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MEASURING AND UNDERSTANDING OLDER PEOPLE'S PREFERENCES FOR HEALTH INTERVENTIONS

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Thesis presented for the degree of Doctor of Philosophy The University of Sydney 2015

Supervisors' Statement

As supervisors of Marcia Rodrigues Costa Franco's doctoral work, we certify that we consider her thesis "Measuring and understanding older people's preferences for health interventions" to be suitable for examination.

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Candidate's Statement

I, Marcia Rodrigues Costa Franco, hereby declare that this submission 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 accepted for the award of another degree.

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Date: 30 March 2015

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Acknowledgements

One of the joys of getting to the end is to look over the journey past and remember all the people who made this experience the most rich to me so far. Without their contribution and support, it would be impossible for me to complete this thesis. I would like to take this opportunity to express my gratitude to all of them.

My deepest acknowledgment must go to my husband Rafael and my little daughter Maria Eduarda. Thanks for fulfilling my life with constant love and happiness, you encouraged me to efficiently overcome the difficulties faced during the journey. Words cannot express how grateful I am for always having you by my side, love you so much!!!

Mum and Dad, thanks for being with me despite the long physical distance. You are the best parents I could ever have, a never-ending source of strength and energy in my life. This thesis is dedicated to you both! Bro, Xande, Toto, Pepeu, my newest godson Joao Gabriel, Marianas and Luiza, thanks for bringing cheerfulness and peace to my life! I feel very fortunate for having you as my family, you are a precious God's gift. Thanks to my in-law family, in special my godson Rick, for the support and for sharing great moments with us!

A very special thanks to my supervisors Manuela, Cathie, Kirsten and Paulo for their valuable scientific guidance. I greatly appreciate all your contributions of time and ideas that made my PhD experience stimulating. It has been my privilege to work with you and learn from your knowledge and experience! I also would like to thank Anne Moseley and Chris Maher for giving me the opportunity to work with them during my PhD studies.

Last but not least, thanks to my friends in Australia who made this such an enjoyable period of life! I would like to mention Leani, Monica, Anna Raquel, Daniel, Paula, Silvinha, Rubinho, Bec, Inez, Mick, Chris, Vinicius, Paty, Bruno, Tie, Gustavo, Marina, Amabile, Pam, Tarci, Ashkan, Jabiz, Sushi, Jaddus, Carise, little Elliot, Pauline, Vicky and all staff from the MSK division. I will never forget the great time

we spent together and I do hope our friendships will extend well beyond our shared time in Sydney.

Publications and presentations

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

Publications

Franco MR, Ferreira ML, Ferreira PH, Maher CG, Pinto RZ, Cherkin DC. Methodological limitations prevent definitive conclusions on the effects of patients' preferences in randomized clinical trials evaluating musculoskeletal conditions. *J Clin Epidemiol* 2013; **66**: 586-98.

Franco MR, Ferreira ML, Howard K, Sherrington C, Rose J, Haines TP, Ferreira P. How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol. *BMJ Open* 2013; **3**: e002355.

Franco MR, Pereira LS, Ferreira PH. Exercise interventions for preventing falls in older people living in the community. *Br J Sports Med* 2014; **48**: 867-8.

Franco MR, Howard K, Sherrington C, Ferreira PH, Rose J, Gomes JL, Ferreira ML. Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment. *J Physiother* 2015; 61: 34-41.

Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, Ferreira ML. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. *Br J Sports Med* 2015; [Epub ahead of print]

Presentations

Franco MR, Ferreira ML, Ferreira PH, Maher CG, Pinto RZ, Cherkin DC. Methodological limitations prevent definitive conclusions on the effects of patients' preferences in randomized clinical trials evaluating musculoskeletal conditions.

Primary Care Research on Back Pain, Odense International Forum XII, Denmark, October 2012.

Franco MR, Ferreira ML, Howard K, Sherrington C, Rose J, Haines TP, Ferreira P. How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol. *5th Biennial Australian and New Zealand Falls Prevention Conference,* Adelaide, Australia, October 2012.

Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, Ferreira ML. Older people's views on exercise: a systematic review and thematic synthesis of qualitative literature. *Australian Physiotherapy Association Conference*, Melbourne, Australia, October 2013. Oral Presentation.

Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, Ferreira ML. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. *The 12th National Conference of Emerging Researchers in Ageing (ERA Conference)*, Sydney, Australia, November 2013. Oral Presentation.

Ferreira M, **Franco MR**, Sherrington C, Ferreira P, Rose J, Gomes J, Howard K. Older people's preferences for exercise programs: a best-worst scaling choice experiment. *6th Biennial Australian and New Zealand Falls Prevention Conference*, Sydney, Australia, November 2014. Oral Presentation (Presented by M Ferreira as M Franco was on maternity leave).

Howard K, **Franco MR**, Sherrington C, Rose J, Ferreira P, Ferreira M. Older people's preferences and smallest worthwhile effect of exercise programs: a benefit-harm tradeoff method and discrete choice study. *6th Biennial Australian and New Zealand Falls Prevention Conference*, Sydney, Australia, November 2014. Oral Presentation (Presented by K Howard as M Franco was on maternity leave). Howard K, **Franco MR**, Tong A, Sherrington C, Ferreira PH, Pinto RZ, Ferreira ML. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. *6th Biennial Australian and New Zealand Falls Prevention Conference*, Sydney, Australia, November 2014. Oral Presentation (Presented by K Howard as M Franco was on maternity leave).

Preface

This thesis is arranged in seven chapters, written so that each chapter can be read independently. The University of Sydney allows published papers that arose from the candidature to be included in the thesis.

Chapter One is an introduction to the thesis and provides an overview of the importance of physical activity to the older population with a specific focus on the current need to improve understanding of the role of older people's perspectives and preferences for health interventions.

Chapter Two is a systematic review of qualitative studies describing the experiences and perceptions of older people in the general community on the benefits and barriers of physical activity participation. This manuscript is presented as published in the *British Journal of Sports Medicine*.

Chapter Three is a systematic and critical review of patients' preference within randomized clinical trials evaluating treatments for musculoskeletal conditions. This review is presented as published in the *Journal of Clinical Epidemiology*.

Chapter Four presents a study using the best-worst scaling method to explore older people's preferences in relation to characteristics of exercise programs, and to examine the relative value placed on particular attributes. This manuscript is presented as published in the *Journal of Physiotherapy*.

Chapter Five is a published protocol of the study designed to determine the smallest worthwhile effect of an exercise programs to prevent falls in older people using two different methods, the benefit-harm trade-off and discrete choice experiments. This protocol is presented as published in *BMJ Open*.

Chapter Six describes the results of the benefit-harm trade-off and discrete choice experiments described in the published protocol presented in Chapter Five. This manuscript is presented in the format required by *Journal of Clinical Epidemiology*, where it will be submitted for publication.

Finally, **Chapter Seven** consists of an overview and discusses the clinical implications and directions for future research in this area.

Each chapter contains its own reference list. Appendices that were published as online supplementary material are included at the end of the relevant chapter. **Appendix A** of this thesis is a synopsis and commentary on a systematic review that evaluates the effectiveness of interventions for preventing falls in older people living in the community. A copy of the 'Guideline for publication' for *Journal of Clinical Epidemiology* is presented in **Appendix B**. Ethical approval was gained from the Human Research Ethics Committee of the University of Sydney (protocol 14404) for studies including individual participant data prior to commencement.

Abstract

Population estimates from 2013 show that 841 million people are aged 60 years or over, an estimate four times higher than that observed in 1950. Demographic projections based on current fertility and mortality data show that this number can reach 2 billion by 2050. This ageing phenomenon poses important challenges as the prevalence of noncommunicable diseases, such as diabetes and hypertension, and falls-related injuries peaks at older ages. Consequently, the demand for health care services is likely to increase considerably. Physical activity is a crucial evidence-based strategy in both the prevention and management of these conditions. The health benefits of regular physical activity for the older population are well established in the literature, and include extending the number of years free of disability, preventing or mitigating functional limitations, reducing the risk of developing a number of chronic diseases and reducing the rate of falls as well as the risk of falling. Nevertheless, almost half of those older than 65 years worldwide fail to meet the recommended minimum level of physical activity to acquire health benefits. In this context, developing effective strategies to further engage older people in participating and maintaining participation in physical activity programs has become a research and policy priority. An important aspect of overcoming this challenge is to investigate older people's preferences and values regarding physical activity.

In the past few decades there has been an increasing recognition of the importance of integrating patients' preferences in the design of health policy and health care. Patients' preference for treatments bring valuable insights into the real acceptable levels of risks and benefits of health interventions, often overlooked when only the perspectives of clinicians and researches are accounted for. Integrating patients' preferences in clinical decision making may motivate patients to initiate and adhere to treatments, resulting in better health outcomes. This thesis will discuss the use of different research methodologies to gain further understanding on how patients' preferences can influence participation, adherence and the effectiveness of health interventions, with a special focus on physical activity programs. The aims of this thesis were to: (i) perform a systematic review of qualitative studies to summarise the experiences and perceptions of older people towards participation in physical activities, (ii) examine the relative value older people place on particular features of exercises programs using the best-

worst scaling method, (iii) systematically and critically review how patients' preferences have been measured and analysed in randomised clinical trials evaluating musculoskeletal conditions, and (iv) describe the estimates of the smallest benefit of exercise programs to prevent falls in older people consider to be worthwhile in terms of falls risk reduction, and compare two different methods for eliciting these estimates, the benefit-harm trade-off and the discrete choice experiment.

Qualitative research can provide better understanding of patients' perspectives and attitudes toward participation in physical activities and help translate the strong evidence of benefits of physical activity into practice. A qualitative systematic review can identify facilitators and barriers to physical activity that are common across different contexts and can inform effective physical activity policies and strategies to increase program uptake and sustain adherence over time. The systematic review of qualitative studies presented in Chapter Two describes the experiences and perceptions of community-dwelling older people on facilitators and barriers to physical activity participation. Synthesis of the results of 132 studies involving 5987 participants revealed six major themes and sixteen subthemes: social influences (valuing interaction with peers; social awkwardness; encouragement from others; dependence on professional instruction), physical limitations (pain or discomfort; concerns about falling; comorbidities), competing priorities, access difficulties (environmental barriers, affordability), personal benefits of physical activity (strength, balance and flexibility; self-confidence; independence; improved health and mental well-being), and motivation and beliefs (apathy, irrelevance and inefficacy, maintaining habits). This thematic synthesis revealed that although some older people believe in the potential of physical activity to improve physical and mental wellbeing, barriers to participation in physical activity include social support and accessibility. Some older people also believe that physical activity is unnecessary or potentially harmful. These findings suggest that strategies to enhance physical activity among older people must aim to improve environmental and financial access to physical activity programs as well as to raise awareness of the health benefits and minimise the perceived risks of physical activity. Moreover, the themes and subthemes identified in this review can inform health-care policy and practice so that older people's perspectives remain central to future discussions regarding the design of effective health services.

Patients' preference for treatment is often neglected in clinical trials, although it has the potential to influence their findings. The rationale within randomised trials is that patients who are allocated to their preferred treatment may be more motivated to adhere to treatment, thus resulting in better outcomes. The opposite would happen with those who do not receive their preferred treatment, leading to worse outcomes. A previous individual patient data meta-analysis has investigated the impact of patients' preferences in clinical trials evaluating musculoskeletal conditions. However, in this meta-analysis, patients from each randomised clinical trial were grouped into those who received their preferred treatment, those who received their non-preferred treatment and patients without a preference. However this approach to categorisation breaches randomisation of treatment allocation and means the analyses cannot produce unbiased estimates of treatment effects. Chapter Three presents a systematic and critical review investigating how patients' preferences have been measured and analysed in randomised controlled trials evaluating treatments for musculoskeletal conditions. The review included a total of 12 randomised clinical trials investigating a range of musculoskeletal conditions, such as low back pain and knee osteoarthritis. Authors used different measurement tools to elicit patients' preference and heterogeneous statistical tests. Five studies investigated if patients' preferences modify treatment effect (difference in outcomes between allocation groups), and seven studies examined the effect of patients' preferences on outcomes (within-group changes in outcome over time). For most, the preference analyses were not pre-planned and therefore underpowered. At present, methodological limitations of the available evidence suggest that it might be too early to conclude whether patients' preferences influence the findings of randomised controlled trials evaluating musculoskeletal conditions. Future studies should focus on developing standardised methods to measure patients' preferences and should also report complete data on subgroups of patients defined by a treatment preference of each randomised arm.

Qualitative research provides an understanding of patient's perceptions and experiences, but does not allow the estimation of the relative value people place on particular attributes of exercise programs. A contemporary research method that has been used to measure patients' preferences is the best-worst scaling choice experiment, a variation of the widely applied discrete choice experiments. Like discrete choice experiments, best-worst scaling studies have strong grounding in economic theory and have become a popular tool for eliciting preferences in relation to health care, impact of interventions on health outcomes and economic evaluation. The method allows people to choose the best and the worst features (attribute levels) through a series of hypothetical but plausible choice scenarios. Chapter Four presents a best- worst scaling study aiming to identify the relative value older people with a previous history of falls or mobility related disability attach to different exercise attributes and levels. This study aimed to determine the relative value older people (n=220) with a history of falls and/or mobility impairment attached to different attribute levels of exercise programs. The attributes tested were identified in the systematic review presented in Chapter Two. A total of nine attributes of exercise programs were included in the choice scenarios. For each of these attributes, five different levels were selected to include a range of reasonable values, which were either actual or hypothetical. For instance, for the attribute transport to exercise venues, the possible levels included in the choice scenarios were: no need to use transport, free transport provided, a small transport subsidy provided, a moderate subsidy provided and no transport provided. The results revealed that features of exercise programs with highest utility (i.e. considered to be more attractive to older people) were home-based exercise and no need to use transport to get to the exercise location. An improvement of 60% in the ability to do daily tasks at home, exercise free of charge and decreasing the chances of falling to 0% were ranked third, fourth and fifth, respectively. Attribute levels with the lowest utility were travel time of 60 minutes, travel time of 45 minutes, out of pocket cost of \$50 and travel time of 30 minutes, in that order. The data generated from this study suggest that older people place higher values on exercise characteristics than on benefits of exercise and, therefore, their decision on whether or not to engage in exercise programs is more influenced by program design and convenience rather than improvements in the health outcomes provided by the program. To effectively increase exercise participation amongst this age group, health-promotion strategies should go further than merely educating and raising awareness about the health benefits that can be gained with exercise. Clinicians, for instance, should advocate for the provision of low-cost exercise opportunities close to where people live and should prescribe home-based exercises to be performed in multiple short bouts. Policy makers should facilitate financial and environmental access to exercise programs.

There is now substantial evidence from systematic reviews of randomised trials that well-designed interventions are statistically effective in reducing the risk of falling among older people. While evidence of benefit is necessary for a health intervention to be implemented, it cannot be used as the sole basis in deciding whether to fund the provision of an intervention for many individuals. The decision regarding whether the estimated beneficial effects of health interventions are clinically relevant or not, should ideally rely on the opinions of older people themselves, i.e. those who directly benefit from it. The smallest worthwhile effect is the smallest effect of a health intervention that would justify associated costs, risks and inconveniences. Estimates of the smallest worthwhile effect are used by clinical trialists to inform the design and interpretation of randomised clinical trials. Chapter Five and Chapter Six present the protocol and the full report of a study designed to determine the smallest worthwhile effect of exercise programs designed to reduce the risk of falling among older people using these two approaches, the benefit-harm trade-off method and discrete choice experiments. We also sought to compare the estimates of the smallest worthwhile effect derived from the two different methods. A total of 220 older people were recruited for the discrete choice experiment study and a sub-sample of 66 patients also participated in the benefit-harm trade-off study. The results revealed that the average smallest worthwhile estimates calculated using the benefit-harm trade-off method and discrete choice experiments were 16% and 35% reduction in the risk of falling, respectively. The study also identified that approximately half of participants of the benefit-harm trade-off study, and over three quarters of those in the discrete choice experiment study reported they would choose not to participate in the exercise program presented to them in the interviews, even if they experienced maximum reduction in the risk of falling. This unexpected finding suggests that, regardless of the method used to elicit the smallest worthwhile effect, most older people do not consider the beneficial effects of exercise programs, including the average beneficial effect reported in meta-analyses of randomised controlled trials investigating exercise programs designed for older people to be worthwhile. It is possible that older people might be carrying somewhat unrealistic expectations of treatment effects or are still not convinced that they are at risk of falls.

Together, the studies presented in this thesis provide comprehensive information on facilitators and barriers to physical activity participation and evaluates the relative

importance older people place on various characteristics of exercise programs, including its benefits. Following the current view that patients' values and needs should remain central to the planning and development of health services, these findings can assist health professionals and policy makers in developing strategies to promote physical activity amongst the older population. In addition, when assessing the impact of patients' preference on the results of randomised trials, methodological limitations of the available evidence suggest that it might be too early to draw any definite conclusions. This thesis also advances the field of addressing the impact of patient's preference within randomised trials by providing guidance on how to move the field forward. Regarding the use of patients' perspectives to interpret the benefits of health interventions, this thesis compares two different methods for estimating the smallest benefit of exercise programs to prevent falls deemed worthwhile by older people. The results will assist in the interpretation of randomised trials and systematic reviews as well as the design of future randomised clinical trials in this area. A more detailed and broader understanding about older people's experiences and preferences, as presented in this thesis, can support a move towards advancing patient-centred healthcare and research in the field of physical activity and ageing.

Chapter One

Introduction

1.1 The ageing population: past, present and future estimates

Declining fertility and improved health and longevity have resulted in the accelerated pace of population ageing observed in the last century.¹ Population estimates from 2013 show that more than one-tenth of the world population or 841 million people are aged 60 years or over – an estimate four times higher than that observed in 1950, when 202 million people were older than 60.² Demographic projections based on current fertility and mortality data show that this number could reach 2 billion by 2050.² The older population is itself ageing. According to demographic projections, the number of people aged 80 years or over, also known as the "oldest old people", will be 392 million by 2050, three times higher than estimates from 2013.² Although the level and pace of population ageing vary across geographic regions, most countries are now experiencing a similar phenomenon.¹

Accordingly, the Australian population follows the world demographics and projections. In Australia, the number of people aged 60 years and over has increased from 2.6 million in 1950³ to around 4.4 million in 2013.⁴ By 2050, the Australian older population is projected to reach 10 million.⁵ While population ageing means, in a positive sense, a human story of increased longevity due to improved health, it also poses challenges. Ageing and overall population growth will, for instance, impact on the presence of diseases and degrees of functioning. In fact, a systematic analysis of the Global Burden Disease Study 2010 including data from 187 countries reports that, in general, the increase in life expectancy is strongly and positively associated with the number of years lost to disability.⁶ The high rate of disability as a consequence of ageing will have far-reaching implications for individuals, societies and health care systems.

1.2 Growing demand for aged health care services

An important challenge for the future is the increasing demand for health services in the primary, secondary and tertiary care for older people in the coming years. Data from primary care in Australia show that people aged 60 or older seek general practitioners' care more often than younger adults. For older Australians the average number of visits

is 8.6 per person, per year compared with an average of 4.0 visits for people aged under 65.⁷ The most common problems managed by general practitioners in the older population include chronic non-communicable diseases such as heart diseases, hypertension and diabetes.⁷

Non-communicable diseases are also the leading cause of deaths globally, accounting for 63% of all annual deaths.⁸ All age groups are affected by these conditions but three quarters of the global burden falls on those over 60.⁹ Most of non-communicable diseases, such as diabetes and hypertension, are projected to increase as population ages given that the prevalence of these conditions peaks at older ages.^{10,11} Nevertheless, in Australia, gains in life expectancy is associated with compression of disability, meaning that Australians are not only living longer but gained on average more years of life without severe or profound limitation.⁷ Yet older people often face some degree of disability in the last few years of life when the most health care costs are expected. For instance, those aged 85 years or over consume three times as much health care per person as those aged between 65 and 74, and twice as much as those 75 and 84.¹² Thus, the needs of an ageing population are likely to increase demand for health care services.

A retrospective analysis of presentations to public hospital emergency departments in Australia, between 1999 and 2009, revealed that the volume of presentations for older people more than doubled over the last decade.¹³ The increase in emergency department admissions is in accordance with data from a previous study,¹⁴ which found that older people are the main consumers of emergency ambulance services. For this age group, chest pain, breathing problems and falls were the most common reasons for emergency ambulance requests¹⁴ - falls also accounting for almost 73% of all injured-related hospitalisations among people aged 65 or older.¹⁵ The estimated cost of acute episodes of hospital care due to falls in Australia is about \$648.2 million.¹⁶

In general, falls account for 20-30% of injuries that require further medical attention¹⁷ and those who fall once are more likely to fall again.¹⁸ Importantly, falls are the leading cause of death among those aged 60 years and older from injuries such as those following severe lacerations, hip fractures and head traumas, resulting in a total of 312,000 deaths in 2010.¹⁹ This represents an increase of about 80% in the number of deaths in this age group over the last two decades.¹⁹ An important risk factor of falling

is frailty, which has been characterised by five criteria: unexplained weight loss, weakness, low activity, exhaustion and slowness.²⁰ Frailty increases vulnerability to functional decline, dependence, institutionalisation, hospitalization and death.²¹

Given projected trends in population ageing, the economic impact of noncommunicable diseases, fall-related injuries and frailty among older people are likely to increase.²²⁻²⁴ Implementation of prevention and management strategies specifically for this age group is therefore urgently needed. Physical inactivity is an important modifiable risk factor contributing to both non-communicable diseases and falls-related injuries and will be the focus of this body of work.

1.3 Physical inactivity and evidence-based physical activity recommendations for older adults

In recent years, physical inactivity has gained considerable attention worldwide. Physical inactivity has figured among the top ten risk factors for global disease burden in 2010 accounting for 3.2 million deaths and 2.8% of the total disability adjusted-life years across all age groups.²⁵ When analyses of the global burden of disease data are conducted specifically for those aged 60 years or over, physical inactivity remains ranked among the top ten risk factors for deaths and total disability adjusted-life years,¹⁹ suggesting that inactivity is an important health concern among the older population.

In the context of non-communicable diseases, physical inactivity is estimated to cause 6-10% of all deaths caused by type-2 diabetes, coronary heart disease, and breast and colon cancer.²⁶ Besides the direct contribution of physical inactivity to non-communicable diseases, it may also have substantial influence on obesity, high blood pressure and glucose levels, which are all considered to be leading risk factors for these diseases.²⁷ With regards to falls-related injury, physically inactive older adults has been reported to be a significant risk factor for falls with the overall falls risk (odds ratio [95% confidence estimate]) calculated at 1.37 [1.14 to 1.64], if compared to those who are physically active.²⁸ The impact of physical inactivity on falls includes increased muscle weakness (1.76 [1.31 to 2.37])²⁹ and balance impairments (1.98 [1.60, 2.46]).³⁰

In light of this evidence, physical inactivity has been identified the main public health concern of the 21st century.³¹ This scenario is even more problematic amongst the older population where, according to international estimates, around 45% of older people do not meet the recommended level of physical activity.³² The proportion is likely to be higher in older age groups. For instance, in Australia around 75% of those aged 75 and over are not sufficiently active to meet the recommended minimum level of physical activity.³³

Physical activity is defined as any body movement that is produced by the contraction of skeletal muscles and that increases energy expenditure.³⁴ Physical activity is often broadly interpreted to include activities ranging from structured exercise programs to incidental day-to-day physical activity. For the purpose of this thesis, the term physical activity will be used to refer to activities that fall into this broad category, including leisure time physical activity, transportation (for example, walking or cycling), occupational related physical activity, household chores, play, games, sports and planned or structured exercise.³⁵

The health benefits of regular physical activity for the general population are extensive. A major benefit of physical activity is that it is crucial in achieving a healthy ageing by both extending the number of years free of disability and reducing the number of years lived with disability.³⁶ The effectiveness of physical activity in preventing or mitigating functional limitations in older adults is also well established in the literature.^{37,38} In addition, there is strong evidence that physical activity significantly reduces the risk of developing a large number of chronic diseases highly prevalent in the older population and is effective in the treatment of these conditions.³⁴ Exercise interventions may also have a role in decreasing frailty.³⁹ Hence, physical activity has been incorporated into clinical practice guidelines for the management and prevention of cardiovascular diseases (e.g. peripheral vascular disease,^{40,41} coronary heart disease and hypertension⁴²), musculoskeletal disorders (e.g. osteoporosis⁴³ and osteoarthritis⁴⁴), chronic obstructive pulmonary disease⁴⁵ and endocrine-related conditions (e.g. obesity,⁴⁶ diabetes,⁴⁷ elevated cholesterol⁴⁸). Aspects of physical activity are also thought to be important in the management of other conditions, such as pain,⁴⁹ congestive heart failure,⁵⁰ syncope,⁵¹ stroke,⁵² back pain,⁵³ constipation,⁵⁴ dementia,⁵⁵

depression and anxiety.^{56,57} Finally, there is evidence that participation in physical activity is associated with reduced risk for clinical depression and anxiety as well as for dementia or cognitive decline.³⁴ Of particular importance to older adults, a recent Cochrane review found strong evidence for the prescription of structured exercise programs (i.e. group or home-based programs) to reduce rate of falls and risk of falling.⁵⁸ Appendix A of this thesis presents a synopsis and commentary on this Cochrane review. This review has a specific focus on the evidence from trials evaluating the effectiveness of exercise compared to control interventions.

The Global Recommendations on Physical Activity for Health guidelines developed by the World Health Organization (WHO) have a specific set of recommendations for adults aged 65 or older, which aims to improve cardiorespiratory and muscular fitness, bone and functional health, reduce the risk of non-communicable diseases, depression and cognitive decline in this age group.³⁵ These recommendations share similar principles from other important sources such as the position stand of the American College of Sports Medicine³⁴ and the recommendations on physical activity for health for older Australians of the Australian Government Department of Health and Ageing.⁵⁹ The WHO recommended levels of physical activity for older adults are as follows:³⁵

- 1. Older people should do at least 150 minutes of moderate intensity aerobic physical activity throughout the week, or do at least 75 minutes of vigorous intensity aerobic physical activity throughout the week or an equivalent combination of moderate and vigorous intensity activity. On an absolute scale, moderate intensity refers to activity that is performed at 3.0 to 5.9 times the intensity of rest and on a scale relative to an individual's personal capacity, moderate intensity physical activity usually refers to a 5 or 6 on a scale of 0-10. In comparison, vigorous intensity refers to activity that is performed at 6.0 or more times the intensity of rest on an absolute scale, and on a scale relative to an individual's personal capacity to an individual's personal capacity a 7 or 8 on a scale of 0-10.
- 2. Aerobic activity should be performed in bouts of at least 10 minutes duration.
- 3. For additional health benefits, adults aged 65 years and above should increase their moderate intensity aerobic physical activity to 300 minutes per week, or

engage in 150 minutes of vigorous intensity aerobic physical activity per week, or an equivalent combination of moderate-and vigorous-intensity activity.

- 4. Older people, with poor mobility, should perform physical activity to enhance balance and prevent falls on 3 or more days per week.
- 5. Muscle-strengthening activities should be done involving major muscle groups, on 2 or more days a week.
- 6. When older people cannot do the recommended amounts of physical activity due to health conditions, they should be as physically active as their abilities and conditions allow.

These WHO physical activity recommendations for older adults are similar to the WHO recommendations for younger adults, however the former has additional items specifically targeting vulnerable populations such as older adults with poor mobility as well as those presenting with health conditions that might prevent them from meeting the recommended levels.

1.4 Low uptake and adherence rate to physical activity

For the health benefits of physical activity to be fully realised, adherence to guidelineendorsed recommendations is crucial. Low adherence is a significant problem particularly for long-term treatment regimens that require lifestyle changes to achieve desirable health outcomes such as engagement in a physical activity regimen.⁶⁰ Findings from a recently published meta-analysis of randomised clinical trials investigating home exercise interventions for the prevention of falls in older adults show that less than a third of the participants (pooled proportion = 21%; 95% confidence interval: 15% to 29%) are fully adherent to their prescribed program.⁶¹ Low adherence continues to be a problem for older people discharged from physiotherapy and prescribed a home exercise program to maintain their function and prevent future falls.⁶² From a health policy perspective, non-adherence to long-term therapies severely compromises the effectiveness of treatment leading to excessive health care costs.⁶⁰ Therefore, policy makers and health professionals face the challenge of further engaging older people in the commencement of and ongoing adherence to physical activity.

1.4.1 Older people's perspectives on barriers and facilitators to physical activity

To better understand low physical activity adherence rates, policy makers and health professionals need to consider older people's experiences, beliefs and attitudes toward engagement with physical activity. Qualitative research can identify a range of facilitators and barriers to physical activity participation which could be used to inform effective strategies to increase program uptake and sustain adherence over time. Although a number of qualitative studies have been conducted in this area, to our knowledge there have been no efforts to systematically summarise and synthesise the findings from these studies.

In comparison with single qualitative studies, systematic reviews of qualitative studies offer a more complete contribution to knowledge by incorporating information from a range of perspectives across different contexts. More importantly, the results of these systematic reviews can be used to inform health-related policy and practice so that the experiences, preferences and needs of patients remain central to any discussion regarding treatment and/or service redesign.^{63,64}

Chapter Two of this thesis presents a systematic review of qualitative studies describing the experiences and perceptions of older people in the general community on the benefits and barriers of physical activity participation; with a view to guide strategies to promote and sustain active lifestyles.

1.5 Patients' preferences for health care

Consideration of patients' or consumers' preferences and values has traditionally been undertaken in qualitative studies. However, patient and consumer preferences are increasingly being assessed using quantitative approaches. Patients' preferences play a crucial role in two important paradigm shifts in the health care field: the moving from a model of care based solely on clinical experience towards what is known as Evidence-Based Medicine or more recently Evidence-Based Health; and the moving from a paternalistic model of care towards a model of Shared Decision Making.⁶⁵ Since the early papers outlining Evidence-Based Medicine, patients' preferences were recognised as an essential component.⁶⁶ According to this model, health professionals are encouraged to integrate their patients' preferences and their clinical expertise with the best available evidence when making clinical decisions.⁶⁷ A similar recognition has been seen in the so-called model of Shared Decision Making. The underlying principle in this context is to empower patients to express their preferences, to ask questions and to participate actively in the decisions about their health.⁶⁸ As interest in both these models - Evidence-Based Medicine and Shared Decision Making – has increased considerably among the health-care research community in the last two decades, the number of quantitative research studies investigating patients' preferences in this area has followed a similar trend.

In general, research on patients' preferences and health-related outcomes typically fall within two broad categories: preference for modes of healthcare delivery and preference for specific treatments and outcomes.⁶⁹ Preference for modes of healthcare delivery is associated with patients' preference for the amount and kind of information they receive from clinicians, involvement in decision-making and the clinician's style of communication. Preference for treatments and outcomes rely on the idea that a patient's desire for a particular treatment is often based on a belief or hope that more favourable outcomes are associated with that treatment.⁷⁰

1.5.1 Patients' preferences in randomised trials

Randomised controlled trials have become the method of choice for determining the effects of health interventions. One factor often neglected by clinical trials but with the potential to influence their findings is patients' preference for treatment. Although patients are often seen as passive recipients of interventions, many patients may have preferences for treatments under evaluation. Their preference for treatment may reflect, for instance, what has worked best for them in the past. Thus, it may be reasonable to consider that their preference could influence treatment outcomes.

Specific study designs, including the comprehensive cohort, the Wennberg and Rucker designs have been developed to evaluate the impact of patients' treatment preferences in clinical trials.⁷¹ These designs have in common the inclusion of "preference arm(s)"

in which participants are allowed to choose their preferred treatment in addition to the "randomised arm(s)" to which participants are randomly allocated.^{71,72} One limitation of these designs is that, comparisons between preference and randomised arms might be biased due to consistent baselines differences between both arms as randomisation is often breached.⁷³ One possible way to overcome this problem is to use randomised controlled trials in which participants' preferences are collected before randomisation and their impact on results is evaluated in statistical analyses.^{74,75}

The rationale within randomised trials is that patients who are allocated to their preferred treatment may be more motivated to adhere to treatment, resulting in better outcomes.⁷³ The opposite would happen with those patients allocated to their non-preferred treatment, leading to worse outcomes.⁷⁶ This rationale is more relevant for randomised trials in which patients are unblinded or where blinding cannot be maintained and therefore, participants are aware of whether they are receiving their preferred or non-preferred treatment.⁷⁷ This is often the case for randomised trials investigating conservative treatments for musculoskeletal conditions.

Musculoskeletal conditions affect approximately 30% (range, 14-47%) of the population and the prevalence increases with age.^{78,79} Common musculoskeletal problems, such as osteoarthritis and spine-related pain are associated with decreased quality of life and increased costs.^{80,81} As the efficacy of interventions for managing musculoskeletal pain and disability has been reported to be only small to moderate,⁸²⁻⁸⁴ preference for treatment may have a role in optimising treatment effects.

Chapter Three of this thesis describes a systematic and critical review of patients' preference within randomised clinical trials evaluating treatments for musculoskeletal conditions. Unfortunately few studies of patients' preferences have specifically targeted older participants. Hence, the review presented in Chapter Three encompasses trials on preference of adults in all age groups.

1.5.2 Eliciting patients' preferences using discrete choice experiments

In the past few decades there has been increasing recognition of the importance of involving health care consumers in the design of health policy and health research.⁸⁵⁻⁸⁷ Patients bring valuable insights into the real costs and benefits of treatment that may be overlooked by researchers and clinicians.⁸⁶ Accordingly, there has been a growing interest in the development of methods for measuring patients' preferences in health care research. A number of these methods involve assessing patients' stated preferences for a service or good. Stated preferences are the preferences that respondents express when presented with hypothetical choices; this contrasts with revealed preferences which are preferences that manifest as choices made in a real market setting.⁸⁸ Stated preference methods have been widely used in market research, transport and environmental economics research, and more recently have been used to elicit patients' preferences of preference relationships between doctor and patient, and preferred outcomes.

Methods used to assess stated preferences include, for instance, the discrete choice experiments, that has strong grounding in economic theory⁸⁹ and has become a popular tool for eliciting preferences in relation to the delivery and outcomes of health care.^{90,91} Discrete choice experiments involve an analysis that quantifies the relative importance of various attributes and how much they contribute collectively to decision-making. Participants are presented with a number of choice scenarios in which they are asked to choose the most preferred option from a choice set, generally containing two or more alternatives.⁹¹ Studies using this method have been previously performed in a wide range of health conditions.⁹²⁻⁹⁴

1.5.2.1 Eliciting older people's preferences for exercise programs

The qualitative systematic review presented in Chapter Two has identified a list of attributes of exercise programs, such as costs, duration and frequency, perceived as important by older people when deciding whether or not to engage in exercise programs. Although this type of systematic review can provide an understanding of

patient perceptions about their experiences, it does not allow the estimation of the relative importance of particular attributes of exercise programs. To supplement qualitative findings and to quantify the value older people attach to different attributes or their preferences for specific attributes, quantitative methods such as discrete choice experiments can be used.⁹⁵

The best-worst scaling is a variation of the widely applied discrete choice experiments,^{96,97} which provides richer information on relative preferences between alternatives with relatively higher statistical efficiency due to the larger amount of choice data.⁹⁸ Briefly, in the best-worst scaling approach, participants are presented with choice scenarios one at a time that require choices to be made within scenarios rather than between scenarios as in the traditional discrete choice experiment. This approach allows participants to choose the best and the worst features (attribute levels) through a series of hypothetical but plausible choice scenarios.⁹⁶

The study presented in Chapter Four used the best-worst scaling approach to explore older people's preferences in relation to characteristics of exercise programs, and to examine the relative value placed on particular attributes.

1.6 Older people's perspective on the smallest worthwhile effect of exercise programs: implications for interpretation and design of randomised trials

Systematic reviews of randomised trials provide substantial evidence that well-designed interventions are effective to improve mobility and to reduce the risk of falls in older people.^{58,99} Although there is a high degree of consensus that evidence from systematic reviews of randomised trials are necessary to guide implementation of most health interventions, it cannot be used as the sole basis of decision-making. In accordance with Evidence-Based Medicine and Shared Decision Making principles, whether the statistically significant effects of exercise programs derived from systematic reviews are clinically relevant or not should ideally be interpreted by older people themselves, those directly benefited from it.

Discussion regarding interpretation of results from single trials or systematic reviews based on clinical relevance rather than statistical significance started in the medical literature with the concept of the Minimal Clinically Important Difference. In 1989, researchers from the McMaster University in Ontario, Canada, defined the Minimal Clinically Important Difference as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troubling side effects and excessive cost, a change in the patient's management".¹⁰⁰ Since then, this term has been adopted, adapted and discussed by different research groups¹⁰¹⁻¹⁰³ and for a range of health conditions and treatment approaches. The concept also referred to as the smallest worthwhile effect of interventions¹⁰² has important implications for the design of controlled trials as these estimates inform sample size calculations; as well as the interpretation of the clinical significance of their findings.

It has been advocated that estimates of the smallest worthwhile effect must satisfy three criteria: it should be intervention-specific; it must focus on the effects of intervention (between-group differences); and, above all, it must be based on patients' perspective.¹⁰² Among the existing methods used to estimate the smallest worthwhile effects, the benefit-harm trade-off has been identified as one that satisfies all three criteria and has emerged from the contingent valuation method. While the contingent valuation method allows to directly estimate the value participants assign to goods and services, usually measured in monetary terms (e.g. as willing to pay for a health interventions),¹⁰⁴ the benefit-harm trade-off method aims to ascertain the smallest benefit of intervention, in non-monetary terms, considered to be worthwhile. Within the benefit-harm trade-off method, participants are presented with a series of scenarios that differ in just one attribute, which is the hypothetical size of the effect of intervention. while other attributes are fixed.^{105,106} For example, participants are initially presented to a scenario including features of exercise programs, such as costs, frequency and travel time, at fixed levels. Participants are then asked if they would find that specific program, given its costs, frequency and travel time, worthwhile, if they experienced treatment effects of varying magnitudes (e.g. 20%, 40% or 60% improvement in their mobility). The smallest treatment effect considered to be worthwhile is the smallest worthwhile effect for that participant. This method has been previously used in different health conditions, such as common cold,¹⁰⁷ low back pain,¹⁰⁶ leg ulcers¹⁰⁸ and breast cancer.¹⁰⁹

The discrete choice experiment⁹¹ is another method that fulfils these criteria but with the advantage that participants are presented with a number of hypothetical scenarios that vary in more than one attribute, allowing the investigation of how people value multiple attributes and the trade-offs they are willing to make between them. For instance, the hypothetical size of the effect of the intervention (e.g. improvements in mobility) as well as varying levels of exercise frequency, costs and types of transport available are presented to participants across different scenarios. Participants are then asked to choose what they are doing at the moment or the exercise program described. In clinical practice, the smallest worthwhile effect of health interventions is likely to depend on the levels of different attributes, for instance how much the intervention would cost and the magnitude of risks and inconveniences.

Chapter Six of this thesis presents the results of a study designed to determine the smallest worthwhile effect of exercise programs designed to prevent falls among older people using two different methods, the benefit-harm trade-off and discrete choice experiments. The protocol for this study is described in Chapter Five.

1.7 Aims of the thesis

The broad aim of this thesis was to contribute to a better understanding of the role of older people's perspectives and preferences for health interventions with a special focus on physical activity interventions. The specific aims of the studies that make up this thesis were to:

- perform a systematic review of qualitative studies to summarise the experiences and perceptions of older people towards participation in physical activity (Chapter Two).
- systematically and critically review how patients' preferences have been measured and analysed in randomised clinical trials evaluating musculoskeletal conditions (Chapter Three).

- 3. examine the relative value older people place on particular features of exercises programs using the best-worst scaling method (Chapter Four).
- 4. to determine the smallest worthwhile effect of exercise programs designed to prevent falls among older people, and to compare these estimates using two different methods: the benefit-harm trade-off method and discrete choice experiments (Chapter Five and Chapter Six).

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Chapter Two

Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature

Chapter Two is published as:

Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, Ferreira ML. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. *Br J Sports Med.* 2015 [Epub ahead of print].

Statement from co-authors confirming authorship contribution of the

PhD candidate

As co-authors of the paper "Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature", we confirm that Marcia Franco has made the following contributions:

- Conception and design of the research
- Development of the search strategy and study selection
- Data extraction, analysis and interpretation of the findings
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Review

Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature

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ABSTRACT

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/ bjsports-2014-094015).

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Accepted 29 December 2014

Background Physical inactivity accounts for 9% of all deaths worldwide and is among the top 10 risk factors for global disease burden. Nearly half of people aged over 60 years are inactive. Efforts to identify which factors influence physical activity behaviour are needed. **Objective** To identify and synthesise the range of barriers and facilitators to physical activity participation. Methods Systematic review of gualitative studies on the perspectives of physical activity among people aged 60 years and over. MEDLINE, EMBASE, CINAHL, PsychINFO and AMED were searched. Independent raters assessed comprehensiveness of reporting of included studies. Thematic synthesis was used to analyse the data.

Results From 132 studies involving 5987 participants, we identified six major themes: social influences (valuing interaction with peers, social awkwardness, encouragement from others, dependence on professional instruction); physical limitations (pain or discomfort, concerns about falling, comorbidities); competing priorities; access difficulties (environmental barriers, affordability); personal benefits of physical activity (strength, balance and flexibility, self-confidence, independence, improved health and mental well-being): and motivation and beliefs (apathy, irrelevance and inefficacy, maintaining habits).

Conclusions Some older people still believe that physical activity is unnecessary or even potentially harmful. Others recognise the benefits of physical activity, but report a range of barriers to physical activity participation. Strategies to enhance physical activity participation among older people should include (1) raising awareness of the benefits and minimise the perceived risks of physical activity and (2) improving the environmental and financial access to physical activity opportunities.

INTRODUCTION

Physical inactivity is responsible for 9% of all deaths worldwide.¹ In the 2010 Global Burden of Disease Study, physical inactivity was among the top 10 risk factors for global disease burden accounting for 3.2 million deaths and 2.8% of the total disability adjusted-life years.² Inactivity is a pandemic condition, with far reaching health, economic, environmental and social consequences.³

Despite the well-known benefits of physical activity, 30% of the world's population fails to reach the levels of physical activity recommended for health benefits.⁴ The situation is even more critical with increased age as around 45% of people aged over 60 do not meet the recommended level of physical activity.⁴ The proportion of those who do not meet the recommended guidelines increases to 75% for those aged 75 and over.⁵ This is a rapidly increasing problem as the number of people aged over 65 years in the world is expected to triple in the next 30 years.⁶ Given this projected trend in population ageing, older people's engagement with physical activities is a public health concern worldwide. Several countries^{7–9} as well as the WHO¹⁰ have issued physical activity guidelines with recommendations specifically for older adults (see box 1).

Older people's engagement with physical activities can be influenced by behavioural factors, such as motivation and personal beliefs, as well as environmental factors, including availability of public transport and exercise venues. Qualitative research

Box 1 Recommended levels of physical activity for older adults (adapted from WHO global recommendations on physical activity for health⁹)

- Older people should do at least 150 min of ► moderate-intensity aerobic physical activity throughout the week or do at least 75 min of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate-intensity and vigorous-intensity activity.
- Aerobic activity should be performed in bouts ► of at least 10 min duration.
- For additional health benefits, adults aged ► 65 years and above should increase their moderate-intensity aerobic physical activity to 300 min per week, or engage in 150 min of vigorous-intensity aerobic physical activity per week, or an equivalent combination of moderate-intensity and vigorous-intensity activity.
- Older people, with poor mobility, should ► perform physical activity to enhance balance and prevent falls on 3 or more days per week.
- Muscle-strengthening activities should be done involving major muscle groups, on 2 or more days a week.
- When older people cannot do the recommended amounts of physical activity due to health conditions, they should be as physically active as their abilities and conditions allow.

To cite: Franco MR, Tong A, Howard K, et al. Br J Sports Med Published Online First: [please include Dav Month Yearl doi:10.1136/bjsports-2014-094015

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can provide better understanding of older people's experiences, beliefs and attitudes towards participation in physical activities and help us translate the strong evidence of benefits of physical activity into practice.¹¹ Previous reviews focusing on specific ethnic groups^{12–14} or programmes to prevent falls¹⁵ have been undertaken in this area, but the inclusion of a targeted population or physical activity type has limited the generalisability of results.

To guide policy for a broad range of community programmes focusing on the promotion and sustainability of active lifestyles, we conducted a comprehensive synthesis that included the perspectives of older people on physical activity. We investigated whether participants' views differed according to type of physical activity investigated. To increase programme uptake and sustain adherence over time at a population level, it is necessary to identify facilitators and barriers to physical activity that are common across different contexts. Such factor can then inform effective population-wide physical activity policies and strategies.

METHODS

We followed the Enhancing Transparency of Reporting the Synthesis of Qualitative research (ENTREQ) framework. ENTREQ is a framework for reporting systematic reviews and syntheses of primary qualitative research. ENTREQ consists of 21 reporting items grouped into five domains: introduction, methods and methodology, literature search and selection, appraisal of included studies, and synthesis of the findings.¹⁶

Search strategy and selection criteria

Comprehensive searches were conducted in MEDLINE, EMBASE, CINAHL, PsychINFO and AMED from inception until 14 June 2013. The search strategies are provided in the online supplementary appendix table S1. We also searched reference lists of relevant studies. The search was restricted to studies published in English, Spanish and Portuguese. Qualitative studies published in peer-reviewed journals that explored older people's perspectives on physical activity were included. Studies were included if all participants were at least 60 years of age, or if the mean reported age of participants was 60 years or over. We considered physical activity to include a range of domains such as leisure, sport, transport and household activity as well as structured exercise programmes. Studies investigating physical activity in a population with a specific health condition (eg, coronary heart disease, diabetes) were considered ineligible because people with particular conditions are likely to have perspectives on physical activity that are unique to that condition and less applicable to the general older population. Structured surveys were excluded. Two independent reviewers (MRF and RZP) screened the titles and abstracts, discarded those that did not meet the inclusion criteria and evaluated full-text versions of potentially relevant studies for eligibility.

Comprehensiveness of reporting

Comprehensiveness of reporting of each primary study was assessed using the consolidated criteria for reporting qualitative research (COREQ) framework, which includes three domains: research team and reflexivity (acknowledgement of the role and influence of the researcher on the research process); study methods; and data analysis and reporting.¹⁷ Assessment of reporting allows readers to assess the trustworthiness and transferability of the study findings to their own setting.¹⁸ Two independent reviewers (MRF and RZP) assessed each study and resolved any disagreements by discussion.

Data synthesis and analysis

We used thematic synthesis to synthesise the findings.¹⁸ Participant quotations and text under the 'results' or 'findings' sections from each study were entered verbatim into HyperRESEARCH V.2.8.3 (ResearchWare Inc., Randolph, Massachusetts, USA) software. One reviewer (MRF) performed line-by-line coding of the findings of the primary studies and recorded concepts on the older adult perspectives on physical activities. Translation of concepts across studies was then performed by grouping similar concepts and creating new ones when necessary. All included studies were re-read to ensure that relevant data were captured and appropriately integrated into preliminary themes and subthemes. All authors reviewed the preliminary analysis to ensure that key data were captured from included studies; and discussed concepts for similarities and differences.¹⁹ An analytical thematic schema was also developed to extend the findings of primary studies, by identifying conceptual links across themes and using mind mapping software Freemind V.0.9.0 Beta 14 (Source-Forge Inc., Mountain View, California, USA).

We also conducted a stratified analysis to investigate whether the themes and their subthemes differed according to type of physical activity. The type of physical activity investigated in the included studies was categorised into three groups: structured exercise programmes, other forms of physical activity or combination of both (ie, structured exercise programmes and other types of physical activity). When a study clearly referred to a subset of physical activity considered to be planned, structured and repetitive for the purpose of conditioning any part of the body, the study was categorised as structured exercise programme. Exercise programmes for falls prevention, yoga, Tai Chi, line dancing, walking groups and programmes that incorporated different types of training such as strength, balance, aerobic and/or flexibility were considered as structured exercise programmes. When a study clearly referred to physical activities other than structured exercise programmes, such as household activities, walking for leisure or transport, other forms of active transport, running and other leisure-time physical activities, the study was categorised as other types of physical activity. When a study referred to any type of physical activity, the study was categorised as a combination of structured exercise programmes and other types of physical activity. Our stratified analysis compared themes and subthemes between structured exercise programmes and other types of physical activity.

RESULTS

Literature search results

In total, 132 studies involving 5987 participants were included (figure 1). Characteristics of included studies are described in the online supplementary appendix table S2. The mean age reported among included studies ranged from 60 to 89 years. The studies were conducted in 24 countries with most conducted in the USA (42%), UK (14%) and Canada (14%). Twenty-four studies (18%) restricted participant inclusion to indigenous or immigrant populations (eg, Korean and Vietnamese immigrants living in the USA; South Asians living in England). In the majority of included studies (85%), participants were considered community dwellers. Fewer studies (15%) from long-term included participants care facilities, assisted-living facilities and hospitals. Sixty-one studies (46%) investigated specifically structured exercise programmes, such as exercise for falls prevention, strength training, yoga and walking groups, whereas 22 studies (17%) focused on other types of physical activities, such as walking and leisure-time physical



Figure 1 Search process and results.

activities. The remaining 48 studies (37%) covered other types of physical activities as well as structured exercise programmes. Table 1 provides detailed information on the studies that reported on each subtheme. This information is also shown stratified by different types of physical activity. The majority of included studies (98%) used focus groups or interviews to collect data.

Comprehensiveness of reporting

The comprehensiveness of reporting varied across studies, and ranged from 2 to 15 of the 18 items of the COREQ framework being reported (see online supplementary appendix table S1). More than 85% of the included studies reported the participant selection strategy, audio/visual recording, and provided participant quotations. Less than 30% of studies reported on data saturation, use of software and participants' feedback given on preliminary findings.

Synthesis

We identified six major themes reflecting older people's perspectives on physical activity: social influences; physical limitations; competing priorities; access difficulties; personal benefits of physical activity; and motivation and beliefs. These major themes and their subthemes are discussed below. Selected quotations to illustrate each subtheme are provided in table 1. Figure 2 shows the thematic schema we developed to illustrate the inter-relationships between the themes.

Social influences

Valuing interaction with peers

Participants from 84 (64%) studies valued the social contact and enjoyed seeing familiar faces or neighbours when performing physical activities, or preferred group-based activities as they could gain a sense of belonging, enjoyment and establish friendships, and reported that this motivated them to continue with the activity. Some participants, especially men, appreciated friendly and fair competition. Good rapport with instructors also motivated participants to continue exercising in a group.

Social awkwardness

In 29 (22%) studies, participants reported a lack of confidence in social settings and were apprehensive about meeting others, particularly in group-based physical activities that involve people of different ages, gender, physical capabilities or cultural backgrounds. Some felt more self-conscious and intimidated in a group that also included younger people, and felt unable to keep up with those who could exercise at a more advanced level. The perceived pressure to keep pace with the class and complete the exercise routines led to a sense of incompetence and disconnection from others. Moreover, participants from ethnic minority groups suggested cultural sensitivity should be considered when promoting physical activity. For example, some Muslim women would not exercise in groups with men due to religious practices requiring gender segregation.

Encouragement from others

In 82 (62%) studies, participants considered support from others to be essential. Support included verbal encouragement, practical help (transportation) or purchased exercise equipment (pedometer, bike) provided by friends and family. Some participants, particularly those who felt more vulnerable, were reluctant to start physical activities without advice from health professionals. Others felt confident, but reported participation in physical activities to be difficult due to the lack of encouragement or overprotectiveness from others who participants thought were unnecessarily concerned for their safety.

Review

Table 1 Illustrative	quotations and references reporting each subtheme		
Themes and subthemes	Participants quotations from primary studies (reference number*)	N (%)	Reference number of studies reporting each subtheme: stratified analysis by type of physical activity*
Social influences			
Valuing interaction with peers	'I make friends and I enjoy my food after the class. It's also a social thing; we catch up with news from others. It's just like a big family.' (33) 'I wanted to be able to do somethingwith other peopleI mean swimming they say is very good exerciseI love swimming but then that is an individual sort of thing and I wanted to do something with another group of people so that you had the social side of it.' (7)	84 (64)	Structured exercise: 5, 6, 10, 16, 24, 27, 33–35, 38, 39, 43, 48, 50, 53, 55, 56, 58, 59, 66, 67, 74, 80, 83, 88–90, 92, 100, 102, 105, 111, 112, 114, 117, 119, 120, 122, 124, 125, 131, 132 Other types of physical activity: 36, 37, 47, 49, 52, 60, 70, 82, 109, 113, 118, 128 Structured exercise and other types of physical activity: 7, 8, 11, 12, 15, 28–30, 40, 45, 57, 62, 65, 68, 73, 75–77, 79, 84–86, 91, 94, 96, 97, 110, 116, 123, 127
Social awkwardness	'I started classes but they were too fast. I was the oldest one and everyone else was youngerandthe rec center which is a lot of younger people who do not share the same kinds of needs that we do. Kinda hard to race an 18-year-old, you know.' (127) 'I just think that maybe there's a male ego thing involved a little bit, but the guys like to be with the guys. Not that they don't love women but they'd rather be in an all-male classYou can get away with anything that you want. If you make a mistake or if you do something that's a little embarrassing, it's not embarrassing when you're with other men because the same things happen to them, whereas in a mixed class they would probably feel uncomfortable.' (38)	29 (22)	Structured exercise: 27, 33, 34, 38, 66, 80, 83, 90, 100, 114, 119, 130, 132 Other types of physical activity: 49 Structured exercise and other types of physical activity: 7, 8, 17, 18, 26, 29, 65, 68, 73, 75–77, 85, 86, 127
Encouragement from others	'My son told me that the only thing I should do now is taking good care of myself and exercising everyday. He bought a stationary bicycle for me to use at home.'(79) 'The doctor said that I had to do exercises otherwise I would end up in a wheelchair, and I did the exercises, but I didn't really like it, it was hard. But he says if you don't do exercise you'll end up in a wheelchair, and if you hear the results of not doing it, you'd better do it!' (120)	82 (62)	Structured exercise: 3, 13, 16, 22, 24, 27, 33, 34, 39, 48, 50, 53, 55, 56, 58, 67, 74, 78, 88–90, 102, 106, 111, 112, 119, 120, 122, 124, 125, 130, 132 Other types of physical activity: 2, 21, 36, 37, 47, 49, 52, 54, 60, 69, 70, 98, 109, 113, 128 Structured exercise and other types of physical activity: 1, 8, 11, 12, 15, 17, 18, 20, 28, 29, 31, 32, 40, 45, 46, 57, 62, 64, 65, 68, 71–73, 75, 77, 79, 84, 91, 94, 96, 108, 116, 121, 126, 127
Dependence on professional instruction	'We would like a class here at the centre where everyone knows everyone else and feels comfortablebut we don't have a leader and we need to know what's safe for older people with different health problems.' (15) 'We have had good people teaching this. They had a super team and there isn't one of them who has not been nice to us you know and they're great, all of them have been super. It all helps doesn't it? If you get someone—an instructor—someone who you didn't like, he was bit nasty, you wouldn't want to come would you. When they are all so nice and welcoming they bring out the best in you. hopefully.' (45)	40 (30)	Structured exercise: 6, 16, 22, 27, 34, 35, 38, 41, 48, 56, 80, 83, 90, 100, 102, 103, 105, 111, 112, 114, 120, 124, 125, 130, 132 Other types of physical activity: 70 Structured exercise and other types of physical activity: 1, 11, 15, 29, 40, 45, 64, 68, 73, 85, 91, 94, 110, 127
Physical limitations	jou, nopelanji (15)		
Pain or discomfort	'I used to perform callisthenics every morning, but it resulted in muscle ache. It made me so uncomfortable. So, I stopped doing it. Maybe I am too old to be active. It seems that nothing is suitable for my growing old body.' (26) 'I had to stop a few times because it was too strenuous for me. Holding things up really tired my arms and I couldn't do it'. (12)	45 (34)	Structured exercise: 3, 6, 13, 14, 16, 55, 56, 59, 61, 78, 80, 83, 92, 93, 95, 100, 102–105, 111, 131, 132 Other types of physical activity: 113 Structured exercise and other types of physical activity: 1, 11, 15, 17, 18, 26, 30, 31, 40, 68, 76, 79, 85, 86, 91, 94, 96, 97, 108, 121, 123
Concerns about falling	'My ageing body degenerates. I even have the problem in keeping balance. It would be better not to do any physical activities. I could get injured.' (26) 'Yes it would motivate me [to perform exercise for fall prevention] by falling it has frightened me and that prevented me going to do exercise because I thought I might fall again.' (63)	37 (28)	Structured exercise: 10, 22, 33, 58, 61, 63, 67, 78, 80, 93, 132 Other types of physical activity: 52, 54, 81, 82, 109, 113 Structured exercise and other types of physical activity: 8, 11, 12, 18, 26, 28–30, 40, 71, 73, 76, 79, 85, 94, 97, 108, 123, 126, 127
Comorbidities	'Well to me it also helps to know that other people don't do stuff because of incontinence.'(85) 'I have a real bad dizziness problem. It bothers me all the time. I feel uncomfortable, so I don't have the mood to participate in activities.' (26)	74 (56)	Structured exercise: 3, 13, 24, 25, 27, 33, 34, 39, 50, 53, 55, 59, 61, 63, 74, 78, 80, 83, 88, 92, 105, 106, 111, 117, 120, 122, 124, 131, 132 Other types of physical activity: 2, 21, 36, 37, 49, 54, 60, 69, 70, 109, 113, 129 Structured exercise and other types of physical activity: 1, 4, 8, 11, 12, 15, 18, 23, 28–32, 40, 46, 57, 64, 68, 71, 73, 75–77, 79, 85, 91, 94, 96, 97, 110, 121, 126, 127
			Continued

Themes and subthemes	Participants quotations from primary studies (reference number*)	N (%)	Reference number of studies reporting each subtheme: stratified analysis by type of physical activity*
Competing priorities	'and doing what I need to do for [husband]he has plenty of appointmentsso I've come to the conclusion that there isn't much time to do anythingyou always put yourself second don't you?' (34) 'My day is busy I don't have time to be bored, and it's hard sometimes to coordinate and that's why I had to stop um classes because it was pick-up time to drive out there and (pick-up the grandchildren), so I have trouble trying to fit classes around duties.' (68)	53 (40)	Structured exercise: 3, 5, 13, 16, 22, 24, 34, 39, 42, 50, 53, 56, 67, 74, 78, 93, 102, 105, 119, 132 Other types of physical activity: 21, 49, 54, 70, 115, 129 Structured exercise and other types of physical activity: 1, 8, 11, 15, 17, 23, 28, 29, 30, 32, 40, 45, 65, 68, 71–73, 75, 77, 79, 85, 86, 94, 101, 121, 126, 127
Access difficulties			
Environmental barriers	'I hate to ask people that I know to drive me, and so even from here to there, it's a bitch. That's my first thought, how am I going to get there? Then I put it out of my mind because I cannot go.' (19) 'You see, the living space is very limited here. There are no places for me to perform physical activity. Most residents just like me, the only thing we can do is to sit the whole day and feel bored.' (26)	72 (55)	Structured exercise: 3, 10, 19, 22, 24, 27, 33, 34, 42, 48, 58, 61, 78, 83, 92, 93, 102, 106, 112, 114, 119, 120, 125, 130, 132 Other types of physical activity: 2, 36, 37, 47, 51, 52, 54, 69, 70, 81, 82, 87, 99, 113, 115 Structured exercise and other types of physical activity: 1, 4, 8, 9, 11, 15, 17, 18, 20, 26, 28, 29, 31, 57, 62, 64, 68, 71, 73, 75–77, 79, 84–86, 91, 94, 108, 110, 126, 127
Affordability	'She [the physiotherapist] gave me an exercise programme. I use it every dayI would like to join a training centre in town, but with my income I have to look wistfully at that' (42) 'I would like to be involved with all of us. You know, in, in one placeIf we could afford it. Right now, I can't afford to go to the gym.' (85)	32 (24)	Structured exercise: 10, 22, 27, 34, 42, 58, 66, 67, 92, 102, 103, 105, 112, 114, 125 Other types of physical activity: 60, 70 Structured exercise and other types of physical activity: 7, 8, 17, 18, 28, 29, 31, 57, 68, 72, 85, 91, 96, 126, 127
Personal benefits of exer	cise		
Strength, balance and flexibility	'I chose to do it [exercise]and I chose it because when I was going to start walking, after mostly sitting for a year, I didn't have any balance. I didn't want to remain sitting.' (33) 'I'm more contented with my own self. It's every time I've been and I walk back across that yard I feel that I've achieved something that I've got a little bit stronger I'm more flexible. I'm not a failure. That's the way I feel about it.' (45)	69 (52)	Structured exercise: 5, 6, 10, 13, 14, 16, 19, 27, 33–35, 42–44, 55, 58, 59, 63, 66, 80, 83, 88, 92, 95, 100, 102–107, 111, 112, 117, 119, 120, 122, 124, 130–132 Other types of physical activity: 54, 60, 70Structured exercise and other types of physical activity: 7, 8, 18, 23, 28–32, 40, 45, 57, 65, 68, 71, 76, 85, 94, 97, 101, 108, 110, 116, 121, 123
Self-confidence	'But mainly, as I say, mainly to give you confidence. I mean as you get older you get scared especially if you fall over. I mean you think you're alright, then you don't, you know? And I mean most of the people there seemed to be pretty fit, reasonably fit, you know, but as I say, it's made a difference by um, or the main thing is giving you more confidence which is a really big thing, you know, a really big thing.' (5) 'Your self-confidence is reinforced when you come here. The sense of well-being and ability and you can do things. Sometimes I forget I'm 86 years old.' (27)	23 (17)	Structured exercise: 5, 27, 34, 35, 42, 56, 59, 80, 83, 88, 89, 100, 102, 114, 119, 131, 132 Other types of physical activity: 70 Structured exercise and other types of physical activity: 12, 28, 32, 65, 110
Independence	'I was willing to do anything that would enable me to carry on living as I was at the time—independently—being able to do my shopping, looking after myself, that was a huge motivation.' (132) 'While I don't aspire to be long lived, I do aspire to stay on my feet for as long as I live' (36)	26 (20)	Structured exercise: 27, 33, 35, 43, 50, 55, 58, 59, 95, 100, 120, 132 Other types of physical activity: 21, 36, 37, 54, 113 Structured exercise and other types of physical activity: 28, 65, 72, 75, 76, 86, 94, 110, 123
Improved health and mental well-being	'Physical fitness keeps you mentally alert and helps you face the day better.' (86) 'I like my shapeI was a little bit chubby, and then I kept walking and then one time I saw myself in the mirror and I said, "My God, oh my God." I said, I like the way I look, I am going to keep walking.' (20)	103 (78)	Structured exercise: 3, 5, 6, 10, 13, 14, 16, 22, 24, 27, 33–35, 39, 42, 43, 48, 50, 53, 56, 59, 67, 74, 80, 83, 88–90, 92, 100, 102, 103, 105– 107, 111, 112, 114, 117, 119, 120, 122, 124, 125, 130–132 Other types of physical activity: 21, 36, 37, 49, 52, 54, 60, 69, 70, 87, 98, 109, 113, 118 Structured exercise and other types of physical activity: 1, 7–9, 11, 12, 15, 18, 20, 23, 28–32, 40, 45, 46, 57, 62, 65, 68, 71–73, 75–77, 79, 85, 86, 94, 96, 97, 101, 108, 110, 116, 121, 123, 126, 127
Motivation and beliefs Apathy	'I hate getting started. I just don't feel like it some days. Laziness!' (78) 'I know all the theory about keeping fit and healthy, and healthy heart and healthy eating and all the rest of it. Keeping as far you can this sort of the muscles in the body supple, so I know all the reasons to do thatIt's not through lack of awareness it's just lack of inclination.' (7)	52 (40)	Structured exercise: 3, 5, 10, 13, 19, 22, 27, 33, 34, 41, 50, 53, 61, 67, 78, 80, 93, 112, 119, 132 Other types of physical activity: 37, 54, 69, 113 Structured exercise and other types of physical activity: 1, 7–9, 11, 15, 17, 18, 26, 28–32, 40, 46, 68, 71, 73, 75, 77, 79, 94, 97, 121, 123, 126, 127

Continued

Themes and subthemes	Participants quotations from primary studies (reference number*)	N (%)	Reference number of studies reporting each subtheme stratified analysis by type of physical activity*
Irrelevance and inefficacy	'When you grow older, your health also becomes worse. It is a natural process and nothing can change it. I am quite old and I don't think physical activity is worthwhile.' (26) 'So really, in the back of your mind, it's always somebody had a fall and she has never really recoveredbut to me that is 80s, I'm thinking that's well away.'(63)	32 (24)	Structured exercise: 19, 42–44, 50, 55, 61, 63, 66, 67, 104, 106, 111, 112, 132 Other types of physical activity: 49, 54, 109, 129 Structured exercise and other types of physical activity: 7, 12, 26, 30–32, 40, 71, 75, 77, 85, 97, 127
Maintaining habits	'I grew up on my grandmother's farm back in the 30s when there was a shortage of men. I was around things that had to be done and just got in the habit of doing them. I was always encouraged to be active-on the farm and in sportsThese early experiences seem to have struck a pattern that has continued all these years!' (72) 'I never exercised before. Now, why should I start? My body will be totally confused if I start now!'(71)	31 (24)	Other types of physical activity: 2, 21, 49, 60, 69, 98, 109, 129 Structured exercise: 27, 43, 50, 53, 105, 117, 124, 132 Structured exercise and other types of physical activity: 7, 11, 17, 26, 28, 31, 40, 68, 71, 72, 77, 97, 101, 121, 127

Dependence on professional instruction

In 40 (30%) studies, participants believed that the presence or the quality of exercise instructors influenced physical activity behaviour. Exercise without an instructor was perceived as not being safe, whereas exercises that were tailored to the participant's physical capacity and individual needs were appreciated.

Physical limitations

Pain or discomfort

Participants reported experiencing a range of unpleasant sensations, including muscle aches, chest pain, shortness of breath and dizziness, and these were reported to influence physical activity behaviour in 45 (34%) studies. Physical activity was perceived as being both physically and emotionally demanding and high-intensity physical activity was considered distressing and intolerable. In contrast, inactivity was occasionally recognised as an aggravator for existing pain and some participants remained physically active to cope with or to relieve pain.

Concerns about falling

In 37 (28%) studies, participants feared falling and sustaining serious injuries during physical activities, and lacked confidence to exercise independently. Some reported that physical activity would increase their risk of injury given their frail status. Past falls increased participants' anxiety about exercising.

Comorbidities

Participants in 74 (56%) studies believed that symptoms and physical limitations caused by existing comorbidities prevented them from exercising. These comorbidities included different health conditions, for instance cancer, urinary incontinence and musculoskeletal disorders. Moreover, participants also reported feeling physically unable to take part in any activity due to poor general health. In contrast, some vigilantly exercised to control chronic conditions, such as hypertension and arthritis.

Competing priorities

In 53 (40%) studies, participants reported having little or no time to perform physical activity due to work and family responsibilities. Some felt that taking care of frail partners and grandchildren was more important than exercising.

Access difficulties

Environmental barriers

Environmental barriers, such as poor access to transport, unsuitable weather, neighbourhood safety, and unavailability of exercise programmes and equipment, were reported in 72 (55%) studies as barriers to physical activity participation. Participants felt unfit and unable to use public transport, when they would need to catch multiple buses, travel for long distances or wait for extended periods. In rural areas, lack of transport options was identified as being an important barrier. Moreover, frail participants living in care homes reported having to rely on others to take them to exercise venues, and appreciated benches placed along the corridor so they could rest. Participants also reported feeling vulnerable when having to walk in busy or unsafe neighbourhoods that demanded more of their attention. Adequateness of pedestrian access to roads, such as short green pedestrian traffic light was also noted as a barrier. Some looked for safer opportunities and preferred walking in shopping centres. Some participants enjoyed walking in quiet areas with attractive scenery.

Affordability

Costs associated with physical activity programmes were considered a major barrier to participation in 32 (24%) studies. Some participants said that they were unable to afford the high costs associated with these programmes but some participants expressed their unwillingness to spend money on physical activity, suggesting that free or government subsidised exercise classes could increase physical activity uptake.

Personal benefits of physical activity *Strength, balance and flexibility*

Participants from 69 (52%) studies believed that physical activity would enhance their physical status, resulting in an improvement in muscle strength, balance or flexibility. Some recognised physical activity as an important strategy to reduce the risk of falls, improve mobility and slow the ageing process.

Self-confidence

In 23 (17%) included studies, mastering an activity gave participants a sense of competence that encouraged them to maintain exercising. Some participants experienced an intense improvement in self-esteem and in the sense of self-worth, feeling enthusiastically able to take part in competitions.





Figure 2 Thematic schema illustrating conceptual interactions among valuing interaction with peers and improved health and mental well-being, personal benefits of exercise and apathy, physical limitations and environmental barriers, and access difficulties and social influences.

Independence

Participants from 26 (20%) studies wanted to avoid having to rely on others and be able to care for themselves and felt that exercising maintained their independence and preserved their sense of self-value. Some participants stated that consideration for family members and taking care of grandchildren was an important reason to stay active.

Improved health and mental well-being

In 103 (78%) studies, participants believed that physical activity was important to maintain general health, to improve mood and relieve stress. Specifically, physical activities were perceived to aid digestion, blood circulation, longevity, weight control, sleep quality and breathing. An immediate improvement in mental alertness was perceived which gave participants the notion that physical activity could effectively prevent mental illness.

Motivation and beliefs

Apathy

Participants from 52 (40%) studies reported that apathy influenced their active behaviour. Some expressed disinterest in physical activity believing that they would not derive any health benefit. However, others—although clearly acknowledging the benefits of physical activity—reported that laziness or low motivation prevented their participation in such activities. In contrast, some participants were proactive in seeking opportunities and demonstrated their willingness to learn and do everything to improve their health.

Irrelevance and inefficacy

In 32 (24%) studies, participants believed that exercise was unnecessary for older adults and may even be harmful. Some participants felt that health inevitably deteriorated with ageing, and that physical activity could not slow this natural process. Others considered that they were too young to fall, and thus, exercise to prevent falls was irrelevant. The notion that falls cannot be prevented but occur by chance or as a result of divine forces, fate or luck was also commonly reported by Chinese people.

Maintaining habits

Participants from 31 (24%) studies reported that their earlier lifestyle influenced their current active behaviour. Some stated being physically active at an older age as the result of having always been physically active, whereas others who had never engaged in any regular physical activity were reluctant to start exercising in the old age.

Stratified analysis based on different types of physical activity

Table 2 shows the number of studies categorised as structured exercise programmes and other types of physical activity per themes and subthemes. The stratified analysis revealed that four subthemes (*dependence on professional instruction, pain or discomfort, affordability, strength, balance and flexibility, and self-confidence*) seemed more relevant to structured exercise programmes, whereas two other subthemes (*environmental barriers and maintaining habits*) seemed more relevant to other types of physical activity.

DISCUSSION

This study has shown that some older people believe in the potential of physical activity to improve physical and mental well-being, but key barriers for their participation include lack of social support, previous sedentary habits, competing priorities, accessibility and apathy. Older people also feel they lack the capacity to engage in physical activity because of their perceived frailty and deem age-related deterioration as being unavoidable and unpreventable.

The ecological model of determinants of physical activity proposed by Bauman *et al*²⁰ can assist the interpretation of our findings. This ecological model is a comprehensive multilevel framework, which includes contributors to an active behaviour at all levels: individual, social, environmental and policy. Our systematic review has identified four themes, which can be categorised as contributors at the individual level: physical limitations; competing priorities; personal benefits of physical activity; and motivation and beliefs. Not surprisingly, some older people seem to have understood the personal benefits of physical activity and its impact on their independence, general health and mental well-being. However, despite the irrefutable evidence demonstrating the benefits of physical activity;²¹ ²²

Table 2	Number (and proportion) of studies grouped by type of
physical a	activity per themes and subthemes

Themes and subthemes	Structured exercise (n=61)	Other types of physical activity (n=22)
Social influences		
Valuing interaction with peers	42 (69%)	12 (55%)
Social awkwardness	13 (21%)	1 (5%)
Encouragement from others	32 (52%)	15 (68%)
Dependence on professional instruction	25 (41%)	1 (5%)
Physical limitations		
Pain or discomfort	23 (38%)	1 (5%)
Concerns about falling	11 (18%)	6 (27%)
Comorbidities	29 (48%)	12 (55%)
Competing priorities	20 (33%)	6 (27%)
Access difficulties		
Environmental barriers	25 (41%)	15 (68%)
Affordability	15 (25%)	2 (9%)
Personal benefits of exercise		
Strength, balance and flexibility	41 (67%)	3 (14%)
Self-confidence	17 (28%)	1 (5%)
Independence	12 (20%)	5 (23%)
Improved health and mental well-being	47 (77%)	14 (64%)
Motivation and beliefs		
Apathy	20 (33%)	4 (18%)
Irrelevance and inefficacy	15 (25%)	4 (18%)
Maintaining habits	8 (13%)	8 (36%)

some still believe that physical activity is unnecessary or deleterious, increasing the risk of injury.

Participation in physical activity can also be commonly associated with pain and discomfort and some older people believe that comorbidities necessitate sedentary behaviour. Yet welldesigned physical activity programmes can actually assist with the management of pain and many common health conditions.²³ To overcome the misbelief that physical activity is potentially harmful, educational strategies at population level should focus on communicating the role of physical activity in gaining health benefits for all²⁴ ²⁵ as well as how well-designed physical activity programmes can help the management of common comorbidities in this age group, such as cardiovascular conditions,²⁶ stroke,²⁷ impaired cognitive function²⁸ and arthritis.²⁹ There also needs to be education of health and exercise professionals to ensure that appropriate programmes are readily available for all older adults.

The remaining two themes (social influences and access difficulties) identified in our review refer to the social and environmental levels, respectively, described in the ecological model by Bauman et al.²⁰ The importance of social interactions inherent to group activities was evident in a large proportion of the included studies. Most participants felt more comfortable to exercise under professional supervision and around people with similar age and background. Interestingly, interaction with peers or instructors was also considered an important motivational factor to drive uptake of those activities that otherwise could be performed individually, such as walking. Provision of group activities as well as other type of supervised activities, which facilitate social interaction should also be considered by policymakers to promote an active lifestyle in this age group. At the environmental level, poor access to transport and lack of adequate venues to safely exercise were reported as access

difficulties to sustain an active lifestyle. Despite the importance of building an environment that promotes active behaviour,³⁰ adequate and accessible public transport to exercise venues remains essential for older people. Notwithstanding, these themes are intrinsically correlated, as shown in figure 2, and should be viewed in this context. For instance, the physical limitations of older people seem to influence their perception of environmental barriers, whereas the perceived benefits of physical activity seem to affect older people's motivation towards participation.

Our findings are broadly consistent with the findings of previous qualitative reviews focusing on ethnic minority groups^{12–14} and mixed methods reviews on programmes to prevent falls¹⁵ and on the oldest old,³¹ which found factors that influence older people's behaviour towards physical activity to include motivation and beliefs, social influences and environmental barriers. A strength of our review is the breadth and comprehensiveness of our results, which are relevant to the general older population and to a range of physical activities. We have included 132 qualitative studies which is a considerably larger number than the four previous systematic reviews with narrower research questions $(n=38, {}^{12}, n=11, {}^{13}, n=18^{14}$ and $n=24^{15}$). In addition, we included articles in Spanish and Portuguese as well as English. Our review provides a pragmatic and analytical framework that synthesises data from 5987 participants in different healthcare contexts, including participants from developed and developing countries, urban and rural populations, ethnic minority and cultural majority groups. Despite these diverse contexts, many of the themes identified were described repeatedly in a large number of included studies, revealing consistency of results across studies.

The themes which emerged from this review enabled us to delineate and explain in detail factors influencing physical activity participation from older people's perspectives. Our stratified analysis based on the different types of physical activity showed some subthemes such as *dependence on professional instruction*, *pain or discomfort*, *affordability*, *strength*, *balance and flexibility*, *and self-confidence* to be more relevant to those engaging in structured exercise programmes. Other specific subthemes identified in this review such as *environmental barriers and maintaining habits* seem to be more important in the context of other types of physical activity. These more specific findings can be applied to different physical activity contexts, with important implications for public health.

Our review has some limitations. Most included studies were conducted in developed countries. Therefore, people from developing countries may be under-represented. However, no apparent variation among themes was observed across different countries. Another limitation of this review is the risk of different use of exercise and physical activity terms among participants and authors. This may limit the validity of the stratified analysis based on different types of physical activity.

Research on understanding physical activity behaviour is essential for the development and improvement of public health interventions.³² The lack of conclusive evidence on determinants of physical activity among the ageing population is alarming and needs to be addressed.²⁰ Our view is that the themes identified in this systematic review reflect the needs and preferences of older people and, therefore, should guide the choice of correlates and determinants of physical activity engagement in future studies. Our findings suggest that strategies to enhance physical activity among older people must aim to improve environmental and financial access to physical activity programmes as well as to raise awareness of the health benefits and minimise the perceived risks of physical activity. Moreover, these outcomes should also inform healthcare policy and practice, so that older people's perspectives remain central to future discussions regarding the design of effective health services.

What are the new findings?

- Thematic synthesis of multiple qualitative studies offers a range of perspectives across different contexts, provides more complete knowledge than that derived from single studies and can inform practice and policy.
- Many older people still believe that physical activity is unnecessary, risky or even potentially harmful; others recognise the benefits to improve physical and mental well-being, but report a range of barriers to physical activity participation.
- Strategies to promote and sustain an active lifestyle among older people should include improvement of environmental and financial access to physical activity opportunities as well as to raise awareness of the health benefits and minimise the perceived risks of physical activity.

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Contributors MRF, AT, KH, CS, MLF and PHF were involved in the design of the review. MRF, AT, KH, CS and MLF developed the search strategy. MRF and RZP performed the study selection. MRF and RZP extracted data from included studies. MRF, AT, KH, CS, MLF and RZP were involved in data analysis. All authors were involved in the interpretation and discussion of results. All authors contributed to the writing and review of the various drafts of the report.

Funding MRF is supported by CAPES Foundation, Ministry of Education of Brazil. CS is supported by a research fellowship funded by the Australian National Health and Medical Research Council (NHMRC).

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

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Supplementary appendix

Appendix Table 1. Search strategy

Order Search terms

Medline, AMED, and PsychINFO via OVID on 14 June 2013

1.	exp Aged/
2.	elder\$.tw.

- aged or geriatric\$).tw.
- 4. (older or senior\$).tw.
- 5. 1 or 2 or 3 or 4
- 6. exercise\$.tw.
- exp Exercise/ or exp Exercise Therapy/
- 8. (physical activit\$ or physical train\$).tw.
- 9. 6 or 7 or 8
- 10. exp qualitative research/
- 11. qualitative.tw.
- 12. interview\$.tw.
- 13. focus group\$.tw.
- 14. thematic\$.tw.
- 15. grounded theory.tw.
- 16. phenomenol\$.tw.
- 17. content analysis.tw.
- 18. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
- 19. 5 and 9 and 18
- 20. stroke.mp.
- 21. cardiovascular disease.mp.
- 22. hypertension.mp.
- 23. diabetes.mp.
- 24. alzheimer.mp.
- 25. infarction.mp.
- 26. 20 or 21 or 22 or 23 or 24 or 25
- 27. 19 not 26 (New search)

EMBASE on 14 June 2013

- 1. 'aged'/exp OR aged
- 2. elder
- 3. geriatric
- 4. older
- 5. senior
- 6. #1 OR #2 OR #3 OR #4 OR #5
- 7. exp AND ('exercise'/exp OR exercise)
- 8. exercise*
- 9. exp AND physical AND activity
- 10. physical AND activit* OR physical AND train*
- 11. #7 OR #8 OR #9 OR #10
- 12. exp AND qualitative AND ('research'/exp OR research)
- 13. qualitative*
- 14. interview*
- 15. focus AND group*
- 16. thematic*
- 17. grounded AND theory*
- 18. phenomenol*
- 19. content AND analysis*
- 20. ethnograph*

- 21. #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20
- 22. #6 AND #11 AND #21
- 23. 'human'/exp OR human
- 24. #24 AND #25
- 25. stroke*
- 26. cardiovascular*
- 27. hypertension*
- 28. diabetes*
- 29. alzheimer*
- 30. infarction*
- 31. drug*
- 32. #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33
- 33. #26 NOT #34

CINAHL via Ebsco on 13 June 2013

- 1. (MH "Frail Elderly") OR (MH "Aged+") OR "older people"
- (MH "Geriatrics") OR (MH "Geriatric Functional Assessment") OR (MH "Rehabilitation, Geriatric") OR (MH "Gerontologic Nurse
 Practitioners") OR (MH "Gerontologic Care") OR (MH "Gerontologic Nursing+") OR (MH "National Gerontological Nursing Association") OR (MH "American Geriatrics Society")
- 3. S1 OR S2
- (MH "Exercise+") OR "exercise" OR (MH "Therapeutic Exercise+") OR (MH "Aerobic Exercises+") OR (MH "Open Kinetic Chain
 Exercises") OR (MH "Group Exercise") OR (MH "Aquatic Exercises") OR (MH "Anaerobic Exercises") OR (MH "Isokinetic
- Exercises") OR (MH "Isometric Exercises") OR (MH "Arm Exercises") OR (MH "Back Exercises")
- 5. (MH "Balance Training, Physical") OR "physical training"
- (MH "Physical Activity") OR "physical activity" OR (MH "Physical Activity (Omaha)") OR (MH "Activity Therapy (Iowa NIC)") OR
 (MH "Activity and Exercise Enhancement (Iowa NIC) (Non-Cinahl)+") OR (MH "Physical Endurance+") OR (MH "Physical Performance") OR (MH "Physical Fitness+") OR (MH "Exercise+")
- 7. S4 OR S5 OR S6
- 8. (MH "Focus Groups")
- 9. (MH "Semi-Structured Interview") OR (MH "Unstructured Interview") OR (MH "Interviews+")
- 10. (MH "Thematic Analysis")
- 11. (MH "Qualitative Studies+") OR (MH "Content Analysis") OR (MH "Meta Synthesis") OR (MH "Grounded Theory")
- 12. (MH "Phenomenological Research") OR (MH "Phenomenology")
- 13. "ethnograph" OR (MH "Ethnographic Research")
- 14. S8 OR S9 OR S10 OR S11 OR S12 OR S13
- 15. S3 AND S7 AND S14
- 16. (MH "Human")
- 17. S15 AND S16
- 18. (MH "Stroke+") OR (MH "Stroke Patients")
- 19. (MH "Cardiovascular Diseases+") OR (MH "Cardiovascular Risk Factors") OR (MH "Diagnosis, Cardiovascular+") OR (MH "Surgery, Cardiovascular+")
- 20. (MH "Hypertension+")
- 21. (MH "Diabetes Mellitus, Type 1+") OR (MH "Diabetes Mellitus, Type 2") OR (MH "Diabetic Patients")
- 22. (MH "Alzheimer's Disease")
- 23. (MH "Infarction") OR (MH "Myocardial Infarction+")
- 24. "drug"
- 25. S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24
- 26. S17 not S25

Author Year[Ref] COREQ score	Country	n	M:F	Age (SD) or [range]	Source	Ethnicity	Data collection	Conceptual methodological framework	Analysis	Research topic
Abolfazl et al (2011)[1] 11	Iran	16	8:8	70 [65-86]	Community	Shiite Muslim	Semi- structured interviews	Content analysis	Content analysis	Structured exercise and other types of physical activity
Annear et al (2009)[2] 9	New Zealand	63	23:40	NS [65-91]	Community	NS	Semi- structured interviews	Content analysis	Content analysis	Other types of physical activity (leisure time physical activity)
Antikainen et al (2010)[3] 5	USA	48	9:39	67 (9·3)	Community and independent living housing facility	Most Black	Open ended questions	Theory of planned behavior	Theory of planned behaviour analysis	Structured exercise (education about aerobics, strength training, and stretching)
Aronson et al (2004)[4] 2	USA	26	NS	NS	Community (rural area)	White, American Indian and Hispanic	Focus groups	Ethnography	Content analysis	Structured exercise and other types of physical activity
Ballinger and Clemson (2006)[5] 13	Australia	11	2:9	76* [69-91]	Community	NS	Semi- structured interviews	Grounded theory	Grounded theory analysis	Structured exercise (exercise for falls prevention)
Beaudreau (2006)[6] 11	USA	12	2:10	NS [65-88]	Community	Caucasian and African American	Focus groups	NS	NS	Structured exercise (Tai Chi)
Beck et al (2010)[7] 12	England	11	4:7	63 (2·3)	Community	White British	Semi- structured interviews	Self-determination theory	Thematic analysis	Structured exercise and other types of physical activity

Appendix Table 2. Characteristics of included studies

Belza et al (2004)[8] 15	USA	71	29:42	72 (7·4)	Community	American Indian/Alaska Native, African American, Filipino, Chinese, Latino, Korean and Vietnamese	Focus groups	Content analysis	Content analysis	Structured exercise and other types of physical activity
Benjamin et al (2011)[9] 12	Canada	48	NS	65 or over	Long-term care settings	NS	Focus groups	Socio-ecological model	Content analysis	Structured exercise and other types of physical activity
Bidonde et al (2009)[10] 14	Canada	9	0:9	75 [67-83]	Community	Caucasian	Semi- structured interviews (photovoice method also used)	Phenomenology	Thematic analysis	Structured exercise (aerobics, strength training, and stretching)
Bjornsdottir et al (2012)[11] 12	Iceland	10	0:10	84 [72-97]	Retirement community	Icelandic	In-depth interviews	Phenomenology	Thematic framework analysis	Structured exercise and other types of physical activity
Bocksnick (2001)[12] 8	Canada and Germany	24	10:14	75 (6·2)	Community	Canadian and German	Interviews	Content analysis	Content analysis	Structured exercise and other types of physical activity
Bocksnick and Hall (2004)[13] 11	Canada	48	11:37	66 [55-86]	Community	NS	Semi- structured interviews	Theory of Planned Behavior and Rubicon Model	Content analysis	Structured exercise (balance exercise)
Brill et al (1999)[14] 3	USA	35	5:30	79 [60-100]	Participants eligible for nursing home care	Most Black	Phone interviews	NS	NS	Structured exercise (strength training)
Brown et al (1999)[15] 10	Australia	81	35:46	NS [60-89]	Community	Non-English and Aboriginal background	Focus groups	NS	Thematic analysis	Structured exercise and other types of physical activity
Buijs et al (2003)[16] 9	Canada	27	3:24	76 [61-90]	Community	NS	Semi- structured interviews	Content analysis	Content analysis	Structured exercise (aerobics, and strength training)

Buman et al (2009)[17] 10	USA	23	10:13	65 (6·0)	Community	Caucasian, African American and Asian	Semi- structured interviews	Constructive Narrative Perspective	Constructive Narrative Perspective Framework	Structured exercise and other types of physical activity
Burton et al (2013)[18] 10	Australia	20	4:16	84 [71-102]	Community	NS	Semi- structured interviews	Content analysis	Content analysis	Structured exercise and other types of physical activity
Calhoun et al (2011)[19] 13	USA	39	9:30	Most over 70	Community	NS	In-depth interviews	Grounded-theory	Grounded theory analysis	Structured exercise (exercise for falls prevention)
Cantu (2011) [20] 14	USA	8	0:8	69 [58-73]	Community	Mexican American	Interviews	Life stories	Content analysis	Structured exercise and other types of physical activity
Cantu and Fleuriet (2008) [21] 11	USA	40	0:40	66 [56-83]	Community	Mexican American	In-depth interviews	Life stories	Ethnographic analysis	Other types of physical activity
Cassou et al (2011)[22] 7	Brazil	25	0:25	70 (6·9)	Community	NS	Focus groups	Content analysis	Content analysis	Structured exercise
Ceria-Ulep et al (2011)[23] 13	USA	47	18:29	NS [65-87]	Community	Filipino	Interviews	NS	Thematic analysis	Structured exercise and other types of physical activity
Chen et al (2001)[24] 8	Taiwan	80	60:50	NS [65-89]	Community	NS	Face to face interviews	NS	NS	Structured exercise (Tai Chi)
Chen et al (2011)[25] 6	Taiwan	97	24:73	NS [60-94]	Community and institutions	NS	Semi- structured interviews	NS	NS	Structured exercise (Yoga)
Chen (2010)[26] 13	China	90	31:59	79 (6·2)	Long-term care institutions	NS	Interviews	Exploratory	Content analysis	Structured exercise and other types of physical activity
Chiang et al (2008)[27] 11	USA	52	8:44	76 (7·4)	Community	Chinese, African American, White and Japanese	Focus groups	Content analysis	Content analysis	Structured exercise (aerobics, strength training, balance exercise, and stretching)

Conn (1998)[28] 10	USA	30	0:30	79 (5·0)	Community	Caucasian	Interviews	Theory of planned behaviour	Content analysis	Structured exercise and other types of physical activity
Costello et al (2011)[29] 13	USA	31	11:20	80 [60-94]	Retirement communities	NS	Focus groups	NS	Phenomenological analysis	Structured exercise and other types of physical activity
Cousins (2000)[30] 9	Canada	143	0:143	77 (NS)	Community	NS	Survey with open ended questions	Health Belief Model	Content analysis	Structured exercise and other types of physical activity (aerobics, strength training, and stretching)
Cousins (2003)[31] 11	Canada	41	8:33	71 [55-92]	Community	-	In-depth interviews	Behavioral models	Framework analysis	Structured exercise and other types of physical activity
Cousins (2003)[32] 11	Canada	41	8:33	71 [55-92]	Community	NS	In-depth interviews	Self-referent thinking model	Content analysis	Structured exercise and other types of physical activity
De Groot and Fagerstrom (2011)[33] 13	Norway	10	5:5	83 [71-91]	Community	NS	Semi- structured interviews	Motivation equation	Content analysis	Structured exercise (exercise for falls prevention)
Dickinson et al (2011)[34] 10	England	187	50:137	75 [60-95]	Community	Chinese, South Asian and White British	Focus groups and semi- structured interviews	Grounded-theory	Constant comparative analysis	Structured exercise (exercise for falls prevention)
Dionigi (2007)[35] 14	Australia	10	4:6	68 [65-72]	Community	White	In-depth interviews	NS	Thematic analysis	Structured exercise (strength training)
Duncan et al (1994)[36] 8	USA	14	9:5	NS [61-81]	Community	Caucasian	In-depth interviews	Grounded theory	Grounded theory analysis	Other types of physical activity (mall walking)
Duncan et al (1995)[37] 10	USA	14	9:5	NS [61-81]	Community	Caucasian	In-depth interviews	Grounded theory	Grounded theory analysis	Other types of physical activity (mall walking)
Dunlop et al (2013)[38] 11	Canada	19	19:0	77 (8·2)	Community	Most European descent	Semi- structured interviews	Social- constructionism	Content analysis	Structured exercise (aerobics, and strength training)

Dunn (2008)[39] 13	USA	14	0:14	60 [56-66]	Community	African American	Focus groups	Grounded theory	Content analysis	Structured exercise (walking)
Dye and Wilcox (2006)[40] 10	USA	28	0:28	Most over 65	Community (rural area)	African American and White	Focus groups	Social cognitive theory	Content analysis	Structured exercise and other types of physical activity
Eggers (1988)[41] 3	USA	56	0:56	75 [65-91]	Community	NS	Open-ended interviews	NS	NS	Structured exercise
Evron et al (2009)[42] 11	Denmark	20	4:16	NS [70-94]	Community	NS	Semi- structured interviews	Phenomenology	Thematic analysis	Structured exercise (exercise for falls prevention)
Ferrand et al (2012)[43] 12	France	38	21:17	75** (4·6)	Community	French	Semi- structured interviews	Self-determination theory	Content analysis	Structured exercise
Fournier and Fine (1990)[44] 6	USA	9	NS	NS [69-85]	Community	NS	In-depth interviews	NS	NS	Structured exercise (aerobics, stretching, and toning movements)
Fox et al (2007)[45] 10	England	24	NS	70 or over	Community	NS	Semi- structured interviews	Phenomenology	Phenomenological analysis	Structured exercise and other types of physical activity
Friedman et al (2012)[46] 12	USA	20	20:0	NS [65-84]	Community	African American	In-depth interviews	Content analysis	Content analysis	Structured exercise and other types of physical activity
Gallagher et al (2010)[47] 11	USA	21	2:19	70 (8·7)	Community	African American	Focus groups (photovoice method)	Content analysis	Content analysis	Other types of physical activity (walking)
Gillis et al (2002)[48] 11	USA	20	10:10	NS [67-82]	Community	NS	Focus groups	Content analysis	Content analysis	Structured exercise
Grant (2001)[49] 9	New Zealand	15	7:8	74 [71-79]	Community	NS	In-depth interviews and focus group	Interpretive paradigm	Inductive analysis and constant comparative method	Other types of physical activity (sport activities)

Grant (2008)[50] 10	New Zealand	26	9:17	76 [70-83]	Community	Caucasian	Interviews with open ended questions	Phenomenology	Inductive analysis and constant comparative method	Structured exercise
Grant et al (2010)[51] 12	Canada	75	13:62	65 or over	Community	NS	Focus groups and semi- structured interviews	NS	Constant comparative analysis method	Other types of physical activity (walking)
Grant et al (2010)[52] 13	Canada	75	13:62	75 [72-77]	Community	Chinese, Italian, Greek, British, Ukrainian and Chilean	Focus groups and semi- structured interviews	NS	Framework analysis	Other types of physical activity (walking)
Greaney et al (2004)[53] 11	USA	29	8:21	77 (4·8)	Community	Most White	Focus groups	Transtheoretical Model of Health Behavior Change	Process of change analysis	Structured exercise
Grossman and Stewart (2003)[54] 10	USA	33	15:18	80 (4·2)	Community	NS	Interviews	NS	NS	Other types of physical activity
Guerin et al (2008)[55] 12	Australia	7	0:7	NS	Low-level residential aged care	NS	Focus groups	NS	Thematic analysis	Structured exercise (predominantly chair-based exercises)
Hardcastle and Taylor (2005)[56] 11	UK	8	0:8	61 [43-77]	Community	NS	Semi- structured interviews	NS	Cross-case analysis	Structured exercise
Hardy and Grogan (2009)[57] 13	UK	48	6:42	69 (7·2)	Community	Most White British	Focus groups	NS	Grounded theory analysis	Structured exercise and other types of physical activity
Hawley (2009)[58] 8	England	9	NS	60 or over	Community and nursing home	NS	Unstructured interviews	Grounded-theory	Grounded theory analysis	Structured exercise (home exercise after falls rehabilitation)
Henwood et al (2011)[59] 14	Australia	18	10:8	NS [65-81]	Community	NS	Focus groups	Content analysis	Content analysis	Structured exercise (strength training)

Heo et al (2013)[60] 8	USA	10	6:4	63 [52-71]	Community	White and African American	In-depth interviews	NS	Constant comparative method	Other types of physical activity (sport activities)
Hill et al (2011)[61] 6	Australia	168	NS	79** (8·5)	Post hospital discharge	NS	Survey with open ended questions	NS	NS	Structured exercise (after hospital discharge)
Hirvensalo et al (1998)[62] 5	Finland	1224	420:804	NS [65-84]	Community	NS	Survey with open ended questions	NS	NS	Structured exercise and other types of physical activity
Horne et al (2009)[63] 8	England	127	46:81	NS [60-70]	Community	South Asian and Caucasian	Focus groups and semi- structured interviews	Ethnography	Framework analysis	Structured exercise (exercise for falls prevention)
Horne et al (2010)[64] 14	England	127	46:81	NS [60-70]	Community	White and South Asian	Focus groups and in-depth interviews	Ethnography	Framework analysis	Structured exercise and other types of physical activity
Horne et al (2012)[65] 10	England	46	23:23	NS [60-70]	Community	South Asian: Indian and Pakistani	Focus groups and in-depth interviews	Ethnography	Framework analysis	Structured exercise and other types of physical activity
Horton and Dickinson (2011)[66] 12	England	30	9:21	70 (NS)	Community	Chinese	Focus groups and in-depth interviews	Grounded-theory	Constant comparative analysis	Structured exercise (exercise for falls prevention)
Host et al (2011)[67] 10	Denmark	14	5:9	77 [68-87]	Community	NS	Semi- structured interviews	Phenomenology	Phenomenological analysis	Structured exercise (exercise for falls prevention)
Hutton et al (2009)[68] 12	New Zealand	20	2:18	73 [68-81]	Community	New Zealand European descent	Focus groups	NS	Thematic analysis	Structured exercise and other types of physical activity
Jancey et al (2009)[69] 10	Australia	16	5:11	NS [65-74]	Community	NS	Semi- structured interviews	Content analysis	Content analysis	Other types of physical activity
Jones et al (2009)[70] 14	USA	27	8:19	73 (8·8)	Community	NS	Focus groups	Phenomenology	Content analysis	Other types of physical activity (pedometer-based intervention)

Kalavar et (2008)[71 11	al]	USA	10	5:5	72 [66-79]	Community	Asian Indian	Focus groups	NS	Inductive analysis	Structured exercise and other types of physical activity
Kluge (20 12	02)[72]	USA	15	0:15	NS [68-87]	Community	Caucasian of European descent	Semi- structured interviews	Phenomenology	Phenomenological analysis	Structured exercise and other types of physical activity
Kolt et al (2006)[73 13]	New Zealand	24	12:12	69 [60-79]	Community	Tongan	Focus groups	Self-efficacy theory	Descriptive analysis	Structured exercise and other types of physical activity
Konradi a (2003)[74 11	nd Anglin]	NS	19	8:11	71 [65-86]	Community	NS	Focus groups	NS	NS	Structured exercise (supervised exercise walking routine)
Koo (2011 12	1)[75]	Australia	22	12:10	76 [60-91]	Community	Chinese	In-depth interviews	Theory of Planned Behavior	Content analysis	Structured exercise and other types of physical activity
Lavizzo-N al (2001)[7	1ourey et 76]	USA	38	NS	65 or over	Community and nursing home	African American	Focus group	NS	NS	Structured exercise and other types of physical activity
Leavy and (2010)[77 10	l Aberg]	Sweden and Ireland	30	NS	75 [65-89]	Community	NS	Semi- structured interviews	Content analysis	Content analysis	Structured exercise and other types of physical activity
Lees et al (2005)[78 9]	USA	66	9:57	65 or over	Community	NS	Focus groups	NS	NS	Structured exercise
Lin et al (2 9	2007)[79]	USA and China	24	6:18	NS [65-87]	Community	Chinese	Focus groups	Theory of planned behaviour	Content analysis	Structured exercise and other types of physical activity
Lindelof e (2012)[80 13	t al]	Sweden	9	3:6	89 [73-91]	Residential care facilities	NS	Semi- structured interviews	Content analysis	Content analysis	Structured exercise (high-intensity functional exercise, including strength training, balance, gait exercises)
Lockett et (2005)[81 8	al]	Canada	22	4:18	76 [60-90]	Community	NS	Focus group (photovoice method)	NS	NS	Other types of physical activity (walking)

Lu et al (2011)[82] 12	USA	50	7:43	84 [60-99]	Assisted living facilities	NS	Focus groups	NS	Constant comparative method	Other types of physical activity (walking corridor)
Lubcke et al (2012)[83] 14	Sweden	8	3:5	74 [65-81]	Community	NS	Semi- structured interviews	Transtheoretical Model and Social Cognitive Theory	Content analysis	Structured exercise (in a senior gym)
Mahmood et al (2012)[84] 10	USA and Canada	66	21:45	NS [65-92]	Community	NS	Focus group (photovoice method)	NS	Deductive analytic strategy (Successive approximation)	Structured exercise and other types of physical activity
Mathews et al (2010)[85] 11	USA	396	110:286	71 (9·3)	Community	African American, American Indian, Latino, Chinese, Vietnamese, non-Hispanic White	Focus groups	Grounded-theory	Constant comparative analysis	Structured exercise and other types of physical activity
Melillo et al (1996)[86] 11	USA	23	14:9	NS [63-82]	Community	Caucasian	Interviews	Content analysis	Content analysis	Structured exercise and other types of physical activity
Michael et al (2006)[87] 12	USA	60	NS	69 [56-84]	Community	Most non- Hispanic Caucasian	Focus groups	Content analysis	Content analysis	Other types of physical activity
Nadasen (2007)[88] 12	South Africa	30	0:30	70 (7·6)	Community	NS	Interviews and focus groups	Grounded theory	Thematic content analysis	Structured exercise (line dancing)
Nadasen (2008)[89] 11	South Africa	30	0:30	70 (7·6)	Community	White, Black and Indian	Interviews and focus groups	Grounded theory	Thematic content analysis	Structured exercise (line dancing)
Navarro et al (2008)[90] 5	Brazil	35	7:28	60 or over	Community	NS	Semi- structured interviews	NS	NS	Structured exercise
Oliffe et al (2010)[91] 10	Canada	36	36:0	70 (8·3)	Community	South Asian	Semi- structured interviews	Ethnography	Content analysis	Structured exercise and other types of physical activity

Patel et al (2011)[92] 11	US	12	0:12	NS [65-89]	Community	Hispanic, non- Hispanic White and African American	Focus groups	Grounded theory	Content analysis	Structured exercise (Yoga)
Pausenberger and Haines (2011)[93] 6	Australia	58	20:38	68 (7·9)	Community	Croatian, Cambodian, Turkish and Arabic	Survey with open ended questions	NS	Qualitative description analysis	Structured exercise (exercise for falls prevention)
Phillips and Flesner (2013)[94] 13	USA	47	5:42	85 (7·2)	Long-term care settings	White	Focus groups	Health Promotion Model	Thematic analysis	Structured exercise and other types of physical activity
Pope et al (2008)[95] 11	USA	5	0:5	83 (7·3)	Assisted-living facility	Caucasian	Focus groups	Theory of Planned Behavior	Long-table approach	Structured exercise (strength training, and balance exercise)
Porras-Juarez et al (2010)[96] 6	Mexico	15	6:9	NS [65-72]	Community	NS	Semi- structured interviews	Health Belief Model	Health Belief Model	Structured exercise and other types of physical activity
Resnick and Spellbring (2000)[97] 10	USA	23	2:21	81 (7·2)	Retirement village	White	Interviews	Naturalistic/ constructivist inquiry	Content analysis	Structured exercise and other types of physical activity
Roper et al (2003)[98] 11	USA	1	1:0	88 (NS)	Community	White	In-depth interviews	Continuity theory	Deductive thematic analysis	Other types of physical activity (running)
Rosenberg et al (2013)[99] 15	USA	35	9:26	67 [50-86]	Community	White, African- American, Asian- American	In-depth interviews	Content analysis	Content analysis	Other types of physical activity
Rydeskog et al (2005)[100] 11	Sweden	15	7:8	75 [63-87]	Community	NS	Semi- structured interviews	Phenomenology	Phenomenological analysis	Structured exercise (strength training)
Scanlon-Mogel and Roberto (2004)[101] 10	USA	15	9:6	71 (3·6)	Community	White	In-depth interviews	Life course perspective	Content analysis	Structured exercise and other types of physical activity

Sharon et al (1997)[102] 11	USA	24	NS	72 [61-82]	Community	Caucasian	Focus groups	NS	Framework analysis	Structured exercise (strength training)
Sharpe et al (1997)[103] 5	USA	13	NS	NS [60-91]	Community (rural area)	NS	Focus groups	NS	NS	Structured exercise (strength training, balance, and stretching)
Simpson et al (2003)[104] 14	England	32	6:26	83 (5·3)	Community (discharged from hospitals)	NS	Semi- structured interviews	NS	NS	Structured exercise (exercise for falls prevention)
Sims-Gould et al (2012)[105] 13	Canada	84	0:84	70 [65-75]	Community	NS	Focus groups	NS	Thematic framework analysis	Structured exercise (strength training and balance exercise)
Sin et al (2004)[106] 13	USA	13	5:8	79 (4·8)	Senior house	Korean	Focus groups	Content analysis	Content analysis	Structured exercise
Sin et al (2005)[107] 8	USA	13	5:8	77 (5·9)	Senior house	Korean	Focus groups	NS	NS	Structured exercise (aerobics, balance exercise, strength training, and stretching)
So and Pierluissi (2012)[108] 14	USA	28	15:13	78 [65-103]	Public hospital	White, African American, Hispanic and Asian	Semi- structured interviews	NS	Thematic framework analysis	Structured exercise and other types of physical activity
Sobczak (1997)[109] 5	England	5	0:5	80 or over	Senior house institution	NS	Focus groups	NS	Grounded theory analysis	Other types of physical activity
Stathi et al (2002)[110] 13	UK	28	13:15	71 [62-81]	Community	NS	Individual interviews and focus groups	NS	Cross-case analysis	Structured exercise and other types of physical activity
Stathi et al (2004)[111] 11	England	13	8:5	69 [63-79]	Community	NS	Individual or group semi- structured interviews	NS	Thematic framework analysis	Structured exercise

Stathi et al (2010)[112] 10	UK	21	7:14	76 (3·9)	Community	NS	Semi- structured interviews	NS	Interpretive qualitative analysis	Structured exercise (aerobics, balance exercise, strength training, and stretching)
Stathi et al (2012)[113] 13	UK	25	15:10	78 [71-92]	Community	NS	Semi- structured interviews	Social constructionism	Content analysis	Other types of physical activity (walking)
Stickney and Vilshanskaya (2005)[114] 8	Australia	58	2:56	60 or over	Community	Non-English background living in Australia and frail older people	Focus groups	Content analysis	Content analysis	Structured exercise
Strath et al (2007)[115] 11	USA	37	16:21	Most over 60	Community	Most White	Survey with open ended questions and semi- structured interviews	Content analysis	Content analysis	Other types of physical activity (walking)
Talbott and Roberson (2011)[116] 3	Czech Republic	NS	NS	NS [61-93]	Retirement center	NS	Interviews with open ended questions	NS	NS	Structured exercise and other types of physical activity
Taylor et al (2003)[117] 6	USA	17	0:17	80 [62-99]	Assisted living facility	NS	Interviews with open ended questions	NS	Constant comparative method	Structured exercise (walking club)
Tse (2010)[118] 10	Hong Kong	26	1:25	85 (5·2)	Nursing homes	NS	Interviews with open ended questions	Content analysis	Content analysis	Other types of physical activity (indoor gardening)
Vernon and Ross (2008)[119] 9	England	22	2:20	NS [65-94]	Community	Black British Caribbean, White Irish and White British	In-depth interviews	NS	NS	Structured exercise (exercise for falls prevention)
Wagstaff (2005)[120] 9	UK	5	0:5	83 [75-94]	Senior house facility	NS	In-depth interviews	Phenomenology	Content analysis	Structured exercise

Weeks et al (2008)[121] 9	Canada	24	5:19	NS [64-85]	Community and long-term care facilities	NS	Interviews with open ended questions	NS	Thematic analysis	Structured exercise and other types of physical activity
Weinstein (1988)[122] 5	USA	12	6:6	NS [65-88]	Community	NS	Interviews	NS	NS	Structured exercise
Welmer et al (2012)[123] 14	Sweden	20	6:14	85 [80-91]	Community	NS	Focus groups	Social constructivism	Content analysis	Structured exercise and other types of physical activity
Whaley and Ebbeck (2002)[124] 14	USA	13	2:11	82 [66-90]	Retirement community	White	Interviews	Self-schemata	Content analysis	Structured exercise (aerobics, strength training, and stretching)
Whaley and Shrider (2005)[125] 10	USA	19	9:10	69 [60-79]	Community	Most White	Semi- structured interviews	Model of effective performance	Content analysis	Structured exercise
Wilcox et al (2003)[126] 5	USA	39	0:39	71 (9·2)	Community (rural area)	African American and White	Survey with open ended questions	Social cognitive theory	Content analysis	Structured exercise and other types of physical activity
Wilcox et al (2005)[127] 11	USA	39	0:39	68 (9·2)	Community (rural area)	African American and White	Focus groups	Social ecological models	Social ecological models	Structured exercise and other types of physical activity
Wilson and Spink (2006)[128] 9	Canada	15	1:14	NS [60-90]	Community	NS	Focus groups	NS	NS	Other types of physical activity
Witcher et al (2007)[129] 14	Canada	10	5:5	82 [70-94]	Community (rural area)	White	Semi- structured and in-depth interviews	Content analysis	Content analysis	Other types of physical activity
Wong et al (2011)[130] 11	Hong Kong	13	NS	76 [69-75]	Patients who attended emergency departments in hospitals due to falls	NS	Focus group	Content analysis	Content analysis	Structured exercise (exercise for falls prevention)
Yang et al (2011)[131] 11	USA	8	1:7	76 [67-82]	Community	NS	Semi- structured interviews	Social constructionism	Layers Model	Structured exercise (Tai Chi)
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Yardley et al (2006)[132] 12	Europe (Denmark, Netherlands, Germany, Greece, Switzerland, UK)	69	19:50	79 [68 - 97]	Community	NS	Semi- structured interviews	Theory of planned behavior	Framework analysis	Structured exercise (exercise for falls prevention)

USA, United States of America; UK, United Kingdom; SD, standard deviation; NS, not stated; n, sample size; REF, reference number.

Country, if not clearly stated in the study, corresponding author's country was used instead.

Age is reported as mean age unless otherwise denoted. If mean age for the qualitative study sample was not provided, range was extracted. If range not provided, eligibility criteria or predominant age reported in the published report when available was used.

* Median age.

**Age data in mixed methods (qualitative and quantitative approaches) not provided separately for participants in the qualitative study.

Reporting criteria	No (%)*	References of studies reporting each criterion
Personal Characteristics of Primary Researchers		
Interviewer or facilitator identified	71 (53.8)	5, 6, 8-11, 13, 15, 19-21, 23, 26, 27, 28, 30-33, 35-39, 42-44, 48-50, 52, 55-59, 61, 62, 64, 66, 70, 72, 75, 77-80, 83, 88, 89, 94, 95, 97, 99-101, 103, 104, 106-108, 116-118, 121-125, 129, 131
Relationship with participants		
Relationship established prior to study commencement	36 (27.3)	6, 8, 10, 13, 20, 21, 26, 28, 33, 36-39, 44, 48, 55-57, 63, 66, 72, 75, 80, 83, 88, 89, 98, 102, 103, 107, 117- 119, 123, 124, 129
Participant selection		
Selection strategy (e.g.: snowball, purposive)	114 (86.4)	1, 2, 5-11, 13-16, 18-35, 38, 41-43, 45-73, 75, 77-89, 91-102, 104-115, 118, 120, 121, 123, 124, 126-132
Method of approach	80 (60·6)	2, 5-9, 11, 12, 15-19, 20, 23, 24, 25, 29-33, 35, 37, 39, 40, 42, 45, 46, 48, 51-55, 57-59, 64, 65, 67-70, 72- 75, 79, 82-89, 92-94, 99, 100, 102-108, 110, 115, 117, 118, 123-127, 130, 132
Number or reasons for non-participation**	46 (35.1)	2, 3, 5, 6, 9, 13, 14, 16, 18, 19, 24, 29, 33, 35, 42, 48, 58, 59, 61, 62, 67, 68, 70, 71, 73, 80, 83, 86, 88, 89, 92, 95, 97, 99-102, 104-108, 119, 123, 124, 129
Setting		
Description of the sample	105 (79.5)	1-3, 7, 8, 10-12, 14, 15, 18-21, 23-35, 39, 40, 43-54, 56, 58, 60-67, 69-75, 77, 79-91, 93-99, 101, 103-108, 110, 111, 113, 115, 117-118, 120-132
Data collection		
Questions, prompts or topic guide	107 (81.1)	1-3, 5-13, 15, 17, 19-33, 35, 39, 40, 42, 43, 46-52, 54, 55, 57, 59, 60, 64, 67-89, 92-95, 97-116, 119, 120, 122-132
Audio or visual recording	114 (86.4)	1, 2, 4-13, 15-29, 31-43, 45-47, 49-57, 59, 60, 64-78, 80-91, 94-102, 104-108, 110-115, 118-121, 123-125, 127-132
Field notes	46 (34.8)	1, 5, 6, 8, 10, 20, 22-26, 29, 34-39, 42, 46, 47, 51-53, 55, 59, 68, 70, 73, 74, 76, 78, 79, 82, 84, 92, 94, 95, 98, 99, 101, 104, 105, 113, 120, 126
Duration	91 (68.9)	1, 5-8, 10, 13, 17-23, 26, 27-29, 31-54, 56, 57, 59, 60, 62, 64, 66, 68-70, 72, 74, 75, 77, 78, 80, 82, 83, 85-87, 91, 94, 95, 97-100, 102, 104-106, 108, 110-113, 115, 117-119, 121, 123, 124, 128-132
Data (or theoretical) saturation	24 (18 2)	10, 11, 16, 17, 26, 29, 35, 40, 47, 56, 57, 59, 64, 65, 68, 82, 92, 99, 108, 110, 113, 128-130
Data analysis	(10.2)	

Appendix Table 3. Comprehensiveness of reporting assessment (Consolidated Criteria for Reporting Qualitative Research Checklist - Adapted)

Number of data coders	85 (64.4)	1, 3, 5, 7-12, 15, 17-21, 23, 26, 27, 29-34, 37-40, 43, 45-47, 51-53, 55, 57-59, 61, 64, 66-68, 70, 71, 73, 74, 76, 77, 79, 80, 82, 83, 84, 86, 87, 91-95, 98-100, 102, 104-106, 108, 110-115, 123-127, 129-132
Protocols for data preparation and transcription	113 (85.6)	1-3, 5, 7-13, 15-23, 26, 27-40, 42, 43, 45-57, 59-61, 63-78, 80-92, 94, 96-102, 104-106, 108-115, 118, 120, 121, 123-125, 127-132
Protocols for translation***	22 (78.6)	8, 9, 23, 24, 27, 34, 43, 63-66, 71, 73, 75, 85, 91, 93, 106, 108, 114, 123, 132
Software	35 (26.5)	5, 7-9, 19, 22, 45, 46, 54, 56, 57, 59, 63-66, 69, 71, 73, 74, 81, 85, 87, 91, 94, 99, 105, 110-113, 119, 121, 127, 132
Participant feedback or member checking	37 (28.0)	1, 7, 10, 11, 13, 16, 17, 20, 35, 38, 39, 43, 50-53, 55, 70, 72, 77, 80, 83, 87, 88, 92, 104, 110-113, 115, 119, 120, 124, 125, 129, 131
Reporting		
Participant quotations presented	120 (90.9)	1, 2, 4-13, 15-21, 23, 26, 27-40, 42-60, 63-92, 94-102, 104-106, 108-125, 127-132
Clarity of major and minor themes	116 (87.9)	1, 2, 5-13, 15-21, 23, 26, 27-40, 42-60, 63-76, 78-92, 94-102, 104-106, 108-115, 118-125, 127-132

*Proportion calculated by reference to the total included studies (n=132) unless otherwise denoted. **Item not applicable for study reference 98. Hence, proportion has been calculated using a total of 131 studies. ***Item not applicable for studies including English-speaking samples. Hence, proportion has been calculated using a total of 26 studies. The studies that did not meet this criterion were study references 12, 77, 79, 81, 107, 114.

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Chapter Three

Methodological limitations prevent definitive conclusions on the effects of patients' preference in randomized clinical trials evaluating musculoskeletal conditions

Chapter Three is published as:

Franco MR, Ferreira ML, Ferreira PH, Maher CG, Pinto RZ, Cherkin DC. Methodological limitations prevent definitive conclusions on the effects of patients' preference in randomized clinical trials evaluating musculoskeletal conditions. *J Clin Epidemiol.* 2013; 66: 586-98.

Statement from co-authors confirming authorship contribution of the

PhD candidate

As co-authors of the paper "Methodological limitations prevent definitive conclusions on the effect of patients' preferences in randomized clinical trials evaluating musculoskeletal conditions", we confirm that Marcia Franco has made the following contributions:

- Conception and design of the research
- Study selection and data extraction
- Analysis and interpretation of the findings
- Writing of the manuscript and critical appraisal of the content

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Journal of Clinical Epidemiology

Journal of Clinical Epidemiology 66 (2013) 586-598

REVIEW ARTICLES

Methodological limitations prevent definitive conclusions on the effects of patients' preferences in randomized clinical trials evaluating musculoskeletal conditions

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Abstract

Objective: To systematically and critically evaluate how patients' preferences have been measured and analyzed in randomized clinical trials (RCTs) evaluating musculoskeletal conditions.

Study Design and Settings: PsycINFO, MEDLINE, EMBASE, Cochrane Central Register of Clinical Trials, CINAHL, LILACS, and PEDro were searched for RCTs in which authors reported that patients' preferences were measured before randomization.

Results: Five studies investigated if patients' preferences modify treatment effect (difference in outcomes between allocation groups), and seven studies examined the effect of patients' preferences on outcomes (within-group changes in outcome over time). Three studies provided data to be used in a statistical model based on tests of interactions. Statistical significance of the effect of preferences on treatment outcomes was not found. Included studies were not powered for tests of interaction, and only two (17%) studies described a preplanned analysis for treatment preference. Four (33%) trials did not show evidence of selective reporting bias. Additionally, authors used heterogeneous methods to measure patients' preferences.

Conclusion: Methodological limitations of the available evidence suggest that it might be early to conclude whether patients' preferences influence the findings of RCTs evaluating musculoskeletal conditions. Future studies should use standardized methods to measure patients' preferences and then individual studies can be pooled in a meta-analysis. © 2013 Elsevier Inc. All rights reserved.

Keywords: Randomized controlled trial; Patient preference; Musculoskeletal; Pain; Rehabilitation; Outcome assessment

1. Introduction

Musculoskeletal pain and disability are important public health conditions affecting approximately 30% (range, 14-47%) of the population [1,2]. Common musculoskeletal problems include spine-related pain, osteoarthritis, and fibromyalgia [2-5]. These conditions lead to decreased quality of life as reported by patients and significant direct and indirect costs to society [6,7]. Systematic reviews evaluating the efficacy of interventions for managing musculoskeletal pain and disability report treatment effects which, in general, are small to moderate in size [8-10].

One factor that is usually neglected in randomized clinical trials (RCTs) and which might influence their findings is the patients' preferences for treatments. The rationale is that patients who receive their preferred treatment may be more motivated to adhere to treatment, resulting in better outcomes [11,12]. In contrast, those who do not receive their preferred treatment might suffer what has been termed "resentful demoralization" and present poor adherence to treatment, leading to worse outcomes [13–15]. This preference effect is likely to be relevant in RCTs in which participants are unblinded or in which blinding cannot be properly maintained as only in these cases patients would know whether they are receiving their preferred or nonpreferred treatment [16]. This is commonly the case with

Funding: This project was not directly supported by any external grants or funds. M.R.F. and R.Z.P. are supported by CAPES Foundation, an agency under the Ministry of Education of Brazil. C.G.M. is supported by a research fellowship funded by the Australian Research Council. None of the authors have any financial or other relationship that might lead to a conflict of interest.

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^{0895-4356/\$ -} see front matter © 2013 Elsevier Inc. All rights reserved. http://dx.doi.org/10.1016/j.jclinepi.2012.12.012

What is new?

- Randomized clinical trials (RCTs) evaluating the effect of patients' preferences in musculoskeletal conditions used heterogeneous methods to measure and analyze patients' preferences. The analyses of patients' preferences were not preplanned in most of the existing studies and underpowered in all those that have used a statistical model including tests for interaction between preferences and group allocation.
- Methodological limitations of the available evidence suggest that it might be too early to conclude whether patients' preference affects the results of RCTs evaluating interventions for musculoskeletal conditions.
- Future trials should report data on subgroups of patients defined by a treatment preference of each randomized arm and use standardized methods to measure patients' preferences.

RCTs on conservative treatments for musculoskeletal conditions, which include noninvasive approaches, such as physical therapy and medications. Importantly, a number of musculoskeletal diseases are long-term conditions and patients are likely to have experienced a range of treatments in the past. Their preference for treatments may reflect what has worked best for them in the past, and hence, it may be reasonable to consider that their preferences will influence treatment outcomes.

A number of designs have been proposed to evaluate the impact of patients' treatment preferences, including the comprehensive cohort, Wennberg, and Rucker designs. These designs have in common the inclusion of "preference arm(s)" in which participants are allowed to choose their preferred treatment in addition to the "randomized arm(s)" in which participants are randomly allocated [17,18]. However, consistent baseline differences between preference and randomized arms would bias the findings of these studies [12]. An alternative approach is a traditional RCT in which patients' preferences are collected before randomization, and its impact on results is evaluated in statistical analyses [19,20].

Two systematic reviews have explored the effect of participants' preferences in clinical trials [15,19]. King et al. [15] used evidence from trials with preference arm(s) including several conditions, such as diabetes, musculoskeletal pain, and depression. The results were inconclusive, possibly because of the heterogeneity of the included trials. In 2008, the Preference Collaborative Review Group conducted an individual patient data analysis of traditional RCTs on musculoskeletal conditions to explore whether preference affects trial findings [19]. In this review, patients from each RCT were classified into three subgroups irrespective of their treatment allocation: patients who received their preferred treatment ("matched"), patients who received their nonpreferred treatment ("unmatched"), and patients without a preference ("indifferent"). As randomization has been breached, inferences from their results are limited to the effect of patients' preferences on outcomes only, and no treatment effect modification can be inferred. Treatment effect modifiers must be expressed in terms of a difference in outcome between treatment groups (treatment effect) rather than a difference in outcome over time (i.e., without consideration of treatment allocation) [21].

Therefore, current evidence on the impact of patients' preferences on treatment effects in clinical trials for musculoskeletal pain and disability is unclear. The objective of this review was to systematically and critically investigate how patients' preferences have been measured and analyzed in RCTs evaluating treatments for musculoskeletal conditions. In addition, we investigated registry entries and protocols to determine whether analyses had been preplanned and the presence of selective reporting bias. We used a statistical approach to analyze the data: when possible, we calculated interaction terms to investigate if patients' preferences modify treatment effect. Our results provide information that will guide future studies in this area.

2. Methods

2.1. Search strategy and study selection

The following databases were searched from the earliest records to the May 27, 2011: PsycINFO, MEDLINE, EM-BASE, Cochrane Central Register of Clinical Trials, CI-NAHL, LILACS, and PEDro. Key words related to randomized controlled trial, patient preference, and musculoskeletal pain were used in addition to subject subheadings and word truncations specific for each database (Appendix A at www.jclinepi.com). Electronic searches were supplemented by hand searching of reference lists of eligible clinical trials. The reference lists of identified systematic reviews were also hand searched for trials. Our search was restricted to trials published in English, Portuguese, and Spanish. One reviewer screened all relevant titles and abstracts and excluded clearly irrelevant articles. Two reviewers independently evaluated full reports for eligibility, and disagreements were resolved by consensus.

Studies that included preference arm(s) in which participants were allowed to choose their preferred treatment (i.e., rather than being randomly allocated) were excluded from the review as important baseline differences between preference and randomized arms may bias the findings of these studies. We considered studies eligible if they were RCTs in which authors reported that patients' preferences were measured before randomization and further investigated the effects of preference on their findings. To be included, trials' participants had to be aged 16 years or older with any musculoskeletal condition. Trial inclusion was not restricted to treatment type, symptom duration, intervention, or clinical setting (i.e., primary care or community settings). Included outcomes were pain and disability.

For eligible trials, the trial report was checked for a statement regarding trial registration or registration number. If a statement was not found, an e-mail message requesting the details of evidence of registration was sent to the authors. In the absence of a reply, the following registers were searched: ClinicalTrials.gov, the International Standard Randomized Controlled Trial Number Register, the Australian New Zealand Clinical Trials Register, and the national register of the country of origin of each author. The search for evidence of registration was assisted by the World Health Organization registry search portal. If the registry entry included a link to the published protocol, the published protocol was retrieved.

2.2. Assessment of risk bias

The PEDro scale was used to assess the risk of bias. The PEDro scale is an 11-item scale, each satisfied item (except for item 1, which, unlike other scale items, pertains to external validity) contributes 1 point to the total PEDro score (range, 0-10 points) [22,23]. Two trained independent raters conducted all assessments. Disagreements were resolved by a third rater. Trial quality was not an inclusion criterion.

2.3. Data extraction and data synthesis

Study characteristics such as types of conditions, sample size stratified by preference and group, duration of complaints, source, interventions, and outcome measures were extracted (Table 1).

We also extracted the following data from each included trial: (1) how preference was measured, (2) whether authors reported if patients' preference influenced treatment outcomes, (3) whether authors reported the use of a statistical model including an interaction term between preference and group allocation, (4) whether the interaction analysis, when reported, was powered for a statistical test of interaction. These additional data are shown in Table 2. Studies were regarded as aiming to assess patients' preferences as treatment effect modifiers only when they reported the use of interaction analyses including an interaction term between preference and group allocation. In all other instances, studies were regarded as aiming to assess the effect of patients' preferences on outcome only.

Two independent reviewers extracted interaction terms for preference vs. group allocation, from trials which provided these data. We also extracted means (final scores or change score), sample sizes, standard deviations, or 95% confidence interval (95% CI) from studies using a standardized data extraction form. Scores for pain intensity and disability were converted to a scale from 0 to 100. When there was insufficient information in trial reports, data were estimated using methods recommended in the *Co-chrane Handbook for Systematic Reviews of Interventions* [24]. If possible, pooling of individual studies would be conducted.

In this review, a statistical model based on test of interaction was used to investigate if patients' preferences modify treatment effect [25]. When data were available, we calculated interaction terms using the approach illustrated in Fig. 1. A forest plot was used to present interaction terms and 95% CI from individual trials. Presenting data in a forest plot are useful to identify the direction of the interaction. In Fig. 1, "effect size 1" is the difference in outcomes between treatment groups for all patients, regardless of treatment preference, and is the usual effect size reported in a trial. Effect sizes 2-4 are effect sizes calculated as the difference between subgroups defined by treatment preference. Thus, the interaction term was calculated by subtracting the mean effect size of the subgroup of patients who prefer treatment A (effect size 3) from the mean effect size of patients who prefer treatment B (effect size 2) and its 95% CI [26] (Appendix B at www.jclinepi.com). The interpretation of this interaction term is the difference in treatment effect because of treatment preference for one specific intervention. That is, the analysis involves demonstrating that the effect of treatment A compared with that of treatment B for one subgroup (patients who have preference for treatment A) is greater, equal, or less than the effect of treatment A compared with that of treatment B in the other subgroup (patients who have preference for treatment B). For instance, if "effect size 3" is greater than "effect size 2", then the size of the interaction tells us how much more benefit patients in the subgroup of preference for treatment A received compared with those in the subgroup of preference for treatment B.

Registry entries and protocols were sought for evidence of any statement regarding preplanned analysis of the influence of patients' preferences on treatment outcomes. Whenever possible, we also investigated whether the analvsis of patients' preference represented selective reporting of outcomes. To investigate if selective reporting occurred, data from primary outcome(s) and time point(s) of assessment included in the published reports were compared with registry entries. If the registry entry was not found, information from published protocols was used. We classified selective reporting of outcomes in two categories: (1) no evidence of selective reporting: the analysis of patients' preferences in the published report was conducted for all primary outcome(s) and time point(s) of assessment described in the registry entry or published protocol and (2) possible selective reporting: the analysis in the published report was not conducted for all primary outcome(s) and

Table 1. Summary of the studies included in the systematic review

Churcher	0	Sample size stratified by	Demotion of commutaint	0	Internetions.	0
Study	Condition	preference and group	Duration of complaint	Source	Interventions	Outcomes measures
Carr et al. [27]	Low back pain	 N = 237 G1 = 118 (preferred G1, 5; not preferred G1, 35; and indifferent, 70) G2 = 112 (preferred G2, 25; not preferred G2, 5; and indifferent, 82) 	At least 6 weeks	Patients referred from physiotherapy departments in hospitals and community health centre	G1: group exercise program vs. G2: individual physiotherapy	Pain and disability
Foster et al. [28]	Knee osteoarthritis	N = 352 With treatment preference = 70 and without a treatment preference = 280 G1 = 116, G2 = 117, and G3 = 119	Subacute or chronic (lasting at least 2 weeks)	Outpatients recruited from physiotherapy centres	G1: advice and exercise vs. G2: advice and exercise plus true acupuncture vs. G3: advice and exercise plus nonpenetrating acupuncture	Pain and function
George and Robinson [29]	Low back pain	N = 105 Preference for G1 = 18 Preference for G2 = 39 Preference of G3 = 7 No preference = 39 Unmatched = 32 Matched = 14 No strong preference = 26	Acute or subacute (1-24 weeks)	Outpatients seeking treatment in university-affiliated clinics	G1: physical therapyvs.G2: physical therapy with graded activityvs.G3: physical therapy with graded exposure	Pain and disability
Johnson et al. [30]	Low back pain	N = 234 G1 = 116 and G2 = 118 No preference = 100, preference intervention = 114, and preference control = 20	3 Months	Outpatients referred by general practitioners	G1: group exercise vs. G2: educational program.	Pain and disability
Moffett et al. [31]	Neck pain	N = 268 G1 = 139 (preferred G1, 24; preferred G2, 40; and indifferent, 75) G2 = 129 (preferred G1, 19; preferred G2, 43; and indifferent, 67)	Subacute or chronic (lasting at least 2 weeks)	Patients recruited from general practitioners and consultants	G1: brief physiotherapy vs. G2: usual physiotherapy	Pain and disability
Moffett et al. [32]	Neck and back pain	N = 315 G1 = 161 (preferred G1, 16 and not preferred G1, 10) G2 = 154 (preferred G2, 4 and not preferred G2, 22)	At least 2 weeks	Outpatients referred by general practitioners	G1: McKenzie vs. G2: brief physiotherapy ^a	Pain and disability
Moffett et al. [33]	Low back pain	N = 187 G1 = 89 (preferred G1, 53 and not preferred G1, 36) G2 = 98 (preferred G1 = 65 and not preferred G1 = 33)	4 Weeks to 6 months	Patients recruited from general practitioners	G1: progressive exercise program vs. G2: usual primary care management	Pain and disability

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Table 1. Continued

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Study	Condition	Sample size stratified by preference and group	Duration of complaint	Source	Interventions	Outcomes measures
Sherman et al. [34]	Back pain	N = 628/477 reported in this article Preference for acupuncture = 167, preference for other CAM = 186, preference to conventional = 76, and missing = 48	At least 3 months	Outpatients from integrated health care systems	G1: individualized acupuncture vs. G2: standardized acupuncture vs. G3: simulated acupuncture	Disability
Smidt et al. [35]	Lateral epicondylitis	N = 185 G1 = 59 (preferred G1, 1; preferred G2, 5; preferred G3, 26; and no preference, 31) G2 = 62 (preferred G2, 6; preferred G1, 3; preferred G3, 22; and no preference, 32) G3 = 64 (preferred G3, 27; preferred G1, 4; preferred G2, 8; and no preference, 27)	At least 6 weeks	Primary care setting and patients from family doctors	G1: wait and see policy vs. G2: corticosteroid injection vs. G3: physiotherapy	Pain and disability
Sorensen et al. [36]	Low back pain	N = 207 G1 = 105 and G2 = 102 G1 = 105 (preferred G1, 4 and preferred G2, 23) G2 = 102 (preferred G1, 4 and preferred G2, 22)	At least 4 months of 12 months	Outpatients referred from general practitioners and chiropractors	G1: educational program vs. G2: individual symptom- based physical training program	Pain and disability
Stewart et al. [37]	Whiplash-associated disorders	N = 134 G1 = 66 and G2 = 68	3–12 Months	Patients recruited with the assistance of the Motor Accidents Authority	G1: advice, exercise, and behavioral graded activity vs. G2: advice alone	Pain, functional ability, and disability
Thomas et al. [38]	Shoulder pain	N = 207 G1 = 104 (preferred G1, 45; not preferred G1, 18; and indifferent, 41) G2 = 103 (preferred G2, 24; not preferred G2, 38; and indifferent, 41)	Not specified	Patients from general practitioners	G1: local corticosteroid injectionvs.G2: physiotherapy	Pain and disability

Abbreviation: CAM, Complementary and Alternative Medicine. ^a They were later randomized to receive an educational booklet.

Table 2. Patients' preferences measurement and analysis (as reported in the article)

Study	How preference was measured	Preference influenced treatment effect?	Interaction analysis	Interaction analysis powered
Carr et al. [27]	"In recognition of a need to acknowledge the influence of treatment preferences of patients, these were recorded at the outset."	No	No	N/A
Foster et al. [28]	"Before randomization, patients were asked to state if they had a treatment preference, and if so, which treatment they would choose, and to indicate the strength of their treatment preference for advice and exercise and acupuncture ("strongly prefer" to "strongly not prefer")."	No	No	N/A
George et al. [29]	"The patient was asked to indicate which treatment they would prefer if given the choice." Patients were also given the option of selecting "no strong preference for any treatment."	Yes	No	N/A
Johnson et al. [30]	"Before randomization, each participant was asked whether they had a preference for which intervention they may be allocated."	Yes	Yes	No
Moffett et al. [31]	"Noninferiority randomized controlled trial eliciting preferences independently of randomization."	No	Yes	No
Moffett et al. [32]	"All consenting participants were asked their treatment preference independently of randomization."	No	Yes	No
Moffett et al. [33]	"Before patients were given their envelope of allocation, they were asked whether they had any preference for the treatment assignment."	No	Yes	No
Sherman et al. [34]	"Participants were asked which treatment they would select if they could have any treatment or training for their back pain at the baseline interview. We coded the responses into acupuncture, other CAM treatment (e.g., chiropractic, massage, and yoga) or medical treatments (e.g., narcotics and physical therapy)."	No	No	N/A
Smidt et al. [35]	"Before randomization, patients were asked about their preferences with respect to treatment."	No	No	N/A
Sorensen et al. [36]	"Before randomization, patients were asked which intervention they would prefer being allocated to."	No	No	N/A
Stewart et al. [37]	"Patients were asked two questions before randomization: (1) How helpful do you believe "advice" will be for your current whiplash problems? (2) How helpful do you believe "advice" plus an "exercise program" will be for your current whiplash problems? Each question was scored on an 11-point numerical rating scale with 0 representing "not at all helpful" and 10 representing "extremely helpful". Subjects were asked to circle the number which best reflected how they felt about each statement. Subjects' treatment preference rating was calculated by subtracting the advice rating from the exercise rating."	No	Yes	No
Thomas et al. [38]	"Information regarding patients' preferences was elicited before randomization using the following question: 'If you had a free choice, would you choose to have physiotherapy or an injection?' Patients could also record no preference for either treatment.''	No	No	N/A

Abbreviations: CAM, Complementary and Alternative Medicine; N/A, non applicable.



Fig. 1. Statistical model based on test of interaction to investigate patients' preferences as treatment effect modifiers. Effect size 1: treatment effect between treatments A and B. Effect size 2: treatment effect between subgroups of patients who preferred B of each randomized arm. Effect size 3: treatment effect between subgroups of patients who preferred A of each randomized arm. Effect size 4: treatment effect between subgroups of participants without a treatment preference of each randomized arm.

time point(s) of assessments as indicated in the registry entry or published protocol. Selective reporting of outcomes was considered not possible to be assessed when trials were unregistered, no protocol had been published, or when the registry entry or published protocol did not provide information regarding any primary outcomes.



Fig. 2. Selection process of trials.

3. Results

The flow of trials through the review is outlined in Fig. 2. The initial electronic database search identified 3,621 studies of interest. After removing duplicates, 3,129 studies were screened by title and abstract, a total of 844 potentially eligible articles were considered for inclusion and the full article retrieved. As a result, 12 published traditional RCTs [27–38], in which patients were randomly allocated to intervention groups, regardless of their treatment preferences, were included in the review. All included studies collected data on patients' preferences before randomization. The conditions investigated were low back pain [27,29,30,33,34,36], neck and back pain [32], neck pain [31], knee osteoarthritis [28], shoulder pain [38], whiplash [37], and lateral epicondylitis [35].

Three trials investigating interventions for musculoskeletal conditions identified in a previous review [19] were not included in the current one. The first was excluded because there was no information in the published report about patients' preferences [39]. The second was excluded because patients' preferences were collected on baseline, but no further analysis was reported [40], and the third cited as "publication pending" in the previous review was not found. Four studies that included preference arm(s), in which participants were allowed to choose their preferred treatment and breaching randomization, were excluded.

The mean (standard deviation) trial quality (Table 3), as measured by the PEDro, scale was 7.1 (1.0). Five included trials were secondary analyses of an original trial, and in these cases, the information provided in both the secondary analyses and main publication was used in their methodological rating on the PEDro scale [28,29,34,37,38].

The included studies used different measurement tools to elicit patients' preferences. The majority of them used simple questions, such as "Which treatment would you select if given the choice?." One trial [37] measured patients' preferences using numerical rating scales. In this trial, patients were asked how helpful they believe the interventions (control or experimental) would be for their low back pain. Each question was scored on an 11-point numerical rating scale with 0 representing "not at all helpful" and 10 representing "extremely helpful." Patients were asked to circle the number which best reflected how they felt about each intervention. Patients' treatment preference rating was calculated by subtracting the group control rating from the experimental group rating. In two trials [28,34], patients could indicate preferences for treatments outside the context of the RCT. Only two trials [28,29] asked patients to indicate the strength of their treatment preference.

Seven studies investigated if patients' preferences influenced outcome only (i.e., they did not report the use of a statistical model including interaction terms between preferences and group allocation) [27-29,34-36,38]. Among these, only one study reported statistical significant influence of patients' preferences on pain ($F_{4,134}$, 3.2;

Table 3. Trials' quality	r assessment	t based on PE	EDro scale								
Study	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	<15% Dropouts	Intention-to-treat analysis	Between-group difference reported	Point estimate and variability reported	Total (0–10)
Carr et al. [27]	~	~	7	z	z	~	7	7	~	7	∞
Foster et al. [28] ^a	≻	≻	≻	≻	z	≻	≻	~	Y	≻	6
George et al. [29] ^a	≻	≻	~	z	z	z	z	~	7	7	9
Johnson et al. [30]	≻	≻	~	z	z	z	~	~	7	7	7
Moffett et al. [31]	≻	~	z	z	z	≻	z	~	7	7	9
Moffett et al. [32]	≻	≻	~	z	z	z	z	~	7	7	9
Moffett et al. [33]	≻	≻	~	z	z	z	~	~	7	7	7
Sherman et al. [34] ^a	≻	z	7	z	z	≻	~	~	7	7	7
Smidt et al. [35]	≻	~	~	z	z	≻	~	~	7	~	∞
Sorensen et al. [36]	≻	≻	≻	z	z	z	≻	Z	7	7	9
Stewart et al. [37] ^a	≻	≻	≻	z	z	≻	≻	7	7	≻	ø
Thomas et al. [38] ^a	≻	≻	۲	z	z	≻	≻	≻	۲	۲	80
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^a Trials which were secondary analysis of the original trial. The secondary analysis and the main publication were considered to rate these studies on the PEDro scale.

P = 0.02) and disability ($F_{4,134}$, 3.6; P < 0.01) [29]. In this study, patients with no treatment preference (indifferent) showed the largest 6-month improvement for both pain and disability. In contrast, those who received their preferred treatment (matched) and those who received their nonpreferred treatment (unmatched) showed similar 4-week and 6-month improvements on pain and disability.

Five studies [30-33,37] investigated the influence of patients' preferences on treatment effect as they reported the use of a statistical model including the interaction term (preference \times group allocation) [41]. Three studies [31-33] stated that the interaction terms were nonsignificant, and two studies [30,37] provided the interaction terms and 95% CI in the published report. Stewart et al. [37] measured preferences using the numerical rating scales mentioned previously. In this study, the interaction term for pain and function was 0.1 (95% CI: -0.3, 0.5) and -0.1 (95% CI: -0.5, 0.3), respectively, meaning that patients with higher preference for exercise in the exercise group did not report better clinical outcomes compared with the control group. Johnson et al. [30] asked patients whether they had a preference for an intervention after an explanation of each treatment arm. The interaction terms were reported for pain and disability in three follow-up points (3, 9, and 15 months). Although the greatest improvement tended to favor those in the intervention group that stated preference for it, results were not significant. Three included studies [27,31,36] provided enough data to calculate interaction terms using the approach illustrated in Fig. 1. For better visualization,

interaction terms and 95% CI from these individual trials were plotted (Fig. 3). Among the 11 interaction terms plotted, only one showed statistically significant results. However, none of the studies that reported interaction terms or that provided data to calculate interaction terms were powered for statistical tests of interaction. Pooling of data was not conducted because included studies used heterogeneous methods to measure patients' preferences, did not provide data to be used in subgroups analysis, and were not sufficiently homogeneous with regard to populations and interventions.

Of the 12 included studies, nine (75%) were registered or presented a previously published protocol [28–32,34,36–38]. Among these nine studies, only two described a preplanned analysis for treatment preference, considered as the description of a prior intention to measure patients' preferences [28,37]. However, these studies did not clearly define on which outcome or time point patients' preferences would be evaluated. Preplanned analyses could not be assessed in three trials as they did not have registry entry or published protocol [27,33,35].

Regarding selective reporting, assessment was possible in seven (58%) trials. Of these, four trials did not show evidence of selective reporting [28,29,32,38], and three were classified as possible selective reporting [31,34,37]. Selective reporting of outcomes was considered not possible to assess in five (42%) trials. For three of these trials, registry entry or published protocol was not available [27,33,35]. In two of these trials, information on any primary outcomes was not provided in the registry entry [30,36].



Fig. 3. Interaction terms calculated using statistical model based on test of interaction. Interaction terms were calculated by subtracting the mean effect size of the subgroup of patients who preferred one intervention from the mean effect size of patients who preferred the other intervention or who did not state preference for any intervention and its 95% CI. The interpretation of this interaction term is the difference in treatment effect because of treatment preference for one specific intervention. CI, confidence interval; NP, Northwick Park neck pain questionnaire; RM, Roland Morris disability questionnaire.

4. Discussion

In this review, we have identified 12 RCTs evaluating treatments for musculoskeletal conditions, in which information about patients' preferences was collected before randomization. Included studies used different methods to measure patients' preferences and heterogeneous statistical tests. Seven studies investigated the influence of patients' preferences on outcomes (changes in outcomes within group), whereas five studies investigated the patients' preferences as treatment effect modifiers (changes in outcomes between randomized groups). In general, included studies did not show a statistically significant influence of patients' preferences on treatment effects, but none of them were powered to test for interactions. In addition, there is evidence that the completeness of registration has not been adequately performed. At present, the methodological limitations prevent inferring definitive conclusions from findings. However, these findings were not unexpected as included studies were not explicitly designed to investigate patients' preferences.

Most of the included studies used simple questions to measure preferences, such as "Which treatment would you select if given the choice?," and information related to how interventions were described, and the uncertainty about the effectiveness of one treatment in comparison with the other was not clearly provided. This simple method to elicit patients' preferences differ from the traditional health economic approach, which reflects the trade-offs made with respect to differing treatment attributes that may drive treatment choice [42]. To assert effectively their preference for a treatment, patients need information about the potential benefits of the interventions and side effects, discomfort, and the amount of effort entailed on both arms of the trial [43]. In fact, the Declaration of Helsinki clearly states that participants of a randomized clinical trial should be informed regarding these factors before giving informed consent [44]. Standardized methods that inform patients about the risks, benefits, costs, and inconveniences of an intervention should be developed and incorporated in future trials. The strength of patients' preferences could also be measured and further investigated in the analyses. One alternative to evaluate the role of patients' preference strength in clinical trials is to conduct sensitivity analyses that incorporate categories of patients defined by strength of preference (e.g., strong preference and low preference).

It has been suggested that interventions can be improved by targeting the provision of specific interventions for patients who respond best to that treatment [45]. This idea can easily be transferred to the context of patients' preference. In this context, a subgroup of patients allocated to a specific intervention would get their preferred treatment and because of that would be more likely to adhere to the treatment resulting in better outcomes. The opposite might also be true, and a subgroup of patients allocated to the same intervention group would not receive the preferred treatment and their response to treatment would be negatively affected by "resentful demoralization." To establish whether patients' preference is a moderator of the treatment effect, the statistical model should include the interaction term (preference by group allocation) [41]. Five studies included in our review reported the use of statistical analyses to investigate whether patients' preferences are treatment effect modifiers. A previous systematic review that investigated the role of patients' preferences within RCTs [19], and two included studies [28,29] used the "matched and unmatched" approach (Fig. 4), in which patients from both randomized arms were mixed and then classified into three subgroups irrespective of their treatment allocation:



Fig. 4. Grouping of participants used in the "matched and unmatched approach." Group 1 (matched participants): those who were randomized to their preferred treatment. Group 2 (unmatched participants): those who were randomized to the treatment that they did not prefer. Group 3 (indifferent participants): those without a preference. Groups 1, 2, and 3 were then compared in the analyses, that is, participants from both interventions arms were mixed across comparisons, and as randomization was breached, no treatment effect modification can be inferred.

patients who received their preferred treatment ("matched"), patients who received their nonpreferred treatment ("unmatched"), and patients without a preference ("indifferent"). As randomization has been breached in this approach, only the difference in outcome over time should be interpreted. By using the approach illustrated in Fig. 1, it is possible to determine whether patients' preferences are treatment effect modifiers.

Lack of power among included studies that calculated interaction terms and also the inability to perform metaanalysis in this review prevented us from making strong conclusions. We acknowledge that this was not a surprise as included studies were not specifically designed to investigate patients' preferences as a treatment effect modifier. In addition, it would be difficult to achieve adequate power in individual studies because tests of interaction require very large sample sizes. Sample size calculations for subgroup analyses are scarce in the literature and are rarely performed. Commonly, trials are powered only to detect the overall treatment effect of health interventions, leading to problems in the power and interpretations of subgroup analyses [46]. The ability of the interaction test to appropriately identify whether treatment effect differs between subgroups improves if the size of the interaction effect is greater than that of the overall treatment effect [46]. For instance, when the size of the interaction effect is twice or greater than that of the overall treatment effect, the interaction test would have at least the same power as that for the overall treatment effect. However, power is significantly reduced for smaller interactions. When the interaction effect and the overall treatment effect have the same size, the sample size for the interaction test should be inflated by a factor of four to achieve the same power as that for the overall treatment effect [46]. Moreover, it is possible to find a higher proportion of patients' who stated a preference for one intervention arm. In this case of imbalance in the proportion of treatment preference between randomized arms, an even bigger sample size might be required to achieve a prespecified statistical power [47]. Therefore, detecting patients' preference interactions within trials is a challenging task as trials are likely not to be powered to detect them. One alternative to overcome this problem is to conduct a meta-analysis and then appropriate statistical power can be achieved. To be used in a meta-analysis that investigates if patients' preferences are treatment effect modifiers, future trials should report data on subgroups of patients defined by a treatment preference of each randomized arm and use standardized methods to measure patients' preferences.

In most of the included studies, the analyses of patients' preferences were not preplanned. Only two (17%) articles previously reported in the registry entry or published protocol that patients' preferences would be collected. Only four (33%) trials did not show evidence of selective reporting bias. Therefore, the completeness of registration should be encouraged in future studies in this area to ensure data transparency.

Our review included only RCTs in which information about patients' preferences was collected before randomization. Random allocation evenly distributes patients with a treatment preference between randomized arms and with all other patient characteristics (e.g., age and weight) [19]. However, there is the belief that it cannot deal with postrandomization effects of patients' preferences on treatment outcomes as, for instance, patients' adherence to treatment [13]. We believe that the included studies have the most appropriate design to evaluate the effect of patients' preferences as it gathers information regarding patients' preferences, but has the rigor of an RCT, designed to increase the chance of having comparable groups regarding both known and unknown confounding factors [12,19,20]. Another criticism is that RCTs might not include a representative sample of the population as patients with strong preferences, who might refuse randomization and whose preferences are more likely to influence treatment outcomes, might not be recruited [12,17]. In fact, other factors rather than preferences such as time constraints or family support can also affect the recruitment in clinical trials.

5. Conclusion

Included studies used heterogeneous methods to measure and analyze patients' preferences. In addition, the analyses of patients' preferences were not preplanned in most of the included studies and underpowered in all those that have used a statistical model including tests for interaction between preferences and group allocation. At present, the methodological limitations of the available evidence suggest that it might be too early to conclude whether patients' preference affects treatment effects in RCTs evaluating musculoskeletal conditions. However, this may not come as a surprise as none of the included studies has been primarily designed to investigate patients' preferences. As assembling a large enough sample size is a major barrier for further trials, future meta-analyses should be considered. In this case, the development of standardized methods to measure patients' preferences and also the reporting of complete data on subgroups of patients defined by a treatment preference of each randomized arm should be encouraged in future studies.

Appendix

Supplementary material

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.jclinepi.2012.12.012.

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<u>Appendix 1:</u> Search Strategies for MEDLINE, EMBASE, Cochrane Central Register of Clinical Trials, CINAHL, LILACS and PEDro Databases

Search strategy for MEDLINE (25/05/2011)

- controlled clinical trial.pt. or double blind method.sh. or single blind method.sh. or clinical trial.pt. or exp clinical trial/ or (clinica\$ adj25 trial\$).ti,ab,sh. or ((singl\$ or doubl\$ or trepl\$ or tripl\$) adj25 (blind\$ or mask\$)).tw. or placebos.sh. or placebo\$.tw. or random\$.tw. or research design.sh. or comparative study.sh. or exp evaluation studies/ or followup studies.sh. or prospective studies.sh. or (control\$ or prospective\$ or volunteer\$).tw.
- 2. animal.mp. not human.sh. [mp=ti, ot, ab, sh, hw, kw, ps, rs, nm, ui]
- 3. 1 not 2
- 4. exp Patient preference/
- 5. exp Patient Acceptance of Health Care/
- 6. Treatment Refusal.sh.
- 7. Preference\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 8. 4 or 5 or 6 or 7
- 9. (back pain or neck pain or whiplash).mp.
- 10. (exp extremities/ or exp joints/) and (pain/rh, th or arthralgia/rh, th)
- 11. musculoskeletal pain.mp.
- 12. musculoskeletal disease/
- 13. 9 or 10 or 11 or 12
- 14. 3 and 8 and 13
- 15. remove duplicates from 14

Search strategies for PsycINFO (24/05/2011)

- controlled clinical trial.pt. or double blind method.sh. or single blind method.sh. or clinical trial.pt. or exp clinical trial/ or (clinica\$ adj25 trial\$).ti,ab,sh. or ((singl\$ or doubl\$ or trepl\$ or tripl\$) adj25 (blind\$ or mask\$)).tw. or placebos.sh. or placebo\$.tw. or random\$.tw. or research design.sh. or comparative study.sh. or exp evaluation studies/ or follow-up studies.sh. or prospective studies.sh. or (control\$ or prospective\$ or volunteer\$).tw.
- 2. animal.mp. not human.sh. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
- 3. 1 not 2
- 4. preference\$.mp. or exp Preferences/
- 5. Treatment Refusal.sh.
- 6. 4 or 5
- 7. (back pain or neck pain or whiplash).mp.
- 8. ((extremities or joint\$) and (pain or arthralgia)).mp.
- 9. exp Musculoskeletal System/ or exp Musculoskeletal Disorders/ or musculoskeletal.mp.
- 10. 7 or 8 or 9
- 11. 3 and 6 and 10

Search strategies for CINAHL (24/05/2011)

- S1. randomized controlled trial or controlled clinical trial or randomized controlled trials or randomized controlled trials or random allocation or double-blind method or single-blind method or clinical trial or clinical trials or placebos or placebo\$ or random\$ or research design or comparative study or evaluation studies or follow-up studies or prospective studies or cross-over studies or control\$ or prospectiv\$ or volunteer\$ or ("volunteer\$") or (MH "Clinical Trials+") or (MH "Cochrane Library") or (MH "Random Assignment") or (MH "Random Sample+") or (MH "Double-Blind Studies") or (MH "Single-Blind Studies") or (MH "Placebos") or (MH "Placebo Effect") or (MH "Concurrent Prospective Studies") or (MH "Prospective Studies+") or (MH "Crossover Design")
- S2. (MH "Animals+") not (MH "Human")
- S3. S1 not S2
- S4. "Preference\$"
- S5. (MH "Treatment Refusal")
- S6. (S4 or S5)
- S7. back pain or neck pain or whiplash
- S8. ((MH "Arthralgia+") OR (MH "Pain+")) AND ((MH "Joints+") OR (MH "Extremities+") OR (MH "Upper Extremity Exercises+"))
- S9. (MH "Musculoskeletal Diseases+")
- S10. "Musculoskeletal pain"
- S11. S7 or S8 or S9 or S10
- S12. S3 and S6 and S11

Search strategies for Cochrane Central Register of Clinical Trials (27/05/2011)

- 1. controlled clinical trial.pt. or double blind method.sh. or single blind method.sh. or clinical trial.pt. or exp clinical trial/ or (clinica\$ adj25 trial\$).ti,ab,sh. or ((singl\$ or doubl\$ or trepl\$ or tripl\$) adj25 (blind\$ or mask\$)).tw. or placebos.sh. or placebo\$.tw. or random\$.tw. or research design.sh. or comparative study.sh. or exp evaluation studies/ or follow-up studies.sh. or prospective studies.sh. or (control\$ or prospective\$ or volunteer\$).tw.
- 2. animal.mp. not human.sh. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 3. 1 not 2
- 4. exp Patient preference/
- 5. exp Patient Acceptance of Health Care/
- 6. Treatment Refusal.sh.
- 7. Preference\$.mp. [mp=ti, ot, ab, sh, hw, kw, ps, rs, nm, ui]
- 8. 4 or 5 or 6 or 7
- 9. (back pain or neck pain or whiplash).mp.
- 10. (exp extremities/ or exp joints/) and (pain/rh, th or arthralgia/rh, th)
- 11. exp musculoskeletal diseases/rh, th
- 12. exp musculoskeletal diseases/su
- 13. musculoskeletal pain.mp.
- 14. 9 or 10 or 11 or 12 or 13
- 15. 3 and 8 and 14
- 16. remove duplicates from 15

Search strategies for PEDro (26/05/2011)

Advanced search Abstract and title: preference Therapy: no selection Problem: no selection Body part: no selection Subdiscipline: no selection Method: clinical trial

Search strategies for LILACS (24/05/2011)

Search on: random\$ AND clinical AND trial

APPENDIX 2. Data used to calculate interaction term using the novel approach.

Table 1. Individual data from studies used to calculate interaction terms.

Study	Outcomes	Subgroups		Intervention A]	Intervention B	Mean Difference	Variance
			N	Mean (SD)	Ν	Mean (SD)	-	
Moffett et al. [22]*				Brief intervention		Usual Physio		
	NP neck score at 12mo	Preferred brief physio	24	-7.8 (18.2)	19	-6.0 (17.1)	-1.86	29.60
		No Preference	75	-2.8 (17.8)	67	-8.6 (18.1)	5.80	9.09
		Preferred usual physio	40	1.6 (17.5)	67	-7.6 (22.1)	9.22	16.78
Sorensen et al. [35] ⁺				Educational		Training		
	Pain at 2mo	Preferred educational	3	30.0 (21.0)	5	40.0 (22.0)	-10.00	250.49
		Preferred training	22	30.0 (21.0)	18	50.0 (22.0)	-20.00	46.49
	Pain at 6mo	Preferred educational	3	50.0 (23.0)	5	60.0 (21.0)	-10.00	250.84
		Preferred training	18	40.0 (23.0)	18	50.0 (21.0)	-10.00	53.89
	Pain at 12mo	Preferred educational	3	60.0 (24.0)	4	65.0 (22.0)	-5.00	303.80
		Preferred training	19	40.0 (24.0)	16	50.0 (22.0)	-10.00	61.50
	Activity limitation at 2mo	Preferred educational	3	42.9 (20.5)	5	42.9 (19.1)	0.00	204.67
	,	Preferred training	22	24.8 (20.5)	19	39.6 (19.1)	-14.85	38.69
	Activity limitation at 6mo	Preferred educational	3	52.8 (21.1)	5	33.0 (17.8)	19.80	192.21
	2	Preferred training	18	33.0 (21.1)	18	46.2 (17.8)	-13.20	42.42
	Activity limitation at 12mo	Preferred educational	3	52.8 (22.4)	4	39.6 (19.5)	13.20	250.17
	-	Preferred training	19	33.0 (22.4)	16	36.3 (19.5)	-3.30	51.46
Carr et al.				Individual physio		Back to fitness program		
[•].	RM at 3mo	Preferred physio	25	-4.8 (21.4)	35	-3.4 (21.4)	-1.45	31.50
		No preference	82	-0.9 (21.4)	70	-4.5 (21.4)	3.54	12.17
	RM at 12mo	Preferred physio	25	-6.4 (21.7)	35	-3.5 (21.7)	-2.86	32.24
		No preference	82	-4.1 (21.7)	70	-3.6 (21.7)	-0.55	12.45

N= sample size; SD= standard deviation; RM= Roland Morris disability questionnaire; NP= Northwick Park neck pain score. * SD estimated from 95% confidence interval of the change score in each groups

[†]Mean estimated from median and SD estimated from whole group in each time point.

\$Sample size estimated from baseline data and SD estimated from 95%CI of difference between group at 3 and 12mo.

Table 2 – Detailed information regarding the calculated interaction terms.

Study	Outcomes	Subgroups	Interaction Term (Difference in means)	SE	95% CI	Z value	P value
Moffett et al. [22]	NP neck score at 12mo	Preferred Brief Intervention vs No Preference	-7.66	6.22	-19.85 to 4.53	-1.23	0.218
		Preferred Brief Intervention vs Preferred Usual Care	-11.08	6.81	-24.43 to 2.27	-1.63	0.104
		Preferred Usual Care vs No Preference	3.42	5.09	-6.55 to 13.39	0.67	0.501
Sorensen et al. [35]	Pain at 2mo	Preferred educational vs Preferred training	10.00	17.23	-23.78 to 43.78	0.58	0.562
	Pain at 6mo	Preferred educational vs Preferred training	0.00	17.46	-34.21 to 34.21	0.00	1.000
	Pain at 12mo	Preferred educational vs Preferred training	5.00	19.11	-32.46 to 42.46	0.26	0.794
	Activity limitation at 2mo	Preferred educational vs Preferred training	14.85	15.60	-15.73 to 45.43	0.95	0.341
	Activity limitation at 6mo	Preferred educational vs Preferred training	33.00	15.32	2.98 to 63.02	2.15	0.031
	Activity limitation at 12mo	Preferred educational vs Preferred training	16.50	17.37	-17.54 to 50.54	0.95	0.342
Carr et al. [8]	RM at 3mo	Preferred physio vs No Preference	-4.99	6.61	-17.94 to 7.96	-0.76	0.450
	RM at 12mo	Preferred physio vs No Preference	-2.31	6.69	-15.42 to 10.79	-0.35	0.729

SE= standard error; 95% CI= 95% confidence interval

Chapter Four

Eliciting older people's preferences for exercise programs: a best-worst scaling choice

Chapter Four is published as:

Franco MR, Howard K, Sherrington C, Ferreira PH, Rose J, Gomes JL, Ferreira ML. Eliciting older people's preferences for exercise programs: a best-worst scaling choice. *J Physiother*. 2015; 61: 34-41.

Statement from co-authors confirming authorship contribution of the

PhD candidate

As co-authors of the paper "Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment", we confirm that Marcia Franco has made the following contributions:

- Design of the research questionnaires
- Data collection
- Analysis and interpretation of the results
- Writing of the manuscript and critical appraisal of the content

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Journal of Physiotherapy xxx (2014) xxx-xxx



Journal of **PHYSIOTHERAPY**

journal homepage: www.elsevier.com/locate/jphys

Research

Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment

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KEY WORDS

Exercise Older people Patient preference Best-worst scaling

ABSTRACT

Ouestion: What relative value do older people with a previous fall or mobility-related disability attach to different attributes of exercise? Design: Prospective, best-worst scaling study. Participants: Two hundred and twenty community-dwelling people, aged 60 years or older, who presented with a previous fall or mobility-related disability. **Methods:** Online or face-to-face questionnaire. **Outcome measures:** Utility values for different exercise attributes and levels. The utility levels were calculated by asking participants to select the attribute that they considered to be the best (ie, they were most likely to want to participate in programs with this attribute) and worst (ie, least likely to want to participate). The attributes included were: exercise type; time spent on exercise per day; frequency; transport type; travel time; out-of-pocket costs; reduction in the chance of falling; and improvement in the ability to undertake tasks inside and outside of home. Results: The attributes of exercise programs with the highest utility values were: home-based exercise and no need to use transport, followed by an improvement of 60% in the ability to do daily tasks at home, no costs, and decreasing the chances of falling to 0%. The attributes with the lowest utility were travel time of 30 minutes or more and out-of-pocket costs of AUD50 per session. Conclusion: The type of exercise, travel time and costs are more highly valued by older people than the health benefits. These findings suggest that physical activity engagement strategies need to go beyond education about health benefits and focus on improving accessibility to exercise programs. Exercise that can be undertaken at or close to home without any cost is most likely to be taken up by older people with past falls and/or mobility-related disability. [Franco MR, Howard K, Sherrington C, Ferreira PH, Rose J, Gomes JL, Ferreira ML (2015) Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment. Journal of Physiotherapy XX: XX-XX]

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Introduction

Falls and mobility-related disability among older people can lead to substantial healthcare costs, morbidity and mortality.¹ These important public health concerns are likely to worsen in the near future, as the number of people aged over 65 years is expected to triple in the next 30 years.² Evidence shows that appropriately designed exercise programs are effective in the prevention of falls and mobility-related disability amongst community-dwelling older people.³

The challenge for policy makers and clinicians is to engage older people in both commencing and adhering to exercise programs. Half of the world's older population is considered to be physically inactive.⁵ Participation of older people in structured exercise programs in this age group has also been reported to be suboptimal.⁶⁻⁸ For instance, estimates of adherence to falls prevention programs, derived from systematic reviews, vary from 74% (95% CI 67 to 80) of participants adhering to group exercise intervention⁷ to 21% (95% CI 15 to 29) adhering to home exercise

interventions.⁸ Adherence to exercise programs among older people has been found to be greater among those with: concerns about the interference of falls in social activities, certain intervention content (ie, balance or walking exercise),⁸ and two or fewer sessions per week.⁷ Although clinicians may use this information when planning exercise programs for this age group, when prescribing an intervention it is also important to take into account patients' preferences in the decision-making process.^{10,11} In a patient-centered healthcare system, shared decision making has been shown to increase adherence to healthcare interventions.¹¹ Evidence from a systematic review of qualitative studies¹² investigating older people's preferences and attitudes towards participation in exercise programs shows that specific attributes of exercise programs, such as costs and transport to exercise venues, are likely to drive their decision about whether or not to engage in those programs, and these are now variables of concern. Nevertheless, studies investigating the relative values that people in this age group actually attach to these different attributes are lacking. Identification of highly valued attributes can help

http://dx.doi.org/10.1016/j.jphys.2014.11.001

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Please cite this article in press as: Franco MR, et al. Eliciting older people's preferences for exercise programs: a best-worst scaling choice experiment. J Physiother. (2014), http://dx.doi.org/10.1016/j.jphys.2014.11.001

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clinicians and policy makers to increase participation and adherence to exercise programs.

The best-worst scaling choice experiment (BWS) method is a variation of the widely applied discrete choice experiment methodology.^{13–15} The BWS provides more information on relative preferences of attributes with higher statistical efficiency, due to the larger amount of choice data from each respondent.¹⁶ BWS applications and analysis are described in the literature.^{17,18} Briefly, in BWS, respondents are presented with one scenario at a time, and are asked to indicate their preference over attribute levels within each scenario, rather than between scenarios, as in the traditional discrete choice experiment. The BWS approach allows respondents to choose the best and the worst features (attribute levels) through a series of hypothetical but plausible choice scenarios. For example, for the attribute transport to exercise venues, three levels are presented: no need to use transport, free transport provided and no transport provided. The additional information provided by BWS can be used to evaluate the impact or relative importance of attribute levels, as they are compared on a common scale. This evaluation is not possible when using a traditional discrete choice experiment.¹⁷ Some authors have suggested that the BWS approach imposes less cognitive burden upon respondents than a traditional discrete choice experiment.¹⁹

The aim of the present study was to explore older people's preferences in relation to the characteristics of exercise programs, and to examine the relative value placed on these particular attributes. To the authors' knowledge, this is the first BWS study conducted in the area of exercise for older people. The findings will therefore assist clinicians and policy makers to improve the acceptability and implementation of different types of exercise programs amongst the older population.

The research question for this study was:

What is the relative value that older people with a previous fall or mobility-related disability attach to different exercise attributes and levels?

Method

The protocol for the present study has previously been published.²⁰ The original aim of the study, as described in the protocol, was to undertake a discrete choice experiment to investigate exercise programs designed to prevent falls. Before commencing the study, this aim was expanded to include a BWS of exercise programs designed to minimise falls and mobility-related disability in older adults. The current BWS was conducted with the same sample recruited for the discrete choice experiment. The results of the discrete choice experiment will be reported elsewhere.

Participant eligibility and recruitment

Participants were community-dwelling people, aged 60 years or older, living in Australia, able to comprehend and read English fluently, who were without marked cognitive impairment. To be eligible, participants needed to report either having had a history of falls (ie, experienced at least one fall since the age of 60 years); or a mobility-related disability (ie, self-reported difficulty in climbing a flight of stairs or walk 800 metres without assistance^{21,22}). A comprehensive sampling approach was undertaken by: contacting eligible participants from six community groups and retirement villages in the Sydney metropolitan area; newspaper advertisements; and electronic sampling using an online panel of Australian participants (provided via Survey Sampling International). Data collection was conducted both online (for those with internet access) and in person. A web-based survey was developed using Research Electronic Data Capture (REDCap) tools.²³

Study design

The BWS case 2 (profile case) was used, in which participants are presented with a series of different hypothetical scenarios, one at a time.¹⁹ Respondents were asked to make their choices within each scenario by selecting the attribute that is best (ie, they were most likely to participate in programs with this attribute) and that is worst (ie, least likely to participate), based on the levels presented.

Establishing the attributes and levels

To determine the relevant attributes, an extensive qualitative systematic review was conducted on the experiences and perspectives of older people participating in physical activity (manuscript under review). The views of 5987 participants from 132 studies led to the development of nine attributes: improvement in the ability to undertake daily tasks at home; improvement in the ability to leave the house to undertake tasks or to socialise; exercise type; time spent on exercise per day; reduction in the chances of falling; frequency (times per week); transport type; travel time; and out-of-pocket costs per exercise session. For each attribute, five different levels were selected to include a range of reasonable values, which were either actual or hypothetical. The

Table 1

Attributes and attribute levels.

Attribute	Levels
Improvement in the ability to	No improvement
undertake daily tasks at home (in	Improvement of 10%
	Improvement of 20%
comparison to no exercise)	Improvement of 50%
	Improvement of 50%
	Improvement of 60%
Improvement in the ability to	No improvement
leave the house to undertake	Improvement of 10%
tasks or to socialise (in	Improvement of 30%
comparison to no exercise)	Improvement of 50%
	Improvement of 60%
Exercise type	Exercise at your home, including
	balance and strength training
	Exercise away from home, including
	balance and strength training
	Exercise in a group including
	halance and strength training
	Tai Chi in a groun setting
	Yoga in a group setting
Time ment on evening	
Time spent on exercise	10 minutes per day
	30 minutes per day
	60 minutes per day
	90 minutes per day
	120 minutes per day
Chances of falling (in comparison	0% chance of falling (0 out of 100)
to an average chance of falling	10% chance of falling (10 out of 100)
each year of 40%)	20% chance of falling (20 out of 100)
	30% chance of falling (10 out of 100)
	40% chance of falling each year would
	stay the same (40 out of 100)
Frequency	1 day per week
1 5	2 days per week
	3 days per week
	4 days per week
	5 days per week
Transport type	No pood to uso transport
Transport type	
	Free transport provided
	A small transport subsidy provided
	A moderate transport subsidy provided
	No transport or subsidy provided
Travel time	Less than 5 minutes
	About 15 minutes
	About 30 minutes
	About 45 minutes
	About 60 minutes
Out-of-pocket costs	Free of charge
	\$5 per session
	\$15 per session
	\$50 per session
	\$100 per session
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Research

choice of levels for each attribute were based on the description of the current exercise programs available for older people in Australia, as well as discussions held with experts in the fields of ageing, and discrete choice experiments. All attributes and their levels are listed in Table 1.

To ensure the comprehension of the attribute levels, a pilot study was conducted, including face-to-face interviews with 34 people aged 60 or older and living in Australia. The results indicated that the attribute descriptions and levels were understandable and that the participants were able to answer the scenarios presented without reporting excessive difficulty. Parameter estimates from analysis of the pilot data were used to inform the final efficient design of the main study.

Experimental design

A Bayesian D-efficient design was used, ^{24,25} assuming normally distributed priors. Priors for the design were obtained from the pilot study, where the parameter estimates were used as the mean values, and the standard errors were used as the standard deviation parameters. The design allowed for all main effects

and was constructed to allow for best-worst choices. In generating the design, it was assumed that the alternative chosen as best was deleted when constructing the pseudo worst-choice task. To ensure plausibility, several constraints were imposed on the attribute level combinations of the design, such as if the *transportation alternatives* attribute took the level of no need to use transport, then the *travel time* attribute was constrained to take a level of less than 5 minutes or 15 minutes.

As each attribute had five levels, the final design had 40 choice tasks and was blocked into four blocks of 10 tasks to ensure that each attribute level was presented to each respondent an equal number of times in the 10 tasks that they answered (ie, to maintain level balance).²⁶ Blocking the design has been shown in previous studies to promote participant completion rates and minimise error due to fatigue.²⁷ Each scenario description contained all nine attributes at different levels across the 10 scenarios presented. Based on the levels presented in each scenario, participants were asked to select the attribute they considered to be the best (ie, they were most likely to participate in programs with this attribute) and worst (ie, least likely to participate). In other words, participants

Considering these factors only, which **one** factor makes you <u>most likely</u> to participate in exercise programs, and which **one** factor makes you <u>least likely</u> to want to participate in exercise programs?

Most likely to want to participate	EXAMPLE	Least likely to want to participate
(Mark one factor only)		(Mark one factor only)
	The out of pocket cost per exercise session is \$5.	
\checkmark	The exercise venue is close to your home, you probably wouldn't need to use transport	
	You have a travel time of about 15 minutes.	
	The exercise is Tai Chi in a group setting.	
	You would exercise 4 days per week.	
	You would exercise about 2 hours [120 minutes] per day.	
	In general, if you don't exercise there will be no improvement in the ease	
	with which you can undertake daily tasks at home over the next year. If you do exercise, there will be an improvement of 30% .	
	Regardless of whether you exercise, the ease with which you can leave the	
	house to undertake tasks or to socialise will stay the same over the next year.	
	On average 40 out of 100 older people fall at least once each year. Diagram A illustrates this data: 40 people are falling and 60 are not falling. On average, your chance of falling each year is 40% (40 out of 100).	\checkmark
	If you do this exercise program, your chance of falling each year would decrease to 20% (20 out of 100), as shown in the diagram B .	
Would you prefer the	exercise program described above or would you prefer what you are doing at th	e moment?
The exercise	program described above \checkmark What I am doing at the moment \Box	

Figure 1. Example of a scenario presented to participants.

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were asked to select the pair of attribute levels that they considered to be furthest apart on the utility scale.¹⁷ From these choices, a mathematical function numerically describing the value that participants attach to different choices was estimated. More details about the study experimental design are provided in Appendix 1 on the eAddenda. An example of a scenario presented to the participants is displayed in Figure 1. After presenting a scenario with nine different attribute levels, the instruction given to the participants was: 'Considering these factors only, which one factor makes you most likely to participate in exercise programs, and which one factor makes you least likely to want to participate in exercise programs?'

Socio-demographics, such as age and gender, as well as health status and physical activity habits data were also collected.

Data analysis

Logistic regression analyses were conducted using a multinomial logit model in statistical software^a to estimate the utility weights that older people attach to different attribute levels of exercise programs. The regression outcome variable, attribute choice, was coded as 1 for a best attribute level, and –1 for a worst attribute level. All remaining attribute levels were coded 0. The model calculated utility coefficients by summing the number of times an attribute level was chosen as best or worst. Statistically significant coefficients indicated the importance of that attribute level in determining overall utility and in influencing preferences. A larger coefficient indicated higher utility (ie, the attribute level was considered to be more attractive to participants).

In a best-worst attribute task analysis, the values of all levels of all attributes are estimated relative to each other on a single scale.¹⁷ This is modelled by omitting one level of a single attribute (reference level), rather than omitting a level of every attribute, and allows a direct comparison of the relative utility (attractive-ness) of the levels across the different attributes, instead of just within attributes. The reference level is usually the attribute level with the lowest utility.

A secondary analysis was conducted to investigate the possible differences in utility between younger and older participants, as defined by the median age (ie, people aged < 66 years versus people aged \geq 66 years), by estimating interactions between attribute levels and age.

Results

Between February and October 2013, 220 of the 319 eligible participants provided valid answers for the BWS experiment (response rate of 69%). Each participant answered 10 scenarios, giving a total of 2200 scenarios in the sample. Patient characteristics are presented in Table 2.

Table 2

Characteristics of respondents (n=220).

Characteristic	n=220
Gender, n female (%)	115 (52)
Age (yr), mean (SD)	68 (6)
Age group (yr), n (%)	
60 to 64	82 (37)
65 to 69	68 (31)
70 to 74	35 (16)
75 to 79	22 (10)
80 to 84	10 (5)
85 +	3(1)
Difficulty in climbing a flight of stairs without	134 (61)
help reported, n (%)	
Difficulty in walking 800 meters without help	118 (54)
reported, n (%)	
Falls since the age of 60 reported, n (%)	153 (70)
Falls in the past 12 months reported, n (%)	104 (47)
People currently doing exercise, n (%)	101 (46)

Tal	ble	3
_		

Participants' preferences for attribute levels of exercise programs.

Attribute level	Utility (95% CI) ^a	<i>p</i> -value ^b
Improvement in the ability to un	dertake daily tasks at home	
60%	2.26 (1.95 to 2.57)	< 0.001
30%	2.10 (1.78 to 2.43)	< 0.001
10%	1.91 (1.58 to 2.24)	< 0.001
50%	1.87 (1.55 to 2.19)	< 0.001
0%	1.20 (0.89 to 1.51)	< 0.001
Improvement in the ability to leave	ve the house to undertake tas	ks or to socialise
50%	2.17 (1.84 to 2.49)	< 0.001
30%	1.98 (1.65 to 2.31)	< 0.001
60%	1.98 (1.66 to 2.30)	< 0.001
0%	1.45 (1.13 to 1.77)	< 0.001
10%	1.37 (1.03 to 1.71)	< 0.001
Exercise type (all of them include	e balance and strength traini	ng)
at home	2.50 (2.22 to 2.78)	< 0.001
in a group	1.87 (1.57 to 2.17)	<0.001
outside home	1.84 (1.54 to 2.14)	<0.001
group yoga	1.49 (1.19 to 1.79)	<0.001
group Tai Chi	1.46 (1.15 to 1.76)	<0.001
Time spent on exercise (min/day))	
10	1.93 (1.61 to 2.25)	<0.001
30	1.86 (1.54 to 2.17)	< 0.001
60	1.50 (1.19 to 1.81)	<0.001
90	1.09 (0.81 to 1.37)	<0.001
120	0.84 (0.56 to 1.13)	<0.001
Chance of falling		
0%	2.20 (1.89 to 2.51)	<0.001
10%	2.09 (1.76 to 2.42)	< 0.001
20%	1.96 (1.64 to 2.29)	< 0.001
40%	1.63 (1.32 to 1.95)	< 0.001
30%	1.61 (1.29 to 1.93)	<0.001
Frequency (times per week)		0.004
3	1.94 (1.63 to 2.26)	<0.001
2	1.88 (1.57 to 2.19)	<0.001
4	1.77(1.45 to 2.10)	<0.001
5	1.76 (1.44 to 2.09)	<0.001
l Transmont turns	1.68 (1.39 to 1.98)	<0.001
Transport type	$2.22(2.01 \pm 2.04)$	-0.001
amall subsidu	2.32(2.01102.04)	< 0.001
free	1.03(1.31101.95)	<0.001
litee	1.60(1.27101.92)	<0.001
moderate subsidy	$1.41(1.08 \ 10 \ 1.74)$	<0.001
Travel time (min)	1.34 (1.03 to 1.66)	<0.001
loss than 5	$2.11(1.91 \pm 2.41)$	-0.001
	2.11(1.01 to 2.41)	< 0.001
15	1.51(1.20101.82)	<0.001
30	0.82(0.31101.13)	< 0.001
45	0.39(0.07100.70)	0.018
bu Out of pocket costs per eversion	0.19 (-0.12 to 0.51)	0.225
	224(102 to 255)	<0.001
ຈບ \$5	2.24 (1.95 to 2.93)	< 0.001
ቁታ \$15	1.30(1.27 to 1.03) 1.08(0.80 to 1.27)	< 0.001
\$50	1.00 (0.00 (0 1.37)) 0.52 (0.26 to 0.70)	< 0.001
\$100 (reference case)	0.32 (0.20 10 0.79)	<0.001
aloo (lelelelle case)	-	-

^a A larger coefficient indicates higher utility (ie, the attribute level is more attractive to participants).

^b Statistically significant coefficients indicate the importance of that attribute level on determining overall utility and in influencing preferences.

The attribute level with the lowest utility (reference level) was *out-of-pocket costs of AUD100*. This level was omitted in the analysis and takes the value of *zero* on the utility scale. The logistic regression results are presented in Table 3. The regression coefficients of best-worst pairs show the additional utility of each attribute level over the reference level. The utility coefficients are also graphically represented in Figure 2. All attribute levels contributed significantly, with the exception of *travel time of 60 minutes*.

The attribute levels with the highest utility were *exercise at* home and no need to use transport. An improvement of 60% in the ability to do daily tasks at home, exercise free of charge and decreasing the chances of falling to 0% were ranked third, fourth and fifth, respectively. In contrast, the attribute levels with the lowest utility were travel time of 60 minutes, travel time of 45 minutes, out-of-pocket costs of AUD50 and then travel time of 30 minutes, in that order.

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Figure 2. Utility weights given to the various levels of the hypothetical attributes of an exercise program by older people with a history of falling or mobility-related disability. Abbreviations: Mod. = moderate subsidy, No subs. = no subsidy, Out. = outside the home, Small. = small subsidy, T.Chi = Tai Chi.

Importantly, certain within-attribute differences were greater than others. As can be seen from Figure 2, the levels of *out-of-pocket costs, travel time* and *time spent on exercise per day* are further apart on the utility scale, showing the largest difference between attribute levels. This means that a change from a low-cost to a high-cost program, from a short to a long travel time, or from exercising for short periods in a day instead of longer periods would considerably influence older people's preferences. In contrast, participants ranked the levels of *frequency* (days per week) and *reduction in the chances of falling* somewhat equally, indicating limited additional value for participants on moving between these levels.

The secondary analysis results for older and younger respondents are presented in Table 4 and also shown graphically in Figure 2. As for the whole sample, the reference level was *out-ofpocket costs of AUD100*. Most attribute levels contributed significantly, with the exception of *travel time of 45 minutes* and *60 minutes* for both age subgroups. In addition, *out-of-pocket costs of AUD50* did not contribute significantly for the subgroup of participants aged 66 or younger.

Amongst the participants aged older than 66 years, the two attribute levels with the highest utility were *exercise at home* and *improvement of 60% in the ability to undertake daily tasks at home*. These attributes were followed by *no need to use transport, improvement of 50% in the ability to leave the house to undertake tasks or to socialise* and *decreasing the chances of falling to 10%*, in that order. Similar to the rankings of the whole sample, for the subgroup of people aged 66 and older, the attribute levels with the lowest utility were travel time of 60 minutes, travel time of 45 minutes, out-of-pocket costs of AUD50 and travel time of 30 minutes.

For the subgroup of people aged 66 or younger, the attribute levels that were more positively valued were in the following order: *no need to use transport, exercise free of charge, exercise at home, decreasing the chances of falling to 0%* and *travel time of less than 5 minutes.* In contrast, the attribute levels with the lowest

utility were travel time of 45 minutes, out-of-pocket costs of AUD50, exercising 120 minutes per day and travel time of 30 minutes.

Discussion

The present study's findings suggest that aspects of exercise programs, such as exercise venue, travel time and out-of-pocket costs are highly valued by older people. Surprisingly, only two health benefits (ie, reduction in the chances of falling to 0% and an improvement of 60% in the ability to undertake tasks inside home) were listed among the five most-highly valued attributes. Therefore, it seems that older people place higher values on exercise characteristics than on their actual benefits and, therefore, their decision on whether or not to engage in exercise programs is less influenced by the improvements in the health outcomes that they provide. These findings have substantial impact on the planning and development of exercise provision and promotion strategies. Accordingly, the findings suggest that unless accessibility to exercise programs is optimised, policy makers and healthcare professionals will still face important barriers in increasing uptake and compliance to exercise among the older population.

The two attribute levels with the highest utility identified in the present study, *exercise at home* and *no need to use transport*, give support to the idea that easy access to exercise programs is generally preferred. In agreement with that, the attribute levels with the lowest utility (ie, least preferred) concerned *travel times* and *out-of-pocket costs*, reflecting participants' aversion to travel long distances and to pay for high-cost exercise programs. In the context of chronic conditions, provision of healthcare services at home or close to home has recently gained growing attention in different countries.^{28–30} For instance, care provided in the community or at home for people with heart failure and multimorbid chronic diseases has shown beneficial effects on outcomes, including improvements in quality of life and functional

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 Table 4

 Interaction terms between attribute levels and age subgroups.

Attribute	Age > 66 yr		Age $\leq 66 \mathrm{yr}$	
Level	Utility (95% CI) ^a	p-value ^b	Utility (95% Cl) ^a	p-value ^b
Improvement in the ability to unde	ertake daily tasks at home			
0%	1.25 (0.80 to 1.71)	< 0.001	1.18 (0.77 to 1.59)	< 0.001
10%	2.23 (1.74 to 2.72)	< 0.001	1.67 (1.23 to 2.11)	< 0.001
30%	2.55 (2.07 to 3.03)	< 0.001	1.76 (1.33 to 2.19)	< 0.001
50%	2.35 (1.88 to 2.82)	< 0.001	1.50 (1.08 to 1.93)	< 0.001
60%	2.80 (2.34 to 3.26)	< 0.001	1.86 (1.46 to 2.27)	< 0.001
Improvement in the ability to leave	e the house to undertake tasks or to soc	cialise		
0%	1.73 (1.25 to 2.21)	< 0.001	1.23 (0.81 to 1.66)	< 0.001
10%	1.84 (1.33 to 2.35)	< 0.001	1.01 (0.56 to 1.46)	< 0.001
30%	2.52 (2.03 to 3.01)	< 0.001	1.57 (1.13 to 2.01)	< 0.001
50%	2.69 (2.21 to 3.17)	< 0.001	1.77 (1.33 to 2.20)	< 0.001
60%	2.65 (2.16 to 3.13)	< 0.001	1.48 (1.06 to 1.91)	< 0.001
Exercise type (all of them include b	palance and strength training)			
at home	3.13 (2.71 to 3.54)	< 0.001	2.03 (1.66 to 2.39)	< 0.001
in a group	2.02 (1.57 to 2.47)	< 0.001	1.71 (1.32 to 2.10)	< 0.001
outside home	2.47 (2.02 to 2.92)	< 0.001	1.40 (1.01 to 1.80)	< 0.001
group yoga	1.60 (1.15 to 2.05)	< 0.001	1.42 (1.02 to 1.82)	< 0.001
group Tai Chi	1.76 (1.31 to 2.21)	< 0.001	1.23 (0.82 to 1.63)	< 0.001
Time spent on exercise (min/day)				
10	2.29 (1.82 to 2.77)	< 0.001	1.65 (1.23 to 2.08)	< 0.001
30	1.99 (1.51 to 2.46)	< 0.001	1.77 (1.35 to 2.19)	< 0.001
60	1.75 (1.29 to 2.21)	< 0.001	1.32 (0.91 to 1.72)	< 0.001
90	1.17 (0.75 to 1.59)	< 0.001	1.02 (0.65 to 1.39)	< 0.001
120	1.16 (0.74 to 1.57)	< 0.001	0.60 (0.24 to 0.97)	0.001
Chances of falling				
0%	2.61 (2.16 to 3.06)	< 0.001	1.90 (1.49 to 2.31)	< 0.001
10%	2.69 (2.21 to 3.17)	< 0.001	1.62 (1.17 to 2.06)	< 0.001
20%	2.46 (1.98 to 2.94)	< 0.001	1.59 (1.15 to 2.02)	< 0.001
30%	2.12 (1.64 to 2.61)	< 0.001	1.22 (0.80 to 1.64)	< 0.001
40%	1.93 (1.45 to 2.41)	< 0.001	1.41 (1.00 to 1.82)	< 0.001
Frequency (times per week)				
1	1.93 (1.49 to 2.38)	< 0.001	1.50 (1.11 to 1.88)	< 0.001
2	2.42 (1.97 to 2.88)	< 0.001	1.47 (1.06 to 1.87)	< 0.001
3	2.26 (1.80 to 2.72)	< 0.001	1.70 (1.28 to 2.12)	< 0.001
4	2.06 (1.57 to 2.55)	< 0.001	1.56 (1.13 to 1.99)	< 0.001
5	2.04 (1.55 to 2.53)	< 0.001	1.56 (1.12 to 1.99)	< 0.001
Transport type				
none required	2.71 (2.25 to 3.18)	< 0.001	2.04 (1.63 to 2.44)	< 0.001
small subsidy	1.71 (1.23 to 2.20)	< 0.001	1.51 (1.08 to 1.94)	< 0.001
free	1.61 (1.13 to 2.09)	< 0.001	1.66 (1.24 to 2.08)	< 0.001
moderate subsidy	1.79 (1.30 to 2.29)	< 0.001	1.12 (0.70 to 1.55)	< 0.001
no subsidy	1.58 (1.12 to 2.05)	< 0.001	1.17 (0.74 to 1.59)	< 0.001
Travel time (min)				
less than 5	2.42 (1.97 to 2.88)	< 0.001	1.88 (1.50 to 2.26)	< 0.001
15	1.90 (1.44 to 2.35)	< 0.001	1.22 (0.81 to 1.62)	< 0.001
30	1.07 (0.61 to 1.53)	< 0.001	0.63 (0.22 to 1.04)	0.003
45	0.49 (0.04 to 0.95)	0.033	0.33 (-0.09 to 0.74)	0.121
60	0.37 (-0.08 to 0.81)	0.109	0.07 (-0.33 to 0.48)	0.724
Out-of-pocket cost per exercise ses	sion (compared to \$100 reference categ	gory)	· · · ·	
\$0	2.52 (2.07 to 2.97)	< 0.001	2.03 (1.63 to 2.43)	< 0.001
\$5	1.83 (1.38 to 2.29)	< 0.001	1.39 (0.99 to 1.79)	< 0.001
\$15	1.27 (0.84 to 1.70)	< 0.001	0.95 (0.57 to 1.33)	< 0.001
\$50	0.68 (0.28 to 1.08)	0.001	0.40 (0.05 to 0.76)	0.026
\$100 (reference case)	-	-	-	-

^a Larger coefficients indicate higher utility (ie, were considered to be more attractive to participants).

^b Statistically significant coefficients indicate the importance of that attribute level in determining overall utility and in influencing preferences.

measures of activities of daily living. These approaches have also resulted in cost savings, by reducing the number of unplanned hospitalisations and emergency department visits.³⁰ Similarly, it can be argued that, based on older people's preferences, the provision of exercise programs in the local community or at home is an approach likely to facilitate participation. Fortunately, home-based balance and strengthening exercise, group exercise and Tai Chi (that could be implemented in community settings) can be effective in preventing falls among older people living in the community, as shown in a recent Cochrane review.⁴ A recent randomised controlled trial has also shown that an effective fallpreventive option for this age group is to integrate simple exercises that target balance and muscle strength into everyday routines, by using strategies such as standing on one leg while waiting for the kettle to boil.³¹ However, another recent trial found that home exercises enhanced mobility but increased fall rates in older people who had recently been in hospital, suggesting that home exercise is not a suitable single intervention in this very high-risk group.³²

Participants' rankings also revealed that high importance was placed on differences between the levels of *out-of-pocket costs*, *travel time* and *time spent exercising per day*. Participants reported being most likely to take up exercise programs that can be undertaken at or close to home and programs without a cost. While it was expected that participants would be unwilling to pay for high-cost exercise programs and travel for a long time to attend an exercise venue, the value allocated to *time spent on exercise per day* was surprising. Interestingly, participants mostly preferred *exercising only 10 minutes per day* and progressively ranked more highly, *shorter periods of exercise*. Unfortunately, a total of 10 minutes of exercise per day is unlikely to be sufficient for broader health benefits.³³ However, performing multiple short bouts of exercise throughout the day may be an attractive option to older people. In fact, this approach is in accordance with existing

Research

guidelines, which suggest that accumulating bouts of exercise produce health benefits.^{34,35}

Surprisingly, the levels related to improvements in health outcomes, while still important, had less impact on older people's preferences than the levels of other attributes. A possible interpretation is that improvement in health outcomes might be valued differently by different subgroups of older people; the secondary analysis suggests that this might be the case. For instance, for participants aged 66 or older (ie, median sample age), three out of the top five attribute levels concerned health benefits, including improvements in ability to undertake tasks at home and outside home as well as reduction in the chances of falling. In contrast, for the subgroup of participants aged 66 or younger, only one aspect related to health improvements (ie, reduction in the chances of falling) was amongst the top five attribute levels. Future studies appropriately powered for subgroup analysis are necessary to confirm these findings.

One limitation of the present study is that, although people with obvious cognitive impairment were excluded, the cognitive ability of each participant was not measured. Although a pilot study was conducted to ensure that participants were able to understand the attribute levels and comprehend the questions in each scenario, it was difficult to determine to what extent different levels of cognitive impairment might have influenced participants' choices. Another limitation is that data collection was restricted to only one country. Older people's preferences may vary across countries and health systems, and may even be influenced by local factors, such as socioeconomic and urban environments, as well as healthcare accessibility. Further research is required to assess the consistency of these findings in different countries and healthcare contexts.

The results from the present study suggest that, in order to enhance exercise uptake in older people with past falls and/or mobility impairment, physiotherapists should advocate for the provision of low-cost exercise opportunities close to where people live and should prescribe home-based exercises to be performed in multiple short bouts. To effectively increase exercise participation amongst this age group, health-promotion strategies should go further than merely educating and raising awareness about the health benefits that can be gained with exercise. Rather, it is imperative to facilitate financial and environmental access to exercise programs. These findings may assist policy makers and clinicians to successfully implement exercise programs in the older population.

What is already known on this topic: Appropriately designed exercise programs prevent falls and mobility-related disability among older people living in the community. However, many older people do not join or complete structured exercise programs. Some attributes of exercise programs, such as cost and transport, are likely to influence participation by older people, but the relative importance of such attributes is unknown.

What this study adds: Older people who had fallen or had mobility-related disability reported that they would be most likely to participate in an exercise program that: they could do at home, required no transport, improved their ability to do home-based daily activities by 60%, incurred no cost, and eliminated their risk of falling. Physiotherapists may be able to improve adherence to exercise programs for older people by improving accessibility rather than by focusing on the health benefits.

Footnote: aNLOGIT 4.0, Econometric Software Inc., USA. eAddenda: Appendix 1 can be found online at doi:10.1016/ j.jphys.2014.11.001

Ethics approval: The University of Sydney Human Ethics Committee approved this study (Protocol number: 14404). All participants gave informed consent before data collection began.

Competing interests: All authors declare that they have no conflict of interest.

Source(s) of support: Marcia Franco is a PhD candidate supported by the CAPES Foundation, Ministry of Education of Brazil. Catherine Sherrington is supported by a research fellowship funded by the Australian National Health and Medical Research Council (NHRMC). This project was not directly supported by any other external grants or funds.

Acknowledgements: Nil.

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APPENDIX

Experimental design

Research over the past decade has explored optimal experimental design strategies that are specifically related to non-linear models, such as discrete choice models, whereby a direct link between the experimental design employed and the standard errors of the parameters produced from that design has been shown. Given this link, designs producing lower standard errors for the same sample size are deemed to be more efficient, with the design generating the lowest possible standard errors representing the optimal design. Unfortunately, unlike linear models, the standard errors of non-linear models are not independent of the parameter estimates themselves. For this reason, it is necessary for the analyst to make a priori assumptions about the parameter estimates when generating the design. Given a design and prior parameters, the expected covariance matrix of the model is computed (of which the square root of the leading diagonal represents the standard errors). Rather than work with the covariance matrix directly, the literature has settled on using the determinant of the matrix instead. This is because the determinant of a matrix geometrically represents the volume of space defined by the matrix. As such, designs with lower D-errors (determinants) will have a smaller volume described by the standard errors and covariances surrounding the point estimates represented by the model parameter estimates.

For the present study, Bayesian D-efficient designs were employed. Rather than the analyst assume exact a priori knowledge of the parameters, Bayesian designs allow the analyst to specify a distribution of parameter priors representing uncertainty as to the exact values the parameters will take in practice. For the designs, normally distributed Bayesian prior parameter distributions were

assumed, with means of 0 and standard deviations of 1, hence reflecting uncertainty about the direction that the parameters might take. Given Bayesian prior parameter distributions, it is necessary to compute the covariance matrix over the range of the parameter priors, which is done via simulation, where the average D-error was calculated over draws taken from the Bayesian distributions. For this purpose, spherical-radial transformed (SRT) draws assuming three radii and two randomly rotated orthogonal matrices were used to simulate the normally distributed prior parameter distributions. Gotwalt et al. (2009)¹ showed that SRT draws are superior in approximating normal distributions than other pseudo Monte Carlo draws, including Halton, Sobol and Gaussian Quadriture, which is why these were used in the present study. This is equivalent to 541 draws given eight Bayesian parameter priors (ie, the transport attribute was used as a base attribute). The design was generated using a co-ordinate exchange algorithm.²⁻⁴ In generating the design, 500 random designs were examined, each allowing 500 exchanges. As such, 250 000 designs were examined, with the design with the lowest D-error selected. To calculate the D-error, the generalised Fisher information matrix, based on the methods proposed by Chaloner and Verdinelli (1995),⁵ was used (see Yu et al. 2009⁶ for additional information). The Bayesian Derror of the final design (with repeated common tasks) was 0.03016.

The design allowed for all main effects and was constructed to allow for best-worst choices. That is, the designs assumed a rank explosion mechanism where pseudo worst choice tasks where constructed, in which the alternative chosen as best was deleted when constructing the pseudo worst choice task (see Vermeulen et al. (2011) for the precise procedure used).⁷ This is consistent with how the data are set up for estimation. The precise number of choice tasks for each design is a function of the number of statements, the number of prior parameters assumed

(related to the degrees of freedom of the design) and the fact that each statement was required to appear an equal number of times over the experiment. The final design had 40 choice tasks and was blocked into four blocks of 10 tasks (ie, each participant answered 10 tasks (scenarios) describing exercise programs). Given that the final design was not orthogonal, the blocking column was generated by minimising the maximum absolute value of the correlation between the blocking column and the design attributes.

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Chapter Five

How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol

Chapter Five is published as:

Franco MR, Ferreira ML, Howard K, Sherrington C, Rose J, Haines TP, Ferreira P. How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol. *BMJ Open.* 2013; 3: pii: e002355.

Statement from co-authors confirming authorship contribution of the

PhD candidate

As co-authors of the paper "How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol" we confirm that Marcia Franco has made the following contributions:

- Writing of the manuscript
- Critical appraisal of the content

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How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol

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To cite: Franco MR, Ferreira ML, Howard K, *et al.* How big does the effect of an intervention have to be? Application of two novel methods to determine the smallest worthwhile effect of a fall prevention programme: a study protocol. *BMJ Open* 2013;**3**:e002355. doi:10.1136/bmjopen-2012-002355

Prepublication history for this paper are available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2012-002355).

Received 16 November 2012 Revised 21 December 2012 Accepted 14 January 2013

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ABSTRACT

Introduction: This project concerns the identification of the smallest worthwhile effect (SWE) of exercise-based programmes to prevent falls in older people. The SWE is the smallest effect that justifies the costs, risks and inconveniences of an intervention and is used to inform the design and interpretation of systematic reviews and randomised clinical trials.

Methods and analysis: This study will comprise two different methodological approaches: the benefitharm trade-off method and the discrete choice experiment to estimate the SWE of exercise interventions to prevent falls in older people. In the benefit-harm trade-off method, hypothetical scenarios with the benefits, costs, risks and inconveniences associated with the intervention will be presented to each participant. Then, assuming a treatment effect of certain magnitude, the participant will be asked if he or she would choose to have the intervention. The size of the hypothetical benefit will be varied up and down until it is possible to identify the SWE for which the participant would choose to have the intervention. In the discrete choice experiment, the same attributes (benefits, costs, risks and inconveniences) with varying levels will be presented as choice sets, and participants will be asked to choose between these choice sets. With this approach, we will determine the probability that a person will consider the effects of an intervention to be worthwhile, given the particular costs, risks and inconveniences. For each of the two approaches, participants will be interviewed in person and on different occasions. A subsample of the total cohort will participate in both interviews.

Ethics and dissemination: This project has received Ethics Approval from the University of Sydney Human Ethics Committee (*Protocol number: 14404*). Findings will be disseminated through conference presentations, seminars and peer-reviewed scientific journals.

ARTICLE SUMMARY

Article focus

- To determine the smallest worthwhile effect (SWE) of exercise programmes to prevent falls and investigate the relative importance of various factors that influence older people's decision to participate or not in these programmes.
- To determine the extent of trade-offs between harms and benefits that older people are willing to accept in making decisions about participation in exercise programmes to prevent falls.
- To investigate whether the benefit-harm trade-off method and the discrete choice experiment yield similar estimates of the SWE of an exercise programme to prevent falls.

Key messages

- Despite the clear evidence that the rate of falls in older people can be reduced with exercise interventions, there has not yet been any formal evaluation of whether potential recipients of such interventions consider effects of the magnitude observed in randomised trials to be worthwhile to justify the costs and inconveniences they experience in participating.
- Trade-offs between the potential benefits and harms of exercise programmes to prevent falls should be weighed by older people deciding whether to participate or not in these exercise programmes.
- The findings of this study should enable the construction of fall prevention programmes with high participation rates, high levels of adherence and high levels of perceived benefit.

INTRODUCTION

Randomised controlled trials have become the method of choice for determining the effects of health interventions. More than 500 000

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ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first study to use robust stated-preference methods (discrete choice methods and benefit-harm trade-off method) to estimate the smallest worthwhile effect of exercise-based programs to prevent falls.
- The results will inform clinical practice, research and policy, as the attributes of an exercise to prevent falls most valued by consumers will be identified.
- The estimates of the smallest worthwhile effect should be interpreted in the context of the included population and interventions only (ie, exercise programs to prevent falls in older people compared to no treatment).

randomised trials have been conducted in health interventions, almost all in the last 50 years. There is a high degree of consensus about how randomised trials should be conducted.¹ Nonetheless, several important methodological issues remain unresolved. One of the most persistent issues concerns how to estimate the smallest worthwhile effect (SWE) of an intervention.

The SWE is, as its name suggests, the smallest beneficial effect of an intervention that justifies the costs, risks and inconvenience of that intervention. Estimates of the SWE of an intervention are needed to design powerful and efficient clinical trials and to determine whether interventions produce effects that are large enough to be worthwhile.² Several approaches have been used to estimate the SWE of intervention. These have been critically reviewed by Barrett *et al*^{β} and Ferreira *et al*.⁴ The authors argue that any valid measure of the SWE of intervention must have three characteristics: judgements about whether the effects of intervention are large enough to be worthwhile must be made by recipients of care, the estimate must be intervention-specific and the method must focus on the effects of intervention (between-group differences) rather than on changes over time (within-group differences).

Many randomised clinical trials and systematic reviews have investigated the impact of interventions targeted at preventing falls in older people and now provide clear evidence that both the rate of falls and risk of falling in older people can be reduced with exercise interventions, which for instance involve challenge to balance abilities and are performed frequently (ie, at multiple times a week over a long period).⁵ ⁶ However, there has not yet been any formal evaluation of whether potential recipients of such interventions consider effects of the magnitude observed in randomised trials to be worthwhile to justify the costs and inconveniences they experience in participating.

This paper presents the protocol of a study designed to determine the SWE of a fall-prevention programme. The study will use a modified contingent valuation method (the 'benefit-harm trade-off method') and the discrete choice experiment to determine what older people who have previously fallen consider to be the SWE of exercise to prevent falls from their own perspective.

The aims of the study are to answer the following questions:

- 1. What do older people who have previously fallen consider to be the SWE of an exercise-based fall prevention programme?
- 2. To what extent is the SWE of an exercise-based fall prevention programme influenced by expectations of the costs, risks or inconveniences of intervention?
- 3. What characteristics of exercise-based fall prevention programmes do older people who have previously fallen value most?
- 4. Do the benefit-harm trade-off method and discrete choice experiment yield similar estimates of the SWE of an exercise-based fall prevention programme?

METHODS AND ANALYSIS

Overview of approach and methods

Different face-to-face interviews will be conducted for each experiment. The first interview concerns the benefit-harm trade-off method and will be used to address aim 1. The second interview will contribute to the discrete choice experiment and will address aims 1-3. A subsample of 60 participants will participate in both interviews to address aim 4. A systematic review of qualitative studies will inform the development of both designs. The review seeks information on the perceptions and experiences of older people on barriers and facilitators of exercise programmes to prevent falls. Data from this qualitative review will be used to determine the potential attributes for both the benefit-harm tradeoff and the discrete choice experiment, such as benefits, costs and inconveniences associated with an exercisebased fall prevention programme.

In the benefit-harm trade-off method, these attributes will have fixed levels and participants will decide the smallest expected benefit of intervention for which he or she would consider choosing to have the intervention. In contrast, in the discrete choice experiment, participants are asked to choose between alternatives defined by a set of attributes with varying levels. In this case, we can identify which attributes are driving participants' preferences, the trade-offs participants make between attributes and how changes in attributes can lead to changes in the patients' willingness to participate in the intervention.

Participants

Participants will be recruited via newspaper, radio and online media advertisements as well as through community organisations that target older audiences. To be eligible to participate in both the benefit-harm trade-off study and the discrete choice experiment, study participants must meet the criteria below:

- ► Community-dwelling people aged 60 years or over,
- ▶ Able to comprehend and read English fluently,

- ▶ Have experienced one or more falls in the past,
- ▶ Present no obvious cognitive impairment,
- Present no serious neurological, cardiovascular or musculoskeletal condition that might hinder their participation in exercise programprogrammes.

Participants will not be excluded based on their participation in exercise programmes (ie, participants who are participating and who are not participating in exercise programmes will be eligible).

Benefit-harm trade-off method

For this approach, the interviewer will describe, for each participant, the potential benefits as well as the costs and risks and inconveniences associated with an exercise-based programme to prevent falls. The participant will then be told to assume that the treatment effect will be of a certain size. Participants will then be asked if, given this expected effect of treatment, they would choose to have the intervention. Subsequently, estimates of the SWE will be elicited by asking the participant to consider the situation in which, hypothetically, the expected effect of intervention is larger or smaller. The size of the hypothetical benefit will be varied up and down in progressively smaller increments until it is possible to identify the threshold benefit of intervention for which the participant would consider choosing to have the intervention. This is the SWE for that participant.

Discrete choice experiment

The discrete choice experiment will be conducted in a way that is consistent with current recommendations.⁷ This part of the study will use a survey which includes the same attributes associated with an exercise-based

programme to prevent falls. Participants will be presented with multiple choice sets of two hypothetical programmes, where the levels of each attribute vary systematically between alternatives and scenarios, and will choose the optimal alternative in each choice set. As it is not feasible to present all participants with all possible combinations of attribute levels, each participant will be presented with a subset of all possible choice sets. An efficient design will be used.⁸ With this approach, the aim is to present participant choice sets that minimise the elements of the asymptotic variance–covariance matrix of the statistical methods used to analyse the data, that is, the aim is to maximise the precision of estimates of the value of attributes.

From participants' choices, a mathematical function that describes numerically the value that respondents attach to different choice options will be estimated. This is one way to quantify patients' preferences for healthcare programmes. The results will be used to estimate the relative value attached to attributes by examining trade-offs that people are willing to make between attributes. As a consequence, it is possible to determine the probability that a person will consider the effects of an exercisebased programme to prevent falls worthwhile, given the particular costs, risks and inconveniences.

Table 1 is an example of a discrete choice study. The example includes nine attributes (costs, transportation alternatives, travel time, type of exercise, frequency, time per day, improvement in the ability to undertake daily tasks at home, improvement in the ability to leave the house to undertake tasks and to socialise and falls risk reduction), with their specific levels. Participants would be asked to choose programme 1 or 2.

Scenario 1	Exercise option A	Exercise option B
Out of pocket cost (\$ per session)	\$100	\$5
Is transport provided	No transport is provided; you need to provide your own	No need for transport
Travel time	About 45 min	5 min or less
Type of exercise	Combination of different types of exercise (balance and strength training),	Yoga
How often do you exercise per week?	1×/week	1×/week
Time per day	30 min	10 min or less
Improvement in the ease with which you can undertake daily tasks at home (daily tasks at home include bathing, dressing, preparing meals and cleaning the house)	10%	30%
Improvement in the ability to leave the house to undertake tasks or socialise (<i>Tasks include shopping, banking, walking outdoors, using public transport</i>)	30%	60%
Falls risk reduction On average, 30 of 100 older people fall at least once each year. Exercise can reduce the number of people who fall to	20 of 100	10 of 100

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The initial design will be tested with a pilot study including community-dwelling older people living in Australia to assess comprehension and understanding of attributes and their levels. From the findings of this pilot study, we will be able to estimate prior parameters, which will inform the efficient design of the final study. Strategies to facilitate appropriate interpretations of the DCE questionnaire will be used, such as diagrams and plain language. If the final design results in a large number of scenarios, the design will be blocked into two blocks to ensure that respondents are not overly burdened by the number of questions.

Sample size

For the benefit-harm trade-off experiment, our simulations indicate that, at least with normally distributed data, a sample size of 60 participants will provide expected CI widths of $\pm \le 0.4$ SDs.

For the discrete choice experiment, the current theory of sampling determines that sample sizes are based upon the characteristics of the design of the study, such as the number of attributes included, the attribute level range, the number of hypothetical scenarios presented and the number of alternatives in each choice set.⁹ Consequently, the sample size cannot be determined until the attributes to be included in the final design are identified. An efficient design, which minimises D-error, will be estimated using NGENE software. D-error is a measure of statistical efficiency of the design (lower D-error indicates greater design efficiency). With an efficient choice design, we expect that a sample size of approximately 200 respondents will be sufficient to answer our questions of interest.

Data analysis

Benefit-harm trade-off method

The distributions of estimates of the SWE elicited in the benefit-harm trade-off will be plotted as frequency histograms. Non-parametric bootstrap methods¹⁰ will be used to generate 95% CIs for effects that are considered to be worthwhile by 20, 50 and 80% of participants.¹¹

Discrete choice experiment

A summary of descriptive statistics will be calculated for respondent samples. Data will be analysed with a mixed multinomial logit model (MMNL). With this approach, it is implicitly assumed that preferences do not vary between responses made by an individual respondent, but variation in preferences between respondents is modelled explicitly. Mixed models allow for dependence of observations provided by the same respondent.^{12–14} The use of MMNLs relaxes the statistical assumptions made with more commonly used fixed effect multinomial logit models and is likely to better explain choice behaviour than fixed effect models.^{15–16} Interactions between attributes and between attributes and population characteristics (eg, age, gender, education and prior recent experience with falls) will be explored by including the appropriate interaction terms in the model. The analysis willprovide an estimate of the probability that participants consider an intervention to be worthwhile (or, more directly, of the log odds that participants would choose to have the intervention) based on any particular combination of attributes, and also will allow us to examine the trade-offs between attributes that participants are willing to accept. In accordance with the recommendations of Lancsar and Louviere, responses deemed by researchers as 'irrational' will not be excluded from analysis, and all available responses will be included in the model.¹⁷

DISCUSSION

This project will determine, from the older person's perspective, the SWE of an exercise programme designed to prevent falls. Estimates of the SWE can be used to determine whether the effects of new and existing fall prevention programmes are large enough to justify their implementation.

The outcomes will be important for falls researchers and policy makers because they will provide the first rigorous analysis of the features of falls prevention programmes that might increase the participants' participation and adherence to these programmes. Therefore, the results could be used to optimise interventions, as they will identify attributes of falls prevention programme that maximise value to the recipients.

This project also has a broader significance as it involves the development of novel methods that are applicable to the design and interpretation of clinical trials across all areas of healthcare. Benefit-harm trade-off studies are simple enough to be routinely conducted prior to clinical trials. This would provide robust, justifiable, empirical estimates of the SWE for use in sample size calculations and the interpretation of trial findings. It is possible that, if these simple procedures were widely adopted, clinical trials could be very different in size; some clinical conditions might be managed very differently, and health resources might be radically redistributed.

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Contributors MLF, CS, KH, JR, TPH and PF conceived and designed the study. MRF drafted the first version of this manuscript. All authors contributed to the writing of the manuscript. All authors critically reviewed and approved the final version of the manuscript.

Funding This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. MRF is supported by CAPES Foundation, an agency under the Ministry of Education of Brazil.

Competing interests None.

Ethics approval This project has received Ethics Approval from the University of Sydney Human Ethics Committee (Protocol number: 14404). Individual

written informed consent will be obtained before the conduct of the research in accordance with the ethics of medical research.

Provenance and peer review Not commissioned; externally peer reviewed.

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Chapter Six

Estimates of the smallest worthwhile effect of exercise programs to prevent falls among older people from the benefit-harm trade-off and discrete choice methods

Chapter Six:

Franco MR, Howard K, Sherrington C, Rose J, Ferreira P, Ferreira ML. Estimates of the smallest worthwhile effect of exercise programs to prevent falls among older people from the benefit-harm trade-off and discrete choice methods. This manuscript will be submitted to *Journal of Clinical Epidemiology*.

Statement from co-authors confirming authorship contribution of the

PhD candidate

As co-authors of the paper "Estimates of the smallest worthwhile effect of exercise programs to prevent falls among older people from the benefit-harm trade-off and discrete choice methods", we confirm that Marcia Franco has made the following contributions:

- Design of the research questionnaires
- Data collection
- Analysis and interpretation of the findings
- Writing of the manuscript and critical appraisal of the content

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Estimates of the smallest worthwhile effect of exercise programs to prevent falls among older people from the benefit-harm trade-off and discrete choice methods

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ABSTRACT

Objective: To elicit estimates of the smallest worthwhile effect (SWE), the smallest effect considered to justify inconveniences and costs of exercise programs to prevent falls among older people. We also aimed to compare estimates derived by two methodological approaches.

Study design and setting: Community-dwelling older people were invited to answer online or face-to-face questionnaires. Discrete choice experiment and the benefit-harm trade-off methods were used to elicit the smallest benefit of an exercise program, in terms of reduction in the risk of falling, that participants would consider worthwhile.

Results: 220 participants and a subsample of 66 participants were included in the discrete choice experiment study and the benefit-harm trade-off study, respectively. The SWE estimates found were, on average, a reduction in the risk of falling of 35% (SD=12.7) in the discrete choice experiment and 16% (SD=10.8) in the benefit-harm trade-off study. Surprisingly, a substantial proportion of participants (50% in the benefit-harm trade-off study and 82% in the discrete choice experiment) did not consider that participation in an exercise program would be worthwhile, even if it reduce their risk of falling to 0%.

Conclusions: These findings suggest that, older people hold high expectations regarding how much benefit they would need to see to consider exercise programs worthwhile. Regardless of the method used to elicit SWE, many people did not consider exercise programs to be worth their associated inconveniences and costs even if they resulted in a complete reduction in the risk of falling. These results can guide the design and implementation of strategies to increase uptake of exercise to prevent falls among older people.

INTRODUCTION

Falls-related injuries are important health events that can lead to a loss of independence [1], hospitalisation or long term care[2] and premature death [3]. Given that falls primarily occur in older age and that the number of people aged over 65 years is expected to triple in the next 30 years [4], costs related to falls are likely to increase significantly in the future. For instance, in NSW, the most populous state in Australia, the direct health care cost of fall-related injuries was estimated at AUD\$558.5 million in 2006/7 and is projected to triple by 2050 [5]. In this context, a substantial body of research has been conducted in recent years investigating strategies that can prevent falls among older people. A recent Cochrane systematic review of randomised controlled trials provides high quality evidence that well-designed exercise programs can reduce the risk of falls by 29% in older people [6].

While robust evidence of treatment benefits derived from randomised clinical trials is considered necessary before medical interventions are implemented in clinical practice, understanding people's perceptions on whether the estimated treatment effects are large enough to justify the associated inconveniences and costs is pivotal in guiding the implementation of community-wide interventions. The smallest worthwhile effect (SWE) is the smallest treatment effect that would justify the costs, risks and inconveniences associated with a health intervention [7-9] and is used to interpret the clinical significance of the results of randomised clinical trials and meta-analyses [10]. However, until now there has been little development of methods to identify the SWEs of interventions to prevent falls and as a result the SWEs are not known.

Estimates of the SWE should satisfy three conditions: it should be intervention-specific; it must be based on patients' perspective; and it must focus on the effects of intervention (between-group differences) rather than changes in outcomes over time (within-group differences) [11, 12]. These criteria, however, are not met by the most commonly used methodological approaches employed to elicit the smallest worthwhile effect of interventions, such as the anchor-based and distributionbased approaches [12]. The benefit-harm trade-off method is a modified contingent valuation approach and involves informing patients of the expected effect of intervention and then asking them whether they feel the effect is big enough to be worthwhile, given the intervention attributes presented to them. Then, holding the inconveniences, costs and harms constant, the patient is asked to imagine that the benefit of the intervention is larger (or smaller) and again asked if they would choose to have the intervention. This procedure is repeated until it is possible to identify, with sufficient precision, the threshold benefit for which the patient would choose to have the intervention. In 2005, Barrett et al applied the benefit-harm trade-off method, to elicit estimates of the smallest worthwhile effect of treatments for the common cold [13]. Since then, this method, which successfully addresses all three criteria (i.e. it is intervention specific, is based on patient perspective and focus on the effect of interventions) has been used to estimate the SWE of interventions for other conditions such as, breast cancer [14], colon cancer [15], leg ulcers [16] and low back pain [17, 18].

A potential limitation of the benefit-harm trade-off method however, is that respondents need to make trade-offs between benefits and harms of an intervention, but only one intervention attribute varies - the hypothetical size of its effect of intervention. As a result, the values patients attribute to the other attributes of that intervention, for instance costs associated with treatment or the time spent going to a clinic, cannot be elicited. Alternative methods, such as discrete choice experiments, where respondents are presented with hypothetical scenarios in which attributes vary within scenarios, allows the investigation of how people value multiple attributes and the trade-offs they are willing to make between them. Importantly, discrete choice experiments have been reported to be valid and reliable in eliciting preferences regarding health care [19], have been widely used in the health area to assess people's preferences for health services [20-22] and satisfy the three criteria previously described to elicit the smallest worthwhile effect of interventions.

In the present study we sought to determine the SWE of exercise programs designed to reduce the risk of falls among older people using these two approaches, the benefit-harm trade-off method and the discrete choice experiment. We also sought to compare the estimates of the SWE derived from the two different methods.

METHODS

This study was approved by the University of Sydney Human Ethics Committee (Protocol number: 14404). The protocol paper has been published [23].

Identifying the attributes. To identify key attributes of exercise programs that are likely to influence uptake, an extensive qualitative systematic review on the experiences and perspectives of participating in physical activity among older people was conducted [24]. Considering the views of 5987 participants from 132 studies, nine attributes were identified: improvement in the ability to undertake daily tasks at home; improvement in the ability to leave the house to undertake tasks

or to socialise; out of pocket cost per exercise session; exercise type; time spent exercising per day; reduction in the risk of falling; frequency (times per week); transport type and travel time. Based on the description of current exercise programs available for older people in Australia as well as discussions held with experts in the fields of ageing and discrete choice experiments, each attribute was assigned five levels.

Pilot study. We conducted a face-to-face pilot study in 34 people aged 60 or over living in Australia to assess the comprehension of attribute descriptions and levels included in each scenario. Results indicated that participants were able to answer the scenarios presented without reporting excessive difficulty. Parameter estimates from analysis of the pilot data were used to inform the final efficient design of the main study.

Participants. The study was undertaken among English-literate, community-dwelling people aged 60 years and older, living in Australia. To be included participants needed to report either having had at least one fall since the age of 60 or mobility-related disability, defined as the difficulty to climb a flight of stairs or walk 800 meters without help. Mobility-related disability was included as an inclusion criterion because it has been reported to be strongly associated with future falls [25]. For the discrete choice experiment study, participants were recruited through newspaper advertisements, personal contact during health-related workshops given at community groups or retirement villages in the Sydney metropolitan area, as well as by electronic sampling using an online panel of Australian participants. A subsample of participants who answered the discrete choice experience electronic questionnaires were randomly selected, re-contacted via e-mail and invited to participate in the benefit-harm trade-off study. Socio-demographics characteristics,

health status and physical activity habits data were also collected for both surveys. Participants' characteristics are presented in Table 1.

Benefit-harm trade-off method. In the benefit-harm trade-off study, participants were given a web-based survey to estimate the SWE of exercise programs designed to reduce the risk of falls among older people. The survey described a typical exercise program as following: "Exercise programs designed for older people often involve attending a group exercise program once a week on an ongoing basis. The cost per session would be about \$5 and you would need to arrange your own transport. Each session would include different exercise components targeting balance and strength and you would be asked to also do the exercises at home regularly." The inconveniences and costs of participating in an exercise program designed to prevent falls were fixed (i.e. group exercise targeting balance and strength training, once a week, cost of \$5 per session, no transport or subsidy provided), and the levels of the benefit presented to participants (i.e., reduction in the risk of falling) varied. Participants were then told that if they did not participate in the exercise program described (this was considered the control for the comparison of benefits), their baseline risk of falling each year would be, on average, 40% (40 out of 100). This baseline risk of falling was chosen based on the average risk reported for different age groups in the literature, which ranges from 30% in people aged between 65 and 70 and 50% among those 80 years of age or older [26, 27]. Participants were then asked whether they would choose to participate in the exercise program if it decreased their current risk of falling to 0% (0 out of 100); i.e. an absolute risk reduction of 40%. This was done to elicit the smallest worthwhile effect of exercise programs, when compared to a control group. The size of this hypothetical effect was then gradually reduced by 10 % (i.e. decreasing their risk of falling to 10%, 20% and 30% in this order). Participants were

asked at each level whether they would choose to take part in the exercise program, given reduction in the risk of falling as well as its inconveniences and costs. The smallest hypothetical benefit of the intervention for which the participant would decide to participate in the intervention was considered the SWE for that patient and could vary from 10% to 40% (i.e. maximum benefit).

Discrete choice experiment. In a discrete choice experiment, health care services are described in terms of different key attributes, with attribute levels that vary across a number of scenarios. In this study for instance, one of the attributes included in the scenarios was reduction in the risk of falling. This attribute was presented to participants at five varying levels, i.e. having an absolute reduction in the risk of falling of 40%, 30%, 20%, 10% and 0% (i.e. similar absolute reductions presented in the benefit harm trade-off study). Other attributes and their levels are presented in Table 2. Considering all attribute levels included in each scenario, participants were asked to select the most preferred option from a set of two alternatives: the exercise program described in the scenario or what they were currently doing. Detailed information on discrete choice experiment methodology is described elsewhere [28, 29].

A Bayesian D-efficient design [30, 31] was used in the design of the discrete choice experiment, assuming normally distributed prior parameter estimates. These parameter estimates were obtained from the mean values from the analysis of the pilot study. The design allows for all main effects and was constructed to allow for best-worst choices. The best-worst choice study results are reported elsewhere [32]. The final design had 40 choice tasks, blocked into four blocks of 10 tasks (i.e. each participant answered 10 tasks (scenarios) describing exercise programs). Each scenario presented all nine attributes, with levels varying across the ten scenarios. An example of a scenario

presented to the participants is presented in Figure 1. For this study, participants chose the preferred option from a set of two alternatives: the exercise program described in the scenario or what they were doing at the moment (i.e. the status quo). From these choices, a mathematical function numerically describing the value participants attach to different choices was estimated. Detailed information on the study experimental design is provided in the Appendix.

Data analysis

To analyse the benefit-harm trade-off study, for each decrease in the risk of falling, the difference between baseline risk and the hypothetically decreased risk was calculated to provide the absolute risk reduction in falls between exercise and no treatment. For instance, decreasing the risk of falling to 0% is equivalent to receiving an absolute benefit (risk difference) of 40% (i.e. a reduction of 40% in the risk of falling), decreasing the risk of falling to 10% corresponds to a benefit of 30%, decreasing the risk of falling to 20% means experiencing a benefit of 20% and decreasing the risk of falling to 30% is equivalent to experiencing a benefit of 10%. The distribution analysis of estimates of the SWE was conducted and mean SWE and standard deviation (SD) were calculated.

A mixed logit (ML) model with a panel specification was used for the discrete choice experiment estimation. A mixed logit model allows consideration of the full distribution of a parameter estimate, and estimates 'random parameters'. 'Random parameter' implies that each individual has an associated parameter estimate on the specified distribution. Whilst the exact location of each individual's preferences on the distribution may not be known, estimates of 'individual-specific preferences' can be accommodated by deriving the individual's conditional distribution, based – within sample – on their choices (i.e. prior knowledge) [33]. Additional discussion is

available elsewhere [29, 33, 34]. All attributes were modelled as linear, except for transport type, which was a categorical variable and was effects coded; a mixed logit model with 1000 Halton draws was used, and random parameters were specified for all attributes of the discrete choice experiment. Cost and travel time were modelled as triangular distributions, all other attributes were modelled as normal distributions. The constant is interpreted as the underlying preference for the status quo, i.e. their current exercise practice (or no exercise). The modelled utility functions were: $V_{new \ exercise} = \beta_1$ frequency + β_2 minutes + β_3 exercise type + β_4 cost + β_5 travel time + β_6 cost + β_7 no transport required + β_8 free transport + β_9 small transport subsidy + β_{10} moderate transport subsidy + β_{11} no transport

or subsidy+ β_{12} home activities + β_{13} activities outside home+ β_{14} falls reduction

 $V_{\text{current exercise}} = \beta_0 + \beta_1 \text{frequency} + \beta_2 \text{minutes} + \beta_3 \text{exercise type} + \beta_4 \text{cost} + \beta_5 \text{travel time} + \beta_6 \text{cost} + \beta_7 \text{no}$ transport required + β_8 free transport + β_9 small transport subsidy + β_{10} modertae transport subsidy + β_{11} no transport or subsidy + β_{12} home activities + β_{13} activities outside home + β_{14} falls reduction

Models were evaluated for goodness of fit using the likelihood ratio Chi-square statistic for the global test of zero model coefficients, the McFadden's pseudo R-squared, and Akaike's information criterion (AIC). The final model was selected on the basis of AIC after testing a number of different model specifications. The directions of estimated coefficients were checked to verify consistency with *a priori* expectations; and goodness of fit was examined using pseudo R^2 and AIC. All analyses used NLOGIT Version 4.01. (Econometric Software, Castle Hill, NSW, Australia, <u>www.limdep.com/products/nlogit/</u>)

Following estimation of the discrete choice experiments models, the SWE of reduction in risk of falling was calculated using the individual specific parameter estimates from the mixed logit models. The 'value' of current practice (including no exercise) was calculated, using the utility

function above, with individual parameter values and corresponding attribute levels reported by each respondent for their current practice. The 'value' of a hypothetical new exercise program was calculated using a similar approach, based upon a hypothetical exercise program consistent with that described in the benefit-harm trade-off study, that is, a group exercise class conducted once per week; 60 minutes duration; \$5 per session; 30 minute travel time and no transport or subsidy provided.

Based on the underlying premise of discrete choice experiments and the random utility framework, it is assumed that respondents will choose the option with the highest value (or utility); the SWE was therefore calculated as the reduction in the risk of falling that would be required to ensure the calculated value of the new program was higher than the value of current practice. Results of the SWE are reported as mean and SD. In addition to means and SD, we calculated for both methods the proportion of respondents who would choose to participate in the exercise program described in the scenario for each level of benefit, i.e. absolute reductions in the risk of falling of 10%, 20%, 30% and 40%. The results are also reported by subgroups of participants currently exercising vs. those not currently exercising.

RESULTS

Between February and October 2013, 220 of the 319 eligible participants provided valid answers for the discrete choice experiment study (response rate of 69%). Most participants, 202 (92%), were recruited through the online panel of Australian participants. Fourteen participants (6%) were recruited via presentations in retirement villages around Sydney metropolitan area, and four

participants (2%) through newspaper advertisement. A subsample of 66 participants who were recruited through the online panel consented and were included in the benefit-harm trade-off study.

Benefit-harm trade-off study

For the benefit-harm trade-off survey, 50% of the participants (n=33) indicated they would not participate in an exercise program to prevent falls after considering the inconveniences and costs involved (i.e. group exercise targeting balance and strength training, once a week, cost of \$5 per session, no transport or subsidy provided), even if they experienced maximum benefit (i.e. reducing their risk of falling to 0%). The remaining 50% of the participants (n=33) would need to experience, on average, an absolute reduction of 16% (SD=10.8) in the risk of falling. The mean represents the size of the benefit participants would need to see to consider exercise to prevent falls worthwhile. Table 3 shows the proportion of participants who would choose to participate in the exercise program after considering inconveniences and costs at each level of benefit, i.e. absolute reductions in the risk of falling of 10%, 20%, 30% and 40%.

Discrete choice experiment study

After considering the attribute levels of the exercise programs described in the scenarios, participants of the discrete choice experiment would need to experience, on average, an absolute reduction of 35% (SD=12.7) in the risk of falling, i.e. having their risk of falling reduced to 5%, to consider the inconveniences and costs of the program worthwhile compared to what they were doing at the moment. The choices of respondents and the value calculations conducted indicated that 82.3% of participants would need a benefit greater than the maximum 40% (complete)

reduction in falls for the exercise program to be valued more highly than their current activity (Table 3).

Table 3 also shows the proportion of respondents who would choose to participate in the exercise program described in the scenario for each level of benefit, for the subgroup of participants currently participating in exercise and those not currently participating. The results of the discrete choice experiment study show that whereas a maximum benefit of 40% would satisfy 32.2% of the participants who were not currently engaged in exercise, less than 10% of those currently engaged in physical activity would agree this benefit would be sufficient for the inconveniences and costs of the new exercise program to outweigh the value attached to their current activity. These differences between subgroups were less obvious in the benefit-harm trade-off study - a benefit of 40% would satisfy 52% of participants who were not exercising, and would satisfy 48.8% of those who were exercising.

DISCUSSION

Our findings show that a large proportion of participants would choose not to participate in an exercise program designed to prevent falls, even if it reduced their risk of falling to 0%. Only about 11% of participants of the discrete choice experiment study and 30% of those in the benefit-harm trade-off study would consider a benefit of 10% in the reduction of the risk of falling worthwhile and similarly only 12% and 36% in the discrete choice experiment and benefit-harm trade-off studies, respectively would consider engaging in exercises to prevent falls if they experience a risk reduction of 20%. These findings suggest that older people have high expectations regarding the benefit exercise programs need to offer in preventing falls. Unfortunately the results suggest that

only 15.4% of the participants in the discrete choice experiment study and 44% in the benefit-harm trade-off would consider the average beneficial effect reported in the latest meta-analyses of about 30% for exercise to prevent falls [6] to be worthwhile. It is clear that many older people do not recognise the benefit of exercise in reducing risk of falling. Our recent systematic review [24] revealed that some older adults still believe that exercise is unnecessary and may even be harmful. Similarly, a cross-sectional study published in 2014 surveying 394 participants has shown that older adults are still not convinced that they are at risk of falls [35].

Our results also reveal that the choice of methods to elicit the SWE of exercise to prevent falls will result in different estimates. The average SWE of 35% (SD=12.7) reduction in the risk of falling found in the discrete choice experiment study was two times greater than that reported in the benefit-harm trade-off study (16%; SD=10.8). Systematic differences in the methodology of two approaches could potentially explain these differences. For instance, in the benefit-harm trade-off study, the mean SWE was derived from data of approximately 50% of the sample, given the remaining participants stated they would not participate in an exercise program even if they experienced the maximum benefit. This is a limitation frequently reported in the benefit-harm trade-off studies used to elicit the SWE of health interventions [13, 18]. This limitation is however addressed in the discrete choice experiment since the analyses accommodate for the inclusion of all participants, including those who reported that they would choose not to participate in the exercise programs with the maximum exercise benefits in the risk of falling. Another possible explanation for the difference in estimates is that the discrete choice experiments allow for variable levels of each attribute, and therefore, the final estimate reflects the relative value participants place on the final program, considering changes in all attributes, not just falls risk. This is not

allowed in the benefit-harm trade-off, and it is likely therefore, that the latter underestimates patients' choices of benefits, which constitutes the smallest worthwhile effect of an intervention. This suggests that it might be the variability in inconveniences and costs of exercise programs that drive older people's perceptions on what constitutes the SWE, and therefore, their decision on whether or not to engage in those programs. This is in accordance with the results of our study investigating the value older people place on particular attributes of exercise programs, which showed that older people place higher values on exercise characteristics than on their actual benefits [32].

To better understand these discrepancies, we also present our results as the proportion of participants who would choose to participate in the exercise program described in the experiments, for each level of benefit. We have observed that, in general, greater proportions of participants of the benefit-harm trade-off study are satisfied with smaller benefits, confirming our notion that this method might underestimate the SWE of health interventions. For instance, after considering inconveniences and costs, the maximum benefit of 40% reduction in the risk of falling was sufficient to satisfy 50% of participants in the benefit-harm trade-off study, whereas the same benefit would satisfy only 17% of participants in the discrete choice experiment study (Table 3). Another approach we used to better understand the different results was to stratify our results by physical activity status. These analyses revealed that, participants in the discrete choice experiment who were exercising needed to see greater benefits to consider the new exercise program worthwhile. This is unsurprising and has been well documented in the health economics literature as a preference for the status quo [36]. The results also revealed that among participants not currently engaged in exercise, the proportion of participants who would choose the exercise
program described in scenario in the discrete choice experiment approximated those of the benefitharm trade-off study, suggesting that the way the comparator is framed in each experiment will result in different estimates. While participants of the discrete choice experiment were asked to choose the exercise program described in the scenario over what they were doing at the moment, participants of the benefit-harm trade-off were asked to decide whether the benefit presented made participating in the exercise program worthwhile compared to not participating in it.

This is the first time that SWE of exercise programs to prevent falls has been elicited, and the first time discrete choice experiments have been used to estimate the SWEs of interventions. The two methodological approaches we used satisfy the three criteria previously described to elicit the SWE of interventions, as they are based on the judgment of patients, incorporate consideration of the inconveniences and costs of the intervention; and are expressed in terms of between-group differences rather than changes on outcomes over time [12]. A limitation of this study is that, in the benefit-harm trade-off study, a large proportion of participants who would not participate in exercise programs even when presented with the maximum exercise benefits, needed to be excluded from our data analysis. This may reflect a limitation of the benefit-harm trade-off method and may limit the comparison of average SWE estimates derived from both methods. Another possible limitation is that the two methodological approaches used different ways of framing the comparator used to elicit the SWE. These differences might explain discrepancies in the results.

CONCLUSION

This study has demonstrated that most older people do not consider the beneficial effects of exercise programs, including the average beneficial effect reported in meta-analyses of randomised controlled trials investigating exercise programs designed for older people, to be worthwhile.

Participants of the discrete choice experiment study needed to see higher exercise benefits to be worth inconveniences and costs of exercise programs. The differences in SWE estimates resultant of the variability in inconveniences and costs of exercise programs in the discrete choice experiment suggest that these aspects are likely to drive older people's perceptions on what constitutes the SWE, and therefore, their decision on whether or not to engage in those programs. These results can be used to inform the design and implementation of strategies to increase uptake of exercise to prevent falls among older people.

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Table 1. Characteristics of respondents

	Respondents of	Respondents of
	DCE (n=220)	BHTO (n=66)
Characteristic*		
Female	115 (52)	37 (56)
Age in years, mean (SD)	68 (6)	68 (6)
Age group		
60-64	82 (37)	20 (30)
65-69	68 (31)	26 (40)
70-74	35 (16)	8 (12)
75-79	22 (10)	8 (12)
80-84	10 (5)	4 (6)
85+	3(1)	0 (0)
Difficulty in climbing a flight of stairs without help reported	134 (61)	45 (67)
Difficulty to walk 800 meters without help reported	118 (54)	41 (63)
Falls since the age of 60 reported	153 (70)	38 (58)
Falls in the past 12 months reported	104 (47)	23 (35)
People currently doing exercise	101 (46)	41 (63)

*Data are frequency (%) unless otherwise indicated SD, standard deviation; DCE, discrete choice experiment; BHTO, benefit-harm trade-off.

Table 2. Attributes and attributes levels

Attribute	Levels
Improvement in the ability to undertake	
daily tasks at home	No improvement
(in comparison to no exercise)	Improvement of 10%
(in comparison to no excremse)	Improvement of 20%
	Improvement of 50%
	Improvement of 50%
The many second in the shift of a large the	Improvement of 60%
Improvement in the ability to leave the	
house to undertake tasks or to socialise	No improvement
(in comparison to no exercise)	Improvement of 10%
	Improvement of 30%
	Improvement of 50%
	Improvement of 60%
Exercise type	
	Exercise at your home including balance and strength training
	Exercise away from home including balance and strength training
	Exercise in a group including balance and strength training
	Tai Chi in a group setting
	Yoga in a group setting
Time spent on exercise	
	10 minutes per day
	30 minutes per day
	60 minutes per day
	90 minutes per day
	120 minutes per day
Chances of falling	
(in comparison to an average chance of	Chance of falling of 0% (0 out of 100)
falling each year of 40%)	Chance of falling of 10% (10 out of 100)
	Chance of falling of 20% (20 out of 100)
	Chance of falling of 30% (10 out of 100)
	Chance of falling each year would stay the same 40% (40 out of 100%)
Frequency	
1.04.0000	l dav per week
	2 days per week
	3 days per week
	A days per week
	5 days per week
Transport type	5 days per week
Transport type	No need to use transport
	Free transport
	A small transport provided
	A small transport subsidy provided
	A moderate transport subsidy provided
Transal times	ino transport, or subsidy provided
i ravei time	Tree them 5 minutes
	Less than 5 minutes
	About 15 minutes
	About 30 minutes

	About 45 minutes
	About 60 minutes
Out of pocket costs	
	Free of charge
	\$5 per session
	\$15 per session
	\$50 per session
	\$100 per session

% improvement (absolute reduction in the risk of falling)	10%	20%	30%	40%
All participants DCE (n=220)	10.9%	11.8%	15.4%	17.7%
All participants BHTO (n=66)	30.3%	36.4%	44.0%	50.0%
Participants not exercising DCE (n=119)	21.1%	23.3%	27.8%	32.2%
Participants exercising DCE (n=101)	3.85%	3.85%	6.92%	7.69%
Participants not exercising BHTO (n=25)	20.0%	32.0%	44.0%	52.0%
Participants exercising BHTO (n=41)	36.6%	39.0%	43.9%	48.8%

Table 3. Percentage of people from the discrete choice experiment (DCE) and benefit-harm trade-off(BHTO) who would choose the exercise program described in the scenarios

*Data shown as percentage unless otherwise indicated

Figure 1: Example of a scenario presented to participants

Considering these factors only, which **one** factor makes you <u>most likely</u> to participate in exercise programs, and which **one** factor makes you <u>least likely</u> to want to participate in exercise programs?

Most likely to want to participate (Mark one factor only)	EXAMPLE	Least likely to want to participate (Mark one factor only)
	The out of pocket cost per exercise session is \$5.	
\checkmark	The exercise venue is close to your home, you probably wouldn't need to use transport.	
	You have a travel time of about 15 minutes.	
	The exercise is Tai Chi in a group setting.	
	You would exercise 4 days per week.	
	You would exercise about 2 hours [120 minutes] per day.	
	In general, if you don't exercise there will be no improvement in the ease with which you can undertake daily tasks at home over the next year. If you do exercise, there will be an improvement of 30% .	
	Regardless of whether you exercise, the ease with which you can leave the house to undertake tasks or to socialise will stay the same over the next year.	
	On average 40 out of 100 older people fall at least once each year. Diagram A illustrates this data: 40 people are falling and 60 are not falling. On average, your chance of falling each year is 40% (40 out of 100). If you do this exercise program, your chance of falling each year would decrease to 20% (20 out of 100), as shown in the diagram B.	
Would you prefer the The exercise p	exercise program described above or would you prefer what you are doing at the program described above \checkmark What I am doing at the moment \Box	e moment?

Chapter Seven

Discussion and Conclusions

7.1. Overview

The broad aim of this thesis was to enhance understanding of older people's perspectives and preferences for health interventions with the emphasis on better understanding older people's participation in physical activity. More specifically, in this thesis, contemporary research methods were used to: (i) synthesise the qualitative literature on experiences and perceptions of older people towards participation in physical activities, (ii) review how patients' preferences have been measured and analysed in randomised clinical trials evaluating musculoskeletal conditions, (iii) examine the relative value older people place on particular features of exercises, and (iv) to estimate older people's perceptions of clinically significant effects of exercise programs to prevent falls, and compare the estimates using two different methods.

7.2 Principal findings

Policy makers and clinicians currently face an urgent need to develop effective strategies to further engage older people in physical activity programs, given the low physical activity participation and maintenance rates observed in this age group. The systematic review of qualitative literature described in Chapter Two identified six major themes and seventeen subthemes central to older people's perspectives on participation in physical activity: social influences; physical limitations; competing priorities; access difficulties, personal benefits of physical activity; and motivation and beliefs. The thematic synthesis performed revealed that although some older people acknowledge the potential benefits of physical activity in improving general health, independence and mental well-being, they also identify important barriers including lack of social support, previous sedentary habits, competing priorities, accessibility and apathy. Some older people still believe that physical activity is unnecessary, and consider age-related deterioration unpreventable and unavoidable. Others, especially some of those who perceive themselves as being physically frail, believe physical activity may be harmful and increase the risk of injuries. These findings suggest that strategies to enhance physical activity among older people must reach beyond raising awareness of the associated health benefits, but also aim to increase environmental and financial access to physical activity programs. Furthermore, the themes and subthemes identified in this

review can be used to inform healthcare policy and practice so that older people's perspectives remain central to future discussions regarding the design of effective health services.

Randomised clinical trials have been accepted as the gold standard design to establish the effectiveness of a health intervention. Patients' preference for treatment, however, might influence the findings of randomised clinical trials. The rationale is that patients allocated to their preferred intervention may be more motivated to adhere to treatment, resulting in better outcomes compared to those patients allocated to their non-preferred treatment. The systematic review presented in Chapter Three aimed to systematically and critically evaluate how patients' preferences have been measured and analysed in randomised clinical trials evaluating musculoskeletal conditions. The results showed that existing studies used different approaches to analyse the influence of patient preference within randomised clinical trials – while most studies (n=7) examined the effect of patients' preferences on outcomes (within-group changes in outcome over time), only five studies investigated whether patients' preferences can modify the effect of intervention on clinical outcomes (difference in outcomes between allocation groups). Importantly, only two studies conducted pre-planned analyses of patients' preferences. This means that most studies were in fact underpowered to conduct tests of interaction between preferences and group allocation. The methodological limitations of the available evidence identified in this review suggest that it might be too early to conclude whether patients' preferences can in fact influence treatment effects of randomised clinical trials evaluating musculoskeletal conditions. Furthermore, this systematic review identified the heterogeneity in methods to elicit patients' preferences for interventions in musculoskeletal research. The lack of data on patient's preferences derived from robust, standardised methods is an important limitation in this research field.

In 2006, the use of the best-worst scaling choice experiment was introduced in health research. Best-worst scaling experiments are a variation of the widely applied discrete choice experiment methodology and have been employed to elicit patients' preferences for a variety of health services such as dermatology consultation,¹ caring experiences,² healthcare reform,³ supportive care interventions in patients with lung cancer,⁴ funding of new health technologies,⁵ and attention-deficit hyperactivity disorder medication.⁶ In this thesis we have used this methodology to estimate the relative importance of the attributes of exercise programs, previously identified in our

qualitative systematic review. The results of this study are presented in Chapter Four and demonstrated that attribute levels most preferred by older people were exercise taken at home and no need to use transport. In agreement with that, the attributes older people least preferred concerned travel times and out-of-pocket costs, reflecting participants' aversion to travel long distances and to pay for high-cost exercise programs. Surprisingly, the levels related to improvements in health outcomes, including improvement in the ability to undertake tasks inside and outside home and reduction in the chance of falling, while still important, had less impact on older people's preferences than the levels of other attributes. Therefore, older people place higher values on factors external to the intervention, if compared to the health benefits derived from that intervention, suggesting that unless accessibility to exercise programs is optimised, policy makers and healthcare professionals will still face important barriers in increasing uptake and compliance to exercise among the older population. Programs that can be undertaken at or close to home without any cost are most likely to be taken up by older people with past falls and/or mobilityrelated disability. Furthermore, participants mostly preferred exercising only 10 minutes per day and progressively ranked more highly, shorter periods of exercise, indicating that performing multiple short bouts of exercise throughout the day may be an attractive option to older people. These findings should be the focus of strategies to further engage this population in physical activity.

Health service consumers have an important role in decision-making as they bring valuable insights into the acceptable levels of risks and benefits of health interventions. Patients' preferences and perspectives are now considered important for interpreting the clinical relevance of results from single trials or systematic reviews. Chapter Five and Chapter Six present the protocol and the full report of a study designed to determine the smallest worthwhile effect (i.e. the smallest effect that justifies the costs, risks and inconvenience of an intervention) of an exercise program for older people using two different methods, the benefit-harm trade-off and discrete choice experiments. The findings showed that the average smallest worthwhile estimates calculated using the benefit-harm trade-off method and discrete choice experiments, were 16% and 35% reduction in the risk of falling, respectively. Unexpectedly, a substantial proportion of participants (50% in the benefit-harm trade-off study and 82% in the discrete choice experiment) did not consider that participation in an exercise program would be worthwhile, even if it reduce

their risk of falling to 0%. These findings suggests that, regardless of the method used to elicit the smallest worthwhile effect, most older people do not consider the beneficial effects of exercise programs, including the average beneficial effect reported in meta-analyses of randomised controlled trials investigating exercise programs designed for older people to be worthwhile.

7.3. Implications and directions for future research

It is broadly accepted that the decision making process require the integration of high-quality scientific evidence and individual preferences for treatments. Patients' (or consumer) preferences for treatments may reflect the real costs and benefits of interventions, usually ignored when only the perspectives of researchers and clinicians are taken into account. In that context, the patientcentred care model has been identified as a foundation of high-quality healthcare, along with effectiveness, safety, efficiency, timeliness, and equity.⁷ This approach has been widely advocated as it may lead to better patient satisfaction and improved health outcomes,⁸ and has become a priority in health services in many other countries, including United Kingdom⁹ and Australia.¹⁰ Despite the efforts to progress patient centredness, clinicians still fail to consistently assess patients' concerns, beliefs and understanding of health conditions, or to include them in the decision-making process.¹¹ Barriers to implement patient centredness include inadequate educational emphasis on patient centred care, dominance of biomedical model in healthcare, and absence of good teaching models and curricula on patient centred care.¹² A potential factor that can help overcome these barriers is the identification of elements of health interventions considered to be relevant for patients. Awareness of the findings from this thesis can assist the implementation of patient- (or consumer-) oriented care into clinical practice.

Findings arising from Chapter Two of this thesis show that among the barriers for older people's participation in physical activity, the misbelief that physical activity is unnecessary or harmful, or that comorbities necessitate sedentary behaviour, needs to be urgently addressed. A recent longitudinal study and a systematic review refute this thinking and demonstrate that physical activity can in fact bring health benefits for all older adults.^{13,14} It is well established in the literature that physical activity has an important role in the management of a range of health conditions in

this age group, for instance stroke,¹⁵ arthritis,¹⁶ and cardiovascular conditions.¹⁷ Further research is needed to identify strategies that can enhance older people's knowledge regarding the real risks and benefits of physical activity. Promising approaches that can be used to overcome these misbeliefs are social marketing strategies and mass media campaigns and behavioural change interventions. Social marketing strategies involves the use of commercial concepts in programs designed to influence the voluntary behaviour of target audiences in order to improve health and society.¹⁸ Mass media campaigns include the routine use of existing media, such as television, radio, and newspapers to produce positive changes or prevent negative changes in health-related behaviours across large populations.¹⁹ There is evidence that mass media campaign to promote walking among sedentary older adults increases both the number of walkers and the number of those meeting the recommended levels of physical activity in terms of total time spent and frequency of walking.²⁰ A future direction for studies in this area is to investigate whether social marketing and mass media campaigns aiming to minimise the perceived risks of physical activity and to raise awareness of the various health benefits that can be gained with exercise are effective to increase physical activity levels among older people. Another potential area to be explored is that of behavioural change interventions. Changing behaviour is complex and involves considering various factors that influence behaviour,²¹ including motivation, cultural and social influences. Current evidence shows that behavior change interventions are successful in promoting physical activity in people with rheumatoid arthritis.²² Factors which influence physical activity participation amongst older people have been identified in the study presented in Chapter Two and include social influences; physical limitations; competing priorities; personal benefits of physical activity; and motivation and beliefs. Such factors reflect the needs and preferences of older people and are amendable to change. Behavioural strategies that may be used to modify these factors include securing social support from family and friends, promoting participant's self-efficacy and perceived competence, providing older people with active choices that are tailored to their personal needs and preferences and encouraging older people to commit to an intervention by developing goal statements that include realistic and measurable plans of action with specified health goals. Future studies should investigate if behavioral strategies addressing the factors identified in Chapter Two increase physical activity participation among the older population.

Patients' preferences for health interventions are thought to influence the results of randomised controlled trials. The findings from the systematic review presented in Chapter Three, however, suggest that considering the limitations of the existing literature, it might be too early to conclude whether patients' preferences can influence the size of treatment effects in randomised clinical trials of musculoskeletal conditions. This systematic review included only randomised clinical trials because the randomisation process ensures that both known and unknown patient characteristics, which may potentially affect treatment outcome are evenly distributed between groups. The disadvantage of this design is that patients with strong preferences for one of the treatments under evaluation may decline to consent to randomisation, which may limit the generalizability of results to clinical populations (i.e., reduced external validity).²³ For that reason, different trial designs, also known as preference trials, have been introduced and include the comprehensive cohort, Wennberg, and Rucker designs. What these designs have in common is the fact that they allow the inclusion of patients with strong preference in a trial by having a "preference arm(s)", to which participants are allocated if they have a strong preference for a certain treatment. Preference arms are conducted alongside the traditional "randomised arm(s)", to which participants are randomly allocated.²³ These preference trials have been conducted in various areas of health research and in 2005, a systematic review of the literature was conducted to investigate the impact of participants and physician intervention preferences on clinical trials.²⁴ The main limitation of these designs, however, is that randomisation is breached, and therefore important baseline differences between preference and randomised arms would potentially bias treatment effects. As the development of study designs which incorporate both the inclusion of patients with strong preferences and random allocation of participants is unlikely to occur, a possible strategy would be to elicit patients' preferences and willingness to participate in intervention trials in the feasibility stage of randomised clinical trials. The information would inform funding agencies on trial design acceptability before they can decide which projects to allocate resources to as well as trialists who would like to design studies with high acceptability and adherence rates. Discrete choice experiments can be conducted with that intent and identify health interventions that include a combination of attributes most highly valued by patients.

The study described in Chapter Four is a best-worst scaling choice experiment and reveals that older people's decision on whether or not to engage in physical activity is not only based on the

health benefits of physical activity, including reduction in the risk of falling and improvements in mobility. Instead, patients carefully considered environmental aspects of exercise programs such as exercise venue, travel time and out-of-pocket costs. Hence, rather than narrowly focusing on health outcomes such as physical benefits that can be gained with physical activity, consultations and clinical decision-making must encompass patients' environmental contexts and accessibility to exercise programs. In the context of teaching patient-centred care, health professionals should be trained to integrate patients' values and preferences when making clinical decisions. The range and depth of older people's perspective toward physical activities should not be a peripheral addendum in professional education, but incorporated as a core component. Findings derived from this thesis can, therefore, inform the development of professional curricula aimed at health professionals providing care for older people.

Findings derived from Chapter Four can also be of use for clinical guideline developers. In recent years, guideline developing institutions have advocated for inclusion of patients' preferences in their recommendations.²⁵ For instance, the National Institute for Health and Care Excellence -NICE guidelines on falls clearly states that 'for all recommendations, NICE expects that there is discussion with the service user about the risks and benefits of the interventions, and their values and preferences.²⁶ This discussion aims to help patients to reach a fully informed decision. However, the guideline does not provide any information on the actual patients' preferences or perspectives that clinicians are expected to hear from service users, for instance difficulties to access, lack of social support, or concerns about sustaining injuries during physical activities. Inclusion of this type of information is needed if the aim is to prepare clinicians to effectively discuss management options with patients. The British Medical Journal published an editorial advocating the use of discrete choice experiments to incorporate patients' preferences into NICE guidelines.²⁵ Although the editorial has been published more than ten years ago, the use of this method into guideline recommendations still remains a challenge. The findings derived from discrete choice experiments reported in Chapter Four show that patients value certain aspects of exercise programs, such as exercise venue, travel time and out-of-pocket costs. Inclusion of this information in the guidelines would assist clinicians when discussing management options with patients. For instance, the provision of exercise programs in the local community or at home without a cost is an approach likely to facilitate participation. Discrete choice experiments have

also recently been used by regulatory agencies to generate healthcare approaches more patientcentred.²⁷ Authors concluded that the methodology used can be applied to a wide variety of medical products, and proposes the ongoing development of a guidance document on incorporating patient preferences into medical-device premarket approval decisions.²⁷ Such a document could also guide the incorporation of consumers' preferences in other aspects of health decision making.

Results of the study described in Chapter Five and Chapter Six reveal that the average smallest worthwhile effect estimates calculated using the discrete choice experiments (35% reduction in the risk of falling) was over two times higher than the one (16% reduction in the risk of falling) found in the benefit-harm trade-off study. The study also identified that approximately half of participants of the benefit-harm trade-off study, and over three quarters of those in the discrete choice experiment study reported they would choose not to participate in the exercise program presented to them in the interviews, even if their risk of falling reduced to 0%. These findings suggest that regardless of the method used to elicit the smallest worthwhile effect, most older people do not consider the beneficial effects of exercise programs, including the average beneficial effect reported in meta-analyses of randomised controlled trials investigating exercise programs designed for older people, to be worth associated costs and inconveniences. Older people might be carrying somewhat unrealistic expectations of treatment effects or are still not convinced that they are at risk of falls. An implication for future studies is to investigate the effect of improving older people's health literacy with regards to their risk of falling on their physical activity behaviour through the use of targeted, disease-specific education resources²⁸. New more effective exercise interventions are also required.

Undertanding patients' preferences and choice has always been a complex research topic in the economic and psychology field. The process of choice may depend on personal factors as well as contextual factors. In psychological theories of choice behaviour, how patients frame the decision making process depends on patients' values and attitudes which are in turn influenced by affect and motivation.²⁹ The economic theories of choice behaviour has evolved over the years fom a classical model, in which consumers seek to maximise their self-interest, and that self-interest has broadly defined consistency properties across different decisions, to a contemporary model in which the process of choice should be framed within a broad spectrum where a wider number of

factors could lead consumers to the most satisfying decision.²⁹ Emotions have recently been recognised as an important driver of decision making.³⁰ For instance, a previous discrete choice experiment study has shown that emotional states may also be considered to influence decision making.³¹ More studies using discrete choice methodology should consider the role of emotional states when eliciting older people's preferences and choices for health treatments.

This thesis makes a unique contribution to the area of patients' preferences for health interventions. The focus of the thesis is to understand the perspectives and preferences of the general older population towards participation in physical activity. Thus, findings from this thesis can guide future work in this field. More studies in this area are needed to better understand whether preferences for physical activity vary across age groups of older people. The older population is a heterogeneous group. People aged 85 years or over, for instance, may present different barriers and preferences regarding physical activity participation as well as pain management. Future research should explore if these preferences vary across subgroups of oldest old or frail older people.

The studies included in this thesis offer a comprehensive and detailed understanding about the preferences, needs and values of older people for health interventions, with a special focus on their participation in physical activity programs. This work is of relevance to policy makers, health professionals and researchers, and can be used to progress patient-centred healthcare and research in the field of physical activity and ageing, provide guidance on how to move the field of patient' preferences within randomised trials forward, and assist in the design and interpretation of future randomised trials and systematic reviews investigating exercise programs designed for older people.

7.4. References

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Appendices

Appendix A

PEDro systematic review update – Exercise interventions for preventing falls in older people living in the community This section features a recent systematic review that is indexed on PEDro, the Physiotherapy Evidence Database (www.pedro.org.au). PEDro is a free, web-based database of evidence relevant to physiotherapy.

Exercise interventions for preventing falls in older people living in the community

► **Gillespie LD**, Robertson MC, Gillespie WJ, *et al.* Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2012;9: CD007146.

BACKGROUND

Falls among older people are an international public health issue that requires significant attention from authorities. Around a third of people aged 65 and over experience at least one fall each year.¹ Falls can lead to serious consequences, such as fractures, hospital admissions, mobility-related disability, loss of confidence and reduction in community participation. Importantly, costs related to falls are dramatically increasing worldwide.²

The previous (2009) version of this Cochrane systematic review of randomised trials³ provided evidence that the rate of falls in older people can be reduced with preventive interventions, such as exercise programmes, cataract surgery and psychoactive medication withdrawal.

AIM

This updated systematic review by Gillespie *et al*⁴ aimed to assess the effects of interventions designed to prevent falls in older people living in the community. Different types of interventions were included, such as exercises, educational programmes, medication and surgery. The focus of this PEDro summary is on the trials evaluating exercise interventions compared to control interventions (ie, usual care and placebo intervention).

SEARCHES AND INCLUSION CRITERIA

This review followed the methodology advocated by the Cochrane Collaboration. Electronic databases (the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINAHL) and online trial registers were searched. Ongoing and unpublished trials were identified by contacting researchers in the field. Randomised and quasi-randomised (eg, allocation by alternation) trials were eligible for this review. There was no language restriction.

INTERVENTIONS

Trials which investigated exercise interventions were grouped by exercise modality into six categories using the Prevention of Falls Network Europe taxonomy:⁵ gait/balance/functional training; strength/resistance training; flexibility; three dimension (Tai Chi, dance, etc); general physical activity; endurance and other. Trials which investigated more than one category of exercise were grouped as exercise containing multiple components.

MAIN OUTCOME MEASURES

The main outcome measures were rate of falls and number of fallers. The rate of falls is defined as the total number of falls

per unit of person time that falls were monitored (eg, falls per person year). The rate ratio compares the rate of falls in intervention and control groups during each trial. For number of fallers, a risk ratio compares the number of people in intervention and control groups who fell once or more (fallers) during the follow-up period.

STATISTICAL METHODS

Rate ratios, risk ratio (RR) and their 95% CIs were calculated for individual trials. For trials that monitored falls for longer than 1 year, the results reported at 1 year, if available, were used to calculate treatment effects. Where appropriate, data were pooled. A preplanned subgroup analyses comparing participants at higher risk of falling (history of falling or one or more risk factors for falls at enrolment) versus lower risk (not selected on falls risk at enrolment) were conducted to explore potential sources of heterogeneity. Funnel plots were used to explore the possibility of publication bias.

RESULTS

This updated review contains 159 trials with 79 193 participants conducted in 21 different countries. High proportions (70%) of the included participants were women. Fifty-one new trials were added to this updated version. Twenty-eight ongoing, or completed but unpublished, trials were identified.

Fifty-nine trials with 13 264 randomised participants compared the effect of exercise on falls with the impact of control interventions. Exercise intervention was delivered in a group setting in 47 trials and at home in 12 trials. Funnel plot asymmetry was minimal. Results are summarised in table 1.

Multiple-component group exercise, multiple-component home-based exercise and Tai Chi reduced both rate of falls and risk of falling. Four trials in which the exercise intervention included just gait, balance or functional training achieved a statistically significant reduction in rate of falls but not risk of falling. One small pilot trial testing balance and strength training embedded in daily life activities also reduced rate of fall but not risk of falling. A larger trial of the same intervention has now been published and also found the intervention to reduce the rate of falls.⁶

Multiple-component group exercise was found to reduce the rate of falls in subgroups of participants at higher and lower risk of falling (p for comparison between effect sizes in high-risk and low-risk participants=0.86). For Tai Chi, a greater reduction in the risk of falling (p for comparison=0.02) and rate of falls was evident in the lower-risk subgroup. The subgroup analyses based on falls risk at enrolment are also presented in table 1.

The pooled effect of six trials including 810 participants showed that exercise is effective to reduce the risk of fracture (RR 0.34, 95% CI 0.18 to 0.63).

LIMITATIONS/CONSIDERATIONS

Falls trials use slightly different definitions of falls and methods to measure falls which can potentially modify trial results. Consensual recommendations include daily recording of falls with monthly or more frequent follow-up conducted by researchers blind to group allocation. However, 45% (72 of 159) of the included trials did not follow the consensual recommendations, which might have led to an under-reporting or over-reporting of falls. To facilitate the comparison of future studies' findings, authors suggest the adoption of consensual recommendations in trials investigating fall prevention strategies.

PEDro systematic review update

Table 1 Comparison of exercise versus control

	Rate of falls			Number of fallers		
	Number of studies	Number of participants	Effect size* rate ratio (95% CI)	Number of studies	Number of participants	Effect size* risk ratio (95% CI)
Exercise versus control						
Group exercise: multiple-component exercise versus control	16	3622	0.71 (0.63 to 0.82)	22	5333	0.85 (0.76 to 0.96)
Individual exercise at home: multiple-component exercise versus control	7	951	0.68 (0.58 to 0.80)	6	714	0.78 (0.64 to 0.94)
Individual exercise: LiFE (balance and strength training in daily activities) versus control	1	34	0.21 (0.06 to 0.71)	1	31	0.73 (0.39 to 1.37)
Group exercise: Tai Chi versus control	5	1563	0.72 (0.52 to 1.00)	6	1625	0.71 (0.57 to 0.87)
Group exercise: gait, balance or functional training versus control	4	519	0.72 (0.55 to 0.94)	3	453	0.81 (0.62 to 1.07)
Group exercise: strength/resistance training versus control	1	64	1.80 (0.84 to 3.87)	1	120	0.77 (0.52 to 1.14)
Individual exercise at home: resistance training versus control	1	222	0.95 (0.77 to 1.18)	1	222	0.97 (0.68 to 1.38)
Individual exercise: balance training versus control	1	128	1.19 (0.77 to 1.82)	-	-	-
Individual exercise: general physical activity (walking) versus control	-	-	-	1	196	0.82 (0.53 to 1.26)
Subgroup analysis by falls risk at baseline						
Group exercise: multiple-component exercise ve	ersus control					
Higher risk of falling	9	1261	0.70 (0.58 to 0.85)	12	1430	0.87 (0.78 to 0.97)
Lower risk of falling	7	2361	0.72 (0.58 to 0.90)	10	3903	0.85 (0.68 to 1.06)
Group exercise: Tai Chi versus control						
Higher risk of falling	2	555	0.95 (0.62 to 1.46)	2	555	0.85 (0.71 to 1.01)
Lower risk of falling	3	1008	0.59 (0.45 to 0.76)	4	1070	0.58 (0.46 to 0.74)

Falls are currently a self-reported outcome so it is not possible to mask study participants to group allocation. This may bias trial findings. In future, technology may enable automated fall monitoring that will eliminate this concern.

This review provides some evidence that fall-preventionintervention can also prevent fractures. Trials of exercise interventions that are large enough to detect effects on fractures in their own right are yet to be conducted. Future falls trials should routinely report fracture outcomes.

CLINICAL IMPLICATIONS

This well-conducted updated review provides robust evidence that exercise interventions can prevent falls in older people living in the community. Group-based and home-based exercise programmes are effective strategies to reduce the rate of falls and the risk of falling in older people living in the community. Multiple-component exercise reduces the rate of falls in people at both high and low risk of falling. Tai Chi reduces the risk of falling and appears to be more effective in people who are at low risk of falling.

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Contributors MRF selected the systematic review and wrote the first draft of the manuscript. MRF, LSMP and PHF contributed to interpretation of the data, revision of drafts and approved the final manuscript.

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.

To cite Franco MR, Pereira LSM, Ferreira PH. *Br J Sports Med* Published Online First: [*please include* Day Month Year] doi:10.1136/bjsports-2012-092065

Received 6 December 2011 Revised 6 December 2011 Accepted 7 December 2011

Br J Sports Med 2013;0:1-2. doi:10.1136/bjsports-2012-092065

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Appendix B

Guidelines for publication *Journal of Clinical Epidemiology*



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