention: 16 wk<br>Follow-up: 16 wk | Denmark |
| Wang, 2018[55] | Knee pain | NR | CG: 248 (100%)<br>IG: 277 (100%) | CG: 39.0 ± 7.1<br>IG: 40.0 ± 6.1 | Pain (WOMAC) | CG: 1 face-to-face group general women's health education session based on healthy diet and physical activity<br>IG: same as CG + behavioural change–based program manual (goal setting and self-monitoring) + 1 telephone coaching session + TM | Intervention: 52 wk<br>Follow-up: 52 wk | Australia |

* Median (IQR).

† Months

ADL, activity of daily living; CBT, cognitive behavioural therapy; CG, control group; CPAQ, Chronic Pain Acceptance Questionnaire; CPVI, Chronic Pain Values Inventory; CQR-19, Compliance Questionnaire Rheumatology 19; DAS28, Disease Activity Score 28; ED, emergency department; FIQ, Fibromyalgia Impact Questionnaire; GCS, Global Change Scale; GHQ, 12-item General Health Questionnaire; GSES, General Self-Efficacy Scale; HAQ, Health Assessment Questionnaire; IG, intervention group; IQR, interquartile range; MFI, Multidimensional Fatigue Inventory; MSK, musculoskeletal; NR, not reported; NRS, Numerical Rating Scale; PCS, Pain Catastrophizing Scale; PROMs, patient-reported outcome measures; PSFS, Patient-Specific Functional Scale; RCTs, randomised clinical trials; ROM, range of motion; SF-36, 36-Item Short-Form Health Survey; SF-8, 8-Item Short-Form Health Survey; SST, simple shoulder test; TM, text message; UC, usual care; VAS, Visual Analogue Scale; WHODAS, World Health Organization Disability Assessment Schedule 2.0; WOMAC, Western Ontario and McMaster Universities Osteoarthritis.

**Table 2**

**Characteristics of text message (TM) interventions.**

| Author, y | TM frequency and sending method | TM characteristics/content and examples (when available) |
|---|---|---|
| Brix, 2019[5] | 10 automated TMs over 4 d (1 sent in the 1st day and 3 sent in the following days), sending method not reported | TMs were reminders to take the medication.<br>Example:<br>"Remember to take the medication as recommended" |
| Campbell, 2019[7] | 93 TMs over a 6-week period delivered at an appropriate time based on patients' recovery progress, automatically sent through the surgeon's SMS bot (StreaMD), which was hosted on a health insurance server | TMs contained recovery instructions with encouraging and empathetic statements, personalised videos from the surgeon, and instructional therapy videos. Patients could send preconfigured keywords and receive additional automated TM.<br>Example:<br>Motivation—"Pain is normal after replacement surgery. It can be specifically intense during the first few days after…" |
| Chen, 2017[9] | 1 TM/d, 2 wk, automatically sent through a platform at 8 PM or at patients' preferred time | TMs were reminders and contained motivational and educational content. |
| Kristjansdottir, 2013$_{a,b}$[30,31] | 3 TMs/d with links to online diaries, 4 wk + up to 2 extra TMs per diary if the diary was not completed, automatically sent through a web server | TMs contained a link to complete online diary and reminders to complete the diary if it was not completed within 20-40 minutes. |
| Kuusalo, 2020[32] | 13 TMs at 1-2 wk intervals for 24 wk, automatically sent through a cloud-based software | TMs were reminders to take medication or contained questions about medication use, adverse effects, and assessment of disease activity. Replies were awaited as letters (Y/N) or numbers (0-10).<br>Examples:<br>"Have you started the prescribed medication?"<br>"Have you had problems with your medication?"<br>"What is the severity of your RA symptoms on a scale from 0 to 10, where 0 corresponds to no symptoms and 10 to as severe symptoms as you can imagine?" |
| Lambert, 2017[34] | 1x/wk, sending method not reported | TMs contained motivational statements.<br>Examples:<br>"Keep up the hard work"<br>"Have you logged your exercises on your app today?"<br>"Well done completing 4 wk of home exercises" |
| Mary, 2018[41] | 1x/wk on the morning at the time medication was to be taken, sending method not reported | TMs were reminders to take medication.<br>Example:<br>"Hello, don't forget to take your methotrexate today. Have a nice day! From the Rheumatology Department in Amiens" (in French). |
| Park, 2017[45] | Fortnightly TM, sending method not reported | TMs contained the same content as telephone counselling, with questions regarding the patient's general condition, information on activities to avoid, encouragement to do exercises, and reminders of the next outpatient visit.<br>Examples:<br>"How are you? Do you have any discomfort or pain in daily living? Avoid hot tub bath or sauna and just have a short shower at home."<br>"What are most important after surgery are knee exercise and the observation of inflammatory symptoms at the surgical site. Check if the surgical site suddenly turns reddish or has severe flush."<br>"The next outpatient visit is on MM/DD at HH o'clock. -Joint Center of A hospital" |
| Smith, 2018[49] | 2 TMs sent on the previous day and on the day of surgery; automatically sent by Lister Care Limited software | TMs contained information regarding the surgical procedure (date, time, location, type of surgery and anaesthesia, food and drink recommendation, waiting time, a link to the hospital web site, and a number to call if they had any questions). |
| Thomsen, 2017[52] | Frequency and timing of the TM were individualised based on patients' preferences and sent through SMS-Track (https://sms-track.com/) | TMs were reminders to increase physical activity by decreasing sedentary behaviour.<br>Examples:<br>"Hello X. Stand up and allow gravity to assist you to digest your lunch. Bonus: you burn more energy when you stand."<br>"Hi X. Regard vacuum cleaning as a free fitness hour. Make a playlist, put music in your ears and do not stop until the list and the cleaning are done."<br>"Hi X. You have some truly privileged colleagues who will be able to see you stand up by your table this afternoon. Show them how to do it, and they might follow your good example." |
| Wang, 2018[55] | 1 monthly TM, sending method not reported | TMs were reminders of key healthy behaviours in accordance with the self-management intervention program. |

N, no; TM, text message; Y, yes.

**Table 3**

**Methodological quality of included RCTs**

| Author (year) | Eligibility criteria | Random allocation | Concealed allocation | Baseline comparability | Blind subjects | Blind therapists | Blind assessors | Adequate follow-up | Intention-to-treat analysis | Between-group comparisons | Point estimates and variability | Total Score (0-10) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brix, 2019[5] | | | | | | | | | | | | 5 |
| Campbell, 2019[7] | | | | | | | | | | | | 5 |
| *Chen, 2017[9] | | | | | | | | | | | | 5 |
| *Kristjansdottir, 2013$_{a,b}$[30,31] | | | | | | | | | | | | 5 |
| Kuusalo, 2020[32] | | | | | | | | | | | | 6 |
| *Lambert, 2017[34] | | | | | | | | | | | | 8 |
| Mary, 2018[41] | | | | | | | | | | | | 6 |
| Park, 2017[45] | | | | | | | | | | | | 6 |
| Smith, 2018[49] | | | | | | | | | | | | 4 |
| Thomsen, 2017[52] | | | | | | | | | | | | 6 |
| *Wang, 2018[55] | | | | | | | | | | | | 4 |

Total score: 9 to 10 excellent, 6 to 8 good, 4 to 5 fair, and <4 poor.
*The PEDro score provided from the PEDro database.
Yes = white; no = grey.
RCT, randomised controlled trial.

patients with frozen shoulder (MD 1.3/100, 95% CI −6.7 to 9.4)[9] (**Fig. 2**), nor pain at rest (MD 0.00/100, 95% CI −16.31 to 16.31) or during walking (MD −5.00/100, 95% −25.09 to 15.09) in patients after knee arthroscopy[5] (**Fig. 2**).

#### 3.6.2. Function

The addition of text messages to usual care did not improve function (MD 0.6/100, 95% CI −7.4 to 8.6) in patients with frozen shoulder.[9] Moreover, text message reminders to take medication did not improve function in patients with rheumatoid arthritis[41] (**Table 4**).

#### 3.6.3. Care-seeking behaviour

Text messages did not reduce the number of visits to doctors (MD −0.0, 95% CI −0.1 to 0.1) or nurses (MD −0.1, 95% CI −0.4 to 0.2), or unscheduled calls to doctors (MD 0.0, 95% CI −0.2 to 0.2), but increased the unscheduled telephone calls to nurses (MD −1.3, 95% CI −2.2 to −0.5) in patients with rheumatoid arthritis.[32] Text messages did also not affect the number of unscheduled contacts with healthcare providers (ie, hospital and general practitioners) after knee arthroscopy[5] (**Table 4**).

#### 3.6.4. Adherence

Positive effects were reported when text messages were added to usual care on the proportion of patients with frozen shoulder adhering to prescribed exercises[9] (**Table 4**) and medication adherence score in patients with rheumatoid arthritis (MD 3.5/100, 95% CI 0.2-6.7).[41] Nonetheless, one study did not find significant differences between groups on the number of missed medication doses and on the proportion of patients nonadhering to all doses prescribed after knee arthroscopy[5] (**Table 4**).

### 3.7. Effects of text messages as a component of a comprehensive intervention compared with any other intervention

#### 3.7.1. Pain

Three studies investigated the association of text messages with a variety of treatments.[31,52,55] Text message reminders added to a smartphone rehabilitation after a multidisciplinary inpatient rehabilitation program for chronic widespread pain did not improve pain in comparison with a smartphone rehabilitation after a multidisciplinary inpatient rehabilitation program (MD 3.6/100, 95% CI −6.4 to 13.6)[31] (**Fig. 2**). However, a text message intervention to increase light physical activity in addition to motivational counselling led to a positive and significant effect on pain compared with usual care (MD 22.4/100, 95% CI 15.6 to 29.1) in patients with rheumatoid arthritis[52] (**Fig. 2**). Moreover, text message reminders added to and compared with health coaching also decreased the odds of knee pain exacerbations in women with knee pain[55] (**Table 4**).

#### 3.7.2. Function

Three studies explored the addition of text messages to a variety of treatments and found contrasting results on function[31,34,52] (**Fig. 2**). The addition of text message reminders to a smartphone rehabilitation after a multidisciplinary inpatient rehabilitation program compared with multidisciplinary inpatient rehabilitation alone for chronic widespread pain did not significantly improve function (MD 3.9/100, 95% CI −4.2 to 12.1).[31] However, the addition of text messages to motivational counselling led to a small positive effect on function (MD 14.0/100, 95% CI 10.3-17.7) in comparison with usual care for patients with rheumatoid arthritis.[52] Moreover, exercise prescription on a mobile app associated with a phone call and text messages improved

**Table 4**

**Effects of text messages added to usual care and compared with usual care alone.**

| Study | Outcome | Available data per group (mean ± SD) | Mean difference (95% CI) |
|---|---|---|---|
| Studies with good methodological quality (ie, PEDro scale 6-8) | | | |
| Kuusalo, 2020[32] | PCS of the quality of life (SF-36; 0-100) | NR | NR |
| | MCS of the quality of life (SF-36; 0-100) | NR | NR |
| | Disease activity (Boolean remission rate; %) | IG: 51% (95% CI 40.0-62.0)<br>CG: 42% (95% CI 32.0-53.0) | 9.0 (−6.2 to 24.2) |
| | Disease activity (DAS28; 0-9.4) | IG: 2.2 ± 1.6<br>CG: 2.2 ± 1.5 | 0.0 (−0.48 to 0.48) |
| | Confidence with treatment (VAS*) | NR | NR |
| Mary, 2018[41] | Function (HAQ; 0-3) | NR | NR |
| | Adherence to medication (Girerd score; 0-36) | IG: −0.38 ± 0.61<br>CG: −0.29 ± 0.84 | −0.09 (−0.44 to 0.26) |
| | Adherence to medication (MPR; %) | IG: 90.0 ± 11.0<br>CG: 89.0 ± 13.0 | OR 0.97 (0.22 to 4.21) |
| | Disease activity (DAS28; 0-9.4) | NR | NR |
| | Erythrocyte sedimentation rate | NR | NR |
| | Serum C-reactive protein levels | NR | NR |
| Studies with fair methodological quality (ie, PEDro scale 4-5) | | | |
| Brix, 2019[5] | Adherence to medication (number of missed doses) | IG: 1.0<br>CG: 2.5 | OR 0.45 (0.04 to 5.08) |
| | Proportion of patients not adhering to all prescribed doses | IG: 63.7%<br>CG: 67.8% | OR 0.88 (0.43 to 1.80) |
| | No of unscheduled contact with healthcare providers | IG: 4.0<br>CG: 7.0 | OR 0.49 (0.14 to 1.77) |
| Chen, 2017[9] | Adherence to exercise (self-reported; %) | IG: 96.6%<br>CG: 85.2% | OR 6.74 (0.74 to 61.66) |
| | Active shoulder forward flexion ROM (degrees) | IG: 148.9 ± 11.5<br>CG: 146.8 ± 10.5 | 2.11 (−3.2 to 7.4) |
| | Active shoulder external rotation ROM (degrees) | IG: 73.2 ± 13.1<br>CG: 64.5 ± 16.9 | 8.71 (1.4 to 16.0) |
| | Active shoulder internal rotation ROM (degrees) | IG: 58.6 ± 23.5<br>CG: 49.4 ± 20.5 | 9.19 (−1.4 to 19.8) |
| | Active abduction ROM (degrees) | IG: 136.7 ± 18.5<br>CG: 136.2 ± 18.0 | 0.50 (−8.3 to 9.3) |

* Scale not reported.

CG, control group; CI, confidence interval; DAS28, Disease Activity Score 28; HAQ, Health Assessment Questionnaire; IG, intervention group; MCS, Mental Component Scale; MPR, medicine possession ratio; NR, not reported; OR, odds ratio; PCS, Physical Component Scale; ROM, range of motion; VAS, Visual Analogue Scale.

function (MD 9.0/100, 95% CI 1.0-17.0) in patients with upper/lower limb conditions compared with usual care.[34]

### 3.7.3. Care-seeking behaviour

One study assessed the effects of adding text and video messages to usual care on care-seeking behaviour.[7] It reduced the number of telephone calls to the surgeon's office (MD 2.1, 95% CI 1.2-3.0) and the number of presentations to the emergency department after knee/hip arthroplasty[7] (**Table 4**).

### 3.7.4. Adherence

Two studies investigated the addition of text messages to different interventions on adherence.[7] The addition of text and video messages to usual care increased daily time performing exercise (MD 8.6 minutes, 95% CI 4.9-12.4) after knee/hip arthroplasty[7,34] (**Table 4**). By contrast, the association of mobile app, phone call, and text messages increased self-reported (MD 13.0/100, 95% CI 2.9-23.1) but not assessor-reported (MD 3.0/100, 95% CI −6.3 to 12.3) adherence score to exercise in patients with upper/lower limb musculoskeletal disorders compared with usual care[34] (**Fig. 2**).

### 3.7.5. Quality of life

Three studies assessed the quality of life.[31,32,52] The addition of text messages to a smartphone rehabilitation after a multidisciplinary inpatient rehabilitation program for chronic widespread pain did not increase the physical component (MD −1.3/100, 95% CI −5.0 to 2.3) but improved the mental component of the quality of life (MD 5.8/100, 95% CI 1.8-9.8)[31] when compared with inpatient rehabilitation alone (**Fig. 2**). The addition of text message reminders to motivational counselling sessions for patients with rheumatoid arthritis resulted in greater improvement in both physical (MD 8.88/100, 95% CI 6.10-11.66) and mental (MD 6.77/100, 95% CI 4.62-8.92) components of the quality of life[52] compared with usual care (**Fig. 2**). No other differences were found[32] (**Table 4**).

**Table 5**

**Effect of text messages as a component of a comprehensive intervention compared with any other intervention.**

| Study | Outcome | Available data per group (mean ± SD) | Mean difference (95% CI) |
|---|---|---|---|
| Studies with good methodological quality (ie, PEDro scale 6-8) | | | |
| Lambert, 2017[34] | Disability (WHODAS; 0-48) | IG 5.1 ± 5.1<br>CG 6.5 ± 6.5 | −0.6 (−2.9 to 1.7) |
| | Perceived global impression of change (GCS; 0-10) | IG 7.9 ± 1.6<br>CG 7.4 ± 1.9 | 0.5 (−0.3 to 1.3) |
| Thomsen, 2017[52] | Daily sitting time (hrs/d) | IG −1.6 (−2.0 to −1.2)<br>CG 0.6 (0.2 to 0.9) | −2.2 (−2.7 to −1.7) |
| | Daily standing time (hrs/d) | IG 1.2 (0.8 to 1.7)<br>CG −0.3 (−0.4 to 0.8) | 1.5 (1.1 to 1.9) |
| | Daily stepping time (hrs/d) | IG 0.5 (0.3 to 0.9)<br>CG 0.0 (−0.3 to 0.6) | 0.5 (0.3 to 0.7) |
| | Breaks of daily sitting time (numbers/day) | IG −0.5 (−3.5 to 2.6)<br>CG −2.0 (−5.0 to 1.1) | 1.5 (−2.2 to 5.8) |
| | Sitting time at work (hrs/d) | IG −1.1 (−1.7 to −0.6)<br>CG 0.0 (0.5 to 0.5) | −1.1 (−1.9 to −0.3) |
| | Sitting time in leisure (hrs/d) | IG −1.3 (−1.7 to −0.9)<br>CG 0.1 (−0.2 to 0.5) | −1.5 (−2.0 to −0.9) |
| | Fatigue (VAS; 0-100) | IG −19.0 (−24.2 to −13.9)<br>CG 7.8 (2.6 to 12.9) | −26.8 (−34.3 to −19.3) |
| | General fatigue (MFI; 4-20) | IG −2.2 (−3.0 to −1.3)<br>CG 1.2 (0.4 to 2.1) | −3.4 (−4.6 to 2.3) |
| | Physical fatigue (MFI; 4-20) | IG −3.18 (−4.0 to −2.3)<br>CG 1.34 (0.5 to 2.2) | −4.5 (−5.7 to −3.3) |
| | Mental fatigue (MFI; 4-20) | IG −1.8 (−2.5 to 1.10)<br>CG 0.65 (0.0 to 1.3) | −2.5 (−3.5 to −1.5) |
| | Reduced activity (MFI; 4-20) | IG −3.28 (−4.0 to −2.5)<br>CG 1.6 (0.8 to 2.4) | −4.9 (−6.0 to −3.8) |
| | Reduced motivation (MFI; 4-20) | IG −1.35 (−2.0 to −0.7)<br>CG 1.26 (0.6 to 1.9) | −2.6 (−3.5 to −1.7) |
| | Self-efficacy (GSES; 10-40) | IG 15.7 ± 39.4<br>CG −6.45 ± 12.8 | 6.2 (4.5 to 7.9) |
| Studies with fair methodological quality (ie, PEDro scale 4-5) | | | |
| Campbell, 2019[7] | Time spent on home-based exercise (min/d) | IG 46.4 ± 17.4<br>CG 37.7 ± 16.3 | 8.6 (4.9 to 12.4) |
| | Number of patients presenting to the ED | IG 0.0<br>CG 4.0 | |
| | Mood state (VAS; 0-10) | IG 7.5 ± 1.8<br>CG 6.5 ± 1.7 | 0.9 (0.5 to 1.3) |
| | Time taking narcotics (days) | IG 22.5 ± 13.4<br>CG 32.4 ± 11.8 | 10.0 (−14.2 to −5.7) |
| | Knee extension ROM (degrees) | IG 1.6 ± 2.8<br>CG 2.6 ± 5.5 | −1.0 (−2.8 to 0.9) |
| | Knee flexion ROM (degrees) | IG 111.9 ± 13.3<br>CG 108.0 ± 12.8 | 3.9 (−1.6 to 9.3) |
| Kristjansdottir, 2013$_{a, b}$[30,31] | Pain catastrophizing (PCS; 0-52) | IG 15.1 ± 9.7<br>CG 15.4 ± 9.2 | −0.3 (−3.5 to −2.9) |
| | Pain acceptance (CPAQ; 0-120) | IG 72.5 ± 15.7<br>CG 63.5 ± 13.3 | 9.7 (2.7 to 15.3) |
| | General health (GHQ-12; 0-12) | IG 1.8 ± 2.5<br>CG 1.8 ± 2.1 | 0.0 (−1.0 to 1.0) |
| | Chronic pain values (CPVI; 0-5) | IG 2.9 ± 1.0<br>CG 2.3 ± 0.9 | 0.6 (0.2 to 1.0) |
| | Fatigue (VAS; 0-100) | IG 52.26 ± 29.18<br>CG 53.20 ± 24.04 | −0.9 (−12.1 to 10.2) |
| | Sleep disturbance values (VAS; 0-100) | IG 43.41 ± 30.60<br>CG 48.90 ± 26.12 | −5.5 (−17.4 to 6.4) |
| Wang, 2018[55] | Knee pain increasing<br>Knee pain improvement | IG odds ratio 0.4 (0.1 to 1.0)<br>CG odds ratio 1.1 (0.5 to 2.4) | |

CG, control group; CI, confidence interval; CPAQ, Chronic Pain Acceptance Questionnaire; CPVI, Chronic Pain Values Inventory; ED, emergency department; GCS, global change score; GHQ, 12-item General Health Questionnaire; GSES, General Self-Efficacy Scale; IG, intervention group; MFI, Multidimensional Fatigue Inventory; PCS, Physical Component Scale; ROM, range of motion; VAS, Visual Analogue Scale; WHODAS, World Health Organization Disability Assessment Schedule 2.0.

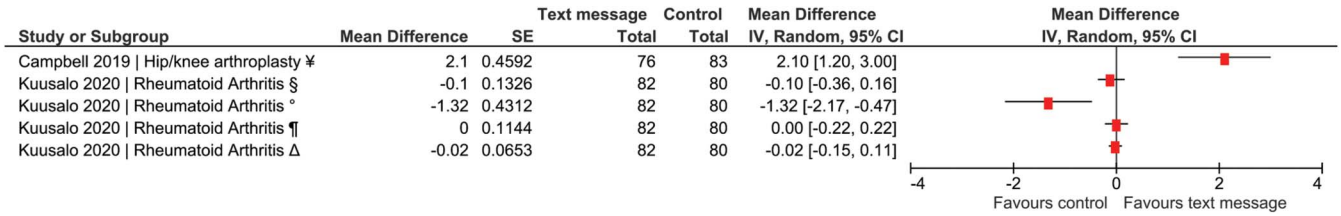


**Figure 3.** Forest plot of care-seeking behaviour. ¥Number of calls to the surgeon's office; §number of calls to doctors; °number of calls to nurses; ¶number of unscheduled visits to nurses; Δnumber of unscheduled visits to doctors.

### *3.8. Effects of text messages compared with telephone counselling*

#### *3.8.1. Function*

One study compared educational and motivational text messages with telephone counselling and found similar results in function after total knee replacement (MD −2.0/100, 95% CI −4.8 to 0.8)[45] (**Fig. 2**).

#### *3.8.2. Patients' feedback and adverse events*

Seven studies reported patients' satisfaction and/or feedback to researchers about the intervention received[7,9,31,32,34,41,49] (Appendix 1, available at http://links.lww.com/PAIN/B75). Generally, patients were satisfied with treatments when text messages were associated with usual care[9,32,41,49] and stated that they would recommend it to other patients.[32,49] One study that associated text messages with a smartphone-based intervention (web-based diaries with feedback from health professionals) added to and compared with inpatient rehabilitation reported that 86% of patients from the IG agreed that the messages and the smartphone rehabilitation were useful.[31] In addition, Campbell et al. reported that a greater percentage of patients from the IG (text and video messages) than from the control group (CG) (usual care) reported being provided with clear instructions on how to recover (94.5% of the IG vs 47.5% of the CG), feeling more encouraged to meet rehabilitation goals (86.3% of the IG vs 37.5% of the CG), and prioritising to do exercises daily (78.3% of the IG vs 51.3% of the CG).[7]

Only 3 studies[32,34,41] reported adverse events, which were related to the medications used to manage rheumatoid arthritis[32,41] and pain during performance of the home exercise program.[34] No study described any adverse events associated with the use of text messages (**Table 6**).

## 4. Discussion

To the best of our knowledge, this is the first systematic review to assess the effect of text message interventions in the management of musculoskeletal pain. Strengths of this review include a comprehensive search strategy, citation tracking, and search for published and unpublished studies. Eleven studies from 10 different countries including patients with 9 musculoskeletal conditions provided a broad overview of the use of text messages in the treatment of musculoskeletal pain. Text messages lead to similar effects on function and life satisfaction when compared with telephone health counselling.[45] When added to and compared with usual care, text messages did not result in additional improvements on pain,[5,9] function,[9,41] quality of life,[32] or use of care[5,32] but lead to positive effects on treatment adherence.[9,41] When text messages were a component of a comprehensive intervention, conflicting results were reported on function[31,34,52] and the physical component of quality of life,[31,52] whereas positive effects were reported on pain reduction,[52,55] mental component of quality of life,[31,52] exercise adherence,[7] and care-seeking behaviour.[7]

One of the limitations of the review is the absence of a meta-analysis, which was not performed because of the heterogeneity of interventions, participants' characteristics, outcomes, and follow-up duration. Moreover, the overall quality of evidence was low, and only the postintervention results were considered when data were summarised because of diversity in the length of interventions and follow-ups. The heterogeneity of the text message interventions and trial designs (ie, text message interventions added to usual care vs usual care alone and text message interventions added to comprehensive multicomponent interventions) also limits the discernment of the individual effects of the text messages. Thus, our understanding of the potential benefits of text messages on pain and function as well as other health-related outcomes is limited, especially when considering their long-term effects. Future clinical trials investigating the effects of text messages as the sole intervention in the treatment of musculoskeletal pain may be needed to identify the isolated effects of the text messages. We also acknowledge, however, that pragmatic clinical trials assessing the effects of text messages in addition to and compared with usual care or other comprehensive multicomponent interventions might better represent clinical practice and be more beneficial to guide clinical implementation.

**Table 6**

**Effect of text messages compared with telephone counselling.**

| Study | Outcome | Available data per group (mean ± SD) | Mean difference (95% CI) |
|---|---|---|---|
| Study with good methodological quality (ie, PEDro scale 6-8) | | | |
| Park, 2017[45] | Disability (WOMAC; 0-4) | IG 0.63 ± 0.32<br>CG 0.58 ± 0.30 | 1.0 (−0.2 to 0.2) |
| | Life satisfaction (Kang scale; 1-3) | IG 2.3 ± 0.24<br>CG 2.2 ± 0.2 | 0.1 (0.0 to 0.2) |

CG, control group; IG, intervention group; WOMAC, Western Ontario and McMaster Universities Osteoarthritis.

There was a lack of information on the specific characteristics of the text message interventions. A few studies stated if the frequency and content of the messages were individualised[7,32,41,52] characteristics that have been previously associated with greater effects of text message interventions in health promotion.[22] Moreover, no study described if the messages were developed based on a theoretical framework. This issue has also been observed in the development of smartphone applications for chronic pain.[33] Although previous systematic reviews found that the theoretical framework did not positively impact messages' effect[22] or may even cause a negative impact[2] on health promotion, their role in text message interventions for the management of musculoskeletal pain is not yet known. Future clinical trials assessing the effects of text messages developed based on a theoretical framework are essential. The findings would allow the understanding of the importance of developing text messages based on a theoretical framework for this population.

Studies included in the review reported that participants were generally satisfied with the treatments provided.[7,9,31,32,34,41,49] Participants felt well informed and would recommend text message interventions to other patients. These findings agree with high acceptance rates and positive feedback stated by patients when text message interventions were delivered to improve medication[51] and exercise[36] adherence as well as lifestyle and risk factors for coronary heart disease.[11] Furthermore, only 3 studies reported adverse events[32,34,41] and no event was associated with the messages received. Although the adverse events may be underestimated, the findings indicate the safety of the interventions.

Text messages represent a relevant way of communication between health professionals and patients and may include provision of instructions, suggestions, and education related to healthcare conditions, self-management, and treatment.[13,20] They may be appropriate strategies when non–face-to-face contact is needed, as for instance in times of pandemic, as they are widely accessible, affordable, and can be frequently used.[40] Regrettably, the possible mechanisms of effects, as well as features, content, and theoretical framework of the text message interventions associated with larger treatment effects in patients with musculoskeletal pain, are not yet known. However, studies that delivered text message interventions to remind and/or motivate patients of key healthy lifestyle behaviour,[55] physical activity participation,[52] or rehabilitation[7,34] reported positive benefits on pain,[52,55] function,[34,52] adherence,[7,34] and care-seeking behaviour.[7] These findings may be related to the importance of lifestyle factors on musculoskeletal pain, such as physical activity, sedentary behaviour, smoking status, and body weight[18,46,48] and may indicate potential benefits of text message as reminders and motivators that could be further investigated. In addition, assessments of the long-term effects of the text message interventions and their benefits to patients with different symptom duration might be beneficial because patients with acute or chronic symptoms might respond to text messages differently. Given included studies did not report clear data on symptom duration, it was not possible to ascertain the specific impact of text message interventions in chronic vs acute conditions.

Studies included in this review indicated some potential benefits when text messages were delivered as an independent intervention or as a support to usual care or other treatments, especially on adherence to treatment and the mental component of quality of life. In sight of the increasing prevalence and burden of musculoskeletal conditions[26,28,39] and the well-established effects of health-promoting and self-management text message interventions on patients with chronic diseases,[2,20,22,51] text messages may represent an accessible strategy that needs to be further explored. Text messages were found to be as effective as telephone counselling for improving function after total knee replacement. This suggests that text messages might be a more cost-effective and practical way to deliver care and rehabilitation after total knee replacement. No cost-effectiveness analysis has been conducted in any of the included trials, however. Policymakers, clinicians, and patients would benefit from this information when making evidence-based, informed decisions on whether or not to implement text messages as part of their management. Studies should ensure that they include and report appropriate concealment of allocation and blinding of assessors (when possible) to decrease potential bias in their results. Ideal characteristics of text message interventions, such as frequency and duration, and possible moderators of the effects also need to be further investigated before their implementation in the management of musculoskeletal pain can be endorsed.

## Conflict of interest statement

The authors have no conflicts of interest to declare.

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## Appendix A. Supplemental digital content

Supplemental digital content associated with this article can be found online at http://links.lww.com/PAIN/B75.

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# CHAPTER FOUR

## TEXT4myBACK – The development process of a self-management intervention delivered via text message for low back pain

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The co-authors of the paper "***Fritsch CG**, Ferreira PH, Prior JL, Vesentini GV, Schlotfeldt P, Eyles J, Robbins S, Yu S, Mills K, Taylor DA, Lambert TE, Clavisi O, Bywaters L, Chow CK, Redfern J, McLachlan AJ, Ferreira ML. TEXT4myBACK – The Development Process of a Self-Management Intervention Delivered Via Text Message for Low Back Pain. Arch Rehabil Res Clin Transl 2021 27;3(2):100128. doi: 10.1016/j.arrct.2021.100128*" confirm that Carolina G Fritsch has made the primary contribution to this study in each of the following areas:

• Data acquisition
• Data analysis and interpretation of findings
• Writing of the manuscript and critical appraisal of content

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

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Original Research

# TEXT4myBACK — The Development Process of a Self-Management Intervention Delivered Via Text Message for Low Back Pain

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*List of abbreviations:* LBP, low back pain.

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**KEYWORDS**
Low back pain;
Rehabilitation;
Telemedicine;
Text messaging

**Abstract** *Objective:* To develop a bank of text messages for a lifestyle-based self-management intervention for people with low back pain (LBP).
*Design:* Iterative development process.
*Setting:* Community and primary care.
*Participants:* Fifteen researchers, clinicians, and consumer representatives participated in the concept and initial content development phase. Twelve experts (researchers and clinicians) and 12 consumers participated in the experts and consumers review phase. Full study sample of participants was N=39.
*Interventions:* Not applicable.
*Main Outcome Measures:* We first conducted two 2-hour workshops to identify important domains for people with LBP, sources of content, appropriate volume, and timing of the messages. The messages were then drafted by a team of writers. Second, we invited expert researchers and clinicians to review and score the messages using a 5-item psychometric scale according to (1) the appropriateness of the content and (2) the likelihood of clinical effectiveness and to provide written feedback. Messages scoring ≤8 out of 10 points would be modified accordingly. Consumers were invited to review the messages and score them using a 5-item psychometric scale according to the utility of the content, the understanding of the content, and language acceptability and to provide feedback. Messages scoring ≤12 out of 15 points would be improved.
*Results:* Exercise, education, mood, sleep, use of care, and medication domains were identified and 82 domain-specific evidence-based messages were written. Messages received a mean score of 8.3 out of 10 points by experts. Twenty-nine messages were modified accordingly. The mean score of the messages based on consumers feedback was of 12.5 out of 15 points. Thirty-six messages were improved.
*Conclusions:* We developed a bank of text messages for an evidence-based self-management intervention using a theory-based, iterative, codesign process with researchers, consumers, and clinicians. This article provides scientific support for future development of text message interventions within the pain field.


Low back pain (LBP) is currently understood as a long-lasting and complex condition.[1] It encompasses related recurrent episodes and is influenced by multiple factors, including biopsychosocial and lifestyle factors as well as comorbidities and pain-processing mechanisms.[1] Most cases of LBP can be defined as nonspecific because it is not possible to identify a specific nociceptive source.[1] LBP is the greatest cause of disability worldwide, affecting approximately 576 million people and accounting for 64.9 million years lived with a disability in 2017.[2] The number of years lived with disability due to low back pain has increased by 17% between 2007 and 2017,[2] and it is expected to continue to rise owing to rises in population and ageing.[1] The economic burden of LBP is also growing, and it is related to both direct (related to health care) and indirect (related to absence at work and reduced productivity) costs.[1] Both the economic and societal burdens of the condition are influenced by the high prevalence of LBP-related disability in the working population leading to work absenteeism or productivity loss.[1]

Current evidence recommends the use of education and self-management as first-line care for LBP.[3] Self-management strategies can be defined as "all tasks that lead individuals to engage in managing their own symptoms, treatments, and the physical, emotional and social impacts of living with a chronic condition."[4] Previous systematic reviews have shown that self-management interventions can improve outcomes, such as pain and disability, when compared to usual care for people with LBP.[5,6] Even though some studies included components of important lifestyle behaviors known to be risk factors of LBP development (ie, physical activity participation, sleep quality, mood),[7] most of these studies failed to include these elements in the interventions delivered.[5,6]

Text message—based programs are effective and cost-effective self-management interventions for various health conditions, such as diabetes, cardiovascular diseases, and HIV.[8-12] Self-management interventions delivered via text messages have provided health promotion benefits, increased physical activity levels, and provided support for successful weight loss and smoking cessation.[9,10,13-15] Because the development and management of LBP are influenced by lifestyle factors,[1,7] people with LBP could benefit from lifestyle-based self-management interventions delivered via text messages. However, no such text message—based program exists to support the management of LBP. Thus, the aim of the current study was to develop a lifestyle-based self-management intervention delivered via text messages for people with LBP. The effectiveness of the intervention is being tested in a randomized clinical trial.

## Methods

### Design

An iterative, codesign process was conducted to develop lifestyle-focused self-management text messages for

individuals with LBP. The process was based on a previously published framework[16] and included 2 phases—the concept and content development phase and the expert and consumer review phase. The study was conducted at the Kolling Institute, the University of Sydney. Ethics approval from the Northern Sydney Local Health District was attained before study commencement (NSLHD RESP 18/173). The feasibility of the text message intervention was later tested in a pilot study.

**Phase 1: concept and initial content development**

The concept of the intervention was first discussed in two 2-hour workshops with researchers, consumer representatives from Musculoskeletal Australia (a support group for people with arthritis and musculoskeletal conditions), and multidisciplinary clinicians (medicine, behavioral change methodology, public health, allied health, pharmacy) with specific knowledge of LBP. Consumer representatives were those who represented patients and the broader musculoskeletal pain community by providing their perspective in decision-making processes, service planning, and improvement of health care and research.

At the first workshop, clinicians, researchers, and consumer representatives met to discuss and decide on the key domains relevant to individuals with LBP based on the main domains found on the "Managing your pain: an A-Z guide" consumer resource developed by Musculoskeletal Australia, which is a consumer organization.[17] This evidence-based consumer guide was created by Musculoskeletal Australia staff and consumers with input from clinicians (ie, rheumatologists, physiotherapists, pain specialists).

The same participants met for the second workshop. The aim of the second workshop was to identify the sources of content that should be used to develop the text messages and decide on the structure of the text message intervention. The participants discussed and decided on the duration of the intervention, the total number of text messages to be sent, frequency of text messages to be sent per week, as well as days and time of day that the messages should be sent. This process was based on scientific evidence.[18,19] Participants also discussed possible names for the text message intervention. The name "TEXT4myBACK" was suggested by 1 of the investigators after the workshop and was approved by the study team.

The messages were then drafted by the team of writers composed of researchers (J.P., G.V.) and consumer representatives (O.C., L.B.) who participated in the initial workshops. The researchers were experienced physiotherapists with expertise and training in the treatment and research of musculoskeletal disorders. The 2 consumer representatives had more than 20 years of experience in working with evidence-based practice and providing information resources and support for consumers and have previously developed consumer guides for people with musculoskeletal pain. They collaborated to systematically formulate a series of messages for each domain from the recommended sources previously identified.

The messages were based on evidence[1,3,17,20-25] and written under the theoretical basis of behavior change methodology[26] previously used in an effective self-management text message intervention.[16] The behavior change techniques used in the text messages included provision of information and encouragement; prompting about consequences, intention formation, monitoring self-behavior, and barrier identification; advice about setting graded tasks; and strategies aimed at relapse prevention and the use of prompting and cues. Each message was developed to convey a single concept and had 1 of 3 aims: education, motivation, or behavior change.

The text messages were developed to be sent to individuals with LBP who may or may not be seeking care for their LBP but are willing to receive a text message—based self-management intervention. The messages were written using simple language and contained common abbreviations. The number of characters of each message was limited to 160, which is the maximum number of characters that can be sent in a single text message. They were designed to be 1-way messages, which do not require a reply from the receivers, and to be sent by an automated software. The software would randomly select the days and times that the messages would be sent. After the initial bank of text messages was developed, writers met to confirm that different text messages did not contain the same content, were in simple and clear language, and within the limit of characters.

**Phase 2: experts and consumers review**

After the initial bank of messages was developed, the research investigators identified key opinion leaders in the field of LBP to be part of the expert review panel. The expert review process aimed to improve the quality of the content of the messages as well as their likelihood of clinical effectiveness. Potential review panel members were sent an invitation by email with a description of the project and the participant information statement detailing the aim and role of the review panel. After the signature of the online consent form, the experts were asked to score each message via an online survey using a 5-item psychometric scale (strongly agree: 5 points; strongly disagree: 1 point) according to (1) appropriateness of content according to available evidence and (2) likelihood of clinical effectiveness. Each message received a total score between 2-10 points by each reviewer. The mean of the total scores for each message and across all reviewers was calculated, providing a total average score of 2-10 points. Panelists were also able to provide recommendations for improvement. It was established that messages receiving a sum score <8 points by any reviewer would be changed and improved according to the reviewer's comment to maximize their quality and likelihood of effectiveness.

After the messages were improved based on experts' reviews, 12 people living with LBP were identified by Musculoskeletal Australia and invited to participate in the review process. Consumer review panel members were sent an invitation by email with a description of the project and the participant information statement detailing the aim and role of the review panel. After signing the consent form, the consumers were asked to complete an online survey assessing each message in terms of (1) perceived utility of the text content, (2) understanding of the text content, and (3) language acceptability. The same 5-item psychometric scale was used for each of the 3 items above. The total score for all 3 items and each message were summed, yielding a total score of 3-15 points for each reviewer (consumer). The

mean of the total scores for each message and across all reviewers was calculated, providing a total average score of 3-15 points for each text message. The consumers were also asked to provide recommendations for improvement. We established that messages receiving a sum score <12 points by any reviewer would be changed and improved according to the comments received.

## Results

### Phase 1: concept and content development

In the first workshop, the following key domains were identified as important for people with LBP: exercise, education, mood, use of care, sleep, and medication.

In the second workshop, content for the development of text messages were sourced from the Low Back Pain Lancet Series,[1,3,20,21] international clinical practice guidelines (ie, the National Institute for Health and Care Excellence guidelines for low back pain,[22] the National Health and Medical Research Council guideline for acute musculoskeletal pain,[23] and the New South Wales Agency for Clinical Innovation model of care for people with acute low back pain[24]), and consumer group educational resources.[17,25] Based on previous evidence,[19] the group established that the acceptable frequency was 4 text messages per week. Twelve weeks of text message intervention was considered an appropriate duration for people with LBP, leading to a total volume of 48 text messages to be delivered. The time slots of 9 AM, 12:30 PM, 4 PM, and 6 PM were identified as potentially appropriate for this population.[19] Considering the importance of advice to remain active for people with LBP,[3] it was agreed that exercise was the domain that needed most emphasis and reinforcement in the messages. Therefore, it was decided that messages from the exercise domain would be sent twice per week, and 1 message from education or mood domains and sleep, use of care, or medication domains will be sent once a week.

In this way, a total of 82 text messages were written to ensure enough messages would be available for personalization and after possible deletions following the expert and consumer reviews. Forty messages were developed for the exercise domain, 10 messages were developed for education and mood domains, 8 messages for use of care domain, and 7 messages for sleep and medication domains. The messages were developed to empower patients, thus sentences with a negative tone using words such as “do not” or “should not” were not included in the messages.

The team of writers reviewed all messages to remove duplicates and to ensure they provided evidence-based information, were of appropriate length, and contained only lay terms. All messages were reviewed by researchers with expertise in behavior change techniques to maximize potential effectiveness and ensure alignment with behavior change (J.R., C.C.). Researchers have over 10 years of experience in developing content for over 11 text message programs for patients with chronic diseases including publishing process,[16] developing a methodology to customize the content for different cultural and ethnic populations,[27] ongoing evaluation of consumer engagement and feedback,[18] as well as identifying the characteristics of the text messages that make them more effective.[28] The messages underwent a further writing process to ensure that the correct message was captured in approximately 160 characters and included the sign of “#Usyd” to enable patients to easily identify where the messages are from.

### Phase 2: experts and consumers review

The expert review panel consisted of 12 experts in the field of LBP, including researchers, pharmacists, physiotherapists, rheumatologists, clinical psychologists, and general practitioners. Each expert reviewed 15 messages to ensure that every message was reviewed by a minimum of 2 experts.

The mean score of the bank of messages was 8.3 out of 10 points. The mean scores of the appropriateness of the content and the likelihood of clinical effectiveness of the messages from each domain are shown in table 1. Experts also shared written feedback related to some messages. Comments were most frequently grammatical suggestions, such as changing or adding words and restructuring sentences for easier understanding. Experts also provided suggestions about the content of the messages, including adapting technical language to improve lay understanding, changing the emphasis of the content, and adding or modifying the examples provided. The reviewers also suggested personalizing some of the messages, shared their own experiences related to the content, and provided positive feedback about some messages. Please refer to figures 1 and 2 to see examples of the iterative process along with quotations of the feedback received and changes made to 1 message of each domain.

Approximately 34% of the bank of drafts (29 messages) received a sum score <8 points by 1 reviewer and were modified according to the written feedback provided. Regarding changes in each domain, the medication domain received the greatest proportion of suggested changes and 57% of these draft messages were improved. This was followed by the education, use of care, and exercise domains, with 50%, 37.5%, and 35% of the draft messages revised, respectively. The domains with the least changes were sleep and mood, with 14% and 10% of the messages improved, respectively. However, only 24% of the bank of drafts had a mean sum score of <8 out of 10 points.

The consumer review panel consisted of 12 people with LBP invited to review the messages and provide feedback. Sixty-seven percent of consumers were women (n=8). Each consumer also evaluated 15 messages to ensure that every message was reviewed by a minimum of 2 people.

The mean score of the bank of messages was 12.5 out of 15 points. The mean scores of the easiness to understand the information, the usefulness of the information, and the acceptability of the language of the messages from each domain are shown in table 2. Consumers also shared written feedback related to some messages. Comments were most frequently related to the content of the messages and suggested the provision of more specific, less technical information and the use of more examples. Some also recommended targeting a few messages to people with specific clinical characteristics. Consumers also provided grammatical advice to alter words and restructure sentences to facilitate understanding, readability, and provide information in a

**Table 1** Survey scores from experts for each text message domain

| Domains | Characteristics Assessed | Score* |
|---|---|---|
| **Exercise domain** | Appropriateness of the content | 4.18±0.92 |
| | Likelihood of clinical effectiveness | 3.98±0.92 |
| | Mean sum score (2-10 points) | 8.19±1.35 |
| **Education domain** | Appropriateness of the content | 4.07±0.98 |
| | Likelihood of clinical effectiveness | 4.04±0.79 |
| | Mean sum score (2-10 points) | 8.08±1.13 |
| **Mood domain** | Appropriateness of the content | 4.60±0.60 |
| | Likelihood of clinical effectiveness | 4.40±0.60 |
| | Mean sum score (2-10 points) | 9.00±1.00 |
| **Use of care domain** | Appropriateness of the content | 4.10±1.02 |
| | Likelihood of clinical effectiveness | 3.75±1.21 |
| | Mean sum score (2-10 points) | 7.96±1.74 |
| **Sleep domain** | Appropriateness of the content | 4.35±0.63 |
| | Likelihood of clinical effectiveness | 4.07±0.73 |
| | Mean sum score (2-10 points) | 8.43±1.00 |
| **Medication domain** | Appropriateness of the content | 4.07±1.00 |
| | Likelihood of clinical effectiveness | 4.07±1.00 |
| | Mean sum score (2-10 points) | 8.14±1.34 |

NOTE. Values are mean ± SD.
* Appropriateness of the content and likelihood of clinical effectiveness scores range from 1-5 points.

friendlier way. They also shared their personal experiences that related to some aspects of the messages, including their difficulties related to the advice provided or the positive effect that the advice had on their pain.

Approximately 42% of the bank of drafts (36 messages) received a score <12 points by 1 reviewer and were modified according to the written feedback provided. Regarding changes in each domain, the education domain had the greatest proportion of changes with 70% of the draft messages improved. It was followed by the sleep, medication, use of care, and exercise domains, with 57%, 57%, 50%, and 40% of the drafts revised, respectively. None of the mood domain messages was changed. However, only 31% of the messages had a mean sum score of <12 out of 15 points. Examples of the final versions of the text messages can be found in table 3.

## Discussion

This article describes an iterative process used for the development of lifestyle-based self-management text messages to support recovery from an episode of LBP. Eighty-two text messages were developed and will be used in a future evaluation of the effectiveness of self-management for people with LBP. The messages contain useful and lay content in a well-accepted language by patients. This approach was

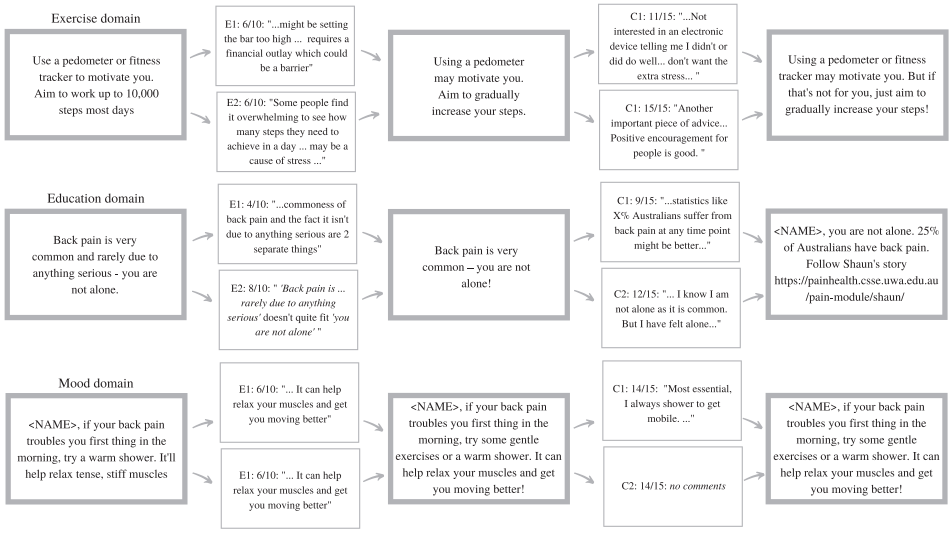


**Fig 1** Examples of the review process of text messages from exercise, education, and mood domains with quotations of the feedback provided by experts and consumers. C, consumer; E, expert.

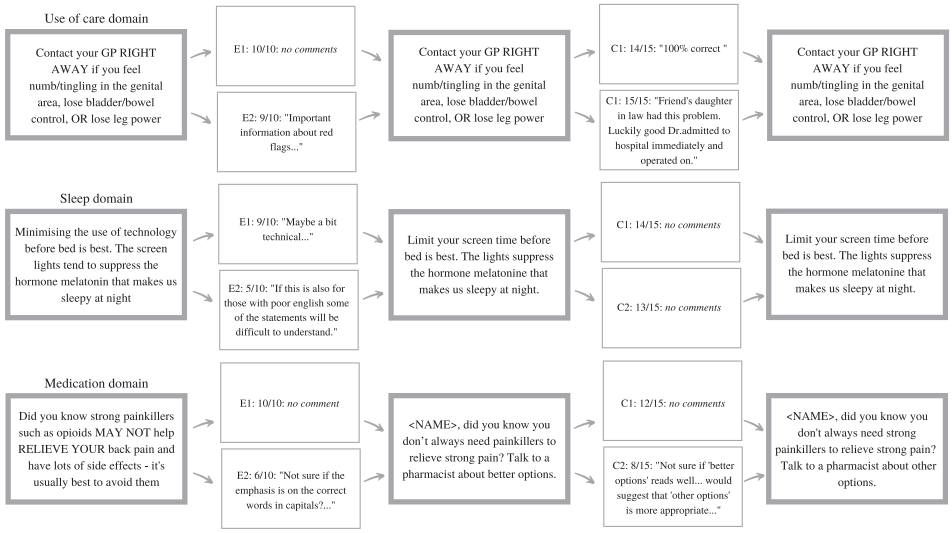


**Fig 2** Examples of the review process of text messages from use of care, sleep, and medication domains with quotations of the feedback provided by experts and consumers. C consumer; E, expert; GP, general practitioner.

based on current evidence[29,30] and on previous text message development processes aimed at preventing cardiovascular events in people with coronary heart disease performed by members of the study team.[16,18] This iterative development was proved to be feasible and aimed to maximize the possible clinical effectiveness and future implementation of the messages.

To our knowledge, this is the first study to describe the development process of a text message intervention aimed to educate and promote self-management in individuals with LBP. The process included researchers, clinicians, consumers, and consumers representatives in the process and followed the recommended framework.[29,30] The characteristics of the overall text message program are valuable to

**Table 2** Survey scores from consumers for each text message domain

| Domains | Characteristics Assessed | Score* |
|---|---|---|
| **Exercise domain** | Information easy to understand | 4.40±0.65 |
| | Information was useful | 4.28±0.87 |
| | Language was acceptable | 4.13±0.81 |
| | Mean sum score (3-15 points) | 12.83±1.50 |
| **Education domain** | Information easy to understand | 4.03±0.76 |
| | Information was useful | 3.57±0.97 |
| | Language was acceptable | 3.70±1.05 |
| | Mean sum score (3-15 points) | 11.30±1.86 |
| **Mood domain** | Information easy to understand | 4.42±0.61 |
| | Information was useful | 4.47±0.51 |
| | Language was acceptable | 4.39±0.50 |
| | Mean sum score (3-15 points) | 13.40±1.12 |
| **Use of care domain** | Information easy to understand | 4.18±0.81 |
| | Information was useful | 3.94±0.97 |
| | Language was acceptable | 3.89±0.99 |
| | Mean sum score (3-15 points) | 11.80±2.55 |
| **Sleep domain** | Information easy to understand | 4.45±0.52 |
| | Information was useful | 4.07±1.10 |
| | Language was acceptable | 4.07±0.80 |
| | Mean sum score (3-15 points) | 12.30±1.18 |
| **Medication domain** | Information easy to understand | 4.45±0.49 |
| | Information was useful | 3.94±0.97 |
| | Language was acceptable | 3.88±0.78 |
| | Mean sum score (3-15 points) | 12.00±12.28 |

NOTE. Values are mean ± SD.
* Information easy to understand, information was useful, and language was acceptable scores range from 1-5 points.

**Table 3** Examples of final text messages developed

| Domain | Example |
|---|---|
| **Exercise domain** | |
| Aim: education | Your back is designed to move. It may feel challenging but too much bed rest can actually make your back pain worse. #Usyd |
| Aim: behavior change | <NAME>, are you making yourself sore by doing too much or too little? Planning breaks and change your position between activities could help. #Usyd |
| **Education domain** | |
| Aim: education | <NAME>, the amount of pain you feel does not mean 'more damage.' Many things can increase your pain like worry, stress, or lack of sleep. #Usyd |
| Aim: education | <NAME>, did you know that 80% of people have back pain during their lives? It might not feel like it now but it does reduce with time. #Usyd |
| **Mood domain** | |
| Aim: motivation | <NAME>, even when you have pain, try to keep doing the things you enjoy, like seeing family and friends. |
| Aim: education/motivation | When you exercise your body releases chemicals that boost your mood and make you feel good, they also 'turn down the volume' on your pain system. #Usyd |
| **Use of care domain** | |
| Aim: education | <NAME>, haven't had a scan or x-ray? It's a good sign because studies have found most of what they show is normal. #Usyd |
| Aim: education | <NAME>, did you know that back pain rarely needs surgery? A nonsurgical treatment based on exercise and activity is usually good enough to help you. #Usyd |
| **Sleep domain** | |
| Aim: education/behavior change | Having problems sleeping? Try progressive muscle relaxation to ease your muscle tension. Tense your muscles 1 at a time, feel the tension, and then relax. #Usyd |
| Aim: advice/behavior change | Can't get to sleep? It may help to have a warm caffeine free drink, read a book, do some stretches or breathing exercises and go to bed when you feel more comfortable. #Usyd |
| **Medication domain** | |
| Aim: education | Endorphins are feel good hormones and your body's natural pain reliever. Your body releases them when you exercise and when you laugh. #Usyd |
| Aim: behavior change/education | Pain medication won't speed up your recovery but can be used with exercise to keep you active and doing the things you want to do. #Usyd |

lead to behavioral modifications, being frequent and unexpected messages key features to drive changes.[18] Thus, the characteristics of the overall text message program were discussed in the initial workshops and were based on scientific evidence.[18,19] Moreover, the developed text messages integrated the preferences and needs of patients with LBP reported in a recent systematic review.[31] The recent systematic review has shown that people with LBP want to receive information about LBP, self-management strategies, treatment options, as well as how to psychologically deal with pain in simple language.[31] Although patients wish to receive general information about LBP management, they also want to receive personalized advice from health care professionals that is more relevant to their symptoms.[31] TEXT4myBACK includes all of these aspects, providing information about LBP, treatment options (such as exercise, medication, surgery), self-management strategies, and advice for improving sleep and mood. The number of text messages developed allows future tailoring of the messages, which may be performed based on participants' characteristics, including physical activity participation, duration of symptoms, and presence of sleep issues.

Previous clinical trials have demonstrated the positive effects of text message interventions on exercise[32] and medication adherence[33,34] for people with musculoskeletal conditions. However, these studies did not describe the methodology for message development.[32-34] The lack of information about the development of text message interventions is also common in studies assessing their effectiveness in preventing cardiovascular diseases[35] and promoting health.[14] Lack of clarity regarding the development of text messages has been a target of criticism of the research field.[36] A comprehensive description of the processes and methodology used to develop text message interventions is encouraged because it will directly affect future research and intervention implementation.[36]

The TEXT4myBACK intervention represents a potential strategy to support self-management of LBP and, if proven effective, could be applied in clinical practice. The description of the development process ensures that messages are evidence-based and suitable for the target population. Conducting an iterative development process and describing the quality of the messages developed enhances the openness of the process and potentially the effectiveness of the intervention.[36] This report allows readers to better understand how the text message intervention was developed and will provide better instruments to assess its mechanisms of effect.[30,37] Moreover, it provides meaningful information to researchers and clinicians to develop their own work and support the progress of text messages in the management of LBP and other painful musculoskeletal conditions.[30] Conducting focus groups with consumers could represent an

alternative option to gain more in-depth feedback from patients on the utility and understanding of the message content. Similarly, consumer perspectives on the acceptability of the language, frequency, and timing of the messages and the duration of the intervention could have been better ascertained using a focus group approach, possibly leading to a more patient-centered and well-accepted intervention.

### Study limitations

Although the TEXT4myBACK intervention development followed the recommended framework[29,30] and included relevant information for people with LBP,[31] it has some limitations worth mentioning. The text messages were designed to be unidirectional only. Even though some may suggest the inclusion of bidirectional, interactive messaging,[29] recent systematic reviews have not identified any significant differences in treatment effects when comparing unidirectional and bidirectional interventions.[13,14] Despite theory-driven text message interventions not being proved more effective than nontheory driven interventions,[13,14] TEXT4myBACK text messages were developed based on behavioral change methodology.[26] The messages included features known to influence engagement, usefulness, and behavioral-change ability aiming to optimize its ability to change behavior, such as repeated presentation of a stimulus, practical advice, positive reinforcement, provision of achievable task-setting suggestions, and reliable and relevant information.[18] Even though the information of the text messages was considered useful and easy to understand and their language was well accepted by consumers, the messages were individually reviewed, and the acceptability of the entire text message intervention was not assessed. Apart from sex, no other participant demographic data have been collected. Although we acknowledge this as a limitation of the study, ascertaining the influence of consumers' demographics on the quality assessment of the text messages was beyond the scope of this study. The effectiveness and acceptability of the TEXT4myBACK intervention will be assessed in a future randomized controlled trial.

## Conclusions

Eighty-two evidence-based self-management text messages were developed to support recovery from LBP. The development of the TEXT4myBACK intervention was based on behavior change techniques,[26] incorporated information and advice that people with LBP wish to receive,[31] and followed recommendations from previous research for text message interventions development.[29,30] A future randomized clinical trial will be conducted to assess the effectiveness and cost-effectiveness of the intervention in improving health-related outcomes of people with LBP. This study provides scientific support for the future development of text message interventions within the pain field.

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# CHAPTER FIVE

## TEXT4myBACK - a text message intervention to improve function in people with low back pain: protocol of a randomised controlled trial

### Chapter Five has been previously published as:

Fritsch CG, Ferreira PH, Prior JL, Clavisi O, Chow CK, Redfern J, Thiagalingam A, Lung T, McLachlan AJ, Ferreira ML. TEXT4myBACK - A Text Message Intervention to Improve Function in People With Low Back Pain: Protocol of a Randomized Controlled Trial. Phys Ther 2021 Mar 24;pzab100. doi: 10.1093/ptj/pzab100. 

## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper "***Fritsch CG**, Ferreira PH, Prior JL, Clavisi O, Chow CK, Redfern J, Thiagalingam A, Lung T, McLachlan AJ, Ferreira ML. TEXT4myBACK - A Text Message Intervention to Improve Function in People With Low Back Pain: Protocol of a Randomized Controlled Trial. Phys Ther 2021 Mar 24;pzab100. doi: 10.1093/ptj/pzab100*" confirm that Carolina G Fritsch has provided the following contributions to the study:

• Conception and design of the research

• Writing of the manuscript and critical appraisal of the content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

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**Protocols**

# TEXT4myBACK: A Text Message Intervention to Improve Function in People With Low Back Pain—Protocol of a Randomized Controlled Trial

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## Abstract

**Objective.** The authors sought to describe the protocol of a randomized controlled trial that will investigate the effects of the TEXT4myBACK self-management text message intervention compared with control in people with low back pain (LBP).
**Methods.** A single-blind (assessor and statistician), randomized controlled trial with economic analysis and process evaluation will be conducted. A total of 304 people with non-specific LBP of less than 12 weeks will be enrolled and randomly allocated either to TEXT4myBACK intervention or control groups. The TEXT4myBACK intervention group will receive 4 semi-personalized text messages per week providing advice, motivation, and information about LBP, physical activity, sleep, mood, use of care, and medication during 12 weeks. The control group will receive 1 text message with a link to a LBP and diet online information package. Outcomes will be assessed at baseline and 3, 6, and 12 months. The primary outcome will be function assessed with the Patient-Specific Functional Scale. Secondary outcomes will include pain intensity, physical activity participation, sedentary behavior, global impression of change, health-related quality of life, and eHealth literacy. Data on demographic characteristics, smallest worthwhile change (ie, smallest function scored needed to be achieved at the end of the intervention to consider it to be worthwhile), health care utilization, and adverse events (ie, any new health issue that occurs during participation in the study) will be collected. An economic and process evaluation will also be conducted.
**Impact.** This study will assess if a self-management text message intervention is effective and cost-effective in improving function of people with LBP. This study can inform clinical practice of a simple, scalable, and affordable intervention for managing LBP.

**Keywords:** Low Back Pain, Mobile Health, Text Messaging



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## Introduction

Low back pain (LBP) is the greatest cause of disability worldwide[1] and is associated with great societal and economic burden.[2] Its economic burden is equivalent to the burden of other chronic non-communicable diseases, such as cardiovascular diseases and cancer.[3] To illustrate, LBP and neck pain led to approximately USD 134.5 billion in health care expenditures, the highest in the United States in 2016.[4] LBP is also related to greater risks of mortality[5] and higher numbers of comorbidities,[6] which further contribute to its burden.

Scientific evidence highlights the need to develop affordable interventions for LBP and to provide advice, education, and self-management as first-line care.[2] Mobile Health could represent innovative and scalable solutions to provide self-management strategies. Text messages are the most studied Mobile Health interventions in promotion, management, and monitoring of health[7] due to their widespread use, minimal costs, and low technology-related knowledge requirements.[7–9] Evidence-based text messages are effective self-management strategies for various health conditions, such as HIV,[10] diabetes,[11] and cardiovascular disease.[12] They also improve behavior and help people to increase physical activity participation,[13] quit smoking,[14] and improve weight management.[15] Text messages are cost-effective[16] and considered useful, engaging, and easy to understand by patients.[17] They could represent a simple and scalable intervention for LBP. However, although previous studies reported some positive effects of digital self-management interventions on pain and other health-related outcomes in people with LBP,[18] only interventions delivered by websites and mobile applications were assessed, and no study investigated the use of text messages. Moreover, a recent systematic review appraised the literature on the effects of text message interventions on musculoskeletal pain, and none of the included studies have included patients with LBP.[19]

TEXT4myBACK is a self-management text message intervention developed through an evidence-based[20,21] iterative process involving clinicians, researchers, consumers, and consumer advocates.[22] A preliminary cohort pilot study was conducted with people with LBP seeking care from community pharmacists to assess the feasibility of the methodological procedures and the delivery of the text message intervention to be implemented in a future randomized clinical trial. Ten people with LBP were recruited via community pharmacists (n = 1) and social media advertisements (n = 9). Participants completed the online consent form and online surveys and received the text messages as planned. Recruitment via social media and online consent form and data collection approaches were found to be feasible. The messages were well accepted: 70% of participants considered the messages to be informative, motivational, and educational and would like to receive them again. This study describes the protocol of the randomized controlled trial that will investigate the effects of the TEXT4myBACK intervention compared with control in people with LBP.

## Methods

### Study Design

This is a single-blind (assessor and biostatistician), randomized controlled trial. Outcomes are assessed at baseline and 3, 6, and 12 months post randomization. This protocol follows the Standard protocol items: recommendations for interventional trials (SPIRIT),[23] Consolidated standards of reporting trials (CONSORT),[24] and Template for intervention description and replication (TIDieR)[25] guidelines.

### Participants

A total of 304 adults living in Australia with non-specific LBP will be included in the study. Participants must meet the following inclusion criteria: (1) be aged 18 years or older; (2) have an episode of non-specific LBP of less than 12 weeks duration, with or without the presence of leg pain; (3) classify pain as "moderate" or above in the SF-12 pain scale (during the past week, how much did pain interfere with your normal work, including work outside the home and housework? 1: not at all, 2: a little bit, 3: moderately, 4: quite a bit, 5: extremely)[26]; and (4) have familiarity with the use and access to a mobile phone that receives text messages. Potential participants will be excluded if any of the following are present: (1) presence of serious spinal pathology, (2) current pregnancy, (3) spinal surgery within the past year, (4) comorbidities that prevent active participation in physical activity programs, (5) inadequate English to understand text messages or complete outcome measures, and (6) any disorder/reason that may reduce capacity to understand and give informed consent.

### Recruitment Method

A recruitment video and advertisement posters (online and paper-based) will be used to identify potential participants via social media, newsletters and newspapers, public notice boards, community events, websites, email lists, and health care practices. The posters contain a quick response code or a link to the online pre-screening form. Once the pre-screening form is completed, potential participants are contacted by telephone to ascertain their eligibility and interest. Eligible participants receive an email with a link to the online consent form and baseline survey (Figure).

### Procedures

#### Randomization and Blinding

Enrolment and randomization are performed with research electronic data capture (REDCap) by the trial coordinator. After the consent form and baseline survey are completed, participants are randomized to the control group or the intervention group in a 1:1 allocation ratio according to a computer-generated allocation sequence. The control intervention and the TEXT4myBACK intervention are assigned automatically on REDCap accordingly. Assessors and statisticians involved with data analysis are blinded to group allocation.

The study involves limited disclosure of the between-group difference to avoid potential performance bias. Participants will be informed they will be randomized to receive information on LBP via different text message formats differing in the volume of messages received. All outcome surveys are completed by participants.

#### Interventions

All participants receive a welcome text message informing that all messages will be signed as "#Usyd" and acknowledging their participation. They also receive messages containing links to the online surveys and advising them to contact the research team if feeling unsafe. Participants can continue with usual care for their LBP as needed. Care seeking for LBP is recorded at baseline and every 4 weeks via the health care utilization surveys.

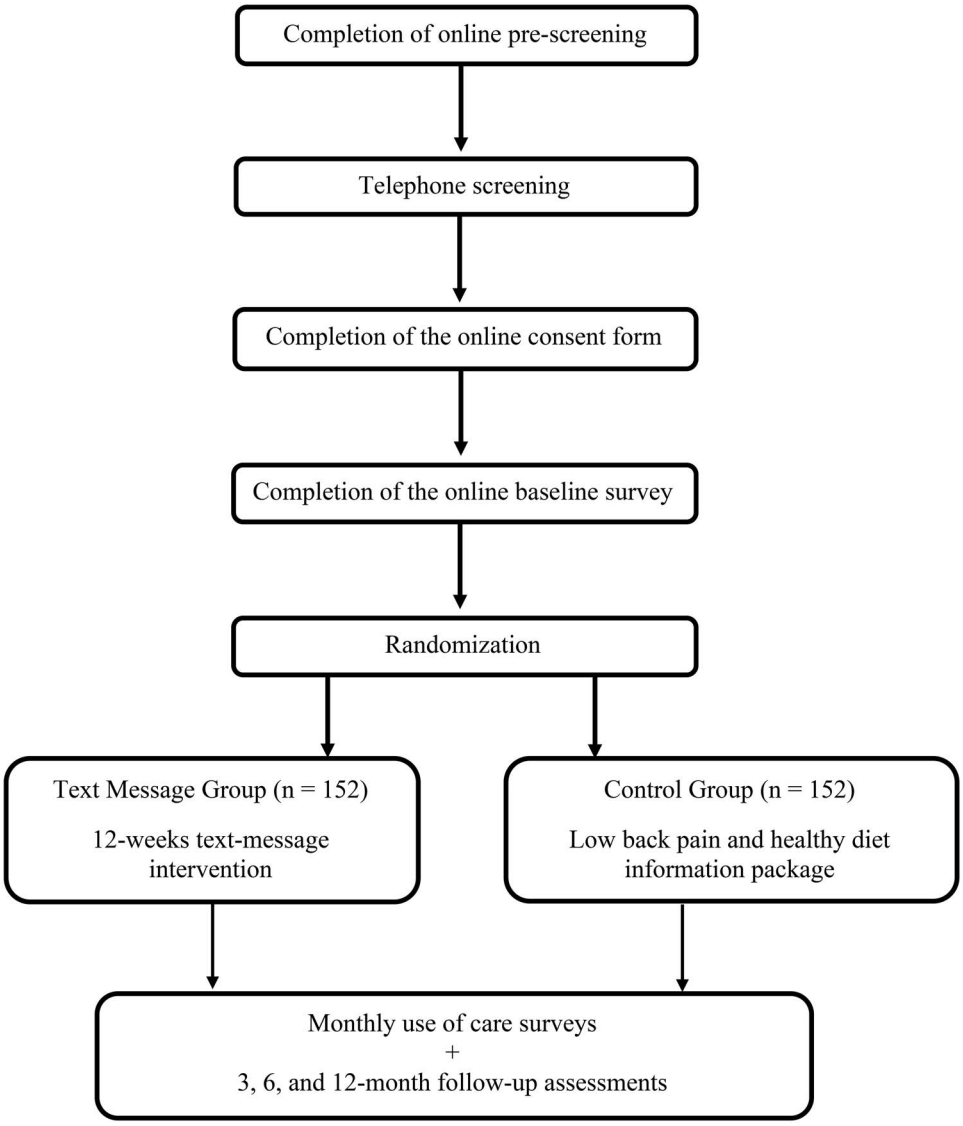


**Figure 1.** Trial flow diagram.

### Intervention Group

The intervention group will receive the TEXT4myBACK self-management text messages providing advice, motivation, and information about LBP, physical activity, sleep, mood, use of care, and medication. The messages were developed through an iterative process previously described involving researchers, health care professionals, consumers, and consumer representatives (being published elsewhere).[22] Message content is based on behavior change methodology,[27] including provision of information and encouragement, prompting about consequences, intention formation, monitoring self-behavior, barrier identification, advice about setting graded tasks, strategies aimed at relapse prevention, and the use of prompting and cues. This methodology has been used in an effective self-management text message intervention.[28]

Some messages will be semi-personalized and include the participant's preferred contact name (Table). The messages are further personalized by targeting their content using an algorithm derived from the key domains (ie, physical activity, education, sleep, mood, use of care, and medication) and according to symptom duration (0–6 weeks vs 6–12 weeks), presence of sleep issues, volume of physical activity (<150 minutes vs ≥150 minutes of moderate-vigorous physical activity), work characteristics (sedentary vs active), and consumption of medication for LBP at baseline. Messages are sent on randomly selected days including weekends but excluding public holidays at random time slots: 9 AM, 12:30 PM, 4 PM, and 6 PM. Sleep-related messages are tagged to be sent at 6 PM and some physical activity messages at 9 AM. The message delivery is managed by customized software (TextQStream V4, Python V.3.6) as previously described[29] using REDCap as user interface.

The messages are designed to be delivered 1-way (to the participant only). Participants can reply to them but are informed that they will not receive a reply in return. Participants can reply "STOP" at any time if they wish to stop receiving the messages. If a "STOP" message is received, the research team will confirm with the participant if they wish to stop the messages or withdraw from the study.

### Control Group

The control group will receive 1 text message containing a link to an interactive LBP and healthy diet information package in REDCap at 2 days post randomization. It contains

**Table.** Examples of the TEXT4myBACK Text Messages

| Domain | Example |
|---|---|
| Exercise | |
| Aim: education | Your back is designed to move. It may feel challenging but too much bed rest can actually make your back pain worse. #Usyd |
| Education | |
| Aim: education | <NAME>, the amount of pain you feel does not mean "more damage." Many things can increase your pain like worry, stress or lack of sleep. #Usyd |
| Mood | |
| Aim: motivation | <NAME>, even when you have pain, try to keep doing the things you enjoy, like seeing family and friends. #Usyd |
| Use of care | |
| Aim: education | <NAME>, did you know that back pain rarely needs surgery? A non-surgical option based on exercise and activity is usually good enough to help you. #Usyd |
| Sleep | |
| Aim: education/ behavior change | Having problems sleeping? Try progressive muscle relaxation to ease your muscle tension. Tense your muscles 1 at a time, feel the tension and then relax. #Usyd |
| Medication | |
| Aim: education | Endorphins are feel-good hormones and your body's natural pain reliever. Your body releases them when you exercise and when you laugh. #Usyd |

general evidence-based information about the prevalence of LBP, classification of non-specific LBP, treatment options, and red flags. Differently from the intervention group, the control group will not receive any semi-personalized educational message about LBP, physical activity, sleep, mood, use of care, and medication. Participants will receive a text message reminder 6 weeks post randomization to complete the study surveys.

## Outcomes

The outcomes are recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials.[30] Participant demographics are assessed at baseline, and the primary and secondary outcomes are collected at baseline and 3, 6, and 12 months via online surveys sent via email and text messages. Automated email reminders are sent, and participants are called at 10 days if the surveys are not completed.

### Primary Outcome

1) Function: Assessed with the Patient-Specific Functional Scale.[31] Participants identify 3 important activities they are unable to do or have difficulty with as a result of their LBP. They will rate each activity using a numerical rating scale of 0 to 10 (0 = unable to perform the activity; 10 = able to perform the activity to the same level as before the injury or/problem).[31]

### Secondary Outcomes

1) Average pain intensity during the past week: Participants rate their average pain in the preceding week with a 0 to 100 visual analogue scale (0 = no pain; 100 = worst pain possible).[32]
2) Physical activity engagement: Participants complete the Active Australia Questionnaire, which contains 8 questions related to physical activity performance in the preceding week. Participants record the number of times and the estimated time spent in each activity.[33]
3) Sedentary behavior: Participants answer the Sedentary Behaviour Questionnaire, which contains 9 questions relating to time spent in sedentary activities on weekdays, which are repeated for weekend days and scored on a 9-point Likert scale.[34]
4) Participant's global impression of change: Participants rate their perceived improvements or deterioration using an 11-point numerical rating scale (−5 = vastly worse; +5 = completely recovered).[35]
5) Health-related quality of life: Participants complete the EQ-5D-5L questionnaire, which is a validated questionnaire[36] to describe and value an individual's health recommended within musculoskeletal populations.[37] It assesses mobility, self-care, usual activities, pain, and emotional health with 5 response levels to each question. It also rates the individual's perception of their health on a 0 to 100 scale (0 = worst health; 100 = best health). The final score provides an overall indicator of health-related quality of life.[36]
6) eHealth Literacy: Participants answer the eHealth Literacy Questionnaire, which is a validated questionnaire that evaluates patients' health literacy gaining a broad profile of their education on health and self-management strategies. The questionnaire consists of 7 different domains, which have 4 to 6 questions each.[38]

### Other Patient Data to Be Collected

1) Descriptive data: demographic characteristics (ie, age, sex, living arrangements, height, weight, employment status, level of education, sleep issues, and medication use), LBP duration, symptom distribution, and comorbidities (Self-Administered Comorbidity Questionnaire[39]) are assessed at baseline.
2) Smallest worthwhile effect: This question asks what function score participants need to achieve at the end of a self-management intervention to consider it to be worthwhile. Participants will score the smallest worthwhile effect on a 0 to 30 visual analogue scale (0 = unable to perform the 3 activities; 30 = able to perform the 3 activities to the same level as before the LBP).
3) Health care utilization: Online surveys assessing LBP care seeking (including visits to allied or alternative health care professionals, medications purchased and

visits to hospitals) are sent to participants every 4 weeks. Participants are asked to consent to share their Medicare data to capture prescription medications and medical services utilized over the 12-month study period.

4) Adverse events: Participants are asked about the occurrence of any new health issue at the 3-, 6-, and 12-month surveys to assess the occurrence of any adverse or serious adverse events. The answers are monitored by the study personnel and overviewed by a medical monitor. Moreover, the health counselor controls all returning messages from participants to ensure safety.

### Sample Size Calculation

Sample size calculation was based on the between-group difference at the primary endpoint (3 months), on the primary outcome (function). In a previous study assessing the effects of physical activity and exercises for LBP, the within-group change on physical function was normally distributed with an SD of 7 out of 30 points on the Patient-Specific Functional Scale.[40] A sample size of 152 per group (total of 304 participants) will achieve 90% power to detect an effect size of 0.4 (or 3 points on a 30-point scale) on function assuming an alpha of .05, allowing for a loss to follow-up rate of 15% at 3 months.

### Data Collection, Management, and Integrity

Data are collected using REDCap, which is a secure, web-based application designed to support data capture for research studies.[41,42] REDCap is located on the University of Sydney secure host server. It is password-protected and only accessible to approved study personnel. REDCap automatically saves the answers to the surveys and blocks any second attempt to complete the survey, avoiding double data entry. Study personnel will monitor data collection via automated reminders to confirm the completion of the surveys and monitor data integrity by data quality checks on REDCap and verification of each completed survey. Participants will be contacted for clarification if needed. A standard operational procedure describing the data monitoring plan was developed by the research team and approved by the sponsor. An Independent Data Safety Monitoring Team will meet to review safety data.

## Statistical Analysis Plan

Data analysis will be blinded, by intention-to-treat, and guided by a detailed statistical analysis plan. Analysis and interpretation (also performed blinded) on the primary and key secondary outcomes will be conducted by the research team and by an independent biostatistician and checked for accuracy. Statistical significance will be defined as $P < .05$ on the basis of a 2-sided test. Adjusted (sensitivity analysis) and unadjusted (main analysis) analyses will be presented for main confounders.

Primary analysis includes function at 3 months, and between-group differences at all follow-up time points will be analyzed with linear regression for continuous outcome measures and logistic regression for dichotomous outcome measures. The remaining time points and outcome measures will be regarded as secondary and analyzed separately with log-binomial regression for dichotomous measures and linear regression analysis for continuous outcomes or logistic regression for dichotomous outcomes. A secondary analysis including data from all follow-ups will be conducted using repeated measures with generalized estimating equations. The coefficient of the group × time interactions will provide estimates of treatment effects over time.

### Cost-Effectiveness Analysis

The primary analysis will be directed from the health sector's perspective, where costs of health care services will be valued at standard rates published by the Australian Government: Medical Benefits Schedule standard fees for medical services and procedures, Pharmaceutical Benefits Schedule cost for medications, and the Australian Refined Diagnosis Related Groups cost weights for hospital services. Private non-medical health care services will be valued at standard rates published by the relevant professional body or a third-party payer.

Medical Benefits Schedule and Pharmaceutical Benefits Schedule data will be merged and analyzed with the monthly health care utilization surveys over the 12 months of the follow-up. Linear mixed models will be used to estimate the difference in mean health care costs utilized and health-related quality of life between the intervention and control group. An incremental cost-effectiveness ratio will be calculated, defined as the difference in total costs divided by the difference in total quality-adjusted life years between the intervention and control groups.

## Process Evaluation

The potential scope of the TEXT4myBACK intervention will be assessed in terms of the number of people reached, the number of potential participants included and excluded, and the reasons for exclusion. The intervention delivery will be evaluated by the number of text messages delivered to each participant and the proportion of messages from each domain.

Participants from the intervention group will receive an online feedback survey after the completion of the 12-month outcome survey. It contains 1 open-ended question regarding participants' experience in receiving the text messages and their beliefs on how the intervention worked or not. It also contains closed-ended questions with either 4- to 5-item Likert scale or multiple choice answers. The questions concern the usefulness of the text messages; their motivational, educational, and informative aspects; adequacy of frequency and duration of the intervention; perceived differences in lifestyle and LBP beliefs; satisfaction; possible recommendation of the intervention to others; and willingness to receive it again. Moreover, participants' replies to the messages will aid the evaluation of their engagement with the intervention.

## Role of the Funding Source

The funders played no role in data collection, management, analysis, or interpretation of the study.

## Ethics

This protocol was prospectively registered (ANZCTR: 12618001263280) and approved by the NSLHD HREC (ETH 13895). The study is conducted at the University of Sydney, Sydney, Australia. It is overviewed by a Steering Committee with a large experience in the conduct of randomized controlled trials. The current protocol is V4 (11/12/2019) and adheres with the Australian National Health and Medical Research Council ethical guidelines for human research. Changes to the protocol will be submitted

to the ethics committee and approval will be granted before implementation.

## Discussion

This manuscript describes the design of the first, to our knowledge, randomized controlled trial that will evaluate the effectiveness and cost-effectiveness of a self-management text message intervention for people with LBP. The messages are evidence based, theoretically grounded, and were well accepted and considered useful by consumers in the feasibility study. The methodological procedures were tested and found to be feasible.

Given that the text messages are in English and will be delivered only to Australians, the generalization of the results to other populations, languages, and cultures is uncertain. Nonetheless, if proven effective, this intervention can be easily implemented in clinical practice. It can also provide scientific support for the future development of self-management text message interventions within the musculoskeletal field.

## Author Contributions

Concept/idea/research design: C.G. Fritsch, P.H. Ferreira, J.L. Prior, O. Clavisi, C.K. Chow, A. Thiagalingam, T. Lung, A.J. McLachlan, M.L. Ferreira, J. Redfern
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Providing facilities/equipment: C.K. Chow, J. Redfern, M.L. Ferreira
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## Ethics Approval

The study is being conducted at the University of Sydney, Sydney, Australia. It is overviewed by a Steering Committee with a large experience in the conduct of randomized controlled trials. The current protocol is V4 (11/12/2019) and adheres with the Australian National Health and Medical Research Council ethical guidelines for human research. Changes to the protocol will be submitted to the ethics committee and approval will be granted before implementation.

## Funding

This study is sponsored by the University of Sydney and is funded by grant from Musculoskeletal Australia.

## Clinical Trial Registration

This protocol was prospectively registered (ANZCTR: 12618001263280).

## Disclosures and Presentations

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

The findings of this study will be disseminated via presentations at national or international conferences and publication in peer-reviewed scientific journals.

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# CHAPTER SIX

## A qualitative assessment of a text message intervention for people with low back pain

Chapter Six has been submitted to the Pain Medicine journal on the 20th of September 2022 and is currently under review**.**

## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper *"**Fritsch CG**, Abdel-Shaheed C, Mohammed R, Ferreira PH, McLachlan AJ, Ferreira ML. A qualitative assessment of a text message intervention for people with low back pain. Pain Medicine, under review"* confirm that Carolina G Fritsch 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

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

**A qualitative assessment of a text message intervention for people with low back pain**

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The TEXT4myBACK randomised controlled trial was registered at the Australian New Zealand Clinical Trial Registry (ACTRN12618001263280). Data collection for the qualitative assessment started on the 16th of March 2022.

**Running title:** Text messages for low back pain

**ABSTRACT**

**Objective:** To assess the usefulness, delivery format, behaviour-change ability and potential for the TEXT4myBACK intervention to be scaled up.

**Design:** Qualitative study.

**Subjects:** Participants who had completed their one-year assessment of the TEXT4myBACK trial. Only participants randomised to the intervention arm were invited to participate in the qualitative analysis.

**Methods:** 64 people were invited to participate in online focus group sessions and provide feedback about the text message intervention received. Online sessions were conducted by two researchers until thematic saturation was achieved. Information was analysed based on framework analysis and thematic data-driven coding.

**Results:** Of the 64 invited, 10 people participated in the online sessions and thematic saturation was reached. Overall, participants were satisfied with the interventions' duration, format and frequency. The messages were perceived to be simple and easy to read and understand. Some believed the messages helped their low back pain recover. Most participants believed the messages helped them to increase physical activity participation. Participants believed the intervention could be improved by further targetting of the messages according to people's residential areas and clinical characteristics and provision of additional information about low back pain management and exercise strategies. When asked about how the intervention could be implemented into healthcare in the future, most believed it could be provided by healthcare professionals either for free or with a small nominal fee.

**Conclusions:** The TEXT4myBACK text message intervention was well-accepted by participants, who believed it was a good reminder and helped them to increase physical activity participation.

**Keywords:** text messaging, back pain, self-management

## INTRODUCTION

Low back pain is the most prevalent pain condition and the number one cause of disability globally (1). Low back pain negatively impacts multiple aspects of life, including work, physical and daily activities and mental health (2, 3). It is also one of the leading causes of healthcare utilisation, including the need for rehabilitation services, and costs (4-7). Scientific evidence recommends the provision of education and self-management strategies for people with low back pain (8). However, previous research from Australia demonstrated that only 20% of patients with low back pain seeking care from general practitioners receive education and advice on how to manage the condition (9). Similarly, a previous study from Canada showed that only 3% of patients with low back pain seeking care from Emergency Departments received education and advice from their treating healthcare professionals (10). Given the increasing number of people suffering from the condition and its associated costs (8), this evidence highlights the need to develop and assess scalable educational and self-management strategies to support recovery from low back pain.

eHealth has been described by the World Health Organisation as 'the use of information and technologies for health' (11). Various types of eHealth interventions are available, such as those provided via the Internet (e.g., websites, mobile phone applications, and video consultations) and telephone (e.g., telephone consultations and text messages). Two previous systematic reviews have investigated the effectiveness of eHealth educational and self-management interventions for people with low back pain (12, 13). They found inconsistent results on disability, pain and pain catastrophising, among other outcomes (12, 13). Interestingly, most available studies included Internet-based interventions (12, 13). Previous qualitative studies have found numerous barriers to engagement with

internet-based interventions, including limited digital (health) literacy, Internet connection challenges and technical issues with Internet-based mobile phone applications or websites (14, 15).

Text messages represent an accessible strategy that could overcome the technological and literacy challenges of educational and self-management interventions delivered through the Internet (16). Text messages present the advantages of having a low development cost and no dependence on Internet connection, receivers' efforts or engagement to be delivered (16). As a result, a number of recent studies have been conducted aiming to establish the role of text messages in the delivery of healthcare (16). For instance, text messages were proven to effectively support the self-management and improve medication adherence in people with breast cancer (17) and rheumatoid arthritis (18), weight loss in people with overweight or obesity (19) and physical activity and healthy behaviour in people with moderate-high risk of developing cardiovascular diseases (20). However, their role in supporting people with low back pain is so far unknown.

We have developed TEXT4myBACK, an evidence-based self-management text message intervention, to support people with low back pain (21). We are currently investigating the effects of the TEXT4myBACK intervention on function of people with non-specific low back pain compared to control (22). In this study, however, we aimed to understand participants' experience in receiving the TEXT4myBACK intervention and their perceptions of the usefulness, delivery format, behaviour-change ability and potential for the intervention to be scaled up.

## METHODS

### *Study design*

This is a qualitative study nested within the TEXT4myBACK randomised controlled trial (22) and reported following the Consolidated criteria for reporting qualitative studies checklist (COREQ-32) (23). The TEXT4myBACK trial is assessing the effects of the TEXT4myBACK text message intervention on function in people with non-specific non-persistent low back pain compared to a control intervention (22). The TEXT4myBACK randomised controlled trial has been approved by the Northern Sydney Local Health District Human Ethics Committee (ETH 13895). The randomised control trial protocol has been previously published elsewhere (22) and registered at the Australian New Zealand Clinical Trial Registry (ACTRN12618001263280). All participants completed an online consent form before they participated in the online qualitative sessions.

### *Participants and recruitment*

People living in Australia with an episode of non-specific, non-persistent (i.e., less than three months) low back pain were invited to participate in the randomised controlled trial. People reporting at least moderate impact on daily activities who had a mobile phone that received text messages were eligible to participate. Those with a serious spinal pathology or contra-indication to participate in physical activity programs, currently pregnant, with a history of spinal surgery in the past year, or who had inadequate English to understand the text messages or complete the outcome measures or any disorder that might reduce their capacity to understand and give informed consent were excluded (22).

Participants randomised to the intervention group who completed their participation in the trial (i.e., completed the 12-month online survey) (n=64) and had previously consented to be contacted for future studies were consecutively invited via email and

telephone calls to participate in an online focus group session with other participants and members of the research team to discuss their experience in receiving the text message intervention. When invited, potential participants were informed about the aim of the sessions (i.e., to understand their experience in receiving the TEXT4myBACK text message intervention). Those interested in participating were asked to sign an online consent form before the sessions. The focus group sessions were scheduled with up to eight participants. The sessions were performed over Zoom® and were around 30 minutes long (24). The sessions were conducted by two researchers: a physiotherapist and junior researcher who was the facilitator, led the discussions with the participants and took field notes (CGF), whilst a senior researcher with experience in qualitative methodology supported the facilitator and provided technical support (CAS). Following each session, the researchers reflected on participants' responses and noted emerging themes and any divergent or convergent views. The facilitator had previous contact with participants when screening them before their enrolment in the TEXT4myBACK trial and when inviting them to participate in the online sessions, whilst the other researcher did not have any previous contact with participants. Both researchers had no previous assumptions about the research topic. The sessions followed a guide with 12 open-ended questions to guide the discussions around the key topics (usefulness, impact, and delivery of the text messages; behaviour change, and future implementation) (Appendix 1). The questions were reviewed by three researchers not involved in their development. Participants were invited to the sessions until no new themes emerged, and thematic saturation was achieved.

***Text message intervention***

The details of the text message intervention and its development process can be found elsewhere (21, 22). The intervention was developed in consultation with researchers, clinicians, consumer representative organisations and consumers (21). A database of 82 text messages was developed to provide advice, motivation and information about low back pain, physical activity, sleep, mood, use of care and medication. The messages were delivered in a semi-personalised way by targeting their content to participants' characteristics (i.e., symptom duration, presence of sleep issues, volume of physical activity, work characteristics, and use of medication) at baseline. The messages were sent on random days of the week (including weekends but excluding public holidays) and at random time slots (i.e., 9 am, 12.30 pm, 4 pm, and 6 pm) by customised software (TextQStream V4, Phyton V3.6) using REDCap data collection software as an interface as previously described (20). The messages were delivered one-way (to the participant only) for three months. However, participants could reply 'STOP' if they would like to stop the program.

**DATA ANALYSIS**

The demographic and clinical characteristics of participants who participated in the focus group sessions were summarised. Continuous data are presented by central tendency (mean and median), and variability (standard deviation [SD] and range) whilst dichotomous data are presented by frequencies and percentages.

The audio recordings from the sessions were transcribed using the 'Dictate' function from Word and were overviewed by a researcher (CGF) to ensure accuracy and completeness. The transcripts were analysed based on framework analysis and thematic data-driven coding (25, 26) using NVivo software (version 12 plus, QRS International Pty Ltd).

Participants' responses were examined for common themes and quotations were extracted and grouped accordingly. The constant comparison technique was used. Common themes and quotations were constantly compared and collapsed or expanded until no new themes emerged (27). Both the individual perspective of participants and the consensus reached among participants were considered in the analyses. The analyses were done based on thematic theory (28) by two independent researchers (CGF, RM) and compared for discrepancies. Any differences were discussed, and a third researcher (CAS) was consulted if no consensus was achieved. The transcripts and the final results were not returned to participants for comments.

## RESULTS

Of the 64 participants invited to participate in the focus group sessions, 20 did not reply to or answer phone calls and e-mails, 17 were not interested in participating, eight reported a lack of time and two reported personal issues for not attending. 17 participants consented to participate in the sessions but only ten attended the seven sessions scheduled. Participants who could not attend one session but expressed interest in participating in future sessions were invited again when the following session was scheduled. Participants who sent their apologies for not attending reported unexpected personal issues on the day (e.g., working until late, car accident) (n=4). Five sessions were conducted with only one participant each. Participants' demographic characteristics are presented in Table 1.

We identified eight themes around the usefulness of the intervention, two themes on perceived effectiveness, four themes on behaviour-change ability, one theme on engagement with the intervention, three themes on suggestions for intervention's implementation and five themes on suggestions for improvement.

## Intervention's perceived usefulness and delivery

### *Characteristics of the intervention*

Overall, participants found the text messages useful and believed they were useful reminders to keep active, increase physical activity participation or get stronger, and focus on better health. Some participants mentioned the messages would not add value to those who were already adequately managing their low back pain, yet would be very helpful for those with low back pain who were not exercising. Some participants also reported that the messages provided mental health support and helped them to become aware that they were not alone. Quotations are presented in Table 2.

Participants believed the text messages were sent for an appropriate duration of time, and at an adequate frequency and time of the day. Nonetheless, one participant mentioned that the messages could have been sent more frequently and some mentioned they would have liked to receive the messages for longer. Participants believed the messages were simple, clear, and easy to read and understand. Moreover, most of them liked the one-way format and some mentioned they enjoyed not having to reply to the messages. Quotations are presented in Table 2.

### *Content of the intervention*

Participants had mixed feelings regarding the educational ability of the intervention. Some people reported the messages did not share anything they were not familiar with. Some reported they learnt new information whilst others mentioned the messages reinforced what was already known and provided reassurance. Nonetheless, generally, the main information taught or reinforced by the intervention was the importance of physical activity for low back pain. Quotations are presented in Table 2.

**Perceived effectiveness of the intervention**

There were varied impressions regarding the intervention's effectiveness. Some participants believed the messages helped their low back pain, whilst others believed they did not. Some participants were unsure about it whilst others reported that their low back pain improved but did not directly relate the improvement to the text message intervention. Some comments related to the intervention's efficacy are presented below:

- "Not for my condition." ID 213
- "Not for mine either." ID 314
- "Although wasn't long after I started doing the… I don't know how we call it, experiment, that my back actually got a lot better. And it does that from time to time, and then it comes back again." ID 86
- "Well I'm not sure that it helped remove my back pain" ID 228
- "I think my back pain has been a bit less, so yeah, thank you." ID 726

Some participants believed the effects of the intervention would depend on the condition of the person who was receiving it. They believed the messages did not address the needs of people with serious back issues, like themselves. Some quotations are illustrated below:

- "I think it depends on the condition of the person who's receiving the messages and what what yeah what the issues are. [...] there were messages that were more applicable to to people who don't have serious medical issues." ID 213
- "For people with more serious pain, maybe, maybe it's it's it doesn't really reach." ID 314

**Intervention's behaviour-change ability**

Most participants believed the text messages helped them to increase their physical activity participation. The messages were perceived as frequent reminders, which also provided motivation and self-awareness about back pain and sedentary behaviour and prompted participants to change. However, a few participants thought otherwise. They believed the messages did not change their behaviour as the information provided was already known. Quotations are illustrated in Table 3.

**Engagement with the text messages**

Participants believed they engaged with the text messages and followed the advice provided. Some also mentioned replying to the messages as exemplified by the following quotes:

- "Yes, I did, I followed them." ID 314
- "Yes, I did what I could." ID 213
- "The messages are okay, and I was answering regularly. […] when you advise things, I prefer to follow that, yeah." ID 374

Some participants identified a lack of clarity and relevance to their clinical condition and geographic location as barriers to following some of the advice provided. One participant also mentioned that the timing of the messages could also be a barrier. Citations are presented below.

- "Sometimes I would ignore it, if I was deeply involved with something or you know where else in a meeting." ID 711
- "For instance, I found myself wondering what does that mean, you know, to talk to your pharmacist about more options about sleep. [...] In that example, I didn't go to the pharmacist" ID 314

- “People with more serious pain, maybe, maybe it's it's it doesn't really reach.” ID 314
- “Those [messages] weren’t relative to the geographics.” ID 86

**Willingness to receive the text messages again**

One participant would not be interested in receiving the intervention again as they reported having other sorts of support and reminders to keep active at the time in case they suffered from back pain again. However, most participants would be happy to receive it again.

- “I have other reasons to look after myself at the moment.” ID 228
- “I mean it’s a really as a good idea to be reminded to move so yeah, it's good idea.” ID 711
- “It wouldn't… it wouldn't upset me at all.” ID 754
- “I would be keen to continue with the program or doing another round.” ID 726
- “Yes, yes.” ID 374
- “Yes, yes, certainly.” ID 756

**Implementation into healthcare**

Most participants believed the intervention could be provided by health care professionals in addition to usual care. Nonetheless, there were varied ideas on which health care professionals could provide it. Most participants mentioned that any healthcare professional could offer the intervention, whilst some were unsure about which healthcare professionals would be more appropriate, and others mentioned physiotherapists, chiropractors, osteopaths, GPs and exercise physiologists. One participant felt that the intervention would seem reliable if it came from healthcare professionals since they

would know what is good for low back pain. However, some believed the messages could also be provided to anyone interested, not just to those seeking care.

Most participants believed the text messages should either be a free intervention or provided at a low fee, especially to those in rural or remote areas or low socioeconomic situations. One participant also mentioned the financial challenges being faced by most people recently and that they would not be willing to pay for a text message intervention. Although some participants acknowledged that people could quickly connect to the intervention if it was for free, they discussed that people could notice the intervention more if they had to pay. Quotations are presented in Table 4.

**Suggestions for improvement**

***Format of the intervention***

Some participants suggested the intervention could go on for a little longer with less frequent messages and one participant mentioned offering the option to reduce the frequency if wanted. Four participants believed that two-way communication could be more useful. It would allow people to clarify what was not fully understood or ask for further suggestions on how to deal with the pain if the advice given had not worked. However, they acknowledged the challenges of two-way communication, such as the responsibilities regarding a health condition and provision of medical advice as well as setting up a different kind of communication. Quotations are presented in Table 5.

***Content of the intervention***

Further tailoring of the intervention according to residential areas (i.e., regional areas vs metropolitan areas) and low back pain clinical characteristics was suggested. Participants

recommended the provision of further general information about low back pain and exercise suggestions. They expressed interest in receiving further information on i) pain processing and how to deal with pain, ii) intervertebral discs and disc decompression, iii) postures and how to move, and iv) places to go for further information. Regarding exercise, many participants believed that providing examples of specific exercises for low back pain could have added value to the intervention. Some acknowledged it would be difficult to provide exercises via text and suggested providing them via a list, draws or booklets for further support. Quotations are presented in Table 5.

## DISCUSSION

This qualitative study assessed participants' experiences when receiving the TEXT4myBACK intervention, a self-management text message intervention delivered for three months to people with an episode of non-specific, non-persistent low back pain. Overall, the intervention's format was well-accepted by participants, who deemed the messages were delivered in adequate frequency and duration, although some would like to have received it for longer. The language was perceived as simple and easy to read and understand. The one-way format was appropriate, yet a few participants would appreciate the option of two-way communication to clarify what was not fully understood or ask for further advice. There were mixed feelings regarding the intervention's effectiveness and its educational ability. However, the effectiveness of the intervention is being assessed in a randomised controlled trial. Participants suggested further targetting of the messages (i.e., targetting the messages according to participants' residential area and low back pain clinical characteristics) and provision of additional information about how to deal with low back pain and exercise suggestions. Most participants believed the messages helped them to increase physical activity through the provision of reminders, motivation and self-

awareness. Barriers to engagement with the messages were lack of clarity, relevance to people's clinical condition and geographic location. Regarding the intervention's potential for future implementation, most participants believed it could be provided by healthcare professionals either for free or at a small nominal fee.

This is the first study to assess people's experience with a self-management text message intervention for low back pain. However, it has limitations that should be acknowledged. Firstly, the qualitative assessment was designed to be conducted via online focus groups as the study was conducted during the COVID-19 pandemic. However, due to the non-attendance of many participants, five people were individually interviewed. This allowed a deeper understanding of their personal experience with the intervention but limited the exchange of ideas and suggestions for improvements as well as reactions and discussions on different opinions and engagement with other participants that may happen in focus group sessions (29). Nonetheless, the use of different qualitative methodologies might be considered a strength as it allows a broader understanding of the phenomenon being studied (29). For example, we used several strategies to document data and participants' sentiments. Brief notes were taken during the sessions, there were discussions of interviewee responses following each session and researchers were reflexive, cognisant of their roles as interviewers and partakers in the data coding and analysis. Researchers went to significant efforts to allow participants to provide descriptive and open responses, and the interview guides were developed to ensure there was minimal prompting or undue influence on participants' answers. Furthermore, the sessions were conducted after the completion of the 12-month surveys, which means there was at least a nine months-gap between the day the last text message was received and the day of the online session. This might have led to some degree of recall bias. Moreover, participants were highly

educated, which might have facilitated their understanding of the content and language of the messages. Additionally, only participants who completed their participation in the TEXT4myBACK trial were invited to participate. Those who were lost to follow-up or who withdrew from the trial could have been dissatisfied with the intervention received and not motivated to complete the trial surveys. Their feedback has been missed, limiting the understanding of participants' negative perceptios of the intervention, reasons for dissatisfaction, barriers for engagament and suggestions for improvement and implementation into health care. Finally, all participants might have a greater interest in a text message intervention than the wider population, since they participated in the TEXT4myBACK randomised controlled trial. This might have influenced their engagement with the messages and their perceived behaviour-change ability.

The current findings are in agreement with previous studies reporting the experience of people with pain receiving eHealth self-management interventions (but not text messages) (14, 15), people with rheumatoid arthritis and osteoarthritis receiving text messages as part of multicomponent interventions (30, 31) and people with other chronic diseases receiving self-management text message interventions (32, 33). People with pain, including low back pain, perceived frequent reminders, receipt of credible information and motivation via eHealth interventions as enablers of engagement (14, 15). Whereas, they reported a lack of tailoring and relevance of the information on their clinical condition, needs and culture as barriers to engagement (14, 15). When text messages were added to multicomponent interventions, people with rheumatoid arthritis and osteoarthritis also perceived the messages as simple, useful, supportive and motivating for behaviour change and increase in physical activity (30, 31). Similarly, breast cancer survivors and people with cardiovascular diseases who received a one-way

self-management text message intervention also reported they were easy to follow and a source of support and motivation for behaviour change (32, 33). They also suggested further tailoring of the messages and the option for two-way communication (32, 33).

Given the good acceptance and behaviour-change ability of the TEXT4myBACK intervention and participants' positive perceptions towards its implementation in healthcare, it might represent a useful tool to be integrated into clinical practice. Clinicians often fail to provide education and self-management strategies to their patients and mention a lack of time and skills as well as tools to recommend patients to use as barriers to doing so (34, 35). By offering a text message intervention in addition to usual care, clinicians could easily overcome these challenges and empower their patients to better manage their condition. Nonetheless, improvements to the TEXT4myBACK intervention might be needed, including further personalisation and tailoring, the addition of specific exercise suggestions and extra information about how to deal with the pain.

Although the intervention was well-accepted and considered useful by participants, its effectiveness, as well as cost-effectiveness, is still being investigated. Furthermore, it is unknown if the text message intervention would be also well-accepted and useful to people with persistent pain since only people with a current episode of non-persistent pain were included in the study. Nonetheless, many messages could still apply to them, such as the ones providing motivation to exercise, coping strategies and advice to improve sleep.

## CONCLUSION

The TEXT4myBACK intervention was well accepted and considered easy to understand. It provided reminders to move, reassurance and support and seemed to help participants to increase their physical activity. Participants believed the intervention could be provided by healthcare professionals at low or no costs. Suggestions for improvement included further tailoring the intervention by further matching the text messages to people's clinical characteristics and residential areas, providing additional information about low back pain management and exercise suggestions, and two-way communication to clarify what was not understood or to ask for further advice. However, it is important to note that participants were highly educated, which might have influenced the results.

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**Table 1.** Participants' demographic characteristics

| Participants' characteristics | All participants (n = 10) |
|---|---|
| Sociodemographic characteristics | |
| Age, mean (SD) [range] | 66.8 (11.2) [41.0 – 80.0] |
| Female, n (%) | 7 (70%) |
| Educational level, n (%) | |
| Certificate III/IV, Diploma/Advance Diploma | 2 (20%) |
| Bachelor's degree | 2 (20%) |
| Masters, PhD | 5 (50%) |
| Other | 1 (10%) |
| Employment status, n (%) | |
| Unemployed | 1 (10%) |
| Part-time | 2 (20%) |
| Full-time | 2 (20%) |
| Retired | 4 (40%) |
| Other | 1 (10%) |
| Duration of current low back pain episode, mean (SD) [range], weeks | 8.30 (3.3) [2.0 – 11.0] |

SD: standard deviation

**Table 2.** Intervention's perceived usefulness and delivery

| **Characteristics of the intervention** |
|---|
| ***Theme 1. Useful reminders*** |
| "When you are in pain and you have problems, it is very easy to forget, and it very easy to get back into old patterns, particularly patterns where you don't move because you don't want to. So those reminders were really helpful." ID 213 |
| "Really useful in terms of … because of covid we weren't really moving, you know, I wasn't really moving around in the office as much. You know when you're at home, you just hinder and you don't hit those sort of water cooler distractions so you can just sit for longer. So yeah I did find it very useful." ID 711 |
| "So reminders just to keep moving and do get a little bit of exercise in between these long bouts of sitting there just sort of talking to people I think it's been a helpful reminder, I found it useful anyway." ID 754 |
| "[the text messages] keep reminding them what they could do so it keeps… it keeps the focus on … on better health." ID 86 |
| "I think, receiving messages, it was a little reminder and reinforcement about doing some stuff that is important. I think the reminders are pretty good, persuasive. We have a busy, you know, life. It's always kind of hard to remember everything. Um, but I think messages is a good way." ID 756 |
| ***Theme 2. Provision of mental health support*** |
| "The concept of having text messages for problems I think it's a very good one. it's just… because they keep them part of the community." ID 213 |
| "Helped me realise too that I wasn't alone and there is a lot of people going through this." ID 314 |

| |
|---|
| “It certainly helped me cope with it mentally. The fact that there was somebody there thinking about pain that wasn't just you. And bit reassorting.” ID 726 |
| ***Theme 3. Appropriate duration, frequency and timing*** |
| “I mean I don't know about anybody else but I receive a lot of text messages and a lot of emails. So, if it was too, it was too frequent you would tend to, just want to jump out, yeah. So I think that was a good amount. It kept everything in front of mind, without being overbearing.” ID 213 |
| “I thought that it was about the right amount of time. […] maybe you know, if you had one or two a week for a bit longer it might have been good” ID 185 |
| “I seem to recall that most of the text messages came during the day, which was good a thing because that, you know, generally I would be at work.” ID 711 |
| ***Theme 4. Simple and clear language*** |
| “They were short, sharp and very sweet, easy to understand, just sort of encouraging. But the best message I got was ‘motion is lotion’.” ID 726 |
| “[the text messages] were simple and easy. Better to have it simple and easy ones without, like, thinking too much … causing problem” ID 374 |
| “It took you two seconds to pick up on the message - all right okay – good. Easy to read, quick having a one-liner is perfect for me.” ID 754 |
| “It was easy to read them, […] it kind of felt they were at pretty good length and language.” ID 756 |
| ***Theme 5. Appropriateness of the one-way format*** |
| "I was very happy with that I didn't have to sort of write another thesis out or reply to someone. I loved that.” ID 754 |
| “The one-way was fine with me.” ID 726 |

| |
|---|
| “I think the one-way format is fine.” ID 86 |
| “You don't have to reply, you don’t have to pick up the phone. You just see them when you're ready. [...] I think that was good when you know you don't have that pressure that you have to reply, or anything.” ID 756 |
| **Content of the intervention** |
| ***Theme 1. Provision of new information*** |
| “The main message I got out of it was to keep moving yeah and rest is not going to be any sort of a solution. And it, even though there is pain it isn't a problem to keep moving push… pushing through that pain is a perfectly good solution.” ID 726 |
| “Some of the things I didn’t know. […] it's it's good to know that that all those things are really helping; that getting up and down does help, that increasing the activity will help rather than thinking it's going to do damage.” ID 185 |
| ***Theme 2. Provision of reassurance*** |
| “But maybe they made me more aware that maybe I was in the right track with a lot of things. [...] Like the blue light at night with the melatonin. Because I have been wearing blue blocking glasses for about 10 years already, so they were good reminders that maybe I was doing the right thing.” ID 314 |
| “A lot of it was kind of … ‘I sort of knew that’, but it was reassuring to see it come from a uni study, so it must be rock” ID 726 |
| ***Theme 3. Provision of information that was already known*** |
| “If you're already conscious of it and seeking seeking therapy for it, I don't don't think it added a lot of value. It just reminded me of the problem that I was quite aware of.” ID 213 |

| |
|---|
| “I think there wasn't anything new there that the actual information taught me. If you've had you know back pain on and off for 40 years, you pretty well researched everything you can.” ID 711 |
| “I found that the text messages were very good, but I was rather hoping for something that I hadn't known already. [...] There was nothing I wasn’t familiar with” ID 314 |

**Table 3.** The behaviour-change ability of the text message intervention

| ***Theme 1. Reminders to move*** |
| --- |
| "I mean, it reminded me to get up and run around and do something different for a few minutes and then come back to my computer." ID 711 |
| "Yeah just the repeated message keep moving." ID 726 |
| "It it was just a quick reminder all right okay I'll go ahead with that and get up and move or you know just… got me functioning" ID 754 |
| "It brought to mind the various strategies that you were suggesting. So they were reminders and I think that is really helpful." ID 213 |
| "They reminded me about moving. […] I thought it was just a useful, you know, get up and go reminder." ID 185 |
| "I think that was good, because sometimes we just forget and think 'Oh, it's just... I'll do this one yeah'… and we don't… or just once in a while. But it is just important, you know, to just do small things quite like more often. So, I think that was pretty good. I'm kind of like try to still keep doing little things that will help." ID 756 |
| ***Theme 2. Self-awareness prompting change*** |
| "If I had been a bit less active that week, perhaps it might have it might be 'oh yeah I haven't done much this week, I better get up and go for a bike ride, I better do this or that', you know. [...] It probably made me think about it more often and more aware of what I was doing in my own efforts to, you know, relieve the pain or treat my back or whatever." ID 86 |
| "I keep on coming back to 'motion is lotion' it's just stuck in my head and every time I get a bit of a twinge … oh … I've got to move." ID 754 |
| "It kept me a bit more honest in doing my own thing about it" ID 228 |

| |
|---|
| “Sometimes I'm a bit more lazy, but then I can feel it, so I’ll try to go for a walk and just do other stuff. So yeah, it's been good.” ID 756 |
| ***Theme 3. Provision of motivation*** |
| “But if I've had a quiet week and you get one of those messages or I haven't been doing stuff it's usually because it's raining or freezing it's like uuuu ‘make the effort’ yeah it's, as I said, encouraging it could have could have increased me in the lows are made me more consistent, perhaps.” ID 86 |
| “Just you know, encouraging me to get up and down and move.” ID 185 |
| ***Theme 4. No effect on behaviour as no new information was provided*** |
| “I don’t think it changed much what I was doing. [...] I was already, you know, seeing a physiotherapist and doing the exercises every day. [...] So, I picked up all of these, a lot of hints and messages along the way” ID 314 |

**Table 4.** Participants' suggestions for intervention implementation in healthcare

| ***Theme 1. Intervention should be provided by healthcare professionals*** |
|---|
| "I think certainly coming out to healthcare professionals, it would give them a tool to quickly engage people in that as a reminder system. It might also be useful in exercise people. You know, making sure that those sorts of things go on. So if you're an exercise professional or a trainer, anyone involved in that… 'here is a series of text messages - just keep on reminding yourself', I think that could be useful." ID 754 |
| "Yeah, that's good yeah health professionals will know which one is better so it's good. Because then yeah we can we can rely on them because they are more… health care professionals yeah." ID 374 |
| "It could it could go hand in hand with a lot of things I think." ID 314 |
| "But I don't know about… whether other… who in health care, everyone has a different opinion on what you should do. [...] I don't know… what the answer is with that one." ID 185 |
| "I think if they sent you these sort of messages... if perhaps your chiropractors on you know 'it's cracker back chiropractor here just reminding you to get off off that lounge', 'get up and dance or go for a walk' (laughs) in your treatment program yeah it could be a really good tool for certain practitioners to use on a regular basis. I could see that it would be good for chiropractors and osteopaths, physiotherapists all those sort of people to use something like that. ID 86 |
| ***Theme 2. Intervention could be provided on demand*** |
| "I do recall there being a quite a quite a good system on WhatsApp I think. It was regarding covid and you could get some information on demand simply and quickly through it. I think it was a WhatsApp thing or something. I don't know, maybe that's a vehicle." ID 726 |

| |
|---|
| “Something people go looking for it yeah that that's fair enough, I wouldn't, personally. But that's that's only my personal view.” ID 228 |
| “I am aware that a lot of people are starting to think about their health a bit more seriously. So that might be really helpful if they have an option in … to do this, you know, without seeing a health professional as well, and just, you know, it's like ‘I need to do something’ just to work more on prevention side as well. I think that would be really good.” ID 756 |
| ***Theme 3. Intervention should be free or provided via a low-fee*** |
| "Maybe a free service would encourage people to move and make the effort and know that they can't hurt themselves. I think that that might have a better effect on long term keeping them out of all the health things you know.” ID 185 |
| “Better if it is a free service, because we are pensioners and difficult to… If it is a free service, definitely it would be better. But if it is a small nominal fee, of course, we can manage it but not a big amount.” ID 374 |
| “I think the practitioners should pay for it, they probably pass that cost on in some way to the patients. Or… for people in remote areas and lower socioeconomic background, it should be free. Especially the remote rural areas, they are just so lacking in health services and distance is really hard.” ID 86 |
| “I would doubt that people would pay a fee for it. There's so many things you know, inflation is going crazy … people are finding it difficult to find the budget to pay their rent, I just can't see that they're going to pay to have … a text prompt.” ID 711 |
| “They [consumers] probably take more notice if they have to pay.” ID 228 |
| “And they will probably demand a little more if they have to pay. Whereas if it's free I think people would connect into it quickly.” ID 754 |

"I am about, you know, it being accessible and available to a broader community. So I think with the free service that will be, you know, service available to many people. Because some people can't afford a lot of things, so, I think that will be good, if that would be available to everyone who need it." D 756

**Table 5.** Suggestions for improvement

| **Intervention's format** |
| --- |
| ***Theme 1. Duration and frequency of the intervention*** |
| "Maybe you know if you had one or two a week for a bit longer it might have been good. […] I think it's good to receive them every now and then maybe. I don't know, probably I don't need them every four times a week, but I probably think if you continued on for a weekly thing, it would be good to just be reminded about things." ID 185 |
| "I prefer to receive the messages longer. Like… helpful helpful to go through all that and read it and answer it, I enjoy that yeah yeah." ID 374 |
| "Three months is probably a good amount of messages. But as long as you give people that option to receive less, perhaps you know, like 'when you want to reduce this down, let us know' sort of thing. Yeah that's what I would suggest." ID 86 |
| ***Theme 2. Two-way communication*** |
| "But you know, for people who have more serious pain or need more serious support perhaps have a two way, so that people can actually message back going, 'this is not working, the the, you know, the suggestion you've just sent me has not worked, and when I started doing what you said this happened', you know." ID 86 |
| "I thought it might help to just feel that there's somebody to communicate… that is communicating with you. And it is a bit frustrating when you've got ongoing issues that you can't talk to you, you know, you can't get back to you and say well you know… I didn't sleep last night." ID 185 |
| "So, even if it's just to clarify something that is not making sense to you. It would be good to have that option, yeah." ID 314 |

| |
|---|
| "So, it would be depending on who's giving… you have to be careful in the medical setting. Yeah, so it would have to be a practitioner, I suppose, sending that advice. Otherwise, it would have to be wise nature keep fairly general. […]<br>Once you start setting up a dialogue you are creating a different kind of, you are creating a very different kind of communication style. […] And when you've got one way communication with anything, you've always got the issue of how people are interpreting that." ID 213 |
| **Intervention's content** |
| ***Theme 1. Further tailoring of the content*** |
| "So, it would probably be better to, if possible, to categorise people into groups of different pains for different reasons. Then the text messages can be focused on the issue that is relevant to them, even if it is a broad group." ID 213 |
| "I think that's a very good idea. I think, with a bit of tailoring it could be excellent, much, much more much more usable." ID 314 |
| "It could be targeted to people, depending on what sort of back pain they've got." ID 86 |
| "But for me in regional areas, for instance, we hardly ever have buses in regional areas. We don't have public transport. So for people in the country, or here at Burke, they might have in town, but it's very rare that those those questions were relative to the geographics. So it maybe could fine tune depending instead of having one size fits all… it's like… 'what's your favorite hobby that keeps you active? Have you been doing that this week?' or you know, 'Is there something you used to do … that you used to love that … like tennis or golf and that you haven't been doing for a while, maybe revisit that' or … Rather than you know … 'if you don't have any public transport, do you walk or how do you get it …' like just make it more relative to the area?! Yeah, |

perhaps.[...] Like ‘get off the bus stop’ earlier, I remember getting that and go ‘we don’t have buses here’. (laughs)” ID 86

***Theme 2. Provision of further information on low back pain***

“Like something fairly new like, maybe a little bit of the biopsychosocial arena… you know the ‘explained pain’ or maybe the new pain reprocessing therapy or something like that. [...] the newer research on how to deal with pain.” ID 314

“If anything I think … hmm… just some schematics about you know what's the best way to move” ID 754

“How to relieve your back with pillows behind your knees, maybe you know those sort of postures that can help back pain.” ID 86

“If you have compressed discs and things like that, you know, there must be a way to … it’s a bit like flossing your teeth isn’t it? There must be ways to… try and habit the disc decompression. And … I didn't feel like any of that was available through your intervention. So, I mean… it would be quite interesting to have more information or even places to go for more information, even if you're not providing it, but you can point in the right direction. [...] It would have been quite nice to have thought more about movement and what movement would do for the back. Like a kind of a unpacking of there little bit.” ID 711

“Like if you have a pain what not to do … and what should I do and certain things. Because some some of my friends, they say it's good to keep a hot hot back under the under the back and then sleep. So those things we don't know.” ID 374

“Maybe some links into some more information might be helpful when you know you're able to read some other stuff at later time.” ID 756

***Theme 3. Provision of exercise suggestions***

| |
|---|
| “I found walking … just simple walking … going for a walk or bike ride or something like that to be helpful. If there's anything else that I could do, that would be interesting.” ID 754 |
| “And then the other [suggestion] would be, you know, what kind of exercise you could do. Because if people know what exercises to do then your prompt is going to make them go from ‘uh yeah, that's right, this is my, this is about my back, and I know that there's this list of exercises, I’m gonna do those.’ Well that's way more effective than ‘I'll get up and get my cup of tea’. Even though getting up and making a cup of tea is a good start, it's not quite as good as doing something… I would have done something if I’d known what to do, but I didn't really.” ID 86 |
| “A little bit of a suggestion for an exercise of some sort, but I think that's complex to do, to give details I think in it… in a short text message you can't really do that. The only possibility was if at the start you send out a list of you know, half a dozen different exercises that could be done … with it, you know you stick them with demonstrations of how to do it. And add just a few words … and in the text message, so – ‘why don't you try exercise number three for for the next five minutes?’ or something.” ID 228 |
| “And if you can give me like… if you can get me on what to do, and like say… any any exercises or things that I can do for my back pain, if you can elaborate on that there's been much more useful, you know what I mean. […] Draws would have been better.” ID 374 |
| “I think it'd be really helpful to have a regime of sort of passive stretching.” ID 711 |

# CHAPTER SEVEN

## The smallest worthwhile change on function from a self-management intervention for non-persistent low back pain

Chapter Seven has been submitted to the Patient Education and Counseling journal on the 28th of September 2022 and is currently under review.

## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper *"**Fritsch CG**, Ferreira PH, Lung T, McLachlan AJ, Ferreira ML. The smallest worthwhile change on function from a self-management intervention for non-persistent low back pain. Journal of Clinical Epidemiology, under review."* confirm that Carolina G Fritsch 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

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

**The smallest worthwhile change on function from a self-management intervention for non-persistent low back pain**

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**Highlights**

- People with low back pain (LBP) need to experience at least 31% improvement in function to consider self-management worthwhile.
- People with lower function scores need to see larger improvements to consider self-management worthwhile.
- Age, gender, educational level, comorbidities, lifestyle (i.e., self-reported sleep issues and sedentary behaviour) or LBP-related (i.e., pain intensity, function, presence of leg pain, pain, duration, and quality of life) factors were not associated with the magnitude of the smallest worthwhile change in function.
- These findings can help to interpret the clinical relevance of changes in function from a patient's perspective.
- The methodology can be incorporated into future clinical trials and used in responder analysis.

**ABSTRACT**

**Objective:** To determine: i) the smallest change in function patients would need to see following a self-management intervention for low back pain (LBP) to consider it worthwhile; ii) the association between patient-related factors and the magnitude of the smallest worthwhile change.

**Methods:** A cross-sectional analysis of 212 participants of the TEXT4myBACK randomised trial was conducted. At baseline, participants nominated the smallest change in function (0-30 scale) following a self-management program they would need to reach to consider it worthwhile. A multivariate regression model estimated the effects of demographic, comorbidities, lifestyle and LBP-related factors on the smallest worthwhile change estimates.

**Results:** On average, people with LBP need to experience an improvement of at least 9.4 points (SD:5.7) in function to consider a self-management intervention worthwhile. Only baseline function severity was significantly associated with the smallest worthwhile estimate (-0.60; 95%CI -0.76, -0.44).

**Conclusion:** On average, an improvement of 9.4 points (or 31%) in function is considered by people with LBP as the smallest change that makes self-management worthwhile. Those with lower levels of function needed to experience greater improvements.

**Practice Implications:** These results may be used to interpret the clinical relevance of change from baseline in function scores following a self-management intervention.

**KEYWORDS**

Sufficiently important difference; low back pain; self-management; function

## 1. INTRODUCTION

Randomised controlled trials are conducted to establish the effectiveness of different interventions on various health outcomes [1]. Analysis of the effects of interventions may include null hypothesis testing and estimation of the size of the effect [1]. However, the effect of an intervention on an outcome of interest may be statistically significant when compared to a control intervention, but fail to reach clinical relevance or significance [1].

Arguably, the definition of clinical significance should be based on judgements of healthcare consumers and should be specific to the intervention of interest [2]. It should also be elicited in a way that allows its users to appraise treatment effects, i.e. the differences in outcomes between the intervention of interest and the control intervention [3]. Since the smallest worthwhile effect is specific to a population and an intervention, it would be arguably randomised controlled trial-specific too. Randomised controlled trials investigate the effects of one intervention (with varied characteristics) compared to a control intervention on a population of specific clinical and demographic characteristics, and therefore require a specific smallest worthwhile effect. In the absence of trial-specific estimates, most researchers will refer to existing estimates, a commonly used one being the minimal clinically important difference or minimal clinically important improvement. These estimates are elicited by anchor-based approaches by associating a change in the outcome with some other subjective assessment of improvement, such as the global rating scale [2, 4]. These methods, however, have been criticised for omitting the perspective of patients or consumers and failing to account for the specific risks, costs and inconveniences of an intervention in the estimating process [2].

Other methods have been used in an attempt to estimate thresholds of clinical significance for the effects of interventions, such as the benefit-harm trade-off approach [5] and discrete choice experiments [6]. These methods have been recommended as gold-standard methodologies to estimate the threshold of clinical significance of treatment effects as they allow researchers to elicit - based on consumers' perspectives - the smallest difference in an outcome between an intervention and a control, that would make that intervention worth its risks, costs and inconveniences [3]. However, there are some barriers to using these approaches, including time and resource commitments.

In the attempt of overcoming past limitations, we have employed a modified benefit-harm trade-off approach that is simpler and less burdensome to the participant and could be

incorporated into the data collection process of randomised trials. A short question added to the baseline survey of a randomised clinical trial can be used to elicit the smallest worthwhile change from the participants' perspective. This question would explain the possible risks, harms and inconveniences expected from the intervention and ask participants which would be the smallest change or improvement in a health outcome they would need to reach at the end of the intervention to consider it worthwhile. It would allow a fast way to elicit the smallest worthwhile change that could be used in a responder analysis.

Thus, this study aimed to: (1) estimate the smallest worthwhile change needed for a self-management intervention consisting of text messages for non-persistent, non-specific low back pain to be considered worthwhile; (2) investigate if demographic characteristics, comorbidities, lifestyle factors and low back pain clinical characteristics were associated with the magnitude of the smallest worthwhile change. We have used data from the TEXT4myBACK trial [7]. TEXT4myBACK is a randomised controlled trial investigating the effects of a self-management text message intervention compared to control on function of people with non-specific, non-persistent low back pain [7]. The TEXT4myBACK clinical trial was approved by the Northern Sydney Local Health District Ethics Committee in Australia (ETH 13895) [7].

## 2. MATERIAL AND METHODS

This study is a cross-sectional analysis of baseline data from 212 participants of the TEXT4myBACK randomised controlled trial [7]. Community-dwelling adults with low back pain living in Australia were invited to participate in the TEXT4myBACK clinical trial [7]. People aged 18 years or older who had an episode of non-specific low back pain for less than 12 weeks, with or without the presence of leg pain, had pain classified at least as 'moderate' on the SF-12 pain scale [8] and had familiarity with the use and access to, a telephone that can receive text messages were included. Pregnant women, people who had spinal surgery within the preceding year, co-morbid health conditions that prevented active participation in physical activity programs, inadequate English to understand the text messages or complete the study surveys or any disorder that reduced their ability to understand and give informed consent were excluded.

People who met the criteria and signed the online consent form were included in the TEXT4myBACK study. Participants completed an online questionnaire in the REDCap

software [9], which included questions on demographic characteristics, comorbidities, low back pain clinical profile, pain intensity, function, physical activity participation, sedentary behaviour, and eHealth literacy.

Physical function was assessed with the Patient-Specific Functional Scale [10]. Participants were asked to name three important activities they were unable to do or had difficulties in performing due to their low back pain. They scored each activity using a numerical rating scale from 0 to 10, where 0 meant unable to perform activity and 10 meant able to perform activity at the pre-injury level. The scores were summed, and their total function score was presented (ranging from 0 to 30 points).

Following this question in the baseline survey, participants were asked to nominate the smallest score on this function scale they would need to achieve to consider a self-management intervention worthwhile. A short description of self-management along with costs and inconveniences was provided (Box 1).

### *2.1 Predictors*

Demographic characteristics (i.e., age, gender, and educational level), comorbidities, lifestyle factors (i.e., self-reported sleep issues and sedentary behaviour), and low back pain clinical profile (i.e., pain intensity, function, presence of leg pain, pain duration, and quality of life) were prospectively chosen as predictors. Comorbidities were assessed with the Self-Administered Comorbidity Questionnaire [11]. Sleep issues were self-reported difficulty in falling asleep or waking up at night. Sedentary behaviour was assessed with the Sedentary Behaviour Questionnaire [12]. Pain intensity was assessed as the average pain intensity in the previous week on a 0-100 visual analogue scale, where 0 was no pain and 100 was the worst pain ever [13]. Quality of life was evaluated with the ED-5Q-5L questionnaire [14].

### *2.2 Statistical Analysis*

#### *2.2.1 Power analysis*

Sample size calculations were conducted with G*Power software (version 3.1.9.2) to ascertain study power. Based on *a priori* sample size calculation, a minimum sample of 178 participants would be required to assess the association of eleven predictors with the estimates of smallest worthwhile change, with power of 0.95 at an alpha error level of 0.05.

*2.2.2 Data analysis*

Baseline demographic data and the distribution of the smallest worthwhile change of participants of both groups were presented by central tendency (mean and median) and variability (standard deviation – SD, 25$^{th}$ and 75$^{th}$ percentile or range). Missing data or drop-outs were not included in the analyses, as they would not represent individualised values.

A multiple linear regression model was used to quantify the effect of the predictors on the magnitude of the smallest worthwhile change scores, and 95% confidence intervals were calculated. The assumptions of the linear model were assessed by performing residual analysis. The modified Breusch-Pagan (BP) test for heteroscedasticity was used to assess the assumption of constant error variance. If the results of the BP test indicated non-constant error variance, robust heteroscedastic consistent standard errors were used. The normality of the error was assessed with Q-Q plots and Kolmogorov-Smirnov test based on model residuals. Standardised residuals greater than the absolute value of 2.0 were considered outliers for secondary analysis. If outliers were detected, a secondary multivariate linear model was conducted without the outliers. Partial eta squared ($\eta 2$) measures the proportion of the total variance in the outcome explained by an independent variable and after accounting for the variance explained by other variables in the model. Partial eta squared was considered to interpret the magnitude of the effect of each predictor, where $\eta 2 = 0.02$ was considered small, $\eta 2 = 0.13$ as moderate and $\eta 2 = 0.26$ as large effect [15]. All the statistical analysis was performed at a .05 level of significance ($p < .05$) using the SPSS software (version 28).

## 3. RESULTS

The demographic characteristics, general health, and low back pain clinical profile of the 212 participants included in the current study are presented in Table 1. Data from further five participants were available but could not be included in the analysis since they misunderstood either the function (n=2) or the smallest worthwhile change questions (n=3) and could not be contacted to correct them. Figure 1 presents the frequencies of the smallest worthwhile change scores. On average, the improvement that participants would need to achieve to consider a self-management text message intervention worthwhile was 9.4 points (SD: 5.7; range 0 - 30), representing 31% of the total function score. 25%, 50% and 75% of the sample (25$^{th}$ percentile, median and 75$^{th}$ percentile) would need to achieve an improvement of at least 5.3, 9.0 and 12.0 points on the 0-30 scale, respectively, to consider the intervention to be worthwhile. These

changes represent improvements of 18%, 30% and 40% of the total function score, respectively.

The results of the multivariate regression model are presented in Table 2. Only baseline function was significantly associated with the elicited magnitude of the smallest worthwhile change. For each point decrease in function, there was an increase of 0.6 point in the smallest worthwhile change estimate (b = -0.60, 95% CI: -0.76, -0.44, p <0.001). This effect size was medium ($\eta 2$ = .219). The results of the modified Breusch-Pagan test indicated non-constant error variance ($\chi 2$ (1) = 32.01, p < 0.001) and robust standard errors were used. The normal Q-Q plot of standardized residuals and the Kolmogorov-Smirnov test indicated non-normal residuals (KS statistic (212) = 0.064, p = 0.036). Furthermore, outliers were detected, and a secondary analysis was conducted excluding the outlier observations. Results of the model effects and the associated 95% confidence interval estimates based on robust standard errors are presented in Table 3. The normal Q-Q plot and results of the Kolmogorov-Smirnov test indicated normality of residuals (KS statistic (201) = 0.058, p = 0.094). Baseline function continued to be the only predictor associated with the smallest worthwhile change estimate. For each point decrease in function, there was an increase of 0.5 point in the smallest worthwhile change estimate (b = -0.50, 95% CI: -0.61, -0.38, p = <.001). The size of the effect of the baseline function score was large ($\eta 2$ = .283).

## 4. DISCUSSION AND CONCLUSION

### *4.1 Discussion*

The present study investigated the smallest change that people with non-specific, non-persistent low back pain would need to reach to consider a (text message-delivered) self-management intervention worthwhile given its costs, inconveniences, and possible harms. For 50% of participants, an improvement of at least nine points (on a 0-30 point scale) was needed to make the intervention worthwhile, which represents an improvement of 30% of the total function scale score. Large variability in responses was observed. Of all predictors investigated, only function was associated with the magnitude of the smallest worthwhile change. People with worse function scores would need to see larger improvements in function to consider a self-management intervention worthwhile. Function scores explained 21.9% and 28.3% of the variance in the smallest worthwhile change estimate after accounting for the variance explained by other variables in the primary and secondary analysis, respectively.

Although function and disability are slightly different outcome measures, the current findings evidence that people with low back pain expect an improvement in function similar to the 30% improvement in disability expected with the natural course of the condition [22] to consider self-management worthwhile. However, it is important to note there is high variability in the estimates, showing that people would need to see vastly different changes in function to consider self-management worthwhile, from no change to full recovery. Interestingly, participants' characteristics did not explain this variability in the estimates other than their baseline function. Large variability was also reported by previous studies using the benefit-harm trade-off method to investigate the smallest worthwhile effect of interventions for low back pain [16, 17]. Given that the benefit-harm trade-off method holds all intervention's characteristics constant or undefined whilst only the effect of the intervention may change, researchers have argued that participants might value the undefined attributes differently, leading to the high variability in the estimates of the smallest worthwhile effect [17]. Since the current study applied a modified benefit-harm trade-off method, the same hypothesis could justify the variability found. Nonetheless, the reason why no association between participants' characteristics and the smallest worthwhile change estimate could be found was beyond the scope of the current study and limited comparisons with previous studies could be done.

This is the first study to investigate the smallest worthwhile change in function for people with low back pain and incorporate it in a clinical trial of low back pain. The estimates found may be used in future responder analysis by calculating differences in the proportion of people achieving the smallest worthwhile change between the intervention and control groups as well as the number needed to treat. This is a simple methodology, which has been shown to be feasible, not time-consuming for participants and could be easily incorporated into future trials, either added to online or printed baseline questionnaires. This could represent an interesting strategy to help elicit the clinical relevance of findings of primary outcomes of randomised controlled trials when used in responder analyses, especially in trials assessing the effectiveness of interventions on populations for which the smallest worthwhile effect is unknown.

Estimating the smallest worthwhile change at baseline surveys of randomised controlled trials presents some advantages over using anchor-based approaches (e.g., the minimal clinically important difference, or minimal important difference). The main advantages are *i)* the definition of the smallest worthwhile change based on patients' perspectives and not on researchers' perspectives or clinimetric properties of the outcome measure, *ii)* estimates are

intervention-specific and consider possible harms, inconveniences and costs of the intervention in question, and *iii)* the possibility of using the individualised estimates in a responder analysis. Inferences of relevant changes through anchor-based approaches might underestimate what is meaningful to patients. Previous studies have estimated the minimal important difference in function (also assessed through the Patient-Specific Functional Scale) for people with low back pain undergoing physiotherapy or educational and stretching sessions through anchor-based approaches [18-20]. They have shown that the minimal clinically important changes in this population lie between 0.8 and 1.3 points, representing 8% to 13% change in the total function score [18-20]. These findings are smaller than the estimates currently found (on average, people would need to achieve a 31% improvement in the total function score to consider self-management worthwhile). Furthermore, two studies have also estimated what would be medium and large clinically important differences in function, which would correspond to patients reporting being at least 'moderately better' and 'quite a bit better' on the global rating scale, respectively [20]. The medium and large changes in function would correspond to 13% and 43% improvements in the total function score [19, 20]. These estimates evidence that even when the clinically important differences are defined according to moderate improvements in the global rating scale (rather than small improvements) they might underestimate patients' perceptions. Thus, using the smallest worthwhile change rather than the anchor-based approaches estimates in responder analysis consider patients' perspectives and can potentially lead to values closer to clinical practice.

Nonetheless, the current study has limitations that should be acknowledged. Although the sample was diverse and recruited from both the community and healthcare practices, it might not represent the perspectives of all the clinical population with low back pain. Participants could have been more motivated to engage in a self-management intervention than people with low back pain interested in other modalities of care since participants decided to enrol in the TEXT4myBACK Study (which is providing a self-management text message intervention). This might have led to smaller worthwhile change estimates. Additionally, certain attributes of the self-management intervention were kept from participants to ensure their blinding once randomised to the interventions. It is possible that different thresholds would have been elicited if a more comprehensive description of the intervention had been provided. Furthermore, the study had a cross-sectional design, therefore it did not adopt a longitudinal perspective and a re-evaluation of participants' smallest worthwhile change after receiving the intervention. Finally, the results of this study represent a worthwhile change in function over time, rather

than an effect on function between groups. Thus, the current estimates should not be used to aid the interpretation of the clinical significance of effects found in randomised controlled trials and systematic reviews investigating self-management interventions.

### *4.2 Conclusion*

People with non-specific, non-persistent low back pain reported that they need to improve nine points, on average, on a 0-30 function scale to consider a self-management intervention to be worthwhile. High variability was found between individual estimates (ranging from 0 to 30 points), highlighting the distinctive assessment made by each participant. However, there were no effects of demographic characteristics, comorbidities, lifestyle and low back pain-related factors on the magnitude of the estimate, except for function score. People with worse function scores require larger improvements to consider the intervention worthwhile.

### *4.3 Practice Implications*

The current estimates might be used in responder analyses of future randomised clinical trials investigating self-management interventions for low back pain. Alternatively, the estimates might also be used by clinicians to track patients' improvements when a self-management intervention is recommended. The methodology might be used by future randomised controlled trials when the intervention's smallest worthwhile effect is unknown.

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**Declarations of interest**

None.

**Authors' contributions**

CGF contributed to the conception and design of the study, data acquisition and analysis and drafted the manuscript. MLF, PHF, AJM contributed to the conception and design of the study. TL contributed to the data analysis. MLF, PHF, TL, AJM contributed to the interpretation of data, revised and edited the manuscript for important intellectual content. All authors approved the final version of the manuscript.

We confirm that all participants' personal identifiers have been removed so that participants described are not identifiable and cannot be identified through details of this study.

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**Box 1.** Smallest worthwhile change question

***Smallest worthwhile effect on function***

Self-management may include recommendations to remain active, read educational material or apply superficial heat. There is usually no cost involved in self-management and there is some time commitment depending on the time needed to read the information and follow the recommendations.

Based on your current score of [sum_function]/30 points, please place the slider below on the **SMALLEST** (lowest) function score you would need to reach at the end of this self-management intervention to consider it worthwhile.

* Please note that the SMALLEST (lowest) score should be equal to or greater than your current score.

|----------|

0 15 30

0 – unable to perform; 30 – able to perform activities to the same level as before the back pain

**Table 1.** Demographic and clinical characteristics of participants

| Participants' characteristics, No. (%) | All participants (n = 212) |
|---|---|
| Sociodemographic characteristics | |
| Age, mean (SD) [IQR], y | 59.8 (13.2) [51.0 – 59.0] |
| BMI, mean (SD) [IQR] kg/m$^2$ | 27.6 (5.9) [17.9 – 27.7] |
| Female sex | 120 (56.6%) |
| Educational level | |
| Senior High School or below | 30 (14.1%) |
| Certificate III/IV, Diploma/Advance Diploma | 55 (26.0%) |
| Bachelor's degree | 50 (23.6%) |
| Post-graduate Diploma/ Graduate Certificate | 31 (14.6%) |
| Masters, PhD or Other | 46 (21.7%) |
| Employment status | |
| Unemployed | 15 (7.0%) |
| Part-time | 43 (20.3%) |
| Full-time | 58 (27.3%) |
| Volunteer | 19 (9.0%) |
| Studying | 4 (1.9%) |
| Full time carer | 8 (3.8%) |
| Retired | 57 (26.9%) |
| Other | 8 (3.8%) |
| General health | |
| Number of comorbidities, median [IQR] | 1.0 [1.0 – 3.0] |
| Number of participants reporting sleep issues* | 111 (52.3%) |
| Number of participants meeting PA guidelines (≥ 250 min mod-vig PA/ week) | 92 (43.4%) |
| Sedentary behaviour (hrs/week), mean (SD) [range] | 8.4 (3.3) [6.0 – 10.1] |
| Quality of life (EQ-5L-5D) index, mean (SD) [range] | 0.7 (0.1) [0.7 – 0.8] |
| Quality of life (EQ-5L-5D) VAS (0-100), mean (SD) [range] | 64.0 (18.1) [50.0 – 80.0] |
| Low back pain clinical profile | |
| Duration of current episode, mean (SD) [IQR], weeks | 7.4 (3.4) [4.0 – 11.0] |
| First episode of low back pain | 34 (14.9%) |
| Presence of leg pain | 98 (46.2%) |
| Care seeking in the past month | 102 (48.1%) |
| Function (PSFS; 0-30), mean (SD) [IQR] | 11.8 (5.4) [8.0 – 16.0] |
| Pain intensity (VAS; 0-100), mean (SD) [IQR] | 51.5 (19.5) [35.2 – 67.5] |

*self-reported difficulties to fall asleep or waking up at night

SD: standard deviation; IQR: Interquartile range; PA: Physical activity; mod-vig: moderately vigorous

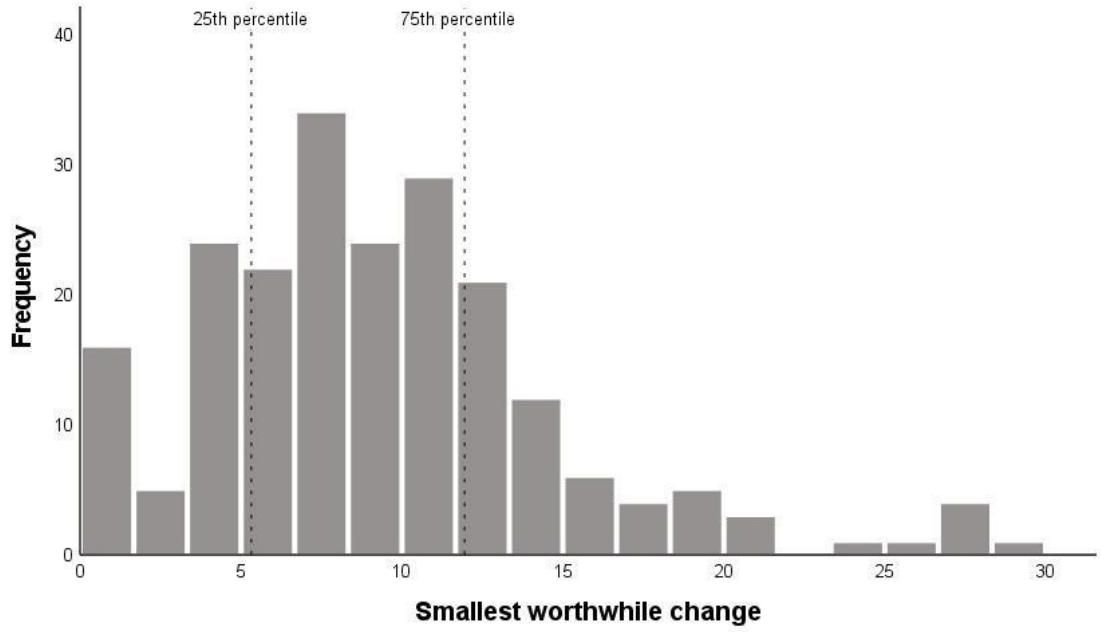
**Table 2.** Regression coefficients (95%CI; p-value) of predictors of the multiple linear model for the smallest worthwhile change estimate

| Predictors | Regression coefficient (95% CI) | p-value |
|---|---|---|
| Age | 0.01 (-0.03, 0.06) | 0.571 |
| Gender | 0.30 (-1.01, 1.68) | 0.630 |
| Education | -0.20 (-1.48, 1.45) | 0.982 |
| Comorbidities | 0.16 (-0.03, 0.06) | 0.547 |
| Sleep issues | -0.33 (-1.80, 1.14) | 0.658 |
| Sedentary behaviour | -0.05 (-0.22, 0.12) | 0.544 |
| Pain intensity | 0.03 (-0.02, 0.07) | 0.216 |
| Function | -0.60 (-0.76, -0.44) | <0.001 |
| Leg pain | 0.41 (-0.91, 1.14) | 0.539 |
| Pain duration | -0.08 (-0.29, 0.13) | 0.448 |
| Quality of life EQ-5D index | 3.77 (-1.36, 8.90) | 0.149 |

**Table 3.** Regression coefficients (95%CI; p-value) of predictors of the multiple linear model for the smallest worthwhile change estimate without outliers

| Predictors | Regression coefficient (95% CI) | p-value |
|---|---|---|
| Age | 0.00 (-0.05, 0.04) | 0.980 |
| Gender | 0.76 (-1.05, 1.21) | 0.894 |
| Education | 0.92 (-0.36, 2.20) | 0.157 |
| Comorbidities | 0.23 (-0.17, 0.63) | 0.255 |
| Sleep issues | -0.36 (-1.59, 0.86) | 0.561 |
| Sedentary behaviour | -0.02 (-0.18, 0.14) | 0.800 |
| Pain intensity | 0.03 (-0.03, 0.07) | 0.068 |
| Function | -0.50 (-0.61, -0.38) | <0.001 |
| Leg pain | 0.38 (-0.77, 1.53) | 0.513 |
| Pain duration | -0.05 (-0.22, 0.12) | 0.546 |
| Quality of life EQ-5D index | 3.72 (-0.34, 7.77) | 0.072 |

**Figure 1.** Distribution of the participant's reported smallest worthwhile change



# CHAPTER EIGHT

## Family-based interventions benefit individuals with musculoskeletal pain in the short-term but not in the long-term: a systematic review and meta-analysis

**Chapter Eight has been published as:**

**Fritsch CG**, Ferreira ML, da Silva AKF, Simic M, Dunn KM, Campbell P, Foster NE, Ferreira PH. Family-based Interventions Benefit Individuals With Musculoskeletal Pain in the Short-term but not in the Long-Term: A Systematic Review and Meta-Analysis. Clin J Pain. 2021;37(2):140-157. doi: 10.1097/AJP.0000000000000897. 

## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper "***Fritsch CG**, Ferreira ML, da Silva AKF, Simic M, Dunn KM, Campbell P, Foster NE, Ferreira PH. Family-based Interventions Benefit Individuals With Musculoskeletal Pain in the Short-term but not in the Long-Term: A Systematic Review and Meta-Analysis. Clin J Pain. 2021;37(2):140-157. doi: 10.1097/AJP.0000000000000897*" confirm that Carolina G Fritsch has made the primary contribution to this study in each of the following areas:

• Conception and design of the research
• Data acquisition
• Data analysis and interpretation of findings
• Writing of the manuscript and critical appraisal of content

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

# Family-based Interventions Benefit Individuals With Musculoskeletal Pain in the Short-term but not in the Long-Term

## *A Systematic Review and Meta-Analysis*

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*and Paulo H. Ferreira, PhD†*

**Introduction:** The benefits of family-based interventions for patients with musculoskeletal pain have been previously shown in individual randomized controlled trials (RCTs), but no systematic review has summarized their effects.

**Materials and Methods:** A systematic review was conducted to assess the effectiveness of family-based interventions on clinical and biopsychosocial outcomes in people with musculoskeletal pain (PROSPERO CRD42018118442). Meta-analyses were performed for the outcomes of pain intensity, disability, mood, self-efficacy, and marital adjustment.

**Results:** Of 1223 records identified, 18 reports representing 15 RCTs were included in the qualitative review and 10 in the meta-analyses. Family-based interventions were more effective to reduce pain (mean difference [MD], −3.55/100; 95% confidence intreval [CI], −4.03 to −3.06) and disability (MD, −1.51/100; 95% CI, −1.98 to −1.05) than individual-focused interventions at short-term, but not at mid term or long term. There were no effects on other outcomes. Family-based interventions were more effective to reduce pain (MD, −6.05/100; 95% CI, −6.78 to −5.33) compared with usual care only at short-term. No effects were found on disability and other outcomes.

**Discussion:** There is moderate-quality evidence that family-based interventions result in small, significantly better pain and disability outcomes in the short-term compared with individual-focused interventions in patients with musculoskeletal pain. Based on low-quality evidence, family-based interventions result in small improvements on pain in the short-term compared with usual care. Future studies should review the content and optimize the mechanisms underpinning family-based interventions in musculoskeletal pain so that the approach could be further tested in adequately powered RCTs.

**Key Words:** musculoskeletal pain, family, systematic review

(*Clin J Pain* 2021;37:140–157)

Musculoskeletal pain conditions are best framed within the biopsychosocial model, which considers the disease and its complex interaction between biological, psychological, and societal factors.[1–3] As an example, pain reported by patients with symptomatic osteoarthritis (OA) is understood to be an interaction between structural pathology (such as effusions and bone marrow lesions) and its impacts on the peripheral nervous system, spinal cord pain signaling, and cortical processing; and psychosocial factors, such as psychosocial comorbidities, socioeconomic status, and coping behavior.[1] The familial environment is embedded within the societal factors of the biopsychosocial model and can have a significant influence on health and behavior.[4–6]

Research has shown an increasing interest in the influence of family members (eg, partners, parents) on healthy lifestyle behaviors, particularly in the management of long-term conditions.[7–9] Studies show that family members can influence the health and behavior of other family members, both positively and negatively.[10–12] While providing support and autonomy seems to have positive effects, being overprotective, controlling, or providing a hostile unhealthy environment can impact negatively on health behaviors and outcomes.[10–12]

The overall evidence assessing the effects of including family members in the management of long-term conditions is growing. For example, involving family members in educational programs for poorly controlled diabetes has been shown to lead to better control of glucose markers (HbA1c) in comparison with usual care.[13] Positive effects of involving family members have also been demonstrated on caloric and fat intake in people with high blood lipoprotein density.[14] Furthermore, greater engagement in physical activity has been observed in patients with coronary artery disease[15] when participating in family-based programs compared with individual-focused interventions alone.

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Musculoskeletal pain conditions such as CLBP and knee OA are among the most common long-term conditions.[16] They are among the top causes of days lived with disability globally[16] and increasing burden to health care systems.[17] Clinical management commonly includes interventions that attempt to change the patient's lifestyle (eg, through exercise, physical activity, and psychological approaches)[1,18] and addresses common comorbidities (eg, obesity).[1] There have been several previous studies investigating the benefit of family-based (ie, involving partners or other family members) compared with individual-focused interventions, for patients with musculoskeletal pain. Results of individual studies have shown greater improvements in measures of partner support,[19] marital function,[20] communication skills,[19] and fear of movement (kinesiophobia)[21] in patients with chronic low back pain (CLBP)[20,21] or OA.[19] Previous systematic reviews have also assessed the influence of including partners in the management of chronic physical illnesses (eg, cancer, diabetes, cardiovascular diseases, musculoskeletal, and chronic pain) and have reported positive effects on pain, pain behavior, catastrophizing, self-efficacy, illness appraisal, spouse relationship, and quality of life.[22,23] The vast majority, however, were conducted on patients with cancer and other chronic diseases, such as cardiovascular diseases, diabetes, and HIV,[22,23] and none has provided specific results for patients with musculoskeletal pain. This is a clear omission within the literature, especially as there is now a growing body of evidence in this field.[24–26] Therefore, the aim of this systematic review was to investigate the effect of family-based interventions on pain intensity and biopsychosocial outcomes compared with individual-focused interventions for patients with musculoskeletal pain.

## MATERIALS AND METHODS

### Search Strategy

The review protocol was registered on the International Prospective Register of Systematic Reviews (CRD42018118442) and followed the Preferred Reporting Items for Systematic review and Meta-Analyses 2009 statement.[27] The following databases were searched from their respective inception dates to January 2020: MEDLINE (via Ovid), AMED (via OVID), EMBASE (via OVID), PsycINFO (via OVID), CENTRAL (via OVID), CINAHL (via EBSCO), Web of Science and PEDro. Keywords (including exploded terms and MESH terms) concerning musculoskeletal pain (and specific disease terms—eg, CLBP) AND family therapy (and specific terms—eg, mother, father, partner) AND randomised controlled trial were combined in the search strategy (Appendix 1, Supplemental Digital Content 1, http://links.lww.com/CJP/A715).

### Inclusion and Exclusion Criteria

Randomized controlled trials (RCTs) published in peer-reviewed journals that investigated the effectiveness of family-based interventions as treatment for musculoskeletal pain, such as CLBP, neck pain, hip pain, shoulder pain, knee pain, OA (knee, hand or hip), fibromyalgia, or rheumatoid arthritis, compared with individual-focused interventions or usual care were included. The search was not restricted by age, gender, race, ethnicity, language, or year of publication.

### Population

We included RCTs concerning family-based interventions in adults (> 18 y of age), adolescents, or children with musculoskeletal pain. Studies of patients with general bodily chronic pain (including patients with musculoskeletal pain, headache, or abdominal pain) were only included if > 50% of the sample reported musculoskeletal pain. Studies focusing on individuals with other types of pain conditions (ie, cancer, neurological diseases or pain arising from nerve root compromise) were excluded.

### Family-based and Individual-focused Interventions

All types of interventions with active participation of patients and family members (ie, spouse/partners, parents, siblings, offspring, or others [eg, close friend, carer/caregiver]) were included in this review. Family-based interventions could be compared to usual care, waitlist control, or individual-focused interventions. Two main analyses were performed to compare the effects of family-based interventions with individual-focused interventions (ie, interventions that were similar to the family-based interventions but without the involvement of a family member) and to compare the effects of family-based interventions with usual care.

### Outcomes

The primary outcome was pain intensity, which could be assessed by, but not limited to, Visual Analogue Scale, Numerical Rating Scale, McGill Pain Questionnaire,[28] and Western Ontario and McMaster Universities Arthritis Index.[29] Secondary outcomes were other biopsychosocial outcomes, including disability, health-related quality of life, relationship with partners/family members, mood (ie, anxiety and depression), pain coping, self-efficacy, and pain catastrophizing.

### Study Inclusion and Data Extraction

Titles/abstracts and full text were screened by 2 independent reviewers (A.K.F.S. and C.G.F.). Any disagreements over study eligibility were resolved through discussion with a third reviewer (P.H.F.). In addition, all references from the selected RCTs were reviewed to supplement the search. Data from included RCTs were extracted by 2 independent reviewers (A.K.F.S. and C.G.F.) and checked for potential errors. The following data were extracted: type of musculoskeletal pain condition, pain/disease duration, sample size, mean age (± SD) of overall and group sample, demographic characteristics, intervention type (including frequency, number, duration, mode and settings), family members and health professionals involved, time points of follow-up, outcome measures at each time point, and main RCT findings. We contacted 5 correspondent authors once through email and requested missing data or information about the protocol design, with 1 author replying.

We extracted data on the mean (± SD) of pain, disability, health-related quality of life, relationship with partners/family members, psychological disability (ie, depression and anxiety), depressive symptoms, pain coping, self-efficacy, and pain catastrophizing on postintervention and follow-up time points for the quantitative analyses. We classified the follow-up period according to time post-intervention as short-term (≤ 10), mid-term (> 10 wk and up to 6 mo), and long-term follow-up (> 6 mo and up to 12 mo) for the meta-analyses, independently of the duration of the intervention, and in agreement with the Cochrane Back and Neck Group recommendations.[30]

## Assessment of Methodological Quality and Strength of the Evidence

The PEDro (Physiotherapy Evidence Database) scale[31] was used to evaluate RCT quality. RCTs were classified as being of excellent (9 to 10), good (6 to 8), fair (4 to 5), and poor (<4) methodological quality.

In addition, the overall quality of the evidence for each outcome was assessed using the Grading of Recommendations Assessment, Development, and Evaluation.[32] We downgraded the evidence by 1 level for each of 3 domains considering: (1) risk of bias (25% of patients from studies with PEDro score <6 points); (2) inconsistency of results ($I^2 > 50\%$); and (3) imprecision (<400 patients in total for each outcome). Indirectness was not considered for this review due to the study focus on a specific population, comparator, and outcome measures. Inconsistency assesses the extent of heterogeneity of the studies' results included in the meta-analyses and indicates poor overall evidence quality when there is uncertainty of where the variability in the results is coming from.[33] Imprecision refers to the uncertainty in the estimates of the treatment effect.[34] The quality of evidence was considered as high quality (ie, further research is unlikely to change the confidence in the estimate of effect), moderate quality (ie, further research is likely to have an important impact on confidence in the estimate of effect and might change the estimate), low quality (ie, further research is likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate), and very low quality (ie, any estimate of effect is uncertain).[35] Assessments were performed by 2 independent reviewers (A.K.F.S. and C.G.F.) and any disagreements were resolved through discussion with a third reviewer (P.H.F.).

## Data Synthesis and Analysis

A narrative synthesis of the findings was conducted regarding included RCTs' populations, interventions, and outcomes. We performed meta-analyses of primary and secondary outcomes when sufficient data were available (ie, at least 2 RCTs with data on a similar outcome and follow-up time point). We performed a random-effects meta-analysis with mean differences for continues variables (eg, pain) and calculated 95% confidence intervals (CIs) and 2-sided *P*-values for each outcome for 2 comparisons: family-based interventions compared with individual-focused interventions, and family-based interventions compared with usual care. The $\chi^2$ test and the I-squared statistic were used to assess heterogeneity (with heterogeneity classified as $I^2 > 50\%$). Secondary analyses per musculoskeletal pain condition were performed according to data availability and follow-up time points (ie, short-, mid-, and long-terms). However, we could only perform separate, secondary analyses for OA, and low back pain (CLBP), as these were the only conditions included in multiple trials. When RCTs included ≥3 comparator groups, we considered the interventions that were more similar within the studies' groups, with the main difference being the inclusion or not of a family member. Thus, if a trial included 2 groups consisting of different family-based interventions, we selected the one that more closely resembled the individual-focused intervention. For example, if the study included 2 family-based interventions (group 1 included cognitive-behavior training while group 2 was educational only) and 1 individual-focused intervention (cognitive-behavior training without the involvement of the spouse), data from group 1 were included in the meta-analyses as the intervention was considered more similar to the individual-focused group. Scores from different outcome measures were converted to a common scale of 0 to 100. All analyses were performed with Review Manager version 5.3.5.

# RESULTS

The search strategy identified 1634 articles (Fig. 1). After removing duplicates, screening titles and abstracts, 33 full-text articles were assessed. A total of 18 articles representing 15 RCTs were included in the qualitative analysis,[19–21,24–26,36–47] and 10 RCTs were eligible for combining in the meta-analyses.[20,21,24,37,38,40–42,44–47] Only 1 RCT recruiting children with musculoskeletal pain met our inclusion criteria[26] and was included in the review to comply with our registered protocol. The RCT was not included in the meta-analysis to reduce heterogeneity in the meta-analytical approach. In addition, 4 RCTs did not provide enough data[19,25,39,43] to be included in the meta-analysis.

RCTs included patients with OA (n = 6),[19,25,36–38,40,41] CLBP (n = 5),[20,21,39,45–47] chronic pain (> 50% musculoskeletal pain) (n = 2),[24,42] rheumatoid arthritis (n = 2),[43,44] and juvenile idiopathic arthritis (n = 1).[26] The mean symptom duration of the overall sample ranged from 1.6[20,45,46] to 18.0 years,[40] and the follow-up duration in the studies ranged from 3 weeks[24] to 60 months.[20,45,46] Trials were conducted in the United States (n = 9),[19,25,36–38,40–43,47] the Netherlands (n = 2),[39,44] Finland (n = 1),[20,45,46] Iran (n = 1),[21] Australia (n = 1),[24] and Denmark (n = 1).[26] The overall characteristics of RCTs and follow-up time points are summarized in Table 1, whereas intervention characteristics are summarized in Table 2.

## Characteristics of Family-based Interventions

The spouse was the most common family member included in intervention delivery in the included RCTs (13 of 15; 86.6%),[19–21,24,36–47] and the majority of the interventions included education models about the musculoskeletal pain condition for patients or patients and family members (eg, how to best cope with pain and arthritis) and/or cognitive-behavior therapy (86.6%).[19,21,24,26,36–44,47] Four RCTs (26.7%) also included the provision of printed educational material[42,44,47] or handouts for exercise.[25] Four RCTs included exercise-based therapy as part of an intervention package,[24,38,44,47] whereas only 1 delivered an exercise-only intervention.[25] Some interventions also included health-related goals for the couple (n = 4)[19,21,41,42,48] or joint home exercise practice (n = 2).[26,36] Six RCTs (40%) also reported providing some training on relaxation techniques.[21,24,36–38,42,43]

Family-based interventions were delivered by psychologists,[20,43,45,46] physiotherapists,[24] nurses,[24,44] arthritis self-care course specialist[19,40,41] or yoga instructor,[25] or by a multidisciplinary team.[21,24,36–39,42,47] Most of the RCTs (n = 9) delivered educational sessions associated with self-management, coping skills training, and/or setting health-related goals for the patients and their family members in group sessions with 3 to 10 patients and their relatives.[19,21,26,38,41–44,47] The majority of the programs were delivered face to face in health care clinics, rehabilitation centers, or hospitals, whereas some were delivered through telephone. Treatments ranged from 4 to 21 sessions delivered on a weekly (77.8%),[21,25,26,36–40,42–44,47] monthly (16.6%),[20,45,46] or a mix of daily and weekly[24] or weekly and monthly[19,41] basis. The duration of each intervention session varied from 20 minutes[40,41] to 8 hours in an inpatient program.[24]

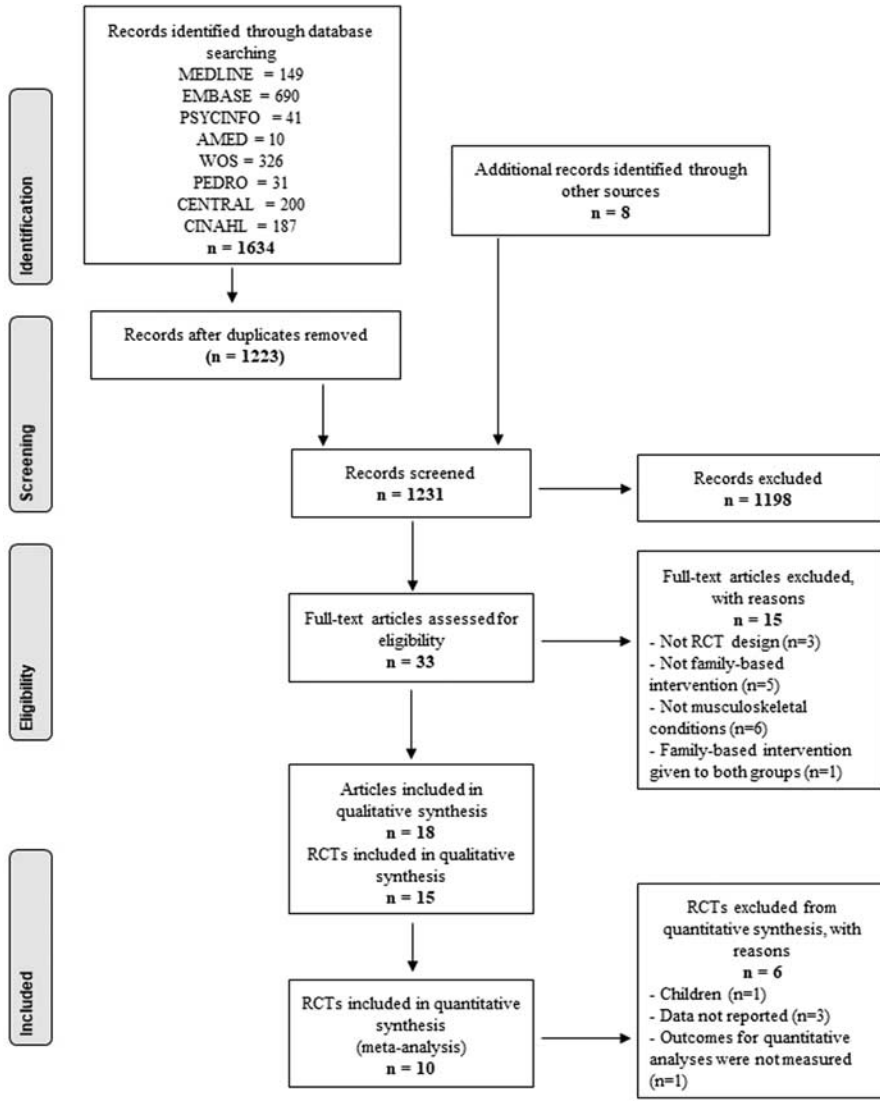


**FIGURE 1.** Flowchart of included RCTs. RCT indicates randomized controlled trial.

## Risk of Bias and Quality of Evidence

The mean score on the PEDro quality scale for included RCTs was 4.7 out of 10 points (Table 3). Only 2 RCTs were of good methodological quality (ie, 6 to 8/10 points).[26,39] None of the included RCTs blinded participants (although this would be impossible given the nature of the interventions), and none clearly reported concealed allocation. Furthermore, only 1 RCT reported blinding of therapists,[43] and 3 reported blinding of assessors.[20,39,45–47] The overall quality of evidence for musculoskeletal pain as the primary outcome was considered moderate for the short-term follow-up ($\leq$10 wk) and low for mid- and long-term follow-up periods assessed with Grading of Recommendations Assessment, Development, and Evaluation scale[32] (Supplementary Table 1, Supplemental Digital Content 2, http://links.lww.com/CJP/A716) when family-based were compared with individual-focused interventions. The overall quality of evidence for pain was considered low for the short-term follow-up and very low for the mid-term follow-up when family-based interventions were compared with usual care (Supplementary Table 4, Supplemental Digital Content 3, http://links.lww.com/CJP/A717).

## Synthesis of Results

Ten RCTs were included in the meta-analyses. Data reported on the primary and secondary outcomes of the systematic review by RCTs that were not included in the meta-analyses are reported in Supplementary Table 2 (Supplemental Digital Content 4, http://links.lww.com/CJP/A718) and Supplementary Table 3 (Supplemental Digital Content 5, http://links.lww.com/CJP/A719).

## Effects of Family-based Interventions Compared With Individual-focused Interventions

Nine RCTs comparing family-based interventions with individual-focused interventions were included in the analyses, performed for the outcomes of pain (n = 8),[21,37,38,40–42,44,47] disability (n = 6),[21,24,37,40,41,44] psychological disability (n = 3),[37,38,44] depressive symptoms (n = 3),[24,40,47] self-efficacy (n = 5),[24,37,38,40,41] or marital adjustment (n = 4).[24,37,38,42] Only 1 RCT had a follow-up <6 weeks[24] with these follow-up data not to be included in the meta-analyses.

**TABLE 1.** Characteristics of Included RCTs

| References, Country | Condition | Symptom Duration (y; Mean ± SD) | Sample Size (% Females) | Age (Mean ± SD) | Outcome Measures Reported | Interventions Arms | Duration of the Intervention | Follow-up Time Points |
|---|---|---|---|---|---|---|---|---|
| Abbasi et al,[21] Iran | CLBP | 6.16 (0.5-23.0) | G1: 10 (%NR) G2: 12 (%NR) G3: 11 (%NR) | Not reported | Pain (VAS)<br>Disability (RMDQ)<br>Kinesiophobia (TSK)<br>Pain Catastrophizing (PCS) | G1: spouse-assisted multidisciplinary pain management intervention<br>G2: individual-focused multidisciplinary pain management intervention<br>G3: usual care | 7 wk | 7 wk and 12 mo |
| Kole-Snijders et al,[39] Netherlands | CLBP | G1: 8.2 ± 8.6 G2: 10.7 ± 8.9 G3: 11.3 ± 8.6 | G1: 59 (63%) G2: 58 (66%) G3: 31 (61%) | G1: 39.7 ± 8.8 G2: 39.2 ± 9.2 G3: 41.1 ± 9.6 | Pain (VAS; MPQ)<br>Pain coping (PCL; CSQ)<br>Pain Behavior (CHIP; PaBS)<br>Pain Catastrophizing (MLPC)<br>Anxiety (NHQ)<br>Aerobic fitness (BAT) | G1: spouse-assisted operant behavioral intervention with cognitive coping skills training<br>G2: spouse-assisted operant behavioral intervention with discussion group<br>G3: waitlist control and individual-focused operant behavioral intervention | 2 mo | 2, 6, and 12 mo |
| Saarijarvi et al,[20,45,46] Finland | CLBP | G1: 1.6 ± 1.4 G2: 2.1 ± 1.9 | G1: 33 (42%) G2: 30 (53%) | G1: 46.5 ± 9.6 G2: 46.4 ± 8.0 | Pain (Pain Index from SNQ)<br>Disability (Impairment Index from SNQ; ADL; FCI)<br>Relationship with partners (MMQ)<br>Psychological distress (BSI)<br>Health attitudes (AS) | G1: spouse-assisted intervention<br>G2: usual care | 5 mo | 5, 12, and 60 mo |
| Turner et al,[47] USA | CLBP | 12.9 (0.59 – 4.0) | Overall N: 96 (48%) Groups: G1: 24 (%NR) G2: 25 (%NR) G3: 24 (%NR) G4: 23 (%NR) | Overall 44.0 (25.0-64.0)* | Pain (MPQ)<br>Physical and psychosocial dysfunction (SIP)<br>Pain behavior (PBC; observer rating of pain behavior)<br>Depression (CES-D)<br>Physical fitness (physical work capacity; strength; flexibility) | G1: spouse-assisted behavior and exercise intervention<br>G2: spouse-assisted behavior intervention<br>G3: individual-focused exercise intervention<br>G4: Usual care | 2 mo | 6 and 12 mo |
| Buchanan et al,[25] USA | OA (73% knee, 54% hip)† | Not reported | Overall N: 17 (47%) Groups: G1: 10 (%NR) G2: 07 (%NR) | G1: 54.0 (50.0-68.0)* G2: 56.0 (50.0-72.0)* | Pain (WOMAC)<br>Disability (WOMAC)<br>Stiffness (WOMAC)<br>Depression (PHQ-8)<br>Sleep (Actigraph; PROMIS; ISI) | G1: partner-assisted yoga<br>G2: individual-focused yoga | 3 mo | 3 mo |
| Keefe et al,[36,37] USA | Knee OA | 10.7 ± 7.83 | G1: 30 (60%) | | Pain (AIMS)<br>Disability (AIMS) | G1: spouse-assisted coping skills intervention | 10 wk | 10 wk, 6 and 12 mo |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | G2: 28 (68%) G3: 29 (52%) | G1: 63.5 G2: 62.8 G3: 61.4 | Marital adjustment (DAS) Pain coping (CSQ) Pain Behavior (observer-rated) Psychological disability (AIMS) Self-efficacy (ASES) | G2: spouse-assisted arthritis education support control G3: individual-focused coping skills intervention | | |
| Keefe et al,[38] USA | Knee OA | Not reported | G1: 18 (50%) G2: 20 (65%) G3: 16 (38%) G4: 18 (61%) | G1: 60.0 ± 12.1 G2: 60.2 ± 9.0 G3: 60.2 ± 8.7 G4: 57.6 ± 14.2 | Pain (AIMS) Marital adjustment (DAS) Pain coping (CSQ) Psychological disability (AIMS) Self-efficacy (ASES) Aerobic fitness (ergometry and muscle strength) | G1: spouse-assisted coping skills intervention G2: spouse-assisted coping skills intervention plus exercise training G3: individual-focused exercise training G4: usual care | Intervention: 3 mo Follow-up: 3 mo | |
| Martire et al,[40] USA | OA (92% knee, 67% back)† | 18.0 ± 14.5 | G1: 13 (100%) G2: 11 (100%) | Overall 71.8 ± 7.8 | Pain (AIMS) Disability (HAS) Relationship with partners (satisfaction with spousal assistance; spousal emotional support and insensitive responses) Depression (CES-D) Self-efficacy (ASES) | G1: spouse-assisted arthritis self-help course intervention G2: individual-focused education intervention | 6 wk | 6 wk |
| Martire et al,[41] USA | Hip or knee OA | G1: 14.3 ± 9.4 G2: 15.3 ± 11.8 G3: 16.1 ± 12.0 | G1: 89 (72%) G2: 99 (73%) G3: 54 (72%) | G1: 68.0 ± 8.0 G2: 69.2 ± 7.2 G3: 68.4 ± 7.5 | Pain (WOMAC) Disability (WOMAC) Stiffness (WOMAC) Depression (CES-D) Self-efficacy (ASES) | G1: spouse-assisted oriented education and support intervention G2: individual-focused oriented education and support intervention G3: usual care | 6 wk | 6 wk and 6 mo |
| Martire et al,[19] USA | Hip or knee OA | G1: 14.1 ± 8.9 G2: 14.5 ± 12.2 | G1:64 (75%) G2: 62 (68%) | G1: 69.0 ± 7.2 G2: 68.7 ± 8.4 | Spousal support and responses (WHYMPI) | G1: spouse-assisted oriented education and support intervention G2: individual-focused oriented education and support intervention | 6 wk | 6 wk and 6 mo |
| Moore & Chaney,[42] USA | CP (> 65% MSK pain) | 16.5 ± 12.6 | Overall: N: 43 (2%) Groups: G1: 17 (%NR) G2: 14 (%NR) G3: 12 (%NR) | Overall 49.3 ± 13.2 | Pain (VAS) Physical and psychological dysfunction (SIP) Marital adjustment (MAT) Mood/emotion (MMPI; SIP) Pain Behavior (spouse-rated - VAS) Other outcomes (care seeking; spouse-rated personal and role skill) | G1: spouse-assisted intervention G2: individual-focused intervention G3: usual care | 3 mo | 3 and 7 mo |
| Ramke et al,[24] Australia | CP (89% MSK pain) | G1: 6.2 ± 3.5 G2: 8.4 ± 4.9 | G1: 19 (68%) G2: 26 (35%) | G1: 45.3 ± 8.4 G2: 47.4 ± 13.2 | Disability (RMDQ) Marital adjustment (DAS) Family impact of pain (FIPS) Self-efficacy (PSEQ) Kinesiophobia (TSK) Depression, anxiety and stress (DASS) | G1: spouse-assisted intervention G2: individual-focused intervention | 3 wk | 3 and 7 wk |

(*Continued*)

**TABLE 1.** (*continued*)

| References, Country | Condition | Symptom Duration (y; Mean ± SD) | Sample Size (% Females) | Age (Mean ± SD) | Outcome Measures Reported | Interventions Arms | Duration of the Intervention | Follow-up Time Points |
|---|---|---|---|---|---|---|---|---|
| Radojevic et al,[43] USA | RA | 11.8 (1-33)* | Overall N: 59 (76%) | Overall 54.4 | Pain (AIMS)<br>Disability (AIMS)<br>Psychological disability (AIMS)<br>Depression (CES-D)<br>Disease activity (assessed by a rheumatologist) | G1: family-based education support<br>G2: family-based behavior therapy support<br>G3: individual-focused behavior therapy<br>G4: usual care | 6 wk | 6 wk and 2 mo |
| Riemsma et al,[44] Netherlands | RA | Not reported | G1: 71 (58%)<br>G2: 71 (66%)<br>G3: 76 (62%) | G1: 57.2 ± 10.3<br>G2: 55.1 ± 10.3<br>G3: 57.0 ± 8.3 | Pain (AIMS)<br>Disability (AIMS)<br>Relationship with partners (social interactions assessment)<br>Psychological disability (AIMS)<br>Self-efficacy (ASES)<br>Disease activity (DAS-28)<br>Health Behavior (self-reported)<br>Fatigue (VAS) | G1: partner-based self-management education intervention<br>G2: individual-focused self-management education intervention<br>G3: individual-focused education | 2 mo | 2, 6 and 12 mo |
| Lomholt et al,[26] Denmark | JIA | G1: 5.1 ± 4.0<br>G2: 7.6 ± 4.0 | G1: 9 (89%)<br>G2: 10 (70%) | G1: 11.4 ± 2.0<br>G2: 12.0 ± 1.4 | Pain (VAS)<br>Disability (FDI)<br>Quality of life (PedsQL)<br>Pain Catastrophizing (PCQ)<br>Pain-specific beliefs (SOPA)<br>Self-efficacy (CASE)<br>Satisfaction with treatment (ESQ)<br>Credibility of treatment (Likert scale) | G1: family-based cognitive behavior intervention<br>G2: usual care | 2 mo | 2 mo |

*Median (min-max).

†Participants with pain in various body areas.

ADL indicates activities of daily living; AIMS, Arthritis Impact Measurement Scale; AS, the Attitude Scale; ASES, Arthritis Self-Efficacy Scale; BAT, Behavioral Approach Tests; BSI, Brief Symptom Inventory; CASE, Children's Arthritis Self-Efficacy Scale; CES-D, Center for Epidemiologic Studies Depression Scale; CHIP, Checklist Interpersonal for Pain Behavior; CLBP, chronic low back pain; CP, chronic pain; CSQ, Coping Strategies Questionnaire; DAS, Dyadic Adjustment Scale; DAS-28, Disease Activity Score; DASS Depression Anxiety Stress Scale; FCI, Functional Capacity Index; FDI, Functional Disability Inventory; FIPS, Family Impact of Pain Scale; G1, group 1; G2, group 2; G3, group 3; G4, group 4; HAS, Health Assessment Questionnaire; ISI, Insomnia Severity Index; JIA, juvenile idiopathic arthritis; MAT, Marital Adjustment Test; MLPC, Multidimensional Locus of Pain Control Questionnaire; MMPI, Minnesota Multiphasic Personality Inventory; MMQ, Marital Questionnaire; MPQ, McGill Pain Questionnaire; MSK, musculoskeletal; NHQ, Nijmegen Hyperventilation Questionnaire; OA, osteoarthritis; PaBS, Pain Behavior Scale; PBC, Pain Behavior Checklist; PCL, Pain Cognition List; PCQ, Pain Coping Questionnaire; PCS, Pain Catastrophising Scale; PedsQL, Pediatric Quality of Life Inventory; PHQ-8, Patient Health Questionnaire-8; PMI, Pain Management Inventory; PROMIS, Patient-Reported Outcomes Measurement Information System; PSEQ, Pain Self-Efficacy Questionnaire; RA, rheumatoid arthritis; RCT, randomized controlled trial; RMDQ, Roland and Morris Disability Questionnaire; SIP, sickness impact profile; SNQ, Standardized Nordic Questionnaire; SOPA, Survey of Pain Attitudes; TSK, Tampa Scale of Kinesiophobia; VAS, Visual Analogue Scale; WHYMPI, West Haven-Yale Multidimensional Pain Inventory; WOMAC, The Western Ontario and McMaster Universities Osteoarthritis Index.

**TABLE 2.** Intervention Characteristics of Included RCTs

| References | Intervention Type(s) and Content(s) | Intervention Characteristics (Number, Frequency, and Duration of Sessions) | Family Members Involved | Health Professionals Involved, Mode, and Setting |
|---|---|---|---|---|
| Abbasi et al[21] | G1: group sessions (6 patients+spouses): education about CLBP self-management, coping skills (including relaxation techniques), influence of the spouse, health-related goal of the couple<br>G2: same as G1 without the involvement of the spouses, information about influence of the spouse and health-related goal of the couple<br>G3: usual care | 7 weekly sessions, 2 h/session | Spouse | Psychologist, orthopedic surgeon, psychiatrist, physiotherapist<br>Face to face<br>Pain clinic |
| Kole-Snijders et al[39] | G1: group sessions (number of participants not reported): operant behavior therapy including 5 wk of inpatient and 3 wk of outpatient (3×/wk) treatment (physical activity goals, physiotherapy, occupational and psychological therapy, spouse group training including education and CBT) with cognitive coping skills<br>G2: group sessions (number of participants not reported): operant behavior therapy (same as G1) and discussion group (reading of pain book for patients)<br>G3: waitlist group: received the operant behavioral therapy after the control period, but they were individualized and did not include spouse group training | Operant behavior therapy:<br>88 h of physiotherapy; 38 h of occupational therapy (frequency and number of sessions not reported); 8 weekly psychology sessions, 0.5 h/session; spouse group training: 7 weekly sessions, 1.5 h/session<br>Cognitive coping skills training and discussion group:<br>12 sessions, 1.6 h/session, frequency not reported | Spouse | Physiotherapists, occupational therapist, behavioral therapist, psychologist<br>Face to face<br>Not reported |
| Saarijarvi et al,[20,45,46] | G1: group sessions (number of participants not reported): couple therapy sessions based on the family systems approach<br>G2: usual care | 5 monthly sessions, 1-2 h/session | Spouse | Psychologist<br>Face to face<br>Rehabilitation center |
| Turner et al[47] | G1: group sessions (5-10 patients): pain behavior, social reinforcement and communication training and behavioral goal setting (spouses attended to 5/8 sessions) +communication booklet+aerobic exercise sessions<br>G2: same as G1 without exercise intervention<br>G3: aerobic exercise sessions without involvement of the spouse<br>G4: usual care | 8 weekly sessions, 2 h/session | Spouse | Psychologist, physiotherapists<br>Face to face<br>Not reported |
| Buchanan et al[25] | G1: group sessions (3-7 patients +partners): yoga sessions and handouts for combined home practice<br>G2: same as G1 without involvement of the partner | 12 weekly sessions, 1.25 h/session | Not reported | Yoga instructor<br>Face to face<br>Community center |
| Keefe et al[36,37] | G1: group sessions (4-6 patients +spouses): CBT to develop pain coping skills (including relaxation techniques) and couples' skills (mutual goal setting, communication, joint home exercise practice)<br>G2: group sessions (4-6 patients +spouses): education on arthritis<br>G3: Same as G1 without involvement of the spouse and couples' skills activities | 10 weekly sessions, 2 h/session | Spouse | Psychologist, nurses<br>Face to face<br>Not reported |

(*Continued*)

**TABLE 2.** (*continued*)

| References | Intervention Type(s) and Content(s) | Intervention Characteristics (Number, Frequency, and Duration of Sessions) | Family Members Involved | Health Professionals Involved, Mode, and Setting |
|---|---|---|---|---|
| Keefe et al[38] | G1: group sessions (3-5 patients +spouses): information about pain, coping skills education (including relaxation techniques) and importance of spouses' involvement<br>G2: same educational sessions as G1 +strength and flexibility training sessions<br>G3: group sessions (4-6 patients): cardiopulmonary, strength and flexibility training sessions without involvement of the spouse<br>G4: usual care | Coping skills training:<br>12 weekly sessions, 2 h/sessions<br>Cardiopulmonary training: 36 sessions, 3×/week, 1.5 h/session<br>Strength training:<br>24 sessions, 2×/week, 1.5 h/session | Spouse | Psychologist, exercise physiologists<br>Face to face<br>Not reported |
| Martire et al[40] | G1: group sessions (4-6 patients): education on arthritis, pain, management and coping skills +spouse-assisted sessions covering emotional and communication aspects of managing arthritis as a couple<br>G2: same educational intervention as G1 without spouse-assisted sessions | 6 weekly sessions, 2 h/educational sessions; 0.3 h/spouse-assisted sessions | Spouse | Arthritis Self-Help Course specialist<br>Face to face<br>Not reported |
| Martire et al[41] | G1: group sessions (4-6 patients +spouses): education on arthritis, pain, management, coping skills, communication and support within the couple and combined health-related goal-settings (topics framed as couples' issue when possible)+up to 5 booster telephone calls<br>G2: same intervention as G1 without involvement of the spouses and framing topics as couples' issues<br>G3: usual care | Group sessions:<br>6 weekly sessions, 2 h/session<br>Booster sessions:<br>up to 5 monthly sessions, 0.3 h/session | Spouse | Arthritis Self-Help Course specialist<br>Face-to-face +telephone booster sessions<br>Not reported |
| Martire et al[19] | G1: group sessions (4-6 patients +spouses): education on arthritis, pain, management, coping skills, communication and support within the couple and combined health-related goal-settings (topics framed as couples' issue when possible)+up to 5 booster telephone calls<br>G2: same as G1 without involvement of the spouses | Group sessions:<br>6 weekly sessions, 2 h/session<br>Booster sessions:<br>up to 5 monthly sessions, duration not reported | Spouse | Arthritis Self-Help Course specialist<br>Face to-face +telephone booster sessions<br>Not reported |
| Moore & Chaney[42] | G1: group sessions (4-6 patients +spouses): pain education, goal setting, problem-solving, relaxation techniques and pain coping strategies +homework assignments (reading or practice of concepts and treatment learned)<br>G2: same as G1 without involvement of the spouses and framing topics as couples' issues<br>G3: usual care | 8 weekly sessions, 2 h/session | Spouse | Psychologist, social worker, nurses<br>Face to face<br>Not reported |
| Ramke et al[24] | G1: group sessions (8-10 patients). education on pain, goal setting, activity pacing, relaxation techniques, exercise and couple interaction and communication training+telephone intervention for spouses only (couple interaction and communication)<br>G2: same as G1 but without involvement of the spouses | Group sessions:<br>21 daily sessions, 8 h/session<br>Telephone intervention:<br>3 weekly sessions, 2 h/session | Spouse | Pain specialist, psychologist, nurse, physiotherapists<br>Face to face +telephone calls<br>Hospital |

(*Continued*)

**TABLE 2.** (*continued*)

| References | Intervention Type(s) and Content(s) | Intervention Characteristics (Number, Frequency, and Duration of Sessions) | Family Members Involved | Health Professionals Involved, Mode, and Setting |
|---|---|---|---|---|
| Radojevic et al[43] | G1: group sessions (3-6 patients+family members): education and discussion about RA<br>G2: group sessions (3-6 patients+family members): education on pain and family support, coping strategies and relaxation training+home practice of learned skills<br>G3: same as G2 without involvement of family members and discussion of the role of family support<br>G4: usual care | Group sessions:<br>4 weekly sessions, 1.5 h/session<br>Home practice: 2 wk | Spouse, adult child, roommate, or family member with daily contact | Clinical psychologist<br>Face to face<br>Not reported |
| Riemsma et al[44] | G1: group sessions (8 patients+partners): education on RA, pain, exercise, depression, goal setting, self-management, relaxation and communication+information booklet and self-help guide+booster sessions<br>G2: same as G1 without involvement of the partners<br>G3: self-help guide only | Educational sessions:<br>5 weekly sessions, 2 h/session<br>Booster sessions:<br>3 tri-monthly sessions, 2 h/session | Spouse (88%), close relative (10%), friend (2%) | Nurses<br>Face to face<br>Not reported |
| Lomholt et al[26] | G1: group sessions (number of participants not reported): CBT with combined (parents and children) and separated parts+workbook, worksheet and guides for home practice and combined goals<br>G2: usual care | 6 sessions, 4 weekly sessions, 2 fortnightly sessions, 2 h/session | Parents | Psychologist<br>Face to face<br>Pediatric Rheumatology Clinic |

CBT indicates cognitive-behavior therapy; CLBP, chronic low back pain; G, group; RA, rheumatoid arthritis; RCT, randomized controlled trial.

Based on overall moderate-quality evidence, family-based interventions had a small, significant positive effect on pain (MD, −3.55/100; 95% CI, −4.03 to −3.06) at short-term follow-up (n = 6) (Fig. 2A). Based on very low- or low-quality evidence, there were no between-group differences at mid (MD, −0.60/100; 95% CI, −4.92 to 3.72) (n = 6), and long-term (MD, 0.38/100; 95% CI, −5.08 to 5.84) follow-ups (n = 5) (Fig. 2A).

Based on moderate-quality evidence, family-based interventions had a very small, significant positive effect on disability (MD, −1.51/100; 95% CI, −1.98 to −1.05) at short-term follow-up (n = 6) (Fig. 2B). Based on very low- or low-quality evidence, there were no between-group differences at mid-term (MD, −0.97/100; 95% CI, −4.31 to 2.37) (n = 3) and long-term (MD, 0.02/100; 95% CI, −3.21 to 3.26) (n = 3) follow-ups (Fig. 2B).

There were no differences between family-based and individual-focused interventions on mood, self-efficacy, or marital adjustment at any follow-up time points (Fig. 3A–C).

## Secondary Analyses

We conducted secondary analyses on pain, disability, mood, self-efficacy, and marital adjustment for RCTs that compared family-based with individual-focused interventions and included patients with OA (peripheral joint,[37,38,41] or peripheral joint and spinal[40] OA) or CLBP.[21,47] For OA, family-based interventions resulted in small positive improvements in pain (MD, −5.22/100; 95% CI, −9.72 to −0.72), and disability (MD, −1.06/100; 95% CI, −1.38 to −0.74) only at short-term follow-up (Fig. 4A and B) compared with individual-focused interventions. No differences were observed for other outcomes and follow-up time points (Fig. 4C–E).

For CLBP, it was possible to perform subgroup meta-analyses only for pain at short- and long-term follow-ups. There were no differences between groups at both short-term (MD, −1.29/100; 95% CI, −8.67 to 6.08) and long-term (MD, 2.01/100; 95% CI, −7.62 to 11.64) follow-up time points (Fig. 5).

## Effects of Family-based Interventions Compared With Usual Care

Six RCTs comparing family-based interventions to usual care[20,21,38,41,42,45–47] were included in the meta-analyses performed for the outcomes of pain (n = 6),[20,21,38,41,42,45–47] disability (n = 3),[20,21,45–47] self-efficacy (n = 2),[38,41] or marital adjustment (n = 2).[38,42] Only 1 RCT[20,45,46] had a follow-up > 12 months (60 mo) and these data were not included in the meta-analyses.

Based on low-quality evidence, family-based interventions had a small positive effect on pain (MD, −6.05/100; 95% CI, −6.78 to −5.33) at the short-term (n = 3). Based on very low-quality evidence, there was no between-group difference (MD, −2.27/100; 95% CI, −10.61 to 6.07) at mid-term follow-up (n = 4) (Fig. 6A). There was no between-group difference on disability at short-term (MD, 1.73/100; 95% CI, −13.84 to 17.30) (n = 2) and

**TABLE 3.** Risk of Bias of Included RCTs

| References | Eligibility Criteria (Not Scored) | Random Allocation | Concealed Allocation | Baseline Comparability | Blind Patients | Blind Therapists | Blind Assessors | Adequate Follow-up (> 85%) | Intention-to-Treat Analysis | Between-Group Comparisons | Point Estimates and Variability | Total Score (0-10) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Abbasi et al*[21] | ✓ | ✓ | × | × | × | × | × | ✓ | ✓ | ✓ | ✓ | 5 |
| Buchanan et al*[25] | ✓ | ✓ | × | ✓ | × | × | × | ✓ | × | ✓ | ✓ | 5 |
| Keefe et al*[36,37] | × | ✓ | × | ✓ | × | × | × | ✓ | × | ✓ | ✓ | 5 |
| Keefe et al*[38] | ✓ | ✓ | × | × | × | × | × | × | × | ✓ | ✓ | 3 |
| Kole-Snijders et al*[39] | ✓ | ✓ | × | ✓ | × | × | ✓ | × | ✓ | ✓ | ✓ | 6 |
| Lomholt et al[26] | ✓ | ✓ | × | ✓ | × | × | × | ✓ | ✓ | ✓ | ✓ | 6 |
| Martire et al*[40] | ✓ | ✓ | × | ✓ | × | × | × | ✓ | × | ✓ | ✓ | 5 |
| Martire et al*[41] | ✓ | ✓ | × | ✓ | × | × | × | × | ✓ | ✓ | ✓ | 5 |
| Martire et al*[19] | ✓ | ✓ | × | ✓ | × | × | × | × | × | ✓ | ✓ | 4 |
| Moore & Chaney[42] | ✓ | ✓ | × | ✓ | × | × | × | × | × | ✓ | ✓ | 4 |
| Radojevic et al*[43] | ✓ | ✓ | × | ✓ | × | ✓ | × | × | × | ✓ | ✓ | 5 |
| Ramke et al[24] | ✓ | ✓ | × | ✓ | × | × | × | × | × | ✓ | ✓ | 4 |
| Riemsma et al*[44] | × | ✓ | × | ✓ | × | × | × | × | × | ✓ | ✓ | 4 |
| Saarijarvi et al*[20,45,46] | × | ✓ | × | × | × | × | ✓ | ✓ | × | ✓ | ✓ | 5 |
| Turner et al*[47] | ✓ | ✓ | × | ✓ | × | × | ✓ | × | × | ✓ | ✓ | 5 |

*PEDro score provided from the PEDro database.
✓ = yes; × = no. Total score: 9 to 10 excellent, 6 to 8 good, 4 to 5 fair, and <4 poor.
PEDro indicates Physiotherapy Evidence Database; RCT, randomized controlled trial.

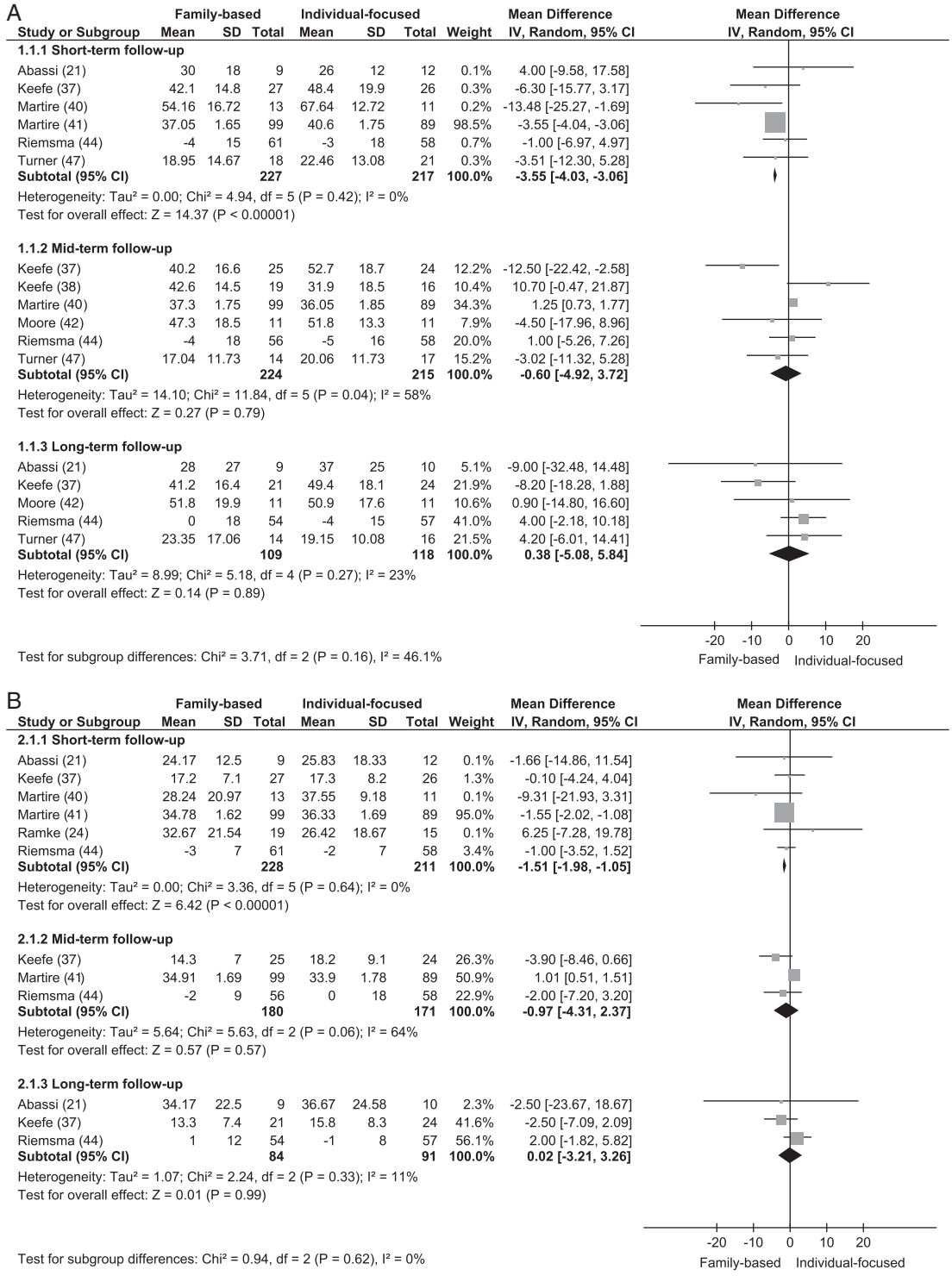


**FIGURE 2.** A, Forest plot of the effect of family-based compared with individual-focused interventions on pain intensity. B, Forest plot of the effect of family-based compared with individual-focused interventions on disability. CI indicates confidence interval.

mid-term (MD, −2.22; 95% CI, −6.49 to 2.06) (n = 2) follow-ups (Fig. 6B).

Family-based interventions had a small, significant positive effect on self-efficacy (MD, −6.06; 95% CI, −6.69 to −5.44) at mid-term follow-up (n = 2) (Fig. 7A). Nonetheless, there was no between-group difference on marital adjustment (MD, −0.96; 95% CI, −9.24 to 7.31) at mid-term follow-up (n = 2) (Fig. 7B).

One RCT that included children with juvenile idiopathic arthritis compared a family-based intervention

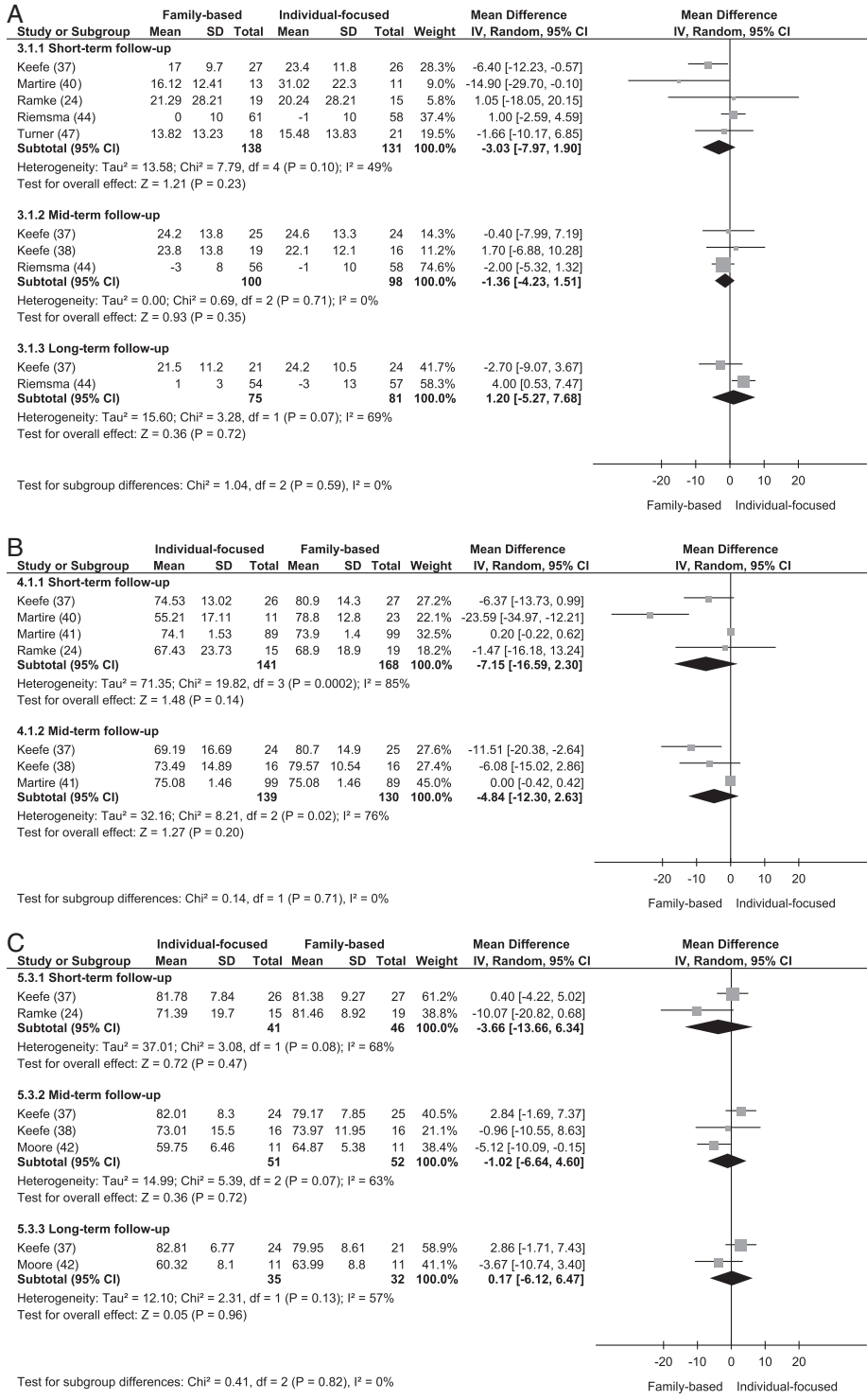


**FIGURE 3.** A, Forest plot of the effect of family-based compared with individual-focused interventions on mood. B, Forest plot of the effect of family-based compared with individual-focused interventions on self-efficacy. C, Forest plot of the effect of family-based compared with individual-focused interventions on marital adjustment. CI indicates confidence interval.

with usual care and was not included in the pooling because of heterogeneity of clinical populations.[26] Results from this RCT showed no differences between groups on pain intensity, disability, and quality of life and secondary outcomes (ie, pain catastrophizing, pain-specific beliefs, self-efficacy, and disease activity) (Supplementary Table 3, Supplemental Digital Content 5, http://links.lww.com/CJP/A719).

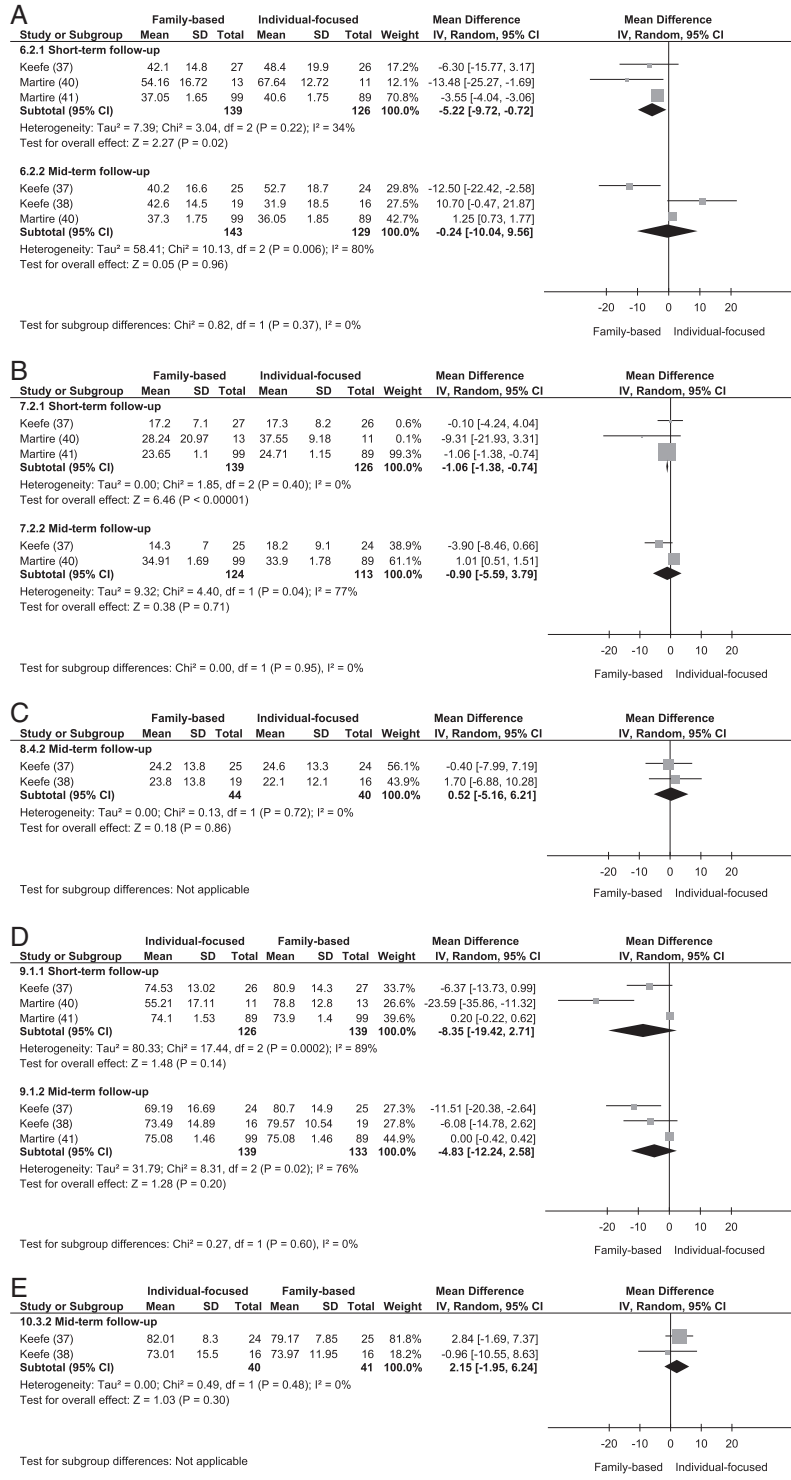


**FIGURE 4.** A, Forest plot of the effect of family-based compared with individual-focused interventions on pain intensity in patients with osteoarthritis. B, Forest plot of the effect of family-based compared with individual-focused interventions on disability in patients with osteoarthritis. C, Forest plot of the effect of family-based compared with individual-focused interventions on mood in patients with osteoarthritis. D, Forest plot of the effect of family-based compared with individual-focused interventions on self-efficacy in patients with osteoarthritis. E, Forest plot of the effect of family-based compared with individual-focused interventions on marital adjustment in patients with osteoarthritis. CI indicates confidence interval.

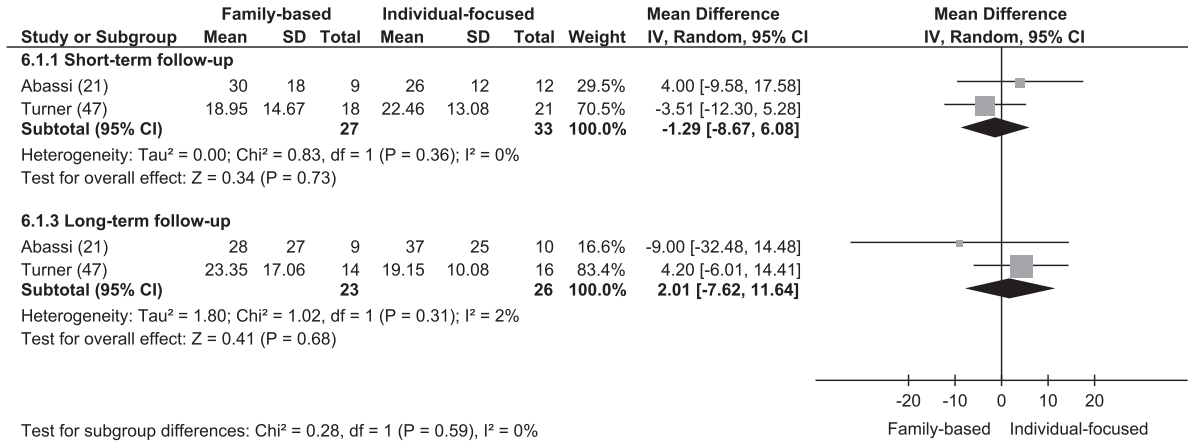


**FIGURE 5.** Forest plot of the effect of family-based compared with individual-focused interventions on pain intensity in patients with chronic low back pain. CI indicates confidence interval.

## DISCUSSION

Fifteen RCTs were included in the qualitative review and 10 RCTs were included in the meta-analyses of this systematic review. Pooled data from primary analyses including all musculoskeletal conditions showed that family-based interventions had small positive effects on pain and disability at the

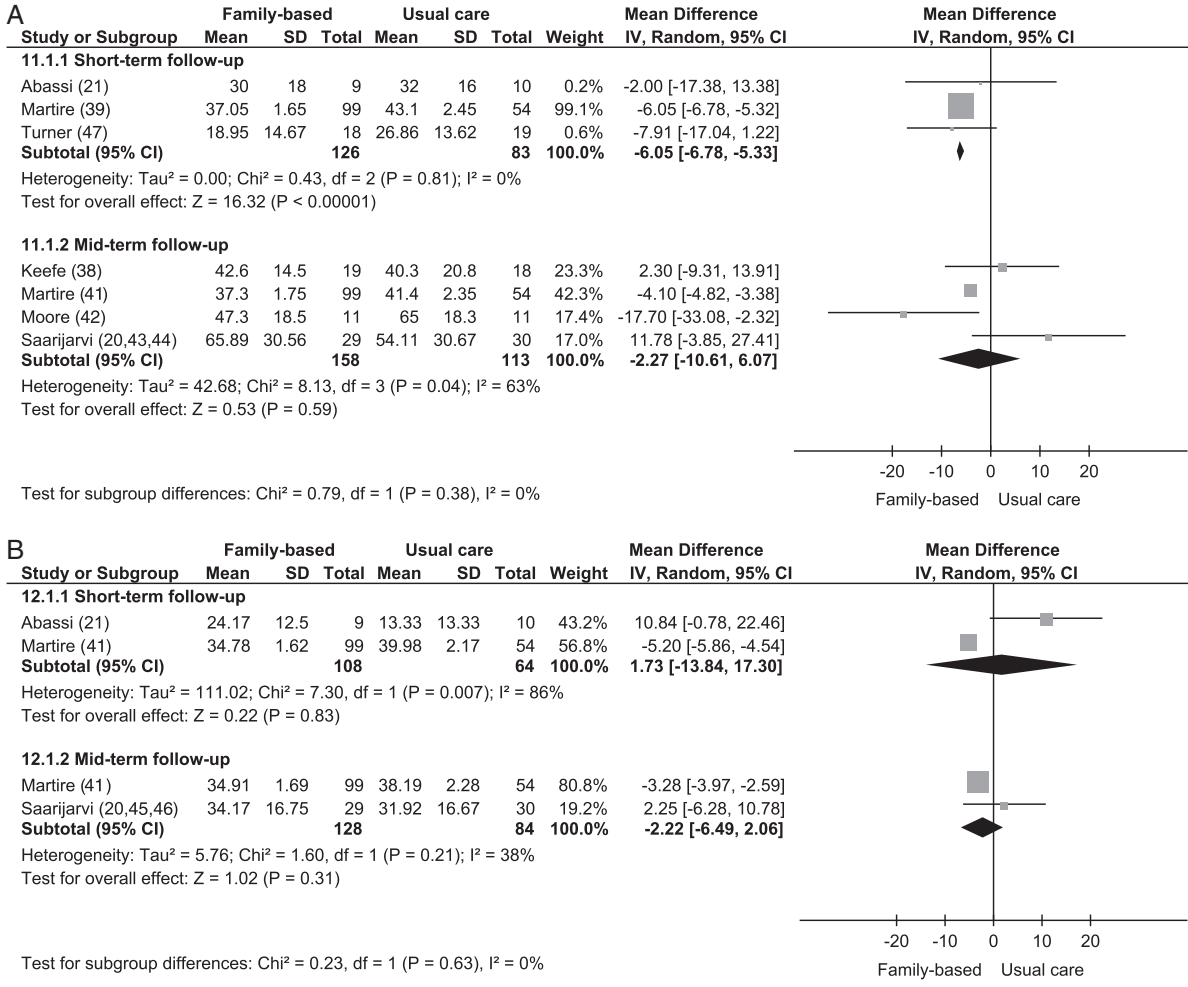


**FIGURE 6.** A, Forest plot of the effect of family-based interventions compared with usual care on pain intensity. B, Forest plot of the effect of family-based interventions compared with usual care on disability. CI indicates confidence interval.

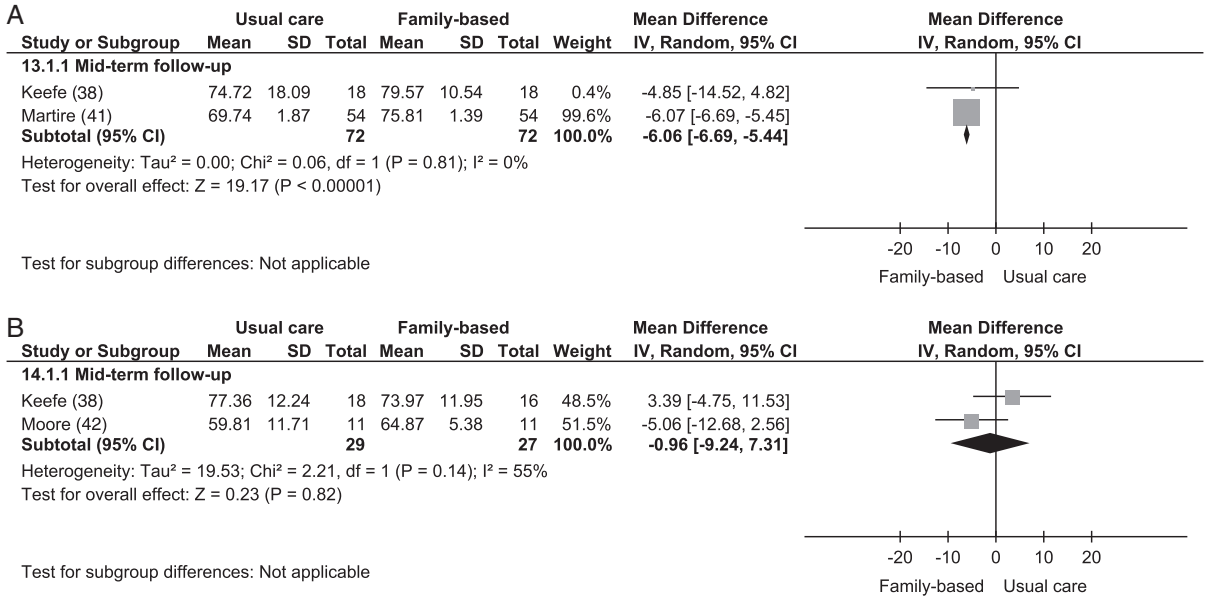


**FIGURE 7.** A, Forest plot of the effect of family-based interventions compared with usual care on self-efficacy. B, Forest plot of the effect of family-based interventions compared with usual care on marital adjustment. CI indicates confidence interval.

short-term compared with individual-focused interventions, but not at mid- and long-term follow-ups, nor on mood, self-efficacy, and marital adjustment. Results from the secondary analyses including patients with CLBP or OA evidenced small positive effects on pain intensity and disability for patients with OA at the short-term, but no effects were observed on pain intensity for patients with CLBP. When compared with usual care, family-based interventions resulted in small greater effects on pain and self-efficacy at the short-term, but not on pain at mid-term follow-up, nor disability or marital adjustment.

To the best of our knowledge, this was the first systematic review to investigate the effect of family-based interventions in the treatment of musculoskeletal pain specifically. Strengths of this review include a comprehensive search strategy, inclusion of patients with various musculoskeletal conditions, and analyses of the effects of family-based interventions on different health-related and relationship outcomes. However, included RCTs were of fair methodological quality and most included patients and their spouses, whereas only 1 RCT included children and their parents. Few studies were included in each meta-analysis (especially in the secondary analysis for CLBP and OA), most of them had a small sample size and did not have a long follow-up resulting in a certain degree of caution when interpreting the precision related to the estimates of the meta-analysis. The low quality of evidence because of serious inconsistency and imprecision at mid- and long-term follow-ups in the outcome of pain should also be considered. Moreover, there were design differences in the original studies regarding the delivery of family-based interventions, including the duration of the intervention and the degree of involvement of family members, which should also be considered as possible limitations of the study.

Various factors may be considered to explain the possible small and inconsistent effects of family-based interventions observed in this review. These factors may include: (1) a few RCTs with overall small sample sizes, with 1 RCT[41] explaining most of the positive results; (2) the presence of treatment contamination—that is, some RCTs[36–38] encouraged patients randomized to individual-focused interventions to communicate more effectively with their family members and share the knowledge gained from the treatment sessions; (3) the fact that individual-focused interventions were evidence-based and shown to be effective in previous studies (eg, standard cognitive behavioral pain management program[49]), perhaps the most important factor. Alternatively, it is possible that family-based interventions might add only small advantages over individual-focused and usual care interventions, and therefore, trials in the field would require much larger sample sizes to detect small between-group differences.[24] This might be even more relevant to RCTs comparing family-based with usual care interventions in children with musculoskeletal pain because parents are usually included in the usual care offered to children.

The characteristics of the family-based interventions could also contribute to the results observed in the review. When comparing RCTs included in the meta-analysis of our primary outcome (pain), there are no clear differences in the characteristics of family-based interventions that had positive effects[37,40,41] and no effect[38,41,42,44,47] on pain. Interventions were delivered within a similar number of sessions (6 to 10[37,40,41] vs. 5 to 12[21,38,42,44,47] weekly sessions) of similar duration (~2 h) with spouses being the family members involved.[21,37,38,40–42,44,47] In addition, interventions had similar components, including education, coping skills training, communication, and goal setting.[21,37,38,40–42,44,47] Moreover, RCTs were of varied sample sizes and there were also no clear differences between the studies with positive and no effects.[21,37,38,40–42,44,47] However, RCTs reporting a positive effect of family-based interventions were conducted with slightly older patients (61 to 71 y) with OA,[37,40,41] whereas RCTs that did not find differences between groups were conducted with younger patients (44 to 60 y) with rheumatoid arthritis,[44] musculoskeletal pain,[42] CLBP,[21,47] and OA.[26] This might indicate that older patients could benefit more from family-based interventions than younger counterparts.

At this stage, we can only speculate why the results from studies conducted with patients with OA and CLBP presented different results. We would not go as far as attributing the differences in effects to types or features of interventions delivered for these 2 conditions, as they were fairly similar (6 to 10 weekly, 2-h groups sessions with spouses or partners involving pain education, coping skills training, combined goal setting). Possible explanations for the differences in results across conditions could include different levels of adherence to treatment. However, only 2 RCTs reported data on intervention adherence.[21,41] Attendance rate by patients to family-based interventions was also similar among the 2 RCTs (89% in both studies), but patients with OA presented a lower attendance rate to individual-focused intervention (58%)[41] when compared with patients with CLBP (89%).[21] The methodological quality of the 2 groups of trials was also similar (PEDro score = 5/10 points). Therefore, it is possible that these differences might reflect differences in response to treatment as a result of specific disease characteristics. It is also possible that age might have influenced patients' response to treatment, as the studies that included patients with OA reported a higher mean age (mean age range, 54 to 71 y) compared with those with CLBP (mean age range, 39 to 46 y). Again, it is possible that older patients might benefit more from having their family members and/or peers involved in their disease management process than younger people. This should be investigated in future clinical trials.

Considering the influence of family members on each other's physical activity levels[5,50] and the importance of physical activity in the management of musculoskeletal disorders,[51,52] it is surprising that none of the RCTs included in the systematic review assessed the influence of family-based interventions on physical activity. Most of the RCTs included in the review delivered interventions based on pain education, pain management, and/or cognitive-behavior therapy,[19,21,24,26,36–44,47] whereas only 4 studies delivered interventions targeting other lifestyle factors, such as physical activity.[24,38,44,47] Perhaps including physical activity components in family-based interventions could represent an effective strategy to optimize the benefits of the family-based approaches for patients with musculoskeletal pain.

Previous systematic reviews have shown positive and promising effects of including family members in the treatment of chronic illnesses on depressive symptoms,[22] pain,[22] marital functioning (satisfaction or partner support),[22,23] self-efficacy,[23] and quality of life.[23] Findings from our meta-analyses only partially support these positive findings. Interestingly, the family-based interventions delivered in the studies included in the previous reviews had similar components to those included in the current review, including disease education and management. However, most of the studies included in the previous reviews were conducted with patients with cancer,[22,23] which might have contributed to the overall larger effect sizes compared with the current review. Furthermore, studies included in the current review were of fair methodological quality, whereas studies included in a previous systematic review were of moderate methodological quality.[23]

In conclusion, there is moderate-quality evidence that family-based interventions result in small but significantly better pain and physical function in the short-term compared with individual-focused interventions in patients with musculoskeletal pain. There is low-quality evidence that family-based interventions have small greater effects on pain at the short-term compared with usual care. However, results might be too small to be considered worthwhile. No differences were found at mid- and long- terms and for the outcomes of mood, depressive symptoms, self-efficacy, and marital adjustment when family-based interventions were compared with individual-focused interventions. A small greater effect was found on self-efficacy but not on marital adjustment when family-based interventions were compared with usual care. Future research that further develops and tests family-based interventions on mid- to long-term outcomes in musculoskeletal pain is needed. Future studies should review the content and optimize the mechanisms underpinning family-based interventions in musculoskeletal pain so that the approach could be further tested in adequately powered RCTs.

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# CHAPTER NINE

**Health coaching intervention with or without the support of an exercise buddy to increase physical activity of people with chronic low back pain compared to usual care: a feasibility and pilot randomised controlled trial**

Chapter Nine has been submitted to the Journal of Pilot and Feasibility Studies on the 26th of September 2022 and is currently under review.

## Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper *"**Fritsch CG**, Ferreira ML, Halliday MH, Roberts K, Josielle C, Mittinty M, Sharpe L, Foster NE, Stamatakis E, Mork PJ, McLachlan AJ, Ferreira PH. Health coaching intervention with or without the support of an exercise buddy to increase physical activity of people with chronic low back pain compared to usual care: a feasibility and pilot randomised controlled trial. Journal of Pilot and Feasibility Studies, under review."* confirm that Carolina G Fritsch 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

Carolina G Fritsch _____ Date: 16/09/2022

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

Professor Manuela L Ferreira _____ Date: 16/09/2022

**Health coaching intervention with or without the support of an exercise buddy to increase physical activity of people with chronic low back pain compared to usual discharge care: a feasibility and pilot randomised controlled trial**

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**ABSTRACT**

**Background:** Exercise buddies might provide social support to help people with chronic low back pain (LBP) to increase their physical activity. This feasibility and pilot randomised controlled trial (RCT) explored the feasibility of the intervention, recruitment and data collection approaches and the potential effects of a health coaching intervention with or without the support of exercise buddies on physical activity in people with chronic LBP versus usual discharge care.

**Methods:** Adults (n=30) discharged from treatment for chronic LBP within the past six months were randomised (1:1:1 allocation ratio) to the Buddy-Assisted Group (health coaching intervention with the support of an exercise buddy), Individual-Only Group (health coaching intervention only), or usual discharge care (e.g., education, exercise recommendations). The feasibility of the trial's procedures was assessed through recruitment rate, data completeness and follow-up rates. Recruitment success was assessed via recruitment rate and considered acceptable if >70% of those screened as eligible. Data completeness was judged to be acceptable if there was ≤20% missing data. Follow-up rate was defined by the proportion of participants completing their follow-up data and considered successful if ≥85%. The acceptability of the interventions was assessed via feedback questionnaires.

**Results:** Recruitment and baseline data completeness were acceptable based on the defined cut points. Data completeness and follow-up rates at three- and six-months were not acceptable, being the lowest rates for the accelerometer data. Six out of seven participants from the Buddy-Assisted Group who completed the feedback questionnaire believed the buddies helped them to increase physical activity and would recommend the intervention to others. Out of the 14 participants from the Individual-Only and Usual Discharge Care groups who completed the feedback questionnaires, 10 participants believed that exercise buddies would help them to increase their physical activity participation.

**Conclusion:** The planned data collection and follow-up approaches would need amending before a future large RCT. Nonetheless, the buddy-assisted health coaching intervention was acceptable to participants. The differences in clinical outcomes will be the focus of a future large RCT.

**Trial registration:** The trial was registered at the Australian New Zealand Clinical Trial Registry (ACTRN12620001118998). Registered 26/08/2020. Retrospectively registered.

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=380441&isReview=true

**KEYWORDS:** physical activity, social support, health coaching, mHealth, low back pain, randomised trial, musculoskeletal pain

## KEY MESSAGES REGARDING FEASIBILITY

1. **What uncertainties existed regarding feasibility?**

   The acceptability of a buddy-assisted health coaching intervention by people with chronic low back pain as well as the feasibility of recruitment, data collection and follow-up were uncertain.

2. **What are the key feasibility findings?**

   Recruitment was successful, but follow-up and data completeness were insufficient. The buddy-assisted health coaching intervention was well accepted by participants.

3. **What are the implications of the feasibility findings for the design of the main study?**

   The data collection and follow-up procedures need amending before a future large RCT, particularly the objective assessment of physical activity.

## BACKGROUND

Low back pain (LBP) is usually defined as pain between the lower rib margins and the buttocks (1, 2). LBP poses a great burden on people (1, 2) and is the leading cause of years lived with disability worldwide (3). LBP impacts multiple aspects of life, affecting people's ability to work, preventing them from engaging in physical activity, and daily and social activities, ultimately reducing their quality of life (4).

Physical activity is an important component of LBP treatment. A recently published network meta-analysis found that exercise improves LBP and disability compared to minimal care (i.e., no treatment, usual care or ineffective interventions) (5). People with LBP are therefore encouraged to be physically active to improve their symptoms (5), decrease the need for analgesics (6) and improve general health (7). Health coaching interventions provide motivation that helps people to achieve healthier behaviours (8). It can also help people to increase physical activity participation (9) and can improve pain and disability of people with low back pain when added to physiotherapy treatment (10). A previous pilot randomised controlled trial (RCT) has assessed the acceptability and preliminary effects of a health coaching intervention on physical activity participation and use of care of people with LBP recently discharged from care (11). Although participants were largely satisfied with the intervention received and the preliminary

exploratory analysis has evidenced potential effects of the intervention in decreasing health care utilisation, no effects were seen on physical activity participation (11).

Recent qualitative studies indicate social support as a potential enabler of physical activity in people with LBP and suggest that exercise buddies might help to overcome barriers to physical activity (12, 13). Previous studies have shown that exercise buddies may offer support and motivation to exercise (14, 15) leading to greater physical activity (16) and fitness increments (17). Despite the challenges people with LBP face to engage in physical activity (13) and the potential benefits of social support to exercise (13), the effect of exercise buddies on the physical activity levels of people with LBP is unknown when combined with health coaching interventions. Before a large RCT is conducted to investigate the added benefit of exercise buddies to health coaching compared to usual discharge care, it is first important to conduct a feasibility and pilot RCT to test out processes of recruitment, intervention delivery, adherence and acceptability, data completeness and follow-up.

## METHODS

### Study design

This study was a pragmatic simple three parallel arm pilot and feasibility RCT and is reported following the CONSORT guidelines for pilot and feasibility studies (18), the TIDieR checklist for reporting interventions (19) and the CONSERVE Statement for reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances (20). The trial protocol was approved by the Sydney Local Health District Human Research Ethics Committee (2019/ETH13224) and registered at the Australian New Zealand Clinical Trial Registry (ACTRN12620001118998). All participants consented to participate before enrolment in the trial.

The original clinical objective of this RCT was to investigate whether a health coaching intervention with or without the support of an exercise buddy is more effective than usual discharge care in improving physical activity and reducing the use of care (i.e., visits to health care professionals and Emergency Departments and number of medications) of people with LBP recently discharged from treatment from two outpatient physiotherapy departments in a public hospital in Sydney, Australia. However, due to ongoing

challenges related to the COVID-19 pandemic, people with non-urgent musculoskeletal conditions were unable to access usual outpatient physiotherapy care. Therefore, important modifications to the trial protocol were implemented to mitigate the impact of the pandemic on the trial and to complete it in a timely fashion. The modifications were planned by the trial investigators and reviewed and approved by the human research ethics committee. Important modifications included adjusting the inclusion criteria, recruitment source and sample size. As a consequence, we report this trial as a feasibility and pilot RCT. The modifications and their timeline are listed in Additional File 1. However, in alignment with the original protocol, the clinical effectiveness of the interventions was assessed as planned and reported in Additional File 8.

**Participants**

Participants were recruited between August 2020 and December 2021. Initially, adults aged 50 years and over discharged from physiotherapy treatment within the past month would be recruited from two outpatient physiotherapy departments in a public hospital in Sydney, Australia. However, in response to the COVID-19 pandemic, important modifications were made to the inclusion criteria and sampling strategy, which were broadened. People reporting being recently (i.e., within the past six months) discharged from community health care providers, such as physiotherapy, chiropractor or general practitioner, were invited to participate by their treating health care professionals or by community or social media advertisements. We aimed to achieve a target sample size of 45 participants in alignment with the initial RCT protocol. However, because of the challenges faced during the COVID-19 pandemic (the restrictions to non-urgent musculoskeletal care and the specific social distancing requirements which impacted on the ability to exercise *with* a buddy), important modifications were made to the sample size, which was reduced from 15 to 10 participants per group (30 participants in total) to finish the trial in a timely fashion.

People were eligible to participate if they: *i)* had non-specific LBP for at least three months and ≥2/10 LBP intensity on an 11-point numeric rating scale (21); *ii)* had been discharged from treatment within the past six months; *iii)* engaged in less than five hours of light to moderate physical activity per week (assessed by the Active Australia Questionnaire) (22); *iv)* had an exercise-buddy to exercise with at least once per week for at least 30 minutes; *v)* had adequate hearing and eyesight and independent ambulatory

status; and *vi)* lived in the states of New South Wales (NSW), Queensland or South Australia. Potential participants meeting the inclusion criteria were asked to nominate one exercise buddy to participate in the trial. Exercise buddies had to be adults with adequate hearing and eyesight and independent ambulatory status who were willing to exercise with the participant. Criteria for exclusion of participants and buddies are presented in Additional File 2.

Potential participants and their exercise buddies were screened for eligibility by researchers either in person (when COVID-19 restrictions permitted) or over the phone. Participants and buddies who were screened face-to-face and were eligible to participate signed a paper-based consent form and completed a paper-based baseline questionnaire. A tri-axial accelerometer device (Axivity AX3) was then secured to the anterior right thigh of participants following standard procedures (23). Participants and buddies who were screened over the phone and deemed eligible received a link to the online consent form and baseline questionnaires via email. The consent form and questionnaire were completed on Research Electronic Data Capture (REDCap – a data capture web-based application designed for research) (24, 25). Following baseline data collection, the accelerometer was posted to participants with instructions, application tapes and a pre-paid envelope so that participants could return the accelerometer to the study team. Furthermore, a researcher helped participants to place the device by supporting them in this over the telephone or via a video conference. Participants were enrolled into the trial and randomised after they confirmed the physical activity assessment using the accelerometer was completed and the accelerometer returned in the post.

**Randomisation**

Randomisation was conducted by a researcher (CGF) on REDCap (24, 25) by using a computer-generated random allocation sequence with block sizes of six and a 1:1:1 allocation ratio. The randomisation was concealed from the researcher until after the assessment was complete. The same researcher enrolled participants in the trial, supported baseline data collection, and informed them about group allocation. The researcher also completed a referral form to the health coaching service with the details of participants randomised either to the Buddy-Assisted or Individual-Only groups. Researchers who contacted participants regarding follow-up data collection (KR, JC) and who conducted the statistical analysis (KR) were blinded to group allocation.

## Intervention

### *Buddy-Assisted Health-Coaching Intervention*

Participants randomised to the Buddy-Assisted Group underwent an initial session with their buddies and a researcher (CGF) via telephone or videoconference. During this session, the researcher explained the buddy's involvement. The researcher reaffirmed that only the participant would receive the health coaching intervention. The researcher helped the participant and their buddy to agree on a combined physical activity goal and discussed how they could overcome possible challenges (e.g., session cancellation). The researcher recommended the combined physical activity goal to initially include a plan to exercise together at least once a week for at least 30 minutes. Given the restrictions imposed by the COVID-19 pandemic, participants and their buddies could exercise together online or independently perform the physical activity on the day and time agreed and check on each other after the exercise session if they could not meet in person. After this first session, the researcher sent participants and their buddies an email confirming their combined goal and sharing the 'Buddy Supportive Brochure' (Additional File 3).

Participants were later contacted by health coaches of the NSW Get Healthy Coaching Service (26), a freely available health coaching intervention provided by the New South Wales Government. Participants could receive up to 13 coaching sessions over six months at their preferred working weekdays and time (am or pm). The calls were approximately 20 minutes long and provided on a tapered schedule. The intervention's primary aim was to increase physical activity, but participants could choose other health-related goals as well (e.g., diet-related goals). All goals were personalised. The Get Healthy Coaching Service was initially provided to anyone living in the states of New South Wales, Queensland and South Australia. However, the service ceased to be delivered to people in Queensland during the trial and participants living in Queensland were no longer able to receive the intervention (Figure 1).

### *Individual-Only Health Coaching Intervention*

Participants randomised to the Individual-Only Health Coaching Group underwent an initial telephone session with a researcher (CGF), who informed them about their randomisation and provided details about the health coaching intervention. Participants received the same health coaching intervention (provided by NSW Get Healthy Coaching Service) (26) as the Buddy-Assisted Group.

### *Usual Discharge Care*

Participants allocated to the Usual Discharge Care Group did not receive any intervention besides their usual discharge care from their treating health care professional (i.e., physiotherapist, chiropractor, or general practitioner). However, they were informed they could self-enrol in the Get Healthy Coaching Service (26) if they wished and were asked to inform the research team if they did so during their participation in the trial.

## Outcomes

### *Process evaluation and feasibility outcomes*

The potential "reach" of the trial (i.e., the participation rate among those who initially expressed interest) was assessed by the total number of included participants divided by the total number of potential participants. The interest in the proposed trial was analysed by the number of people no longer interested in the intervention divided by the total number of potential participants.

The feasibility of the RCT procedures including recruitment rate, data completion rate and follow-up rate were also assessed. The recruitment rate was analysed by the proportion of people who were screened as eligible participants and consented to participate in the RCT. The recruitment rate was considered acceptable if over 70%. Data completeness was defined by the proportion of missing data and was considered acceptable if $\leq 20\%$. Follow-up rate was defined by the proportion of participants who completed at least one outcome measure and was considered acceptable if $\geq 85\%$ at both three- and six-months time-points.

The acceptability of the interventions, perceived mechanisms of effect and opportunities for improvements were assessed through feedback surveys sent via email to participants after the completion of the six-month questionnaires. Participants in each intervention arm were asked different questions. The feedback surveys consisted of an initial open-ended question either asking participants to share their experience of the interventions (Individual-Only or Buddy-Assisted intervention) or the possibility of receiving health coaching intervention to increase physical activity levels and having an exercise buddy (Usual Discharge Care Group). Participants also answered closed-ended questions (Likert-scale or multiple-choice questions) regarding the perceived usefulness and

acceptability of the interventions, barriers, facilitators and possible mechanisms of impact. Attendance to, acceptability of and satisfaction with the health coaching intervention were also assessed through self-reported attendance at the health coaching sessions and their perceived helpfulness (0-10 scale, where 0 = not helpful at all and 10 = extremely helpful) in the weekly online diaries.

***Exploratory clinical outcomes***

The exploratory clinical outcomes were physical activity (assessed as the number of daily steps), time spent in static postures, average LBP intensity in the previous week, LBP-related disability, use of health care, and goal achievement. The outcome measures were assessed at three- and six-months post-randomisation, being six months the primary endpoint.

*Number of daily steps and static postures*

The number of daily steps and time spent in static postures were objectively assessed via a thigh-worn tri-axial accelerometer (Axivity AX3) for seven days. Researchers either placed the accelerometer or instructed participants on how to place it on their right thigh following standard procedures (23). By convention, valid wear days were defined as ≥600 minutes of wear time per day and we included participants with ≥3 valid wear days over seven days. The physical activity level was assessed as the mean number of daily steps whilst the mean daily time in static postures was calculated by the time participants spent sitting, standing, and laying.

*Pain*

Average LBP intensity in the previous week was assessed via 0-100 visual analogue scales, where 0 represented no pain and 100 the worst pain possible (21).

*Disability*

LBP-related disability was assessed with the Roland and Morris Disability Questionnaire (RMDQ) (27). The total disability score ranges from 0 (no disability) to 24 (maximal disability) (27).

*Use of health care*

Participants were asked about visits to health care professionals, medication consumption and visits and admissions to hospitals due to their LBP within the previous week.

*Goal achievement*

Participants were also asked about their physical activity participation, physical activity goal achievement (individual and combined goals for participants from the Buddy-Assisted Intervention Group) as well as changes in goals and physical activities through weekly diaries over the six months.

*Adverse events*

Adverse events were considered as any harmful, unpleasant, or undesirable response, reaction, or outcome experienced by a participant. Adverse events that were expected as part of the intervention included transient increases in LBP intensity or delayed onset of muscle soreness related to the commencement of unaccustomed physical activity. Serious adverse events were defined as events that could result in death, were life-threatening, required or prolonged inpatient hospitalisation. Adverse events were assessed through the weekly diaries.

**Statistical analysis**

Demographic baseline continuous data were presented as a central tendency (mean or median) and variability (SD or range). Categorical data were summarised as proportions. Data completeness was assessed by calculating the percentage of missing data of primary and secondary clinical outcomes. The recruitment rate was analysed by the proportion of eligible people who consented to participate in the trial. Follow-up rate was defined by the proportion of participants who completed at least one clinical outcome measure. The number of self-reported attendance to the health coaching sessions and their perceived helpfulness were summarised per randomised arm as a central tendency (mean) and variability (SD). The mean and SD per intervention arm for each clinical outcome measure were calculated. In alignment with the original RCT protocol, the between-group differences in the clinical outcome measures were explored with linear mixed models.

The feedback surveys were analysed in two ways. The percentage of both Likert-scale, as well as multiple choices answers, were calculated. Additionally, the number of participants choosing the Likert-scale and multiple-choice options was also calculated.

Answers to the open-ended question were analysed based on independent thematic data-driven coding by two researchers and were triangulated between researchers for discrepancies.

## RESULTS

A total of 162 people expressed interest in participating in the trial. The reasons for inclusion/exclusion as well as follow-up data collection are reported in Figure 1. Participants reported learning about the trial via social media (n=90, 55.5%), radio (n=24, 14.8%), health care professionals (n=16, 9.9%), seniors' newsletters or websites (n=10, 6.2%), word of mouth (n=7, 4.3%), and others (n=11, 6.8%). Of the 162 screened, 38 met the inclusion criteria and were invited to participate and 30 participants (and their 30 buddies) consented to the trial. Of the 30 participants enrolled, 13 (43.3%) reported learning about the trial via social media, nine (30.0%) via radio, four via their treating health care professionals (13.3%), three via newsletters or websites (10.0%) and one via word of mouth (3.3%). The baseline characteristics of participants in total and per arm are presented in Table 1. The baseline characteristics of 29 of the 30 exercise buddies who consented to participate are presented in Table 2 since one buddy consented to participate but declined to complete the baseline questionnaire.

### *Feasibility outcomes*

30 participants out of 162 people expressing initial interest in participating in the trial were enrolled, leading to an intervention reach of 18.5%. Thirteen per cent of people who had registered to participate in the pre-screening were no longer interested when contacted by the researcher for full screening. The recruitment rate was 78.9% (30 out of 38 eligible participants were enrolled in the RCT) and considered acceptable. Data completeness of the baseline questionnaire was 100% whilst baseline accelerometer data were available for 96.7% of participants (one accelerometer was lost when posted back to the research team). Three participants from the Buddy-Assisted, two from the Individual-Only and one from the Usual Discharge Care groups have withdrawn from the trial and two participants from the Individual-Only Group were lost to follow-up (Figure 1). Data completeness was not acceptable at three- and six-months, as there were 33.3% and 26.7% missing data, respectively, for the online questionnaire, 46.7% for the accelerometer data at both time-points and 46.4% for the online weekly diaries. The follow-up rate also did not meet the pre-determined success cut-off point, as only 66.7%

and 73.3% of participants completed at least one outcome measure at three- and six-months, respectively. The follow-up rate for the likely primary clinical outcome (number of steps assessed via accelerometer) was 53.3% at both three- and six-months.

One participant from the Individual-Only and one from the Buddy-Assisted groups resided in the state of Queensland and were unable to receive the health coaching intervention as the Get Healthy Coaching Service stopped delivering services to the residence of Queensland since the Get Healthy Coaching Service contract was not renewed by the Queensland Government. The participant from the Individual-Only Group decided to self-enrol in a different health coaching intervention whilst the participant from the Buddy-Assisted Group decided to withdraw from the RCT. The seven participants from the Buddy-Assisted Group included in the analysis reported receiving on average 5.8 health coaching sessions from the maximum of 13 available sessions and assessed their helpfulness through a mean of 7.3 on a 0–10-point scale. They reported achieving their individual physical activity goals on 55% and their combined goal on 52% of the completed weekly diaries. The six participants from the Individual-Only Group included in the analysis reported receiving on average 3.6 sessions and assessed their helpfulness as 5.5 points on a 0-10-point scale. They reported achieving their individual physical activity goals on 49% and exercising with someone on 43% of the completed weekly diaries. The nine participants from the Usual Discharge Care Group included in the analysis reported exercising with someone on 49% of the completed weekly diaries.

***Participants' feedback***

*Buddy-Assisted Group*

Seven participants completed the closed-ended questions in the feedback survey (Table 3). The most frequently reported advantages of an exercise buddy were increased motivation to exercise (reported by four out of seven participants), having the opportunity to talk to the buddy whilst being active (reported by three out of seven participants), and not having to exercise alone (reported by three out of seven participants). Three out of seven participants agreed that the greatest disadvantages of exercise buddies were difficulty in finding a physical activity/ time/ place that worked for both and feeling demotivated facing own limitations. Only two participants provided written feedback. One reported the vital role of exercise buddies to motivate and support exercise

adherence. The second mentioned that although their buddy forgot they were still committed to the trial, they walked together. Further information is reported in Additional File 4.

Six exercise buddies completed the closed-ended questions (Table 4). Five buddies reported that the greatest advantage of acting or stepping in as an exercise buddy increased their own motivation to exercise. Three out of six buddies agreed that the greatest disadvantage of being an exercise buddy was having to accommodate patients' pace of exercise. Further information is reported in Additional File 5.

*Individual-Only Health Coaching Group*

Six participants completed the closed-ended questions. Three of the six were satisfied with the Get Healthy Coaching Service and reported it helped them to increase their physical activity participation. The greatest challenges to increase physical activity were lack of time (reported by three participants) and joy in exercise (reported by two participants). Three participants believed an exercise buddy would further help them to increase physical activity. As reported by this group of participants, the possible advantages of exercise buddies would be increased motivation (reported by four participants) and support to exercise and having time to talk to the buddy whilst being active (reported by three participants). Four participants believed that finding a physical activity/ time/ place that worked for both would be a disadvantage (Additional File 6).

Two participants provided written feedback. Whilst the health coaching intervention helped them to keep active and motivated and assisted in the management of their LBP, more information on specific back exercises were felt to be needed (Additional File 6).

*Usual Discharge Care Group*

Eight participants completed the feedback survey. Six of the eight responders believed that health coaching intervention after discharge from treatment would help them to increase physical activity, whilst seven believed that an exercise buddy would help them to further increase their activity levels. However, five believed it would be difficult to agree on a combined physical activity goal. Five participants also believed that the greatest advantages of exercise buddies would be to motivate and support them to exercise and have the time to talk with their buddy whilst being active. Nonetheless, seven

participants believed that the greatest disadvantage would be the difficulty in finding a physical activity/ time/ place that worked for both (Additional File 7).

Only one participant (12.5%) in the Usual Discharge Care group reported self-enrolling in the Get Healthy Coaching Service and enjoying it. Another participant from the Usual Discharge Care group answered the open-ended question reporting walking alone with little motivation before their neighbour started walking with them every day and helping them to walk further (Additional File 7).

***Exploratory clinical outcomes***

Baseline and follow-up mean ± SD values for each intervention arms are reported in Table 5. At baseline, the Buddy-Assisted Group presented a mean number of daily steps of 10,358.7 ± 5,109.9, which slightly increased at three- (11,171.6 ± 6,692.4) and six-months (10,802.1 ± 7,416.0). The Individual-Only Group presented a mean number of daily steps of 12,026.1 ± 9,489.7 at baseline, which slightly increased at three- (12.794.7 ± 8,643.6) and slightly decreased at six-months (11,896.0 ± 7,180.7). The Usual Discharge Care Group presented a mean number of daily steps of 8,637.2 ± 5,422.6) at baseline, which increased at three (mean 11,305.2 ± 9,051.2) and six-months (9,951.7 ± 5,473.6). The exploration of clinical outcomes, per intervention arm, was assessed through linear mixed models and presented in Additional File 8.

***Adverse events***

A total of 106 adverse events were reported in the weekly diaries. 46 adverse events were reported by the Buddy-Assisted Group, 19 by the Individual-Only Group and 42 by the Usual Discharge Care Group. 69%, 87% and 62% of the events reported by the Buddy-Assisted, Individual-Only and Usual Discharge Care groups were considered as possibly related to the trial. 85% of the possibly related adverse events were expected increases in LBP and muscle soreness related to exercise. There was only one serious adverse event reported by a participant from the Buddy-Assisted Group, which was not related to their participation in the trial. There was no serious adverse event related to the trial.

## DISCUSSION

The main results of this pilot and feasibility RCT included successful recruitment and baseline data completeness. However, data completeness at three- and six-month follow-

ups were not acceptable. Data completeness was poorest for accelerometer data, the likely primary outcome of a future main RCT. The satisfaction level of most participants receiving the health coaching intervention was high, and they reported that it helped them to increase physical activity participation. Participants in the Buddy-Assisted Group reported that their buddies' support further assisted them to increase physical activity by providing extra motivation to exercise. Furthermore, most participants from both Individual-Only and Usual Discharge Care groups believed exercise buddies could further motivate them to increase physical activity. Since the analysis of the clinical outcomes was exploratory and unpowered, these results should be interpreted with caution.

Some methodological challenges faced in this trial were previously reported in other studies (28-30). For instance, the challenges involved in objectively measuring physical activity participation. Despite participants' agreeing to wear the accelerometers, three participants at three months and four at six months returned the devices without having worn them. Additionally, nine devices were lost either by participants or by the Australian post. Similarly, a previous study investigating the feasibility of assessing families' physical activity participation during the COVID-19 pandemic also reported that 10 accelerometer devices were lost either by participants (n=1) or the postage system (n=9) (28). Moreover, a previous feasibility study assessing the effects of educational sessions (three face-to-face sessions followed by weekly telephone contacts) on the physical activity level of older women also reported low accelerometer data completeness rates (29). Data were available for only 27.5% of participants at all time-points (29). However, a previous pilot study investigating the feasibility of weekly face-to-face walking and educational sessions on physical activity participation of older adults reported only a 20% loss to follow-up and accelerometer missing data post-intervention (30). This might indicate that a possible way to overcome the low accelerometer data collection rate might be to increase face-to-face contact and interaction of participants with the study team. In fact, the accelerometer data completeness rate was 100% for participants who physically presented to the physiotherapy department to have the accelerometer secured on their thigh, suggesting better compliance with future accelerometer wearing if participants attend a first in-person session. However, regular face-to-face contact might restrict recruitment to specific geographical locations and increase participants' travel time-

related burden and the trial's financial and personnel resources, which might in turn decrease the feasibility of the strategy.

Although we can only hypothesise about the causes for the low follow-up and data completeness rates, some reasons may be considered. They might be related to the changes to the recruitment and data collection methods in response to the COVID-19 pandemic (face-to-face *vs.* remote recruitment and data collection). They may also be associated with the negative impacts of the COVID-19 pandemic on participants' life leading to later disinterest in the trial despite their initial willingness to participate, given that other trials within the musculoskeletal field also faced challenges with data collection during the pandemic (31). Furthermore, the trial was conducted during many periods of lockdowns and restrictions of activities and social interactions, which might have also negatively impacted their participation in the trial. Alternatively, they might also result from dissatisfaction with the health coaching intervention and the low self-reported number of sessions received. Therefore, the characteristics of the health coaching intervention might also be reconsidered in a future trial. Nonetheless, the intervention provided was already established and freely available and no changes could be made to this.

Although this is the first trial assessing the feasibility of the intervention, recruitment and data collection approaches of including an exercise buddy to support physical activity participation of people with LBP, it has limitations that should be acknowledged. Firstly, important modifications to the trial protocol were implemented following the challenges faced with recruitment and intervention delivery due to the COVID-19 pandemic, especially due to restrictions to access non-urgent musculoskeletal care in hospitals, the low number of people seeking care for LBP and limits to social interaction. Although the modifications have been reported following the CONSERVE guideline (20), the low number of participants included in the trial limits the understanding and generalisability of the feasibility and feedback findings. Even though the buddy-assisted health coaching intervention was well-accepted by participants and their buddies, and participants from the Individual-Only and Usual Discharge Care groups expressed interest in having an exercise buddy, these findings are based on the feedback received from a small number of participants. Additionally, the greater loss to follow-up and withdrawal rates seen in the intervention groups might indicate "selective attrition" – that is, participants from the

treatment groups seemed more likely to withdraw. Secondly, although the completion rate of the weekly diary was low and the number of coaching sessions reported might have been underestimated, the number of intervention sessions was below what would be expected (since participants could have received up to 13 sessions). Furthermore, participants from the Individual-Only and Usual Discharge Care groups were not asked to exercise with a buddy, yet they reported exercising with another person on almost half of the completed weekly diaries. Besides, participants randomised to the Usual Discharge Care group increased their mean number of daily steps over the trial. One can hypothesise that it could be related to the fact that people volunteered for a trial focused on physical activity and exercise buddies, and were therefore motivated to increase their physical activity participation and exercise with someone. Finally, participants were highly active at baseline with accelerometer data showing, on average, between 8,600 and 12,000 daily steps, which is similar to the number of daily steps reported by a prospective study with data from over 460,000 Australian adults (32).

The findings indicate that the approaches should be changed before a future main RCT, especially the physical activity data collection. One alternative to improve physical activity data collection could be to recruit people who wear smartwatches, which have been shown to have good validity for step count (33). However, different devices present different measurement errors (33), so inclusion criteria should be targeted to specific devices. Additionally, wearable activity trackers, including smartwatches, are effective strategies to improve physical activity participation of people across various age groups and clinical characteristics (34). Therefore, people who wear smartwatches could be more active than others and not represent the large population of people who suffer from chronic LBP. Finally, participants would need to allow researchers to have access to their data, as needed with Fitbit data (35). Alternatively, self-reported physical activity participation could overcome the loss of data and decrease the burden on participants and the budget needed to purchase and mail the accelerometer devices. Nonetheless, previous studies have shown that self-reported physical activity questionnaires do not present acceptable validity against accelerometer data in people with chronic LBP (36, 37). Thus, to decrease discomfort (38) and increase acceptability by participants (39) and still collect valid physical activity data, wrist-worn accelerometers could be used instead of thigh-worn accelerometers. Wrist-worn accelerometers present good agreement and excellent correlation with waist-worn accelerometers for step counting in the free living

environment of people with chronic pain (40) and could represent a better data collection strategy.

Positive feedback was received by participants and buddies randomised to the Buddy-Assisted Group about their experience in exercising together, whilst participants from the Individual-Only and Usual Discharge Care groups expressed interest in having an exercise buddy. Given the encouraging feedback received, the research question about whether the exercise buddy effectively increases physical activity participation of people with LBP should be explored in a future large-scale, fully powered RCT. However, changes to the trial design might be warranted. One could consider the Multiarm, multistage (MAMS) RCT design (41). Through this design, the Buddy-Assisted and the Individual-Only groups could be compared with the Usual Discharge Care group and an interim analysis could be done to drop the losing arm (Buddy-Assisted or Individual-Only group) if there is no evidence of superiority. The Usual Discharge Care group would be maintained as it represents the current treatment pathway of LBP and would allow a cost-effectiveness analysis. Through this design, the sample size and resources needed to conduct the trial would be minimised. Additionally, changes could also be done to the inclusion criteria of participants. Only people not meeting the physical activity guidelines (i.e., engaging in less than 150 minutes of physical activity per week) could be included to ensure the interventions are delivered to those who need them. This inclusion criterion could also help to decrease between-arm contamination since secondary analyses from previous RCTs assessing physical activity interventions evidenced that greater baseline physical activity participation predicted future between-arm contamination (42). Furthermore, due to the importance of physical activity participation for the management of LBP, people not being recently discharged from treatment could also be included in the trial to optimise recruitment and future implementation of the findings. However, the physical activity data collection approach should be amended to improve the data completeness rate. Assessing the number of steps to estimate the total volume of physical activity via wrist-worn accelerometers might represent a valid strategy to overcome challenges with low adherence to the thigh-worn accelerometer and provide reliable data.

## CONCLUSIONS

This feasibility and pilot RCT showed that although recruitment and baseline data completeness were sufficient, data completeness and follow-up rates at three- and six-

months were poor. The buddy-assisted health coaching intervention was well accepted by participants. Before proceeding to a future large-scale RCT, we recommend changes to the design, participants' inclusion criteria and data collection approaches.

## LIST OF ABBREVIATIONS

CONSERVE: CONSORT and SPIRIT Extensions for Randomised Controlled Trials Revised in Extenuating Circumstances

CONSORT: Consolidated standards of reporting trials

COVID-19: Coronavirus disease-19

LBP: Low back pain

MAMS: Multiarm, multistage

NSW: New South Wales

RCT: Randomised controlled trial

RMDQ: Roland and Morris Disability Questionnaire

SD: Standard deviation

## FIGURES

**Figure 1.** Flow-chart of trial participants

## ADDITIONAL FILES

**Additional File 1. Main modifications to the trial's protocol**

**File format:** .docx

**Title of data:** Main modifications to the trial protocol

**Description of data:** The data presented describes and presents the dates when the main modifications were made to the trial protocol.

**Additional File 2. Reasons for exclusion of trial's participants and their buddies**

**File format:** .docx

**Title of data:** Reasons for exclusion of trial participants and their buddies.

**Description of data:** The data presents the reasons for exclusion of trial potential participants and their buddies.

**Additional File 3. Buddies supportive material**

**File format:** .pdf

**Title of data:** Buddies supportive material.

**Description of data:** The file presents the supportive material shared with participants randomised to the Buddy-Assisted Group and their buddies.

**Additional File 4. Further feedback provided by participants randomised to the Buddy-Assisted Group**

**File format:** .docx

**Title of data:** Further feedback provided by participants randomised to the Buddy-Assisted Group.

**Description of data:** The file presents the feedback received from participants randomised to the Buddy-Assisted Group.

**Additional File 5. Further feedback provided by buddies from participants randomised to the Buddy-Assisted Group**

**File format:** .docx

**Title of data:** Further feedback provided by buddies from participants randomised to the Buddy-Assisted Group.

**Description of data:** The file presents the feedback received from buddies from participants randomised to the Buddy-Assisted Group.

**Additional File 6. Further feedback provided by participants randomised to the Individual-Only Group**

**File format:** .docx

**Title of data:** Further feedback provided by participants randomised to the Individual-Only Group.

**Description of data:** The file presents the feedback received from participants randomised to the Individual-Only Group.

**Additional File 7. Further feedback provided by participants randomised to the Usual Discharge Care Group**

**File format:** .docx

**Title of data:** Further feedback provided by participants randomised to the Control Group.

**Description of data:** The file presents the feedback received from participants randomised to the Usual Discharge Care Group.

**Additional File 8. Exploratory analysis of between-arm differences in clinical measures at baseline, 3-months and 6-months**

**File format:** .docx

**Title of data:** Exploratory analysis of between-arm differences in clinical outcome measures at 3- and 6-months.

**Description of data:** The file presents the estimates of treatment effect and the 95% confidence interval in the exploratory clinical outcome measures at 3- and 6-months.

## DECLARATIONS

***Ethics approval and consent to participate:*** The trial was approved by the Sydney Local Health District Human Ethics Committee (2019/ETH13224). All participants completed a consent form prior to their participation in the trial.

***Availability of data and materials:*** The datasets used and/or analysed during the trial are not publicly available due to participants' consent to their data being shared by the University of Sydney and the Sydney Local Health District, but are available from the corresponding author on reasonable request.

***Competing interests:*** The authors declare that they have no competing interests.

***Funding:*** The trial was funded by the Sydney Local Health District. The funding body had no role in the design of the trial and collection, analysis, and interpretation of data and in writing the manuscript.

***Authors' contributions:*** CGF made substantial contributions to the conception and design of the work, data acquisition and interpretation, and drafted the manuscript. MH made substantial contributions to the conception and design of the work and data acquisition. KR made substantial contributions to the design of the work, data acquisition and analysis. JC made a substantial contribution to data acquisition. MM made substantial contributions to the design of the work. NF, ES, PJM, AJM, MLF and PHF made substantial contributions to the conception, design and interpretation of the RCT. All authors read, edited and approved the final version of the manuscript.

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**Table 1.** Baseline demographic and clinical characteristics of participants

| Participants characteristics | Buddy-Assisted Group (n=10) | Individual-Only Group (n=10) | Usual Discharge Care Group (n=10) | All participants (n=30) |
|---|---|---|---|---|
| Demographic characteristics | | | | |
| Age, mean (SD) | 63.7 (9.1) | 63.2 (9.1) | 63.0 (7.7) | 63.3 (8.2) |
| Female, n (%) | 7 (70) | 7 (70) | 7 (70) | 22 (71) |
| BMI, mean (SD) | 30.5 (6.4) | 30.7 (6.2) | 26.1 (3.0) | 29.2 (5.7) |
| Employment status | | | | |
| Unemployed, n (%) | 1 (10) | 0 (0) | 1 (10) | 2 (7) |
| Working, n (%) | 2 (20) | 6 (60) | 5 (50) | 13 (43) |
| Volunteer, n (%) | 0 (0) | 1 (10) | 0 (0) | 1 (3) |
| Retired, n (%) | 7 (70) | 3 (30) | 3 (30) | 14 (47) |
| Educational level | | | | |
| High school or below, n (%) | 2 (20) | 1 (10) | 2 (20) | 5 (17) |
| Certificate/ diploma, n (%) | 7 (70) | 3 (30) | 2 (20) | 12 (40) |
| Bachelor degree, n (%) | 0 (0) | 2 (20) | 1 (10) | 3 (10) |
| Post-graduate/ Masters/ PhD, n (%) | 1 (10) | 4 (40) | 5 (50) | 10 (33) |
| Living arrangements | | | | |
| Single, n (%) | 2 (20) | 2 (20) | 1 (10) | 5 (17) |
| Married, n (%) | 8 (80) | 4 (40) | 6 (60) | 18 (60) |
| De facto, n (%) | 0 (0) | 3 (30) | 1 (10) | 4 (13) |
| Rather not say, n (%) | 0 (0) | 1 (10) | 2 (20) | 3 (10) |
| Comorbidities | | | | |
| Cardiovascular disease, n (%) | 3 (30) | 1 (10) | 1 (10) | 5 (17) |
| Hypertension, n (%) | 4 (40) | 5 (50) | 1 (10) | 10 (33) |
| Diabetes, n (%) | 1 (10) | 1 (10) | 1 (10) | 3 (10) |
| Osteoarthritis, n (%) | 3 (30) | 2 (20) | 4 (40) | 9 (30) |
| Osteoporosis, n (%) | 2 (20) | 1 (10) | 0 (0) | 3 (10) |

| | | | | |
|---|---|---|---|---|
| Other musculoskeletal conditions, n (%) | 4 (40) | 4 (40) | 3 (30) | 11 (37) |
| Mental health issue, n (%) | 2 (20) | 0 (0) | 1 (10) | 3 (10) |
| Other comorbidities, n (%) | 4 (40) | 2 (20) | 3 (30) | 9 (30) |
| Low back pain characteristics | | | | |
| Low back pain duration, years, mean (SD) | 10.9 (9.8) | 16.3 (11.8) | 15.9 (17.8) | 13.8 (13.4) |
| Presence of leg pain, n (%) | 9.0 (90) | 7.0 (70) | 5.0 (50) | 21 (68) |
| Low back pain intensity in the previous week (VAS, 0-100), mean (SD) | 46.3 (30.6) | 47.6 (21.3) | 46.6 (19.4) | 47.6 (23.4) |
| Disability (RMDQ, 0-24), mean (SD) | 11.4 (7.7) | 9.8 (5.2) | 11.2 (3.8) | 10.9 (5.6) |
| Care seeking behaviour within the past month | | | | |
| Visit to health care professional, n (%) | 3 (30) | 1 (10) | 6 (60) | 10 (33) |
| Medicine consumption | 7 (70) | 2 (20) | 7 (70) | 14 (47) |
| OTC analgesics, n (%) | 7 (70) | 2 (20) | 6 (60) | 15 (50) |
| OTC supplements, n (%) | 0 (0) | 0 (0) | 4 (40) | 4 (13) |
| Prescribed analgesics, n (%) | 4 (40) | 0 (0) | 3 (30) | 7 (23) |
| Prescribed opioids, n (%) | 0 (0) | 0 (0) | 1 (10) | 1 (3) |
| Physical activity participation | | | | |
| Total self-reported walking, min/week, mean (SD) | 173.0 (157.2) | 123.5 (73.1) | 209.2 (214.6) | 168.6 (155.1) |
| Total self-reported mod-vig PA, min/week, mean (SD) | 114.5 (125.4) | 138 (151.9) | 49.5 (52.8) | 100.7 (117.8) |
| Objectively measured number of daily steps, mean (SD) | 10,358 (5,109) | 12,069 (9,498) | 8,624 (5,421) | 10,351 (6,810) |
| Objectively measured time in static postures*, hrs/day, mean (SD) | 21.2 (1.0) | 20.8 (1.5) | 21.2 (1.1) | 21.0 (1.2) |

* static postures: sitting, standing and laying

SD: standard deviation; BMI: body mass index; VAS: Visual Analogue Scale; RMDQ: Roland-Morris Disability Questionnaire; OTC: over the counter; mod-vig PA: moderate-vigorous physical activity

**Table 2.** Baseline demographic characteristics of buddies

| Demographic characteristics | Exercise buddies (n=29) |
|---|---|
| Age, mean (SD) | 62.0 (14.6) |
| Female, n (%) | 17 (59.0) |
| BMI, mean (SD) | 27.2 (8.8) |
| Employment status | |
| Unemployed, n (%) | 9 (31.0) |
| Working, n (%) | 13 (44.8) |
| Volunteer, n (%) | 4 (13.8) |
| Other or not reported, n (%) | 3 (10.3) |
| Educational level | |
| High school or below, n (%) | 9 (31.0) |
| Certificate/ diploma, n (%) | 10 (34.5) |
| Bachelor degree, n (%) | 6 (20.6) |
| Post-graduate/ Masters/ PhD, n (%) | 4 (13.8) |
| Living arrangements | |
| Single, n (%) | 5 (17.2) |
| Married, n (%) | 18 (62.0) |
| De facto, n (%) | 5 (17.2) |
| Rather not say, n (%) | 1 (3.4) |
| Relationship with the patient | |
| Spouse/partner | 17 (58.6) |
| Friend | 7 (24.1) |
| Mother | 3 (10.3) |
| Child | 2 (6.9) |
| Comorbidities | |
| Cardiovascular disease, n (%) | 6 (20.7) |
| Hypertension, n (%) | 3 (10.3) |
| Diabetes, n (%) | 4 (13.8) |
| Osteoporosis, n (%) | 1 (3.4) |
| Low back pain, n (%) | 11 (37.9) |
| Other musculoskeletal conditions, n (%) | 6 (20.7) |
| Mental health issue, n (%) | 0 (0.0) |
| Other comorbidities, n (%) | 7 (24.1) |
| Physical activity participation | |
| Total self-reported walking, min/week, mean (SD) | 286.8 (287.7) |
| Total self-reported mod-vig PA, min/week, mean (SD) | 240.0 (355.5) |

SD: Standard Deviation, BMI: Body Mass Index, mod-vig PA: moderate-vigorous physical activity

**Table 3.** Feedback from participants randomised to the Buddy-Assisted Group

| Likert-scale questions | Not at all/ not really<br>n (%) | Neutral<br>n (%) | Somewhat/ extremely<br>n (%) |
|---|---|---|---|
| Pre-intervention session was useful | 0 (0.0) | 0 (0.0) | 7 (70.0) |
| Pre-intervention session helped patients and buddies to be more supportive | 0 (0.0) | 2 (28.6) | 5 (71.4) |
| Pre-intervention session helped to identify suitable combined goal | 0 (0.0) | 2 (28.6) | 5 (71.5) |
| Having the pre-intervention session over the phone or by videoconference was appropriate | 0 (0.0) | 2 (28.6) | 5 (71.4) |
| Buddies Supportive Brochure was useful | 1 (14.3) | 2 (28.6) | 4 (57.2) |
| Buddies Supportive Brochure was easy to understand | 0 (0.0) | 1 (14.3) | 6 (85.7) |
| Advice from the Buddies Supportive Brochure was followed | 1 (14.3) | 0 (0.0) | 6 (85.7) |
| Health coaching intervention helped to increase physical activity participation | 2 (28.6) | 0 (0.0) | 5 (71.4) |
| Effective communication with the health coach | 0 (0.0) | 0 (0.0) | 7 (70.0) |
| Satisfaction with the health coaching service | 1 (14.3) | 1 (14.3) | 5 (71.4) |
| How much the health coaching intervention helped to increase physical activity participation | 3 (42.9) | 0 (0.0) | 4 (57.1) |
| Buddies' support helped to increase physical activity participation | 1 (14.3) | 0 (0.0) | 6 (85.7) |
| It was difficult to find a suitable combined physical activity goal | 3 (42.9) | 2 (28.6) | 2 (28.6) |
| Having an exercise buddy improved the buddies' relationship | 0 (0.0) | 3 (42.9) | 4 (57.1) |
| Recommendation of buddy-assisted health coaching intervention to people with low back pain after discharge from treatment | 1 (14.3) | 0 (0.0) | 6 (85.7) |
| Willingness to have the buddy-assisted health coaching intervention following a new episode of low back pain | 3 (42.9) | 1 (14.3) | 3 (42.9) |

**Table 4.** Feedback from buddies of participants randomised to the Buddy-Assisted Group

| Likert-scale questions | Not at all/ not really agree n (%) | Neutral n (%) | Somewhat/ extremely agree n (%) |
|---|---|---|---|
| Pre-intervention session was useful | 1 (16.7) | 0 (0.0) | 5 (83.3) |
| Pre-intervention session helped patients and buddies to be more supportive | 1 (16.7) | 2 (33.3) | 3 (50.0) |
| Pre-intervention session helped to identify suitable combined goal | 2 (33.3) | 0 (0.0) | 4 (66.6) |
| Buddies Supportive Brochure was useful | 1 (16.7) | 0 (0.0) | 5 (83.3) |
| Buddies Supportive Brochure was easy to understand | 1 (16.7) | 0 (0.0) | 5 (83.3) |
| Advice from the Buddies Supportive Brochure was followed | 2 (33.3) | 1 (16.7) | 3 (50.0) |
| Buddies' support helps patients to increase physical activity participation | 1 (16.7) | 0 (0.0) | 5 (83.3) |
| It was difficult to find a suitable combined physical activity goal | 4 (66.6) | 2 (33.3) | 1 (16.7) |
| Being an exercise buddy improved the buddies' relationship | 1 (16.7) | 2 (33.3) | 3 (50.0) |
| Recommendation for people with low back pain to exercise with a buddy | 0 (0.0) | 1 (16.7) | 5 (83.3) |
| If asked, would agree to be an exercise buddy again | 0 (0.0) | 2 (33.3) | 4 (66.6) |
| Preference to also enrol in an individual health coaching intervention | 2 (33.3) | 1 (16.7) | 3 (50.0) |
| Being enrolled in an individual health coaching intervention would positively affect the role as an 'exercise buddy' | 1 (16.7) | 0 (0.0) | 5 (83.3) |

**Table 5.** Exploratory clinical outcome measures per intervention arm at baseline, 3-months and 6-months

| | Baseline | | | 3-months | | | 6-months | | |
|---|---|---|---|---|---|---|---|---|---|
| Outcome measures, mean (SD) | Buddy-Assisted Group (n=10, physical activity=9) | Individual-Only Group (n=10, physical activity=10) | Usual Discharge Care Group (n=10, physical activity=10) | Buddy-Assisted Group (n=6, physical activity=4) | Individual-Only Group (n=6, physical activity=5) | Usual Discharge Care Group (n= 8, physical activity=7) | Buddy-Assisted Group (n=7, physical activity=3) | Individual-Only Group (n=6, physical activity=5) | Usual Discharge Care Group (n= 9, physical activity=8) |
| Number of daily steps | 10,358.70 (SD 5,109.93) | 12,026.13 (SD 9,489.67) | 8,637.21 (SD 5,422.63) | 11,171.64 (SD 6,692.42) | 12,794.67 (SD 8,643.60) | 11,305.20 (SD 9,051.25) | 10,802.15 (SD 7,416.00) | 11,896.00 (SD 7,180.67) | 9,951.75 (SD 5,473.65) |
| Time in static postures (hours/day) | 21.19 (SD 1.04) | 20.66 (SD 1.46) | 21.16 (SD 1.13) | 21.58 (SD 0.91) | 21.20 (SD 1.50) | 20.84 (SD 1.57) | 21.23 (SD 1.18) | 21.10 (SD 1.19) | 21.36 (SD 0.88) |
| Average pain in the previous week (0-100) | 46.30 (SD 30.58) | 47.60 (SD 21.29) | 46.60 (SD 19.43) | 48.33 (SD 29.68) | 32.00 (SD 27.81) | 48.25 (SD 22.69) | 44.14 (SD 28.51) | 37.33 (SD 34.63) | 53.33 (SD 23.52) |
| Disability (0-24) | 11.40 (SD 7.70) | 9.80 (SD 5.24) | 11.20 (SD 3.79) | 12.00 (SD 7.48) | 8.17 (SD 5.27) | 11.12 (SD 3.98) | 8.43 (SD 6.40) | 7.5 (SD 6.19) | 9.78 (5.80) |
| Care seeking, n (%) | 3 (30.0%) | 1 (10.0%) | 6 (60.0%) | 1 (16.7%) | 0 (0.0%) | 2 (25.0%) | 2 (28.6%) | 0 (0.0%) | 5 (55.5%) |
| Number of participants reporting taking medications in the past week, n (%) | 7 (70.0%) | 2 (20.0%) | 7 (70.0%) | 3 (50.0%) | 3 (50.0%) | 6 (75.0%) | 4 (57.1%) | 3 (50.0%) | 7 (77.8%) |
| OTC analgesics | 7 (70.0%) | 2 (20.0%) | 6 (60.0%) | 3 (50.0%) | 3 (50.0%) | 6 (75.0%) | 3 (42.8%) | 3 (50.0%) | 7 (77.8%) |
| OTC supplements | 0 (0.0%) | 0 (0.0%) | 4 (40.0%) | 1 (16.7%) | 0 (0.0%) | 0 (0.0%) | 1 (14.3%) | 0 (0.0%) | 0 (0.0%) |
| Prescribed analgesics | 4 (40.0%) | 0 (0.0%) | 3 (30.0%) | 1 (16.7%) | 0 (0.0%) | 3 (37.5%) | 2 (28.6%) | 0 (0.0%) | 2 (22.2%) |
| Opioids | 0 (0.0%) | 0 (0.0%) | 1 (10.0%) | 0 (0.0%) | 0 (0.0%) | 1 (12.5%) | 0 (0.0%) | 0 (0.0%) | 1 (11.1%) |

SD: standard deviation, OTC: over the counter

# CHAPTER TEN

# Discussion and Conclusion

## 10.1 Purpose of the thesis

The overall aim of this thesis was to investigate innovative, scalable and affordable interventions for the treatment of low back pain, which is an extremely prevalent, burdensome, and costly condition to both individuals and society. To attain this aim, this thesis included eight studies with various research designs (e.g., a study with web-based data, systematic reviews, a meta-analysis, a qualitative study, and a pilot randomised controlled trial). These studies were reported in **Chapters Two to Nine**.

## 10.2 Overview of the main findings

In **Chapter Two**, the online public interest for the most disabling musculoskeletal conditions (i.e., gout, low back pain, neck pain, osteoarthritis, and rheumatoid arthritis) was investigated through analysis of *Google Trends* data from its inception until December 2020. The study evidenced two well-defined periods in the public interest in musculoskeletal conditions: 1) between 2004 and 2008, when the interest for low back pain and neck pain was stable whilst the interest for gout, osteoarthritis and rheumatoid arthritis decreased; 2) between 2008 and 2020 when the online public interest in all conditions grew, being low back pain and neck pain the conditions presenting the greatest increases (approximately 7% per year). These results are consistent with previous findings, which also indicated non-linear increases in the online interest for low back pain in Italy, [1] gout, [2] and osteoarthritis. [3] The association between changes in the online public interest for all conditions and the sociodemographic index (SDI) of English-speaking countries were also investigated in **Chapter Two**. Small negative associations were found between the changes in the online interest for low back pain (-0.007, 95%CI -0.011 to -0.003), neck pain (-0.005, 95%CI -0.009 to -0.001) and rheumatoid arthritis (-0.009, 95%CI -0.017 to -0.001) and countries' SDI between 2013 and 2020, suggesting that countries with lower SDI presented higher annual increases in the online interest for these conditions. This finding could be related to inadequate health care access [4] and lack of educational campaigns [5] in countries of middle and low SDI. Nonetheless, the associations' estimates are small and possibly not relevant. Besides, increases in the relative interest in the causes of all conditions were found as well as decreases in the interest in their treatment. In regards to queries and topics related only to the treatment of the conditions, a reduction in the proportion of queries and topics related to the pharmacological treatment of rheumatoid arthritis along with increases in the proportion

of pharmacological treatment for gout, general treatment for osteoarthritis and diet for rheumatoid arthritis were found.

Since text messages represent a possible strategy to provide education and self-management to people with various health conditions, **Chapter Three** systematically appraised the literature on the use of text messages in the treatment of musculoskeletal pain. A small number of heterogeneous randomised controlled trials (n=11) of limited methodological quality (mean PEDro score of 5.4/10 points) were found. When text messages were added to and compared with usual care, they did not provide additional benefits on pain intensity, function, quality of life and use of care. Yet, they increased treatment adherence. When text messages were added to comprehensive interventions and compared to a control, inconsistent results were found on function and physical component of quality of life whilst benefits were found on pain, mental component of quality of life, exercise adherence and use of care. When text messages were a sole intervention and compared to telephone counselling, similar effects were reported on function and life satisfaction. Overall, participants were satisfied with the treatments received and would recommend them to others. Similar results have been found by two other systematic reviews assessing the effects of web-based digital interventions for the management of low back pain. Nine studies of limited methodological quality were included in each review, which found mixed effects of the web-based interventions on various health outcomes of people with low back pain, including pain intensity and disability. [6,7] None of the studies included in **Chapter Three** and in the previous reviews assessed the effects of text message interventions on health outcomes of people with low back pain, which evidenced the need to develop and assess the effects of this low-cost intervention on health outcomes of this population.

**Chapters Four, Five, Six and Seven** of the thesis aimed to start filling this gap. **Chapter Four** described the iterative development process of TEXT4myBACK, a lifestyle-based self-management intervention for low back pain. The TEXT4myBACK development was an iterative process that involved clinicians, researchers, consumer representatives and consumers and followed the recommended framework. [8,9] 82 evidence-based text messages were developed. They aimed to provide education, motivation or change behaviour and conveyed one of the following six domains: exercise, education, mood, use of care, medication, and sleep. The effects of the TEXT4myBACK intervention are

currently being assessed through a randomised controlled trial described in **Chapter Five**. The TEXT4myBACK intervention consists of the delivery of four text messages per week on random days and times. The text messages are targetted according to the duration of symptoms, physical activity levels, presence of sleep issues, work characteristics (i.e., sedentary *vs.* active work), and medication consumption as reported by participants at the baseline survey. The primary aim of the trial is to assess the effect of the TEXT4myBACK intervention on function of people with non-persistent, non-specific low back pain compared to a control intervention.

**Chapter Six** assessed participants' experience with the TEXT4myBACK intervention. This study was conducted after an amendment to the initial protocol was approved by the ethics committee, since the initial protocol did not plan for a qualitative analysis of the intervention through focus groups. It found that the interventions' characteristics, including their duration, frequency, one-way format and language, were well accepted by participants. Overall, participants believed the text messages helped them to increase their physical activity participation and to change their behaviour. Yet, there were mixed responses regarding the perceived effectiveness of the messages as some participants believed the messages helped their symptoms, whilst some believed it did not and others were unsure. There were also inconsistent beliefs about the educational ability of the messages with a few people reporting they did not provide any new information. Suggestions for improvements included further tailoring of the intervention (according to participants' low back pain clinical characteristics and residential area), the possibility of two-way communication, the provision of further information on how to deal with the pain and suggestions of exercise. Participants believed the text messages could be provided by health care professionals either for free or for a low nominal fee. These findings are similar to the ones reported by qualitative assessments of one-way text message interventions supporting cancer survivors and people with cardiovascular diseases. [10,11] Overall, participants were also satisfied with the text message interventions received, liked the one-way format and believed the messages helped them to improve healthy behaviours. [10,11] Similarly, participants would also like to have the option for two-way communication and suggested further targetting of the program. [10,11]

**Chapter Seven** investigated the smallest worthwhile change in function that participants from the TEXT4myBACK randomised controlled trial would need to achieve to consider

that intervention worth its potential risks, costs and inconveniences. On average, people with low back pain presented a baseline function score of 11.8 on a 0-30 function scale and would need to achieve an improvement of at least 9.4 points on the same scale to consider self-management worthwhile. This change represents a 31% improvement in the total function score. No demographic characteristics, lifestyle factors, number of comorbidities or low back pain characteristics were associated with the magnitude of the estimate, except for the function score. For each point increase in baseline function, there was a reduction of 0.60 points (95% CI -0.76 to -0.44) in the magnitude of the smallest worthwhile change. This means that people with worse function scores need to see larger improvements to consider self-management worthwhile. The chapter presented a novel approach to estimate clinical significance thresholds in clinical trials. The approach was shown to be feasible and can be used in future clinical trials of interventions for which the threshold for clinical significance of the change in outcomes is unknown.

Given the impact of multiple factors on pain and its complexity [12] as well as the influence of family members on pain [13] and behaviour, [14,15] the investigation of the effects of interventions that include support from family members for the management of musculoskeletal pain is essential. **Chapter Eight** systematically reviewed the effects of family-based interventions compared to individual-focused interventions (i.e., interventions similar to the family-based interventions but did not involve a family member) and usual care on pain and disability of people with musculoskeletal pain. There was moderate-quality evidence that family-based interventions improved pain (MD, -3.55/100; 95% CI, -4.03 to -3.06) and disability (MD, -1.51/100; 95%CI, -1.98 to -1.05) at the short-term only when compared to individual-focused interventions. When compared to usual care, family-based interventions reduced just pain (MD, -6.05/100; 95%CI, -6.78 to -5.33) at the short term. No effects were found on other secondary health-related and relationship outcomes. The secondary analyses including patients with low back pain or osteoarthritis only evidenced small positive effects on pain intensity (MD, -5.22/100, 95%CI, -9.72 to -0.72) and disability (MD, -1.06/100, 95%CI, -1.38 to -0.74) for patients with osteoarthritis at the short-term. No effects were found on pain intensity for patients with chronic low back pain.

Despite the influence of family members on each other's physical activity level [16,17] and the relevance of physical activity for the management of low back pain, [18] none of the

trials included in **Chapter Eight** investigated the effect of family-based interventions on physical activity participation in people with musculoskeletal pain (including low back pain). This has highlighted the need to explore the effects of family-based interventions on this outcome. Thus, **Chapter Nine** explored the feasibility of a buddy-assisted health coaching intervention for people with chronic low back pain recently discharged from treatment compared to individual-only health coaching intervention and usual discharge care, the recruitment and data collection approaches through a feasibility and pilot randomised controlled trial. It is important to note that the health coaching intervention provided was already established and freely available, whilst the buddy intervention was designed by the research team and did not result from a formal development process. Thus, people with low back pain did not contribute either to the development or the design of both health coaching and buddy interventions provided in **Chapter Nine**. The recruitment success of the trial was assessed against the a priori estimated recruitment rate and considered acceptable (i.e., more than 70% of eligible participants were enrolled). The data completeness rate was successful at baseline, when there was less than 20% missing data, but not at three and six months follow-ups. The follow-up rates were also not successful, since there was more than 15% loss to follow-up. Nonetheless, the buddy-assisted health coaching intervention was well-accepted by participants, who believed their buddies helped them to increase their physical activity. Furthermore, most participants from the Individual-Only and Usual Discharge Care groups expressed interest in having exercise buddies, who could motivate them to increase physical activity participation.

## 10.3 Limitations of the thesis

Some methodological limitations of the studies included in this thesis should be acknowledged. In **Chapter Two**, the *Google Trends* data used in the analysis presents some constraints, including i) lack of information on the absolute number of searches conducted as well as on the characteristics of people conducting the searches and their intentions when searching online; ii) sample arguably not representative of people who use a different search engine (e.g., *Yahoo* search), who do not search for health information online (e.g., older people, people with limited access to the Internet or limited technology-related knowledge), and who conduct the searches in other languages but not English (since the terms are not automatically translated into all languages). [19] Thus,

conducting the searches in English and the analysis of the association between the changes in the online public interest for all conditions and the SDI of English-speaking countries limited both the internal and external validity of the results. The results might not represent the interest of people who conduct the searches in languages that are not automatically translated to English by *Google*. Meanwhile, the association of the changes in the interest in musculoskeletal conditions with the countries' SDI might not reflect the global association and the interest of some populations who conduct their searches in languages other than English. Finally, the terms used in the search strategy related to the musculoskeletal conditions and not their symptoms (e.g., osteoarthritis *vs.* knee pain), which might be more often used by the public.

The systematic review presented **in Chapter Three** included studies of limited methodological quality and high level of heterogeneity in terms of interventions, outcome measures, follow-up periods and musculoskeletal conditions. Therefore, a meta-analysis was not possible and the effects of text messages on health-related outcomes of people with musculoskeletal pain were still uncertain. In addition, the included studies provided limited information on the characteristics of the text message interventions, therefore the distinctive components that may lead to better outcomes could not be explored.

Although the development process of the TEXT4myBACK intervention described in **Chapter Four** followed the current suggested framework, [8,9,20] it also presents some limitations worth discussing. The text message intervention was developed based on discussions between experts (including researchers and health care professionals) and consumer representatives following the Medical Research Council framework, [20] which has been criticised for meeting researchers' needs (and not necessarily patients' needs) and being a 'one-off' event. [21] Some authors suggest that the development of eHealth interventions should be a continuous process of development and testing until the intervention is considered useful and accessible by consumers. [21] Additionally, people with low back pain were not involved in the workshops to develop the concept and framework of the intervention. People with low back pain only reviewed a sample of individual text messages and did not provide feedback on the entire intervention. Although the text messages were considered useful and easy to understand, the potential usefulness and acceptability of the entire intervention were not evaluated, which might have limited the acceptability, adherence, effectiveness and scale-up potential of the

intervention. This is, however, addressed in the qualitative study presented in **Chapter Six**. Furthermore, the TEXT4myBACK intervention was designed to be one-way (to the participant only). Although there is no evidence of greater treatment effects of two-way text message interventions, [22,23] some people who received one-way text message interventions expressed their preference for a two-way program. [10,11].

The study reported in **Chapter Six** presented some limitations worth acknowledging. It was conducted after the participation in the TEXT4myBACK trial was completed, which was at least nine months after the last text message was received and might have led to recall bias. Additionally, the fact that some participants were individually interviewed rather than interviewed through a focus group has limited the discussion between participants and might have restricted ideas for suggestions for improvement and implementation in health care. However, interviews provided an open space for participants to share their views without feeling pressured by people with different opinions and allowed a deeper understanding of participants' individual experiences and perceptions of the intervention. The main limitation of **Chapter Seven** is that the estimates of the smallest worthwhile change cannot be used to interpret the clinical relevance of treatment effects (i.e., the differences in outcomes between the intervention of interest and the control intervention) [24] as they represent the smallest worthwhile change rather than the smallest worthwhile *effect* associated with self-management. [24] Additionally, the studies presented in **Chapters Six and Seven** present some shared limitations. Firstly, although participants were recruited nationally in Australia, they may not share the same characteristics as other English and non-English-speaking populations, limiting the generalisability of the findings. Secondly, their thoughts and feedback might differ from people interested in other treatment modalities since they were interested in participating in the TEXT4myBACK randomised controlled trial and receiving a self-management text message intervention.

**Chapter Eight** presented moderate-quality evidence of the effects of family-based interventions in the short-term. However, the mid and long-term effects found need to be interpreted with caution due to the low quality of evidence in these follow-up time-points. Additionally, there was a large heterogeneity between the characteristics of family-based interventions provided (including interventions' duration, degree of involvement of family members, and the components of the interventions), which limited the comparison

between studies. Thus, the ideal characteristics of family-based interventions could not be explored and definite recommendations could not be made.

The pilot and feasibility randomised controlled trial presented in **Chapter Nine** has been significantly impacted by the restrictions imposed in response to the COVID-19 pandemic, which included lockdowns and recommendations to stay at home and minimise social interactions. The restrictions in place also prevented people with non-urgent musculoskeletal conditions to access usual outpatient physiotherapy care. Therefore, important modifications have been done to the trial's protocol, including the reduction in the study sample size, which have been reported following the CONSERVE statement. [25] Additionally, data collection and follow-up rates were not successful, which further decreased the data collected and the understanding and generalisability of the trial's findings. Thus, the exploration of the preliminary effects of the interventions was underpowered and should be interpreted with caution. Furthermore, a greater loss to follow-up and withdrawal rates were seen in the intervention groups, which might indicate selection attrition (i.e., that participants from the intervention groups were more likely to drop out). Besides the impact of the pandemic on the trial, the lack of involvement of people with low back pain in the development of the health coaching intervention and the design of the buddy intervention might have also contributed to the greater loss to follow-up and withdrawal rates seen in the intervention groups. Finally, participants were highly active and took approximately 10,000 steps daily, therefore their views regarding the intervention received might not represent the views of those who are less physically active.

## 10.4 Clinical implications and directions for future research

**Chapter Two** evidenced the increasing online interest in the most disabling musculoskeletal conditions, which can be related either to the increasing use of the internet to seek health information [26] or to the growing worldwide prevalence of gout, osteoarthritis and rheumatoid arthritis. [27-29] Nonetheless, the growing interest highlights the importance of the online availability of evidence-based information about musculoskeletal conditions. The specific public interest assessed through the analysis of queries and topics indicates what information the public seems to be more interested in and might inform the development of educational resources. Based on the findings of

**Chapter Two**, some examples of consumer-relevant information that could be added to educational interventions comprise the causes of musculoskeletal conditions and the common structures affected by them, how to diagnose gout, osteoarthritis, and rheumatoid arthritis, how to make a differential diagnosis of gout and rheumatoid arthritis distinguishing them from other conditions, the role of exercise for the management of low back pain, neck pain and osteoarthritis, and diet for the management of rheumatoid arthritis and gout.

**Chapter Three** indicated there are many questions regarding the use of text messages in the treatment of musculoskeletal pain that remain unanswered. The questions include i) the effects of the intervention on pain and function of people with musculoskeletal pain either as sole interventions or added to usual care or comprehensive multicomponent interventions, ii) the specific intervention characteristics (e.g., frequency, duration, theoretical framework, content) that lead to better results and are better accepted by patients, iii) the possible mechanisms of effects of the intervention, iv) the cost-effectiveness of text message interventions. These questions indicate what should be investigated by future high-quality randomised controlled trials to provide more definitive answers. When these answers are available, evidence-based and informed decisions regarding the implementation of text message interventions in health care will be possible.

**Chapters Four, Five, Six and Seven** started to answer some of the questions discussed above. The thorough description of the development process of the TEXT4myBACK intervention presented in **Chapter Four** can guide the development of future text message interventions to support people with low back pain or other painful conditions either by researchers or clinicians. For example, the framework and the development process used were simple and feasible and can inform the development of text message interventions in middle or low-income countries, where low back pain is also highly prevalent and burdensome [30] and health care access is limited. [31] Researchers and clinicians could use the process described as a starting point, allowing for improvements such as involving patients earlier in the process to optimise the potential acceptability and effectiveness of the intervention and inform modifications according to the uniquenesses of their populations, realities, languages and cultures. Offering text message interventions to people with low back pain in middle- and low-income countries could represent a

scalable and accessible solution to tackle the increasing burden and costs of low back pain and the wrong information often provided to patients which can cause harm (e.g., recommendation of bed rest). [30] Nonetheless, the randomised controlled trial presented in **Chapter Five** is still ongoing, therefore the effects of the TEXT4myBACK intervention on pain and function as well as the cost-effectiveness of the intervention will be elucidated in the future.

The development process of the TEXT4myBACK intervention described in **Chapter Four** along with participants' feedback presented in **Chapter Six** provide the TEXT4myBACK study team with greater instruments to assess the potential mechanisms of effects of the intervention if it is proven effective. It seems that text messages acted as physical activity reminders and prompted participants to change their behaviours. Moreover, the suggestions for improvement presented in **Chapter Six** might direct a future fine-tuning of the intervention. A text message intervention that allows a two-way communication if the receiver is willing, that accommodates the individualities of the low back pain clinical characteristics and participants' residential locations and might be delivered for longer than three months if so people wish might be better received by people with low back pain. Finally, the results of **Chapter Six** provide insights into possibilities for implementation of the TEXT4myBACK intervention into clinical practice if it is proven effective. Participants' suggestion for the intervention to be provided by health care professionals might indeed help physiotherapists and exercise therapists to support their patients to self-manage their condition since they have previously reported a lack of tools and difficulties in integrating self-management strategies into their clinical care. [32,33]

Since the smallest worthwhile effect of self-management interventions for low back pain is unknown, the methodology presented in **Chapter Seven** might be used by the TEXT4myBACK study team in a responder analysis to aid the understanding of the clinical relevance of the trial's findings. The study team might calculate the proportion of participants who achieve their individual smallest worthwhile change, the differences between groups, as well as the number needed to treat. However, one may consider the smallest worthwhile change estimates found too high and not achievable within research and clinical practice settings, which might lead to the conclusion that self-management is not worthwhile. Nonetheless, the mean smallest worthwhile change of 31% in function is

similar to the improvements in disability expected within the natural history of the condition [34] and might be achieved in both research and clinical settings. It is important to note that the smallest worthwhile change estimate is population-specific and it might not apply to populations with different characteristics, such as persistent low back pain. Previous studies have estimated that people with persistent low back pain need to see a median improvement of at least 20-30% in pain and disability over the natural history of the condition to consider physiotherapy worthwhile. [35,36] The results might indicate that the requirements of people with persistent and non-persistent pain are different. However, results of previous studies represent the smallest worthwhile effect of physiotherapy rather than the smallest worthwhile change of self-management and comparisons between both methodologies and results are limited. The likely implications of persistent pain on the smallest worthwhile change estimate represent a relevant question that might be investigated in a future study with a methodology similar to the one applied in **Chapter Seven**.

Additionally, the methodology described in **Chapter Seven** might be used in future randomised controlled trials investigating the effects of interventions for which the smallest worthwhile effects are also unknown. However, the smallest worthwhile change should be used in responder analysis only since it represents the smallest change people would need to see at the end of a self-management intervention to consider it worthwhile rather than the smallest worthwhile effect (i.e., the smallest effect of an intervention compared to a control so that people can consider it worthwhile). Using the smallest worthwhile change presents many advantages over using minimal clinically important difference defined by anchor-based approaches, given the former is based on the opinions of patients rather than defined by researchers or based on clinimetric properties of the outcome of interest. Moreover, the smallest worthwhile change is intervention specific and considers the possible harms, inconveniences and costs of the intervention in question. For example, a self-management intervention presents different risk attributes, associated costs and inconveniences when compared to surgical interventions. Allowing this differentiation when eliciting the smallest worthwhile change is vital for the assessment of the clinical significance of interventions with diverse characteristics.

**Chapter Eight** has highlighted that further research is needed to assess the effect of family-based interventions on pain, disability and other health-related outcomes of people with low back pain. Future clinical trials should ensure they are adequately powered to test the effects of the intervention and should test the mid and long-term effects of the family-based intervention provided and their cost-effectiveness. Additionally, the characteristics of the family-based interventions should be reviewed so that the mechanisms of effect are optimised. Finally, the findings of **Chapter Eight** have highlighted the lack of investigation of the effects of family-based interventions on the physical activity levels of people with musculoskeletal conditions. Given the limited physical activity participation of people with musculoskeletal conditions, [37,38] the importance of keeping active for pain management, [39-41] function [40,41] and general health, [40,41] along with the evidence of the impact of family members on each other's physical activity levels, [14,16] the effects of incorporating physical activity on family-based interventions should be further explored.

Findings from **Chapter Nine** have evidenced that the data collection and follow-up processes need to be amended before a future large-scale randomised controlled trial is conducted, especially the physical activity data collection. One alternative to thigh-worn accelerometer devices could be to recruit people who wear smartwatches, which present good validity to count steps. [42] However, the inclusion criteria of people who wear smartwatches might need to be further targeted to a specific device, since different devices present different measurement errors. [42] Additionally, participants would need to allow researchers to have access to their data, such as needed with Fitbit data, [43] which could also add further barriers to data collection. Another alternative could be to use wrist-worn accelerometers. Previous studies have shown that people report less discomfort and greater acceptability when wearing wrist-worn accelerometers compared with thigh-worn devices. [44,45] Additionally, wrist-worn accelerometers present good agreement and excellent correlation with waist-worn accelerometers to count steps of people with chronic pain [46] and could represent a more feasible whilst reliable data collection strategy.

Future research could combine the interventions discussed in this thesis to further support self-management and encourage physical activity participation of those with low back pain. Qualitative findings of Chapters Six and Nine indicate that people with low back pain receiving the TEXT4myBACK or health coaching interventions and those exercising

with an exercise buddy were overall satisfied and believed the interventions motivated them to become more active. Given the importance of physical activity and self-management in the treatment of low back pain [47] as well as the low-cost and scalability of text messages, [48] telephone health coaching sessions and encouragement to exercise with a buddy, combining these interventions might optimise their effects and help to tackle the increasing burden and health care costs associated with low back pain. [12] Through this combined intervention, people with low back pain would receive support and motivation to increase physical activity participation via the health coaching intervention, self-management strategies and physical activity reminders via regular text messages, and further motivation and social support from their exercise buddies. The combined intervention would address both physical and psychosocial complaints of those with low back pain. The acceptability, usefulness, effectiveness and cost-effectiveness of the combined intervention could be explored in future studies.

## 10.5 Conclusions

The findings of this thesis expand the current knowledge on innovative, scalable, and affordable interventions for the management of low back pain. It presented the online interest of the general public in the most burdensome musculoskeletal conditions, which might be used to guide the development of online educational resources. This thesis has also appraised the use of text messages for the management of musculoskeletal pain and presented the development process and qualitative assessment of a self-management text message intervention for the management of low back pain. It also showed that, on average, people with low back pain need to improve at least 31% on the total function score to consider self-management worthwhile. The effects of family-based interventions on pain intensity and disability of people with musculoskeletal pain have been summarised. The acceptability of a buddy-assisted health coaching intervention has been explored through a pilot randomised controlled trial as well as the recruitment, data collection and follow-up approaches. Suggestions for the design of a future large-scale randomised controlled trial were made.

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# APPENDICES

# Appendix One: Supplementary material for Chapter Two

**Supplemental Digital Content 1 –** Search strategy

| **Musculoskeletal condition** | **Google search strategy** |
|---|---|
| **Gout** | gout arthritis + gouty arthritis + gout disease |
| **Low back pain** | low back pain + lower back pain + lumbago + low backache + back pain |
| **Neck pain** | neck pain + neck ache + cervicalgia + cervical pain |
| **Osteoarthritis** | osteoarthritis + osteoarthrosis + arthrosis + osteoarthroses + degenerative arthritis |
| **Rheumatoid arthritis** | rheumatoid arthritis + rheumatoid nodule + rheumatoid vasculitis |

**Supplemental Digital Content 2 –** English-speaking countries included in the socio-economic analysis

| Musculoskeletal condition | English-speaking countries included in the analysis |
|---|---|
| **Gout** | Australia, Canada, Ghana, India, Ireland, Kenya, Nigeria, New Zealand, South Africa, Singapore, United Kingdom, United States. |
| **Low back pain** | Antigua & Barbuda, Australia, Bahamas, Barbados, Belize, Canada, Fiji, Ghana, Guyana, India, Ireland, Jamaica, Kenya, Liberia, Nigeria, New Zealand, Papua New Guinea, South Africa, Singapore, Saint Lucia, Sierra Leone, Saint Vincent, Trinidad and Tobago, United Kingdom, United States of America |
| **Neck pain** | Australia, Bahamas, Barbados, Belize, Canada, Fiji, Ghana, Guyana, India, Ireland, Jamaica, Kenya, Nigeria, New Zealand, Papua New Guinea, South Africa, Singapore, Saint Lucia, Trinidad and Tobago, United Kingdom, United States of America |
| **Osteoarthritis** | Australia, Canada, Ghana, India, Ireland, Jamaica, Kenya, Nigeria, New Zealand, South Africa, Singapore, Trinidad and Tobago, United Kingdom, United States of America |
| **Rheumatoid arthrtis** | Australia, Barbados, Canada, Ghana, India, Ireland, Jamaica, Kenya, Nigeria, New Zealand, South Africa, Singapore, Trinidad and Tobago, United Kingdom, United States of America |

**Supplemental Digital Content 3 –** Detailed description of the classification of related queries and topics

| **Theme** | **Classification** |
|---|---|
| Classification-related | Queries and topics related to the diagnosis and classification of the condition. They were subclassified into:<br>*i) general classification inquiry* (e.g., 'what is osteoarthritis');<br>*ii) ICD code* (e.g., 'ICD10 rheumatoid arthritis');<br>*iii) imaging* (e.g., 'radiography', 'magnetic resonance imaging', 'radiographic classification of osteoarthritis') |
| Symptom-related | Queries and topics related to the symptoms of the condition. They were subclassified into:<br>*i) general symptom inquiry* (e.g., 'osteoarthritis symptoms');<br>*ii) pain*;<br>*iii) stiffness*;<br>*iv) other clinical symptoms* (e.g., 'paresthesia', 'skin ulcer', etc.) |
| Cause-related | Queries and topics related to the cause of the condition. They were subclassified into:<br>*i) general cause inquiry* (e.g. 'cause');<br>*ii) specific known causes of the condition* (e.g. 'obesity and osteoarthritis', 'heredity and rheumatoid arthritis') |
| Interfering/ risk factors | Queries and topics known to interfere on symptoms or to be risk factors or general risk factors about the development of the condition (e.g., 'stress', 'posture', 'pillow', 'risk factor'). |
| Treatment-related | Queries and topics related to diet and food. They were subclassified into:<br>*i) general treatment inquiry* (e.g., 'treatment for osteoarthritis');<br>*ii) pharmacological treatment* (e.g. pharmaceutical drug, 'duloxetine');<br>*iii) supplement* (e.g., 'vitamin', 'chondroitin');<br>*iv) diet* (e.g., 'food for gout', 'diet rheumatoid arthritis');<br>*v) exercise and physical activity* (e.g., 'yoga and low back pain');<br>*vi) biomechanical interventions* (e.g., 'back brace');<br>*vii) physiotherapy, chiropractic, osteopath, and acupuncture* (e.g., 'acupuncture for back pain'); |

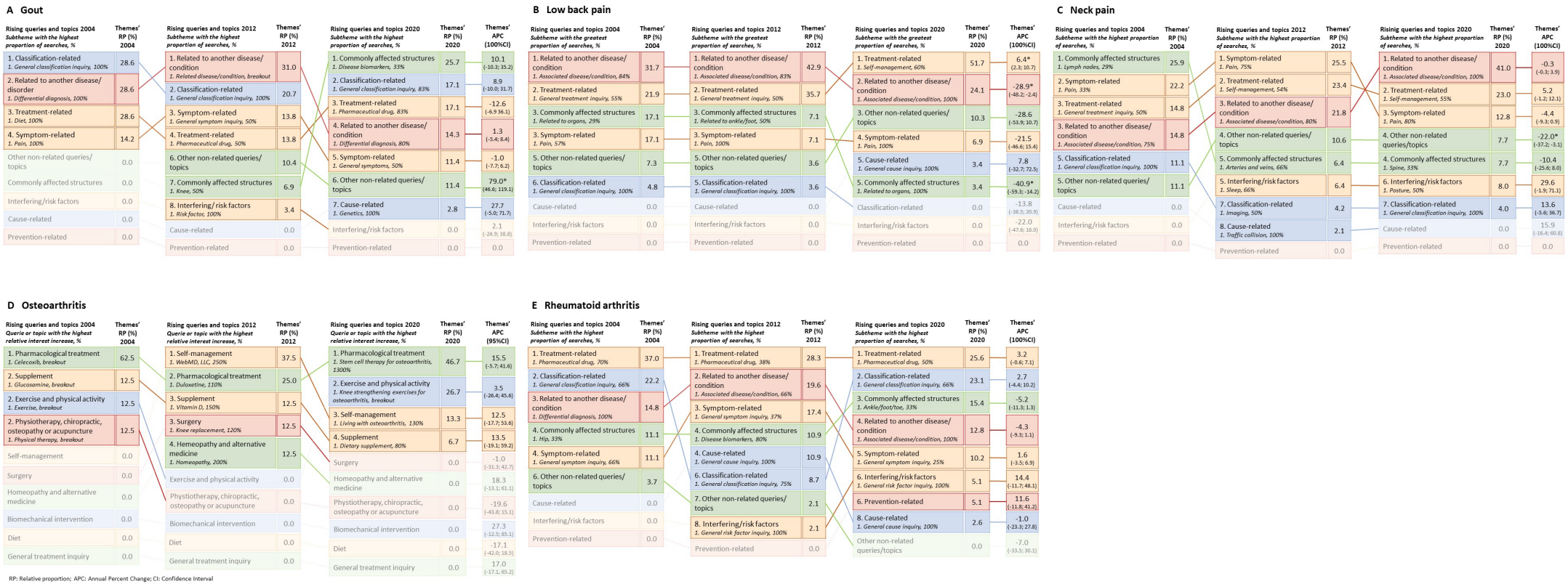
| | |
|---|---|
| | *viii) surgery* (e.g., ‘anterior cervical discectomy and fusion’);<br>*ix)* Homeopathy and alternative/natural medicine (e.g., ‘herbal medicine’, ‘homeopathy’);<br>*x) self-management and educational consumer-focused resources* (e.g., ‘Arthritis Australia’, ‘Arthritis Foundation’, ‘WebMD’) |
| Related to another disease/disorder | Queries and topics relating the conditions to other symptoms, diseases, or disorders. They were further classified into:<br>*i) differential diagnosis* (e.g., ‘rheumatoid arthritis vs osteoarthritis’, ‘osteoporosis vs osteoarthritis’);<br>*ii) disorder/condition associated with the musculoskeletal condition* (e.g., ‘low back pain and pregnancy’, ‘kidney disease and gout’) |
| Prevention-related | Queries and topics related to the prevention of the condition (e.g., ‘how to prevent rheumatoid arthritis). |
| Commonly affected structures | Queries and topics related to body structures commonly affected by the condition. They were subclassified into:<br>*i) affected joints* (knee, hip, wrist/ hand/ finger, ankle/ foot/ toe, shoulder, spine);<br>*ii) related to muscle/joint structures* (e.g., ‘joint’, ‘ligament’, ‘synovial joint’)<br>*iii) disease biomarkers* (e.g., ‘uric acid’);<br>*iv) artery and veins*;<br>*v) related to organs* (e.g., ‘kidney and gout’, ‘kidney and lower back pain’) |
| Other non-related queries and topics | Queries and topics not related to the condition (e.g., ‘pneumonia’, ‘asthma’). |

**Supplemental Digital Content 4 -** Association between the annual percentage change in the interest for musculoskeletal disorders and the sociodemographic index of English-speaking countries

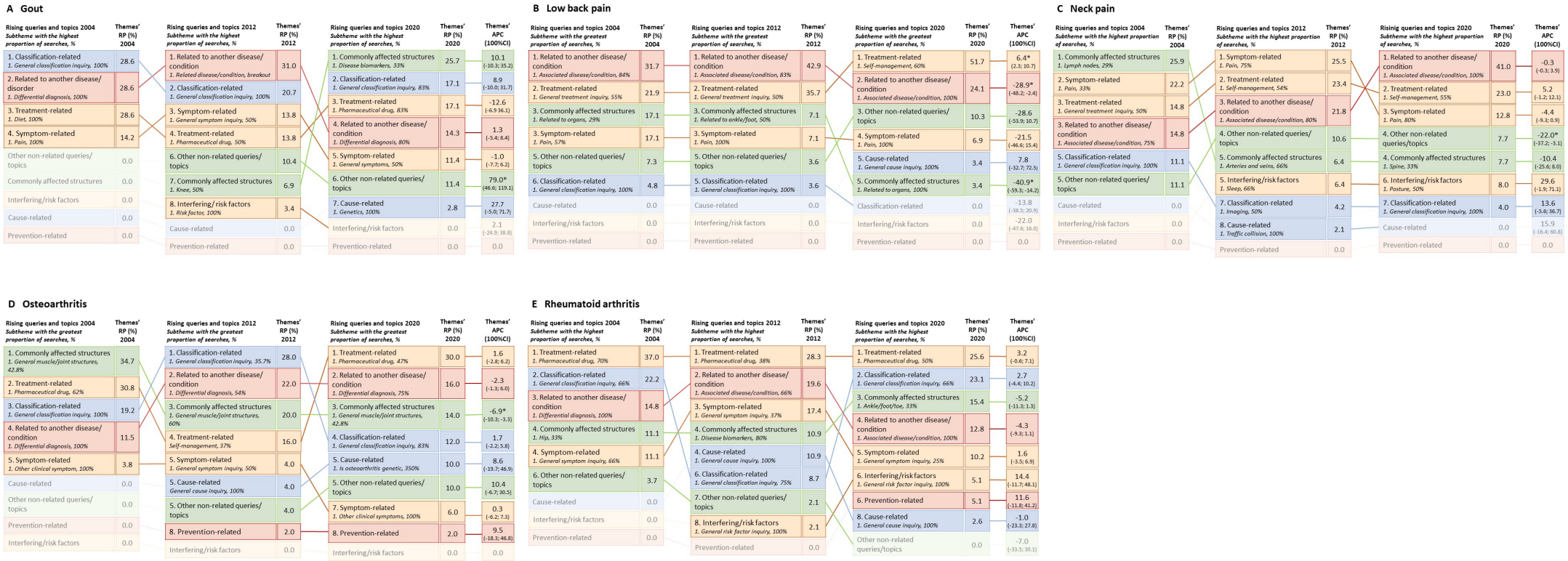
| Musculoskeletal condition | 2004-2012 | | 2013-2020 | |
|---|---|---|---|---|
| | **Estimate (95%CI)** | **p value** | **Estimate (95%CI)** | **p value** |
| **Gout** | 0·0063 (0·0004; 0·0122) | 0·05 | -0·0019 (-0·0074; 0·0036) | >0·05 |
| **Low back pain** | 0.0000 (-0·0022; 0·0022) | >0·05 | -0·0072 (-0·0111; -0·0033) | <0·05 |
| **Neck pain** | 0·0016 (-0·0009; 0·0041) | >0·05 | -0·0048 (-0·0087; -0·0009) | <0·05 |
| **Osteoarthritis** | -0·0004 (-0·0043; 0·0035) | >0·05 | -0·0062 (-0·0138; 0·0014) | >0·05 |
| **Rheumatoid arthritis** | -0·0008 (-0·0037; 0·0021) | >0·05 | -0·0093 (-0·0171; -0·0015) | <0·05 |

95%CI: 95% Confidence Interval

Supplemental Digital Content 5.Changes in the relative popularity of the rising topics and queries' themes for each musculoskeletal condition



Supplemental Digital Content 6.Changes in the relative popularity of the rising topics and queries' themes related to the treament of each musculoskeletal condition



# Appendix Two: Supplementary material for Chapter Three

**Supplementary Table 1** - Search strategies for Medline, Embase, CINAHL and PEDro databases

| | **MEDLINE** |
|---|---|
| 1. | ((cell or celullar or mobile or smart) and phone).mp. |
| 2. | (telephone* or phone* or text*).mp. |
| 3. | short message service*.mp. |
| 4. | exp Telephone/ |
| 5. | SMS.mp. |
| 6. | text messag*.mp. |
| 7. | 1 or 2 or 3 or 4 or 5 or 6 |
| 8. | exp Pain/ |
| 9. | exp Musculoskeletal Diseases/ |
| 10. | (low* back adj3 (pain* or ach*)).mp. |
| 11. | (low* and (backpain or backache)).mp. |
| 12. | ((lumbar or spinal vertebral) and pain*).mp. |
| 13. | (lumbago or dorsalgia).mp. |
| 14. | ((knee* or hip* or hand* or shoulder* or neck or elbow* or ankle* or wrist* or foot or feet) adj3 pain*).mp. |
| 15. | non-cancer pain.mp. |
| 16. | acute pain.mp. |
| 17. | chronic pain.mp. |
| 18. | musculoskeletal pain.mp. |
| 19. | 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 |
| 20. | clinical trial/ or controlled clinical trial/ or randomized controlled trial/ |
| 21. | clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ |
| 22. | random* control* trial*.mp. |
| 23. | 20 or 21 or 22 |
| 24. | 7 and 19 and 23 |
| | **EMBASE** |
| 1. | exp telephone/ |
| 2. | exp mobile phone/ |
| 3. | exp text messaging/ |
| 4. | short message service.mp. |
| 5. | SMS.mp. |
| 6. | (text* or text messag*).mp. |
| 7. | ((cell or celullar or mobile or smart) and phone).mp. |
| 8. | 1 or 2 or 3 or 4 or 5 or 6 or 7 |
| 9. | exp pain/ |
| 10. | exp musculoskeletal disease/ |
| 11. | musculoskeletal pain.mp. |

| | |
|---|---|
| 12. | (low* back adj3 (pain* or ach*)).mp. |
| 13. | (low* and (backpain or backache)).mp. |
| 14. | ((lumbar or spinal vertebral) and pain*).mp. |
| 15. | (lumbago or dorsalgia).mp. |
| 16. | ((knee* or hip* or hand* or shoulder* or neck or elbow* or ankle* or wrist* or foot or feet) adj3 pain*).mp. |
| 17. | non-cancer pain.mp. |
| 18. | acute pain.mp. |
| 19. | chronic pain.mp. |
| 20. | 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 |
| 21. | exp controlled clinical trial/ or exp clinical trial/ or exp controlled study/ or exp randomized controlled trial/ |
| 22. | random* control* trial*.mp. |
| 23. | 21 or 22 |
| 24. | 8 and 20 and 23 |
| | **PEDro** |
| | Telephone + musculoskeletal + clinical trial |
| | Text message + musculoskeletal + clinical trial |
| | SMS + musculoskeletal + clinical trial |

**Supplementary Table 2** – Overall quality of evidence of evidence for the outcomes of pain and function

| Studies | Quality assessment | | | | | N of participants | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome (number of studies)** | **Methodological limitations of studies** | **Consistency** | **Directness** | **Precision** | **Publication bias** | **Intervention group** | **Control group** | **Overall quality evidence** |
| Pain (n=5) [5; 9; 28; 29; 47; 50] | Serious[a] | No serious Inconsistency | Serious[b] | Serious[c] | Not suspected | 314 | 302 | ++, low |
| Function (n=6) [9; 28; 29; 31; 36; 40; 47] | Serious[a] | No serious Inconsistency | Serious[b] | Serious[c] | Not suspected | 273 | 273 | ++, low |

**Legend:** [a]lack of allocation concealment and blinding; [b]differences in the text message and control group interventions' characteristics; [c]wide 95% confidence intervals

**Supplemental Table 3** – Patients' feedback about the interventions received

| Author, year | Patients' feedback |
|---|---|
| Campbell, 2019[7] | 94.5% of IG *vs.* 47.5% of CG reported being provided with clear instructions on how to recover from surgery; 53.4% of IG *vs.* 31.3% of CG felt a personal connection to the surgeon throughout the recovery; 75.3% of IG *vs.* 28.8% of CG reported that the surgeon motivated throughout the recovery; 86.3% of IG *vs.* 37.5% of CG felt encouraged to meet the daily rehabilitation goals; 78.3% of IG *vs.* 51.3% of IG prioritised to do rehabilitation exercises daily. |
| Chen, 2017[9] | The mean satisfaction with text message intervention was 4.9±0.24 out of 5 points. |
| Kristjansdottir, 2013$_{a,b}$[28,29] | 23.3% of IG agreed somewhat that the participation had been experienced as a burden, 20.9% were neutral, 20.9% disagreed somewhat to the statement, and 34.9% totally disagreed with the statement. 86.0% of IG agreed somewhat or totally that participation was useful, 7.0% were neutral and 7.0% participants disagreed somewhat or totally with the statement. |
| Kuusalo, 2019[30] | 100% of IG would have recommended text message monitoring for other RA patients, 94% found the monitoring messages technically easy to answer, and >80% felt secure and satisfied with their treatment. |
| Lambert, 2017[31] | There were no between-group differences in satisfaction with support received (MD 0.5/10, 95%CI -0.5 to 1.5) and service delivery (MD 0.3/10, 95%CI -0.5 to 1.1). Participants reported extra feedback in relation to the use of a mobile app. |
| Mary, 2018[36] | Participants from both intervention groups had a higher level of satisfaction (4-point Likert scale) than CG ($p<0.01$), with no difference between the intervention groups (IG1 2.23±0.95 *vs.* IG2 2.28±0.85 *vs.* CG 1.73±0.62). |
| Smith, 2018[44] | 80% of IG *vs.* 40% of CG reported their overall hospital experience as 'very good'. 85% of IG *vs.* 65% of CG reported that they understood the instructions 'very well' and were 'very well' informed regarding time o surgery. 0% of IG *vs.* 10% of CG reported their experience as 'bad'. 80% of IG reported pre-hospital and day of surgery text messages were 'very helpful' and 75% reported that they improved their hospital experience 'very much'. 70% of CG reported that a text message providing information before and during the day of surgery would improve their experience. |

**Supplementary Table 5** – PRISMA Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 61 |
| **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. | 61 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 61,62 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 62 |
| **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. | 62 |
| 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. | 62 |
| 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. | 62 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | Supplementary Table 1 |
| 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). | 62 |

| | | | |
|---|---|---|---|
| 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. | 62 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 62 |
| 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. | 62 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 62 |
| 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. | 62 |
| 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). | 62 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | NA |
| **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. | 63 |
| 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. | 63-67 |
| 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). | 64,68 |
| 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. | 64, 68-71 |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | NA |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 64, Supplementary Table 2 |

| | | | |
|---|---|---|---|
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | NA |
| **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). | 71,72 |
| 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). | 71 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 72 |
| **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. | 72 |

*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

# Appendix Three: Supplementary material for Chapter Six

**Supplementary document 1** – Focus group session guide

1. Welcome participants and introduce facilitators.
2. Introduce purpose, benefits, and general focus group procedure.
   *Example: The aim of the session here today is to gain a deeper understanding of your experience in receiving the text message intervention. We want to gain a better understanding of the usefulness, impact, and delivery of the text messages; behaviour-change ability, and their future implementation. The knowledge gained today will enable us to enhance the program and implement it in health care*.
3. Establish group agreement that information disclosed within the group will remain in the room, and that mutual respect for participants and facilitators be upheld at all times.
4. Confirm that the focus group will be audio-recorded and gain participants' verbal consent to turn audio recording.
5. Turn on audio recording and state the date, time, number of people present and facilitators present.
6. Start the discussions and pose the following questions as needed:
    a. How was your experience with receiving the text message intervention for your low back pain?
    b. How was the intervention effective or not effective?
        i. Would you be willing to receive it again or recommend it to others?
    c. Do you feel you engaged with the intervention?
        i. Which factors do you believe helped you or discouraged you to engage with the text messages?
    d. How do you believe that the intervention could be improved?
        i. Would there be any preferred duration (for how many months would you be willing to receive the text messages), frequency of the text messages (how many messages per week), format (one-way or two-way), language?
    e. Do you feel that the text messages changed your behaviour in some way?
        i. Example: increase some physical activity, decrease sitting time; or change the beliefs about back pain; change your sleeping habits; follow advice from the text messages; etc

f. How do you think the text message intervention could be implemented into health care?
    i. Example: should it be provided to the community in general and people with back pain who are interested could self-enrol into it? Should it be provided by health care practitioners? Which ones?
    ii. Should it be a free service? Or would it be reasonable for patients to pay if there was a fee for it?

7. Use the questions as a guide allowing the focus group to unfold through participant discussion and conversation. Ask participants to share any other comments or suggestions they may have before closing the session.
8. Thank participants for their attendance and stop recording.

**Supplementary Document 2 -** Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care.* 2007. Volume 19, Number 6: pp. 349 – 357

| No. Item | Guide questions/description | Reported on Page # |
|---|---|---|
| **Domain 1: Research team and reflexivity** | | |
| *Personal Characteristics* | | |
| 1. Inter viewer/facilitator | Which author/s conducted the inter view or focus group? | Page 104 |
| 2. Credentials | What were the researcher's credentials? E.g. PhD, MD | Page 97 |
| 3. Occupation | What was their occupation at the time of the study? | Page 104 |
| 4. Gender | Was the researcher male or female? | Page 97 |
| 5. Experience and training | What experience or training did the researcher have? | Page 104 |
| *Relationship with participants* | | |
| 6. Relationship established | Was a relationship established prior to study commencement? | Page 104 |
| 7. Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. personal goals, reasons for doing the research | Page 104 |
| 8. Interviewer characteristics | What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic | Page 104 |
| **Domain 2: study design** | | |
| *Theoretical framework* | | |
| 9. Methodological orientation and Theory | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | Page 106 |
| *Participant selection* | | |
| 10. Sampling | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Pages 103 and 104 |
| 11. Method of approach | How were participants approached? e.g. | Pages 103 and 104 |

| | | |
|---|---|---|
| | face-to-face, telephone, mail, email | |
| 12. Sample size | How many participants were in the study? | Pages 103 |
| 13. Non-participation | How many people refused to participate or dropped out? Reasons? | Pages 103 and 104 |
| *Setting* | | |
| 14. Setting of data collection | Where was the data collected? e.g. home, clinic, workplace | Page 104 |
| 15. Presence of non-participants | Was anyone else present besides the participants and researchers? | Page 104 |
| 16. Description of sample | What are the important characteristics of the sample? e.g. demographic data, date | Page 107 |
| *Data collection* | | |
| 17. Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Supplementary document 1 |
| 18. Repeat interviews | Were repeat interviews carried out? If yes, how many? | Page 106 |
| 19. Audio/visual recording | Did the research use audio or visual recording to collect the data? | Page 105 |
| 20. Field notes | Were field notes made during and/or after the inter view or focus group? | Page 104 |
| 21. Duration | What was the duration of the inter views or focus group? | Page 104 |
| 22. Data saturation | Was data saturation discussed? | Page 104 |
| 23. Transcripts returned | Were transcripts returned to participants for comment and/or correction? | Page 106 |
| **Domain 3: analysis and findings** | | |
| *Data analysis* | | |
| 24. Number of data coders | How many data coders coded the data? | Page 106 |
| 25. Description of the coding tree | Did authors provide a description of the coding tree? | Page 106 |
| 26. Derivation of themes | Were themes identified in advance or derived from the data? | Page 106 |
| 27. Software | What software, if applicable, was used to manage the data? | Page 105 |
| 28. Participant checking | Did participants provide feedback on the findings? | Page 106 |
| *Reporting* | | |
| 29. Quotations presented | Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number | Pages 109-113, 115-118, 120-122, 124-127 |
| 30. Data and findings consistent | Was there consistency between the data presented and the findings? | Pages 106-127 |

| | | |
|---|---|---|
| 31. Clarity of major themes | Were major themes clearly presented in the findings? | Pages 106-127 |
| 32. Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Pages 106-127 |

# Appendix Four – Supplementary material for Chapter Eight

**Supplementary Table 1.** Overall quality of evidence of studies included in quantitative analysis comparing the effects of family-based interventions to individual-focused interventions on pain at short-term, mid-term and long-term follow-ups

| Studies | Quality assessment | | | Number of participants | | Effect* | Overall quality evidence |
|---|---|---|---|---|---|---|---|
| | **Risk of Bias** | **Inconsistency** | **Imprecision** | **Family-assisted intervention** | **Individual-focused intervention** | **MD (95% CI)◊** | |
| *Pain* | | | | | | | |
| Short-term | Serious Risk of bias§ | No serious inconsistency‡ | No serious imprecision† | 227 | 217 | -3.55 (-4.03, -3.06) | ⊕⊕□ Moderate |
| Mid-term | Serious Risk of bias§ | Serious inconsistency┼ | No serious imprecision† | 224 | 215 | -0.60 (-4.92, 3.72) | ⊕□□ Low |
| Long-term | Serious Risk of bias§ | No serious Inconsistency‡ | Serious imprecision\| | 109 | 118 | 0.38 (-5.08, 5.84) | ⊕□□ Low |

* Negative values favour family-assisted intervention

◊ Mean difference (MD) and 95% confidential interval (95% CI) of family-assisted intervention compared to individual-only intervention

§ More than 25 % of participants from studies with low methodological quality (PEDro score < 6 points).

‡ $I^2 < 50\%$; ┼ $I^2 > 50\%$.

† > 400 participants combined for each outcome; | < 400 participants combined for each outcome.

**Supplementary Table 2.** Results of outcomes not included in the meta-analysis at short, mid and long-term follow-ups of studies comparing family-based interventions to individual-focused interventions

| Study | Outcome | Available data per group - mean±SD | | | p value, effect size (ES) | | |
|---|---|---|---|---|---|---|---|
| | | Short-term follow-up | Mid-term follow-up | Long-term follow-up | Short-term follow-up | Mid-term follow-up | Long-term follow-up |
| Abbasi (2012) | Kinesiophobia (TSK; 0-51) | IG 17.4±4.0<br>CG 18.3±6.7 | NA | IG 20.3±9.1<br>CG 25.1±6.9 | p = 0.002<br>ES = 0.37 | NA | p = 0.003<br>ES = 0.33 |
| | Pain catastrophising (PCS, 0-52) | IG 23.0±7.4<br>CG 24.3±8.6 | NA | IG 22.4±11.3<br>CG 24.3±7.3 | p = 0.12<br>ES = 0.14 | NA | p = 0.87<br>ES = 0.01 |
| Kole-Snijders (1999) | Pain (VAS 0-10) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| | Pain (MPQ 0-78) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| | Pain Coping (CSQ, scale NR) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| | Pain Behavior (CHIP, scale NR) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| | Pain Behavior (PaBS, scale NR) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| | Pain Catastrophising (subscale of PCL, score NR) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| | Anxiety (NHQ, score NR) | NR | NR | NR | p>0.05 | p>0.05 | p>0.05 |
| Turner (1990) | Physical and psychosocial dysfunction (SIP, scale NR) | IG 3.63±2.98<br>CG 5.49±6.79 | IG 4.51±5.68<br>CG 6.35±10.08 | IG 4.75±3.40<br>CG 4.73±7.85 | p<0.05 | p>0.05 | p>0.05 |
| | Pain behavior (PBC, scale NR) | IG 31.72±6.71<br>CG 37.48±8.61 | IG 31.21±7.63<br>CG 35.06±8.61 | IG 33.36±6.73<br>CG 35.81±9.73 | p<0.05 | p>0.05 | p>0.05 |
| | Pain behavior (rated by observer, scale NR) | IG 2.74±2.85<br>CG 3.00±3.24 | IG 2.00±2.74<br>CG 4.50±4.16 | IG 2.75±2.67<br>CG 2.40±2.29 | p<0.05 | p>0.05 | p>0.05 |
| Buchanan (2017) | Pain (WOMAC, 0-20) | NR | NA | NA | p>0.05 | NA | NA |
| | Disability (WOMAC, 0-68) | NR | NA | NA | p>0.05 | NA | NA |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Depression (PHQ-8, 0-24) | NR | NA | NA | p>0.05 | NA | NA |
| Keefe (1996, 1999) | Pain coping – coping attempts (CSQ, scale NR) | IG 76.88±24.91<br>CG 76.89±25.75 | IG 73.38±19.94<br>CG 79.99±17.88 | IG 76.34±20.83<br>CG 77.13±28.70 | NR | NR | NR |
| | Pain coping – pain control/rational thinking (CSQ, scale NR) | IG 3.86±3.54<br>CG 2.19±4.15 | IG 4.48±3.12<br>CG 1.75±4.56 | IG 4.57±3.11<br>CG 2.47±4.61 | NR | NR | NR |
| | Pain Behavior (observer-rated, scale NR) | IG 3.69±4.20<br>CG 5.32±4.62 | IG 4.63±5.56<br>CG 6.95±5.62 | IG 5.24±6.01<br>CG 8.05±6.36 | NR | NR | NR |
| | Self-efficacy (ASES; 0-300) | Included in the MA | Included in the MA | IG 239.68±44.82<br>CG 215.26±48.68 | NR | NR | NR |
| Keefe (2004) | Pain coping – coping attempts (CSQ; scale NR) | NA | IG 73.76±25.78<br>CG 47.44±20.29 | NA | NA | p=0.003<br>ES=0.26 | NA |
| | Pain coping – pain control/rational thinking (CSQ; scale NR) | NA | IG 3.81±2.71<br>CG 1.50±4.67 | NA | NA | p=0.019<br>ES=0.21 | NA |
| Martire (2003) | Satisfaction with spousal assistance (1-4 score) | IG 3.11±0.54<br>CG 3.23±0.52 | NA | NA | p>0.05 | NA | NA |
| | Satisfaction with spousal emotional support (9-36 score) | IG 26.92±7.11<br>CG 25.73±7.67 | NA | NA | p>0.05 | NA | NA |
| | Insensitive responses from spouses (7-28 score) | IG 10.92±3.28<br>CG 12.27±3.69 | NA | NA | p>0.05 | NA | NA |
| Martire (2007) | Self-efficacy (ASES; 20-200) | IG 147.71±2.85<br>CG 148.78±2.97 | IG 151.62±2.78<br>CG 150.15±2.91 | NA | p=0.15 | p=0.46 | |
| | Depression (CES-D; 0-30) | NR | NR | NA | NR | NR | NA |
| Martire (2008) | Spousal support (WHYMPI subscale; 0-6) | IG 4.02±0.19*<br>CG 3.15±0.19* | IG 4.15±0.21*<br>CG 3.75±0.19 | NA | p>0.05 | p=0.03<br>ES=0.22 | NA |
| | Distracting responses (WHYMPI subscale; 0-6) | IG 2.18±0.17*<br>CG 1.46±0.17* | IG 2.14 ±0.21*<br>CG 1.60±0.20* | NA | p=0.07<br>ES=0.59 | p>0.05 | NA |
| | Punishing responses (WHYMPI subscale; 0-6) | IG 1.17±0.16*<br>CG 1.21±0.16* | IG 1.18±0.19*<br>CG 1.18±0.18* | NA | p=0.05<br>ES=0.03 | p>0.05 | NA |
| | Solicitous responses (WHYMPI subscale; 0-6) | IG 3.12±0.20*<br>CG 2.81±0.21* | IG 3.12±0.22*<br>CG 2.94±0.21* | NA | p>0.05 | p>0.05 | NA |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Moore (1985) | Physical and psychological dysfunction (SIP; scale NR) | NA | IG 12.8±10.9<br>CG 13.7±8.7 | IG 13.4±14.6<br>CG 11.4±6.1 | NA | p>0.05 | p>0.05 |
| | Pain behaviour (spouse rated VAS; 0-10) | NA | IG 4.73±1.85<br>CG 5.18±1.33 | IG 5.18±1.99<br>CG 5.09±1.76 | NA | p>0.05 | p>0.05 |
| | Depression (MMPI-168, subscale NR) | NA | IG 76.20±18.00<br>CG 75.50±14.80 | IG 72.80±19.40<br>CG 73.70±14.00 | NA | p>0.05 | p>0.05 |
| | Somatization (MMPI-168, subscale NR) | NA | IG 73.20±16.10<br>CG 75.70±12.40 | IG 72.10±20.00<br>CG 74.10±11.20 | NA | p>0.05 | p>0.05 |
| Ramke (2016) | Family impact of pain (FIPS; 0-10) | NA | IG 4.02±2.04<br>CG 3.67±2.49 | NA | NA | p>0.05 | NA |
| | Kinesiophobia (TSK; 17-68) | NA | IG 27.50±8.79<br>CG 28.03±6.58 | NA | NA | p>0.05 | NA |
| Radojevic (1992)§ | Pain (AIMS, 0-10) | IG 5.17±2.12<br>CG 5.79±2.03 | IG 4.73±2.37<br>CG 4.61±2.58 | NA | p>0.05 | p>0.05 | NA |
| | Disability (AIMS subscales combined, score NR) | IG 12.27±9.43<br>CG 15.63±11.77 | IG 11.93±8.99<br>CG 14.44±10.67 | NA | p>0.05 | p>0.05 | NA |
| | Psychological disability (AIMS subscales combined, score NR) | IG 6.05±3.33<br>CG 6.36±3.47 | IG 5.94±2.33<br>CG 6.01±4.08 | NA | p>0.05 | p>0.05 | NA |
| | Depression (CES-D, 0-60) | IG 11.93±12.21<br>CG14.86±13.36 | IG 9.60±8.29<br>CG 11.79±9.71 | NA | p>0.05 | p>0.05 | NA |
| | Pain Coping (PMI, active coping subscale, 7-35) | IG 23.20±4.70<br>CG 22.21±5.58 | IG 22.87±5.11<br>CG 22.29±5.58 | NA | p>0.05 | p>0.05 | NA |
| | Pain Coping (PMI passive coping subscale, 11-55) | IG 29.06±7.57<br>CG 30.57±6.57 | IG 27.33±7.44<br>CG 29.86±7.09 | NA | p>0.05 | p>0.05 | NA |
| Riemsma (2003) | Emotional support from partner (1-4 scale) | IG 0.00±0.50 [a]<br>CG 0.00±0.40 [a] | IG 0.00±0.40 [a]<br>CG 0.00±0.50 [a] | IG 0.00±0.50 [a]<br>CG -0.1±0.40 [a] | p>0.1 | p>0.1 | p>0.1 |
| | Esteem support from partner (1-4 scale) | IG -0.20±0.70 [a]<br>CG 0.00±0.70 [a] | IG 0.00±0.50 [a]<br>CG 0.00±0.70 [a] | IG 0.00±0.70 [a]<br>CG -0.20±0.70 [a] | p>0.1 | p>0.1 | p>0.1 |
| | Informational support from partner (1-4 scale) | IG 0.00±0.70 [a]<br>CG 0.00±0.50 [a] | IG -0.1±0.60 [a]<br>CG -0.2±0.60 [a] | IG -0.1±0.60 [a]<br>CG -0.2±0.70 [a] | p>0.1 | p>0.1 | p>0.1 |
| | Tangible support from partner (1-4 scale) | IG 0.00±0.70 [a]<br>CG -0.1±0.50 [a] | IG -0.10±0.50 [a]<br>CG -0.10±0.60 [a] | IG 0.00±0.70 [a]<br>CG -0.20±0.70 [a] | p>0.1 | p>0.1 | p>0.1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Problematic support from partner (1-4 scale) | IG 0.00±0.50 [a]<br>CG0.00±0.30 [a] | IG 0.00±0.60 [a]<br>CG -0.10±0.40 [a] | IG 0.00±0.70 [a]<br>CG 0.00±0.40 [a] | p>0.1 | p>0.1 | p>0.1 |
| Overprotection from partner (1-4 scale) | IG 0.20±1.00 [a]<br>CG 0.00±0.90 [a] | IG 0.30±1.00 [a]<br>CG 0.00±0.80 [a] | IG 0.00±0.90 [a]<br>CG 0.00±0.90 [a] | p>0.1 | p>0.1 | p>0.1 |
| Self-efficacy function (ASES, 9-45) | IG 0.00±0.50[a]<br>CG 0.00±0.50[a] | IG 0.00±0.60 [a]<br>CG 0.00±0.50 [a] | IG 0.10±0.70 [a]<br>CG 0.00±0.70 [a] | p>0.1 | p>0.1 | p>0.1 |
| Self-efficacy pain (ASES, 5-24) | IG 0.1±0.70 [a]<br>CG 0.00±0.70 [a] | IG 0.00±0.70 [a]<br>CG 0.30±0.70 [a] | IG 0.00±0.70 [a]<br>CG 0.30±0.70 [a] | p>0,1 | p>0.1 | p=0.06 |
| Self-efficacy other symptoms (ASES, 6-30) | IG 0.00±0.60 [a]<br>CG 0.00±0.70 [a] | IG 0.00±0.70 [a]<br>CG 0.20±0.60 [a] | IG -0.20±0.70 [a]<br>CG 0.30±0.70 [a] | p>0.1 | p>0.1 | p=0.000 |

*Mean (SE); §Not included in the meta-analysis as did not report the number of participants per group; [a]Difference from baseline

TSK: Tampa Scale of Kinesiophobia; PCS: Pain Catastrophizing Scale; VAS: Visual Analogue Scale; MPQ: McGill Pain Questionnaire; PCL: Pain Cognition List; CSQ: Coping Strategies Questionnaire; CHIP: Checklist Interpersonal for Pain Behavior; PaBS: Pain Behavior Scale; NHQ: Nijmegen Hyperventilation Questionnaire; SIP: Sickness Impact Profile; PBC: Pain Behavior Checklist; WOMAC: The Western Ontario and McMaster Universities Osteoarthritis Index; PHQ-8: Patient Health Questionnaire-8; ISI: Insomnia Severity Index; ASES: Arthritis Self-Efficacy Scale; CES-D: Center for Epidemiologic Studies Depression Scale; WHYMPI: West Haven-Yale Multidimensional Pain Inventory; MMPI: Minnesota Multiphasic Personality Inventory; FIPS: Family Impact of Pain Scale; AIMS: Arthritis Impact Measurement Scale; PMI: Pain Management Inventory; FDI: Functional Disability Inventory

**Supplementary Table 3.** Results of outcomes not included in the meta-analysis at short, mid and long-term follow-ups of studies comparing family-based interventions to usual care

| Study | Outcome | Available data per group - mean±SD | | | p value, effect size (ES) | | |
|---|---|---|---|---|---|---|---|
| | | Short-term follow-up | Mid-term follow-up | Long-term follow-up | Short-term follow-up | Mid-term follow-up | Long-term follow-up |
| Abbasi (2012) | Kinesiophobia (TSK; 0-51) | IG 17.4±4.0<br>UC 27.2±7.1 | NA | IG 20.3±9.1<br>UC 29.7±9.6 | NR | NA | NR |
| | Pain catastrophising (PCS, 0-52) | IG 23.0±7.4<br>UC 25.7±6.7 | NA | IG 22.4±11.3<br>CG 24.6±7.8 | NR | NA | NR |
| Saarijarvi (1991a, 1991b, 1992) | Disability (Impairment Index from SNQ, 0-9) | NA | NA | IG 6.62±2.77<br>UC 5.27±2.97 | NA | NA | p>0.05 |
| | Disability (FCI, 0-5) | NA | NA | IG 3.52±1.06<br>UC 3.13±0.90 | NA | NA | p>0.05 |
| | Relationship with partners (14 items of DAS, scale NR) | NA | NA | Adjustment<br>IG 3.76±0.68<br>UC 3.82±0.54<br>Communication<br>IG 3.78±0.60<br>UC 3.75±0.51 | NA | NA | Adjustment<br>NR<br><br>Communication<br>p=0.006 |
| | Psychological distress (BSI, scale NR) | NA | NA | IG 0.98±0.54<br>UC 0.71±0.48 | NA | NA | p=0.005 |
| Turner (1990) | Physical and psychosocial dysfunction (SIP, scale NR) | IG 3.63±2.98<br>UC 5.37±5.93 | NA | NA | NR | NA | NA |
| | Pain behavior (PBC, scale NR) | IG 31.72±6.71<br>UC 36.18±9.69 | NA | NA | NR | NA | NA |
| | Pain behavior (rated by observer, scale NR) | IG 2.74±2.85<br>UC 3.86±3.15 | NA | NA | NR | NA | NA |
| | Depression (CES-D 20, 0-60) | IG 7.36±5.89<br>UC 7.03±5.02 | NA | NA | NR | NA | NA |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Keefe (2004) | Pain coping – coping attempts (CSQ; scale NR) | NA | IG 73.76±25.78<br>UC 51.01±21.16 | NA | NA | p=0.001<br>ES=0.30 | NA |
| | Pain coping – pain control/rational thinking (CSQ; scale NR) | NA | IG 3.81±2.71<br>UC 2.62±3.57 | NA | NA | p=0.015<br>ES=0.20 | NA |
| | Psychological disability (AIMS, 0-10) | NA | IG 2.21±1.21<br>UC 1.80±1.04 | NA | NA | p=0.80 | NA |
| Martire (2007) | Self-efficacy (ASES; 20-200) | IG 147.71±2.85<br>UC 138.31±3.82 | IG 151.62±2.78<br>UC 139.48±3.73 | NA | p=0.66 | p=0.89 | NA |
| | Depression (CES-D; 0-30) | NR | NR | NA | NR | NR | NA |
| Moore (1985) | Physical and psychological dysfunction (SIP; scale NR) | NA | IG 12.8±10.9<br>UC 20.3±9.60 | NA | NA | NR | NA |
| | Pain behaviour (spouse rated VAS; 0-10) | NA | IG 4.73±1.85<br>UC 6.00±1.71 | NA | NA | NR | NA |
| | Depression (MMPI-168, subscale NR) | NA | IG 76.20±18.00<br>CG 82.1±14.40 | NA | NA | NR | NA |
| | Somatization (MMPI-168, subscale NR) | NA | IG 73.20±16.10<br>UC 90.70±11.80 | NA | NA | NR | NA |
| Radojevic (1992)§ | Pain (AIMS, 0-10) | IG 5.17±2.12<br>UC 5.50±2.38 | IG 4.73±2.37<br>UC 5.47±2.11 | NA | p>0.05 | p>0.05 | NA |
| | Disability (AIMS subscales combined, score NR) | IG 12.27±9.43<br>UC 16.24±9.68 | IG 11.93±8.99<br>UC 15.09±9.39 | NA | p>0.05 | p>0.05 | NA |
| | Psychological disability (AIMS subscales combined, score NR) | IG 6.05±3.33<br>UC 6.61±3.58 | IG 5.94±2.33<br>UC 5.57±3.72 | NA | p>0.05 | p>0.05 | NA |
| | Depression (CES-D, 0-60) | IG 11.93±12.21<br>UC 11.93±8.65 | IG 9.60±8.29<br>UC 12.27±11.35 | NA | p>0.05 | p>0.05 | NA |
| | Pain Coping (PMI, active coping subscale, 7-35) | IG 23.20±4.70<br>UC 20.60±6.33 | IG 22.87±5.11<br>UC 21.67±6.83 | NA | p>0.05 | p>0.05 | NA |
| | Pain Coping (PMI passive coping subscale, 11-55) | IG 29.06±7.57<br>UC 30.33±8.32 | IG 27.33±7.44<br>UC 33.27±9.34 | NA | p>0.05 | p>0.05 | NA |
| Lomholt (2015) | Pain (VAS, 0-10) | IG 3.50±0.73<br>UC 3.23±0.69 | NA | NA | p=0.81 | NA | NA |

| | | | | | | |
|---|---|---|---|---|---|---|
| Disability (FDI, 0-60) | IG 9.78±3.12<br>UC 10.90±3.02 | NA | NA | p=0.81 | NA | NA |
| Pain catastrophising (PCQ, 1-5) | IG 1.61±0.27<br>UC 2.11±0.25 | NA | NA | p=0.10 | NA | NA |
| Symptom self-efficacy (CASE, 1-5) | IG 2.95±0.34<br>UC 2.14±0.32 | NA | NA | p=0.09 | NA | NA |
| Activity self-efficacy (CASE, 1-5) | IG 3.40±0.32<br>UC 2.59±0.30 | NA | NA | p=0.10 | NA | NA |
| Emotion self-efficacy (CASE, 1-5) | IG 3.25±0.31<br>UC 2.38±0.29 | NA | NA | p=070 | NA | NA |

IG: Intervention Group; UC: Usual Care NA: Not Applicable; NR: Not Reported; §Not included in the meta-analysis as did not report the number of participants per group TSK: Tampa Scale of Kinesiophobia; PCS: Pain Catastrophizing Scale; SNQ: Standardized Nordic Questionnaire; ADL: Activities of Daily Living; FCI: Functional Capacity Index; DAS: Dyadic Adjustment Scale; BSI: Brief Symptom Inventory; SIP: Sickness Impact Profile; PBC: Pain Behavior Checklist; CES-D: Center for Epidemiologic Studies Depression Scale; CSQ: Coping Strategies Questionnaire; AIMS: Arthritis Impact Measurement Scale; ASES: Arthritis Self-Efficacy Scale; MMPI: Minnesota Multiphasic Personality Inventory; PMI: Pain Management Inventory; VAS: Visual Analogue Scale; FDI: Functional Disability Inventory; PCQ: Pain Coping Questionnaire; CASE: Children's Arthritis Self-Efficacy Scale.

**Supplementary Table 4.** Overall quality of evidence of studies included in quantitative analysis comparing the effects of family-based interventions to usual care on pain at short-term and mid-term follow-ups

| Studies | Quality assessment | | | Number of participants | | Effect* | Overall quality evidence |
|---|---|---|---|---|---|---|---|
| | Risk of Bias | Inconsistency | Imprecision | Family-assisted intervention | Usual care | MD (95% CI)◊ | |
| *Pain* | | | | | | | |
| Short-term | Serious Risk of bias§ | No serious inconsistency‡ | Serious imprecision\| | 126 | 83 | -6.05 (-6.73, -5.37) | ⊕□□ Low |
| Mid-term | Serious Risk of bias§ | Serious Inconsistency┼ | Serious imprecision\| | 158 | 113 | -2.27 (-10.61, 6.07) | □□□ Very low |

* Negative values favour family-assisted intervention

◊ Mean difference (MD) and 95% confidential interval (95% CI) of family-assisted intervention compared to usual care

§ More than 25 % of participants from studies with low methodological quality (PEDro score < 6 points).

‡ $I^2 < 50\%$; ┼ $I^2 > 50\%$.

†> 400 participants combined for each outcome; | < 400 participants combined for each outcome.

**Supplementary Table 5.** PRISMA Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 159 |
| **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. | 159 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 159,160 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 160 |
| **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. | 160 |
| 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. | 160 |
| 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. | 160 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | Supplementary Table 1 |
| 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). | 160 |

| | | | |
|---|---|---|---|
| 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. | 160 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 160 |
| 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. | 161 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 161 |
| 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. | 161 |
| 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). | 161 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | 161 |
| **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. | 161,162 |
| 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. | 163-168 |
| 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). | 169 |
| 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. | 143, 149, 151-155, S. Tables 2 and 3 |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | 162, 168, 170-174 |

| | | | |
|---|---|---|---|
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 162, 168, S. Tables 1 and 4 |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | 168, 171, 173 |
| **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). | 173, 174 |
| 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). | 174 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 174,175 |
| **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. | 159 |

*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

For more information, visit: **www.prisma-statement.org**.

# Appendix Five – Supplementary material for Chapter Nine

**Supplemental document 1.** Main changes to the trial's protocol

| What was described in the initial protocol (V2) | What was changed, when |
|---|---|
| **Health coaching sessions:** | |
| Participants would receive up to 10 health coaching sessions | Participants would receive up to 13 health coaching session. *V3, 21.02.2020* |
| **Inclusion criteria:** | |
| Adults over the age of 50 years who have been undergoing tratment for LBP either at the Musculoskeletal Outpatient or the Physiotherapy Outpatient Aged-Care Service at Concord Hospital will be invited to participate in the trial. | Adults over the age of 50 years who have been underoing treatment for LBP will be invited to participate in the trial. Potential participants may be receiving treatment at Concord Hospital (at either the Musculoskeletal Outpatient Physiotherapy Department or the Physiotherapy Outpatient Aged Care Service) as well as private physiotherapy, chiropractic or general practitioner services. *V4, 16.04.2020*<br>Patients who live in NSW, SA or QLD will be eligible to participate and have been discharged from treatment within the past months. *V6, 29.11.2020*<br>Patients who have been discharged from treatment within the past six months would be eligible to participate. *V8, 17.04.2021* |
| | Addition of social support (Duke Social Support Scale) and self-efficacy (Exercise Self-Efficacy) scales as outcome measures. *V4, 16.04.2020*<br>Social support and self-efficacy scales no longer outcome measures but as additional medical information being collected. *V9, 16.06.2022* |
| | Addition of a question about the relationship status of the buddy and the participant (i.e., family member, friend, carer). *V4, 16.04.2020* |
| | Additional information regarding what would happen if the participant and the buddy would like to stop exercising together (i.e., reason would be recorded and a new introductory session would be |

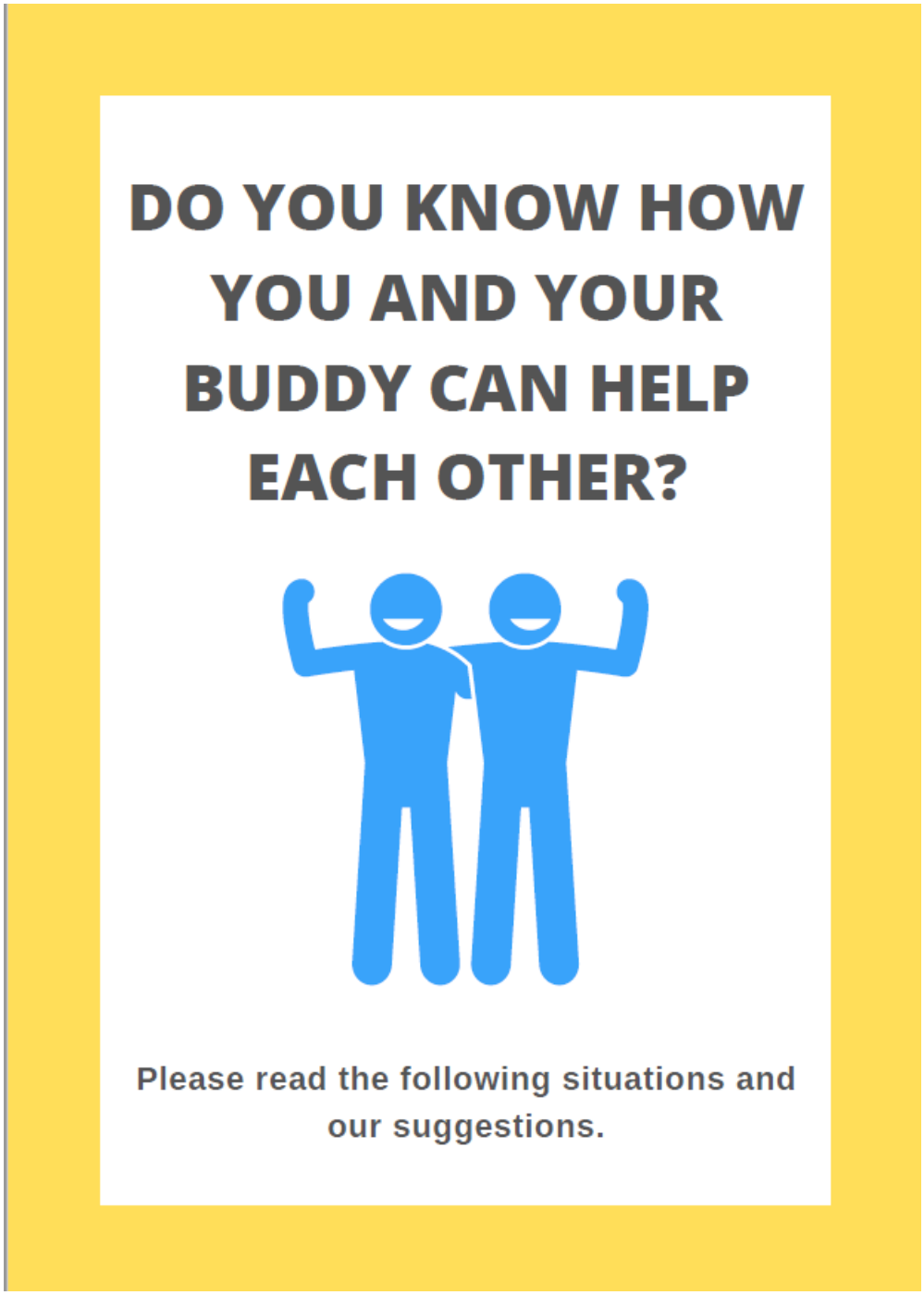
| | |
|---|---|
| | held with the participant and the new buddy). *V4, 16.04.2020* |
| | Addition of a question about how participants became aware of the study within the screening process. *V4, 16.04.2020* |
| **Data collection processes:** | |
| Pariticipants could complete the data collection measurements in person, online or via phone and have the accelerometer placed on the right thigh by a member of the study team or receive it via post. | The research team will schedule a video call with participants to help them to place the accelerometer on their thigh. *V6, 29.11.2020* |
| Physiotherapist discharging patients would be sent a feedback survey about their expectations and barriers for referring partients to a health coaching service. | Physiotherapists feedback survey was removed as no longer applicable. *V9, 16.06.2022* |
| **Sample size:** | |
| This study is designed to be a pilot trial to test the feasibility of the approach, and preliminary efficacy of the individual, and the "buddy" Get Healthy physical activity coaching intervention to set up a main large NHMRC partnership trial. However, a sample size of 15 participants per group will provide 80% power to detect a difference of 2,000 steps between groups, with a SD of 2,000 steps, and alpha level of 0.05. The sample size calculation was performed in compliance with the knowledge that an increase in of 1,000 steps/day is associated with decrease in the risk of all-cause mortality and metabolic syndrome. | A sample size of 10 participants per group (30 participants in total) has been agreed upon. This reflects the challenges experienced by most clinical trials during the COVID-19 pandemic with participant recruitment, the number of individuals seeking care for low back pain and the specific requirements of this study to be able to exercise with a buddy or exercise partner. The sample size is adequate for a pilot study assessing the feasibility of a discharge program (GHS Coaching service) following treatment for low back pain. *V9, 16.06.2022* |

**Supplemental document 2.** Reason for exclusion of study participants and their buddies.

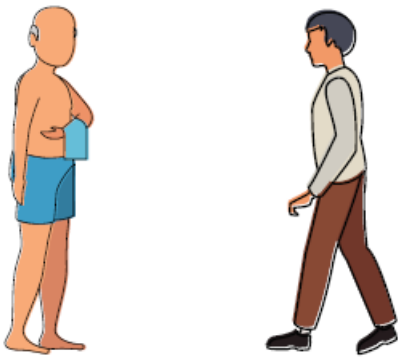
Potential participants were excluded if they: *i)* had specific spinal conditions (e.g., radiculopathy, spinal stenosis); *ii)* participated in vigorous sports activities; *iii)* had any spinal, hip or knee surgery within the past year; *iv)* had corticosteroid injections in the spine within the past month; *v)* had any comorbidity that prevented physical activity participation; *vi)* presented a higher risk of having an adverse event due to exercise (assessed with the Adult Pre-Exercise Screening); *vii)* had a diagnosis of fibromyalgia or a systematic arthritic condition, cognitive impairment and history of unexpected falls in the previous year.

Exercise buddies were excluded if they reported: *i)* any comorbidity that prevented physical activity participation; *ii)* higher risk of having an adverse event due to exercise (assessed with the Adult Pre-Exercise Screening); or *iii)* a diagnosis of fibromyalgia or a systematic arthritic condition, cognitive impairment and history of unexpected falls in the past year.

**Supplemental document 3.** Buddy Supportive Brochure



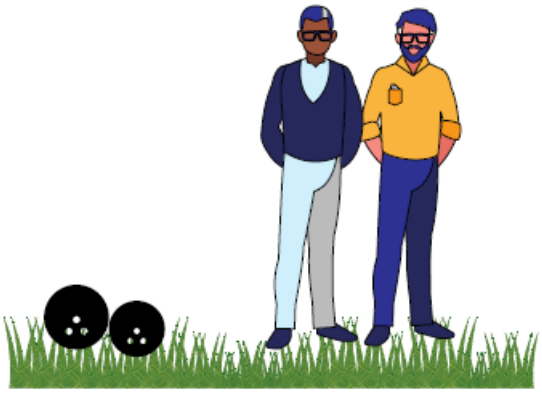
**1.** Joseph has agreed to be a buddy for Anthony in the trial. Now they need to establish one combined goal to exercise together once a week. It was a bit complicated, as Joseph's preferred activity is to go swimming while Anthony's preferred activity is to walk.



However, they knew that bowling was an activity that both of them enjoyed. So, they decided the goal in a collaborative way and planned to go bowling. Anthony would like to go on Wednesday mornings, but Joseph worked and was available only on the weekends. They found that Saturday mornings would fit them best.

Joseph would like to bowl for 2 hours, but this was not a realistic idea considering Anthony's back pain. Bowling for a long time could be too much, as it is not an activity that Anthony was used to doing. Thus, they decided that playing for 30 minutes would be a good option.

In this way, their combined goal was established: go bowling every Saturday at 10am for 30 minutes at the local bowling club. They started with this plan for 3 to 4 weeks and adjusted it according to their experience.



***When planning your physical activity goal with your buddy, try to do it in a collaborative way - matching preferences and times that fit both of you better. As people have different interests and agendas, finding an activity that both of you enjoy and fitting it in both of your schedules can be a bit tricky. Try to talk to your buddy and build this goal in a collaborative way. Goals that are specific, measurable, achievable, realistic, and timely tend to be more effective. Consider it when planning yours! And remember, you can always change it if you want!***

**2.** Louise has agreed to be a buddy for Carolina and go to exercise classes on Thursday mornings. When Carolina rescheduled and cancelled their plans for the third time in a week, Louise felt angry.

She was really tempted to say so, but then she remembered how difficult it was for Carolina. So, instead of being critical, she made a time to meet with her to sort the problem out. Louise knew that being critical and pressuring Carolina could make her feel guilty, which could worsen her back pain and their relationship. They met and together solved some of the problems that Carolina was having. In the following week, they went to the classes as planned.

***Back pain can fluctuate and get in our way. Or sometimes some unexpected events happen and make it difficult to stick to our goals. Buddies should try to understand each other in this sense. Acting in a critical and hostile way with each other or putting pressure to stick to the plan can have a negative impact. Optimising communication as well as offering a warm and supportive environment helps to improve problem solving skills and overcome the problems.***

**3.** Ian agreed to be Rebecca's buddy to exercise. They decided to go for a walk together on Sunday mornings. They achieved their goal in the first two weeks. Rebecca cancelled the walk on the third week. Ian felt like he should control Rebecca more and force her to go walking with him, because he knew that walking helped Rebecca's health.

However, he realised that maybe this action might discourage Rebecca to exercise. So, he accepted her decision and decided to go for the walk by himself, as walking was positively affecting his health as well. Ian thought that telling Rebecca that he went for a walk and felt great after it could encourage her to walk with him again. And it did! Rebecca went with him for a walk the following week.

***Although we may think that controlling our buddies' activity may help them, we should try to understand and support their decisions. Accepting each other's decisions and trying to be a good exercise partner can have a very positive impact on your buddies behaviour.***

**Supplemental document 4.** Further feedback provided by participants from the Buddy-Assisted Group

| Multiple choice questions | n (%) |
|---|---|
| Greatest barriers for achieving individual physical activity goals | |
| Lack of time | 1 (14.3%) |
| Lack of motivation | 2 (28.6%) |
| Pain intensity | 1 (14.3%) |
| Fear of pain | 2 (28.6%) |
| Fear that the pain would increase after exercising | 2 (28.6%) |
| Sickness | 3 (42.9%) |
| Others – buddy not being able to exercise much of the time | 1 (14.3%) |
| mental health | 1 (14.3%) |
| Enablers in achieving individual physical activity goals | |
| Motivation from the health coach | 1 (14.3%) |
| Support from the health coach | 1 (14.3%) |
| Monitoring from the health coach | 1 (14.3%) |
| Individualised goals | 2 (28.6%) |
| Personal will to change | 4 (57.1%) |
| Finding a pleasant physical activity | 5 (71.4%) |
| Other – having committed to a buddy | 1 (14.3%) |
| Greatest advantages of having an exercise buddy | |
| Increased own motivation to exercise | 4 (57.1%) |
| Increased support to exercise | 2 (28.6%) |
| Increased joy of exercise | 1 (14.3%) |
| Having time to talk with the buddy whilst being active | 3 (42.9%) |
| Not having to perform the physical activity alone | 3 (42.9%) |
| Other – going for an interesting walk rather than my usual walk | 1 (14.3%) |
| Greatest disadvantages of being an exercise buddy | |
| Difficulty in finding a physical activity/ time/ place that worked for both | 3 (42.9%) |
| Buddy cancelling the sessions | 1 (14.3%) |
| Feeling demotivated facing own limitations | 3 (42.9%) |
| Other – Buddy forgetting about the study | 1 (14.3%) |

Open-ended answers:

Two participants provided written feedback about their participation in the Buddy-Assisted Health Coaching Group. One participant enjoyed having and exercise buddy and reported that '*to have an exercise buddy is ideal as I personally need motivation and moral support to follow through my daily commitment to exercise having been diagnosed for osteoporosis and lower back pain'*. However, they reported the health coaching

intervention was not as expected since the solutions came from their suggestions rather than from the professional experience from the coach. The second participant mentioned that their buddy forgot that they were still committed to the study, but the buddy still agreed to go with them for a short walk.

**Supplemental document 5.** Further feedback provided by buddies from the Buddy-Assisted Group

| Multiple-choice questions | n (%) |
|---|---|
| Greatest advantages of being an exercise buddy | |
| Increased own motivation to exercise | 5 (83.3%) |
| Providing and receiving support | 1 (16.7%) |
| Increased joy of exercise | 2 (33.3%) |
| Not wanting to let buddy down | 1 (16.7%) |
| Desire to be a good model to the buddy | 2 (33.3%) |
| Greatest disadvantages of being an exercise buddy | |
| Difficulty in finding a physical activity/ time/ place that worked for both | 2 (33.3%) |
| Buddy cancelling the sessions | 1 (16.7%) |
| Having to change my rhythm because of my buddy | 3 (50.0%) |
| Feeling demotivated facing my buddy's limitations | 1 (16.7%) |
| Multiple-choice questions | n (%) |
| Greatest advantages of being an exercise buddy | |
| Increased own motivation to exercise | 5 (83.3%) |
| Providing and receiving support | 1 (16.7%) |
| Increased joy of exercise | 2 (33.3%) |
| Not wanting to let buddy down | 1 (16.7%) |
| Desire to be a good model to the buddy | 2 (33.3%) |
| Greatest disadvantages of being an exercise buddy | |
| Difficulty in finding a physical activity/ time/ place that worked for both | 2 (33.3%) |
| Buddy cancelling the sessions | 1 (16.7%) |
| Having to change my rhythm because of my buddy | 3 (50.0%) |
| Feeling demotivated facing my buddy's limitations | 1 (16.7%) |

One buddy answered the open-ended question and was thankful for the opportunity. They also mentioned that '*the experience has been fruitful for both [name] and I. Our renewed general vigour we attribute to scheduled,scheduled exercise.*'

**Supplemental document 6.** Feedback from participants of the Individual-Only Group

| Likert-scale questions | Not at all/ not really n (%) | Neutral n (%) | Somewhat/ extremely n (%) |
|---|---|---|---|
| Health coaching intervention helped to increase physical activity participation | 3 (50.0%) | 0 (0.0%) | 3 (50.0%) |
| Effective communication with the health coach | 3 (50.0%) | 0 (0.0%) | 3 (50.0%) |
| Satisfied with the health coaching intervention | 3 (50.0%) | 0 (0.0%) | 3 (50.0%) |
| How much the health coaching intervention helped to increase physical activity participation | 3 (50.0%) | 0 (0.0%) | 3 (50.0%) |
| Belief that support of an 'exercise buddy' would further increase physical activity participation | 1 (16.7%) | 2 (33.3%) | 3 (50.0%) |
| Belief of how difficult it would be to find a combined physical activity goal with an 'exercise buddy' | 3 (50.0%) | 1 (16.7%) | 2 (33.3%) |
| Belief that having an 'exercise buddy' would positively impact the relationship | 0 (0.0%) | 1 (16.7%) | 5 (83.3%) |
| Interest in the health coaching intervention after discharge from physiotherapy for low back pain | 3 (50.0%) | 0 (0.0%) | 3 (50.0%) |

| Multiple-choice questions | n (%) |
|---|---|
| Greatest challenges to increase physical activity during the health coaching intervention | |
| Lack of joy in exercise | 2 (33.3%) |
| Lack of time | 3 (50.0%) |
| Belief that physical activity will not affect the back pain | 1 (16.7%) |
| Other – inability due to ongoing back pain | 1 (16.7%) |
| Possible greatest advantages of having an exercise buddy | |
| Increase motivation to exercise | 4 (66.7%) |
| Increase support to exercise | 3 (50.0%) |
| Increase joy of being active | 1 (16.7%) |
| Having time to talk with the buddy while being active | 3 (50.0%) |
| Not having to perform physical activity alone | 2 (33.3%) |
| Possible greatest disadvantages of having an exercise buddy | |

| | |
|---|---|
| Difficulty in finding a physical activity/ time/ place that work for both | 4 (66.7%) |
| Buddy cancelling the sessions | 1 (16.7%) |
| Feeling demotivated facing own limitations | 1 (16.7%) |

Two participants provided written feedback, and both considered the coaching sessions helpful. One participant reported that *'there is a temptation to gradually fall away with ongoing exercise*' after discharge. The health coaching intervention helped to '*keep me on track in terms of ongoing activity to keep the back strong and manage it better*'. However, one participant would like more information on specific exercises and found it hard to find the right time to the health coaching sessions due to work and tiredness after work.

**Supplemental document 7.** Feedback received from participants of the Usual Discharge Care Group

| Likert-scale questions | Not at all/ not really n (%) | Neutral n (%) | Somewhat/ extremely n (%) |
|---|---|---|---|
| Health coaching intervention after discharge from treatment would be helpful to increase physical activity participation | 0 (0.0%) | 2 (25.0%) | 6 (75.0%) |
| Belief that support of an 'exercise buddy' would further increase physical activity participation | 0 (0.0%) | 1 (12.5%) | 7 (87.5%) |
| Belief of how difficult it would be to find a combined physical activity goal with an 'exercise buddy' | 1 (12.5%) | 2 (25.0%) | 5 (62.5%) |
| Interest in being offered the health coaching buddy-assisted intervention after discharge from treatment for low back pain | 1 (12.5%) | 4 (50.0%) | 3 (37.5%) |

| Multiple-choice questions | n (%) |
|---|---|
| Greatest advantages of having an exercise buddy | |
| Increased own motivation to exercise | 5 (62.5%) |
| Increased support to exercise | 5 (62.5%) |
| Increased joy of exercise | 1 (12.5%) |
| Having time to talk with the buddy whilst being active | 5 (62.5%) |
| Not having to perform the physical activity alone | 3 (37.5%) |
| Greatest disadvantages of being an exercise buddy | |
| Difficulty in finding a physical activity/ time/ place that worked for both | 7 (87.5%) |
| Buddy not having patience to go on patients' pace | 1 (12.5%) |

Only one participant (12.5%) from control group reported self-enrolling in the health coaching intervention. They reported *"In general, feels very good with health coaching. But I would like to suggest a video or at least 1 session face to face. I Feel a little scared to do the exercises wrong. If I have a video to see during the exercise will be much better."*.

Another participant from the control group completed the open-ended question and reported walking alone in the beginning of the study before walking with their neighbour*: "But then with lockdown a neighbour started coming with me EVERY day. It meant I walked further without noticing pain levels. I felt I was helping her emotional stability and she was assisting me to keep moving."*

**Supplemental document 8.** Exploratory analysis of between-arm differences in clinical outcome measures at 3- and 6-months

| | 3-months | | | 6-months | | |
|---|---|---|---|---|---|---|
| Outcome measures, estimates of treatment effects (95%CI) | Individual-Only Group vs Usual Discharge Care Group | Buddy-Assisted Group vs Usual Discharge Care Group | Buddy-Assisted Group vs Individual-Only Group | Individual-Only Group vs Usual Discharge Care Group | Buddy-Assisted Group vs Usual Discharge Care Group | Buddy-Assisted Group vs Individual-Only Group |
| Number of daily steps | 261.22 (-4,539.33, 5,061.78) | -462.45 (-5,960.21, 5,035.30) | -723.67 (-6,575.07, 5,127.72) | 822.47 (-3,883.71, 5,528.64) | -1,601.91 (-7,127.40, 3,923.58) | -2,424.38 (-8.377.68, 3,528.92) |
| Sedentary behaviour (hours/day) | 0.49 (-0.55, 1.53) | 0.30 (-0.87, 1.47) | -0.19 (-1.44, 1.06) | -0.04 (-1.06, 0.98) | -0.23 (-1.42, 0.96) | -0.19 (-1.47, 1.10) |
| Low back pain intensity in the previous week (VAS, 0-100) | -20.07 (-35.88, -4.27) | -0.25 (-16.05, 15.55) | 19.83 (2.95, 36.69) | -22.97 (-38.49, -7.44) | -5.46 (-20.48, 9.56) | 17.51 (1.10, 33.91) |
| Disability (RMDQ, 0-24) | -2.51 (-6.88, 1.86) | 0.15 (-4.22, 4.52) | 2.66 (-2.00, 7.33) | -2.10 (-6.40, 2.19) | -0.22 (-4.38, 3.94) | 1.88 (-2.65, 6.42) |
| Number of medication types in the past week | 0.47 (-0.62, 1.56) | 0.07 (-1.03, 1.16) | -0.40 (-1.57, 0.76) | 0.42 (-0.66, 1.49) | 0.27 (-0.77, 1.31) | -0.15 (-1.28, 0.99) |
| Number of health care sessions in the past week | -0.12 (-1.09, 0.84) | 0.21 (-0.76, 1.75) | 0.33 (-0.70, 1.36) | -0.29 (-1.24, 0.67) | 0.00 (-0.93, 0.93) | 0.29 (-0.72, 1.30) |
| Total care in the past week* | 0.29 (-1.22, 1.80) | 0.20 (-1.31, 1.72) | -0.08 (-1.70, 1.53) | 0.12 (-1.36, 1.61) | 0.27 (-1.17, 1.71) | 0.14 (-1.42, 1.72) |

* Number of medication types of medication and number of health care sessions

95%CI: 95% Confidence Interval, VAS: Visual Analogue Scale; RMDQ: Roland-Morris Disability Questionnaire

**Supplemental document 9.** CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a pilot or feasibility randomised trial in the title | 1 |
| | 1b | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | 2 |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 4,5 |
| | 2b | Specific objectives or research questions for pilot trial | 5 |
| **Methods** | | | |
| Trial design | 3a | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 5 |
| | 3b | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | 5,6 |
| Participants | 4a | Eligibility criteria for participants | 6,7 |
| | 4b | Settings and locations where the data were collected | 7 |
| | 4c | How participants were identified and consented | 6,7 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 8,9 |

| | | | |
|---|---|---|---|
| Outcomes | 6a | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 9-11 |
| | 6b | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | 5,6 |
| | 6c | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | NA |
| Sample size | 7a | Rationale for numbers in the pilot trial | 6 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | NA |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 7 |
| | 8b | Type of randomisation(s); details of any restriction (such as blocking and block size) | 7 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 7 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 7 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 7 |
| | 11b | If relevant, description of the similarity of interventions | 8,9 |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 11,12 |

| | | | |
|---|---|---|---|
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective | 12, Figure 1 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | 12, Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 6 |
| | 14b | Why the pilot trial ended or was stopped | NA |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| Numbers analysed | 16 | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers<br>should be by randomised group | Table 5, Supplemental document 8 |
| Outcomes and estimation | 17 | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any<br>estimates. If relevant, these results should be by randomised group | Table 5, Supplemental document 8 |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | 12-15 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 15 |
| | 19a | If relevant, other important unintended consequences | NA |
| **Discussion** | | | |
| Limitations | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | 17,18 |

| | | | |
|---|---|---|---|
| Generalisability | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | 19 |
| Interpretation | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and<br>considering other relevant evidence | 15-17 |
| | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | 19 |
| **Other information** | | | |
| Registration | 23 | Registration number for pilot trial and name of trial registry | 2,5 |
| Protocol | 24 | Where the pilot trial protocol can be accessed, if available | NA |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 22 |
| | 26 | Ethical approval or approval by research review committee, confirmed with reference number | 5 |