Effectiveness of McKenzie Method–Based Self-Management Approach for the Secondary Prevention of a Recurrence of Low Back Pain (SAFE Trial): Protocol for a Pragmatic Randomized Controlled Trial

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Background. Although many people recover quickly from an episode of low back pain (LBP), recurrence is very common. There is limited evidence on effective prevention strategies for recurrences of LBP.

Objective. The purpose of this study was to determine the effectiveness of a McKenzie method–based self-management approach in the secondary prevention of LBP.

Design. This will be a pragmatic randomized controlled trial.

Setting. Participants will be recruited from the community and primary care, with the intervention delivered in a number of physical therapist practices in Sydney, Australia.

Participants. The study will have 396 participants, all of whom are at least 18 years old.

Intervention. Participants will be randomly assigned to either the McKenzie method–based self-management approach group or a minimal intervention control group.

Measurements. The primary outcome will be days to first self-reported recurrence of an episode of activity-limiting LBP. The secondary outcomes will include: days to first self-reported recurrence of an episode of LBP, days to first self-reported recurrence of an episode of LBP leading to care seeking, and the impact of LBP over a 12-month period. All participants will be followed up monthly for a minimum of 12 months or until they have a recurrence of activity-limiting LBP. All participants will also be followed-up at 3, 6, 9, and 12 months to assess the impact of back pain, physical activity levels, study program adherence, credibility, and adverse events.

Limitations. Participants and therapists will not be masked to the interventions.

Conclusions. To our knowledge, this will be the first large, high-quality randomized controlled trial investigating the effectiveness of a McKenzie method–based self-management approach for preventing recurrences of LBP. If this approach is found to be effective, it will offer a low-cost, simple method for reducing the personal and societal burdens of LBP.

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Low back pain (LBP) is the health condition that carries the greatest burden worldwide accounting for approximately 10.7% of total years lived with disability, according to recent Global Burden of Disease Studies reports.[1-3] The point prevalence of activity-limiting LBP, lasting more than 1 day, is estimated to be 11.9%,[4] and 1-month prevalence of activity-limiting LBP is around 23.2%.[4] Additionally, almost half of the people who experience LBP are expected to seek care.[5] Therefore, the direct and indirect costs related to LBP are enormous: approximately $9 billion annually in Australia[6] and $90 billion in the United States.[7]

The majority of people with an episode of nonspecific LBP improve quickly;[8,9] more than 80% recover within 3 months.[10] However, recurrences of back pain are common, with 12-month recurrence rates reported in the literature ranging from 24% to 80%.[11-13] Thus, the recurrent nature of LBP is one of the major reasons why the condition carries such a large social and economic burden worldwide.

Although thousands of trials have been conducted to investigate treatments for LBP, surprisingly few have investigated interventions to prevent LBP. A 2016 systematic review on prevention of LBP[14] found 21 randomized controlled trials with a total of 30,850 participants. This systematic review showed evidence that both exercise alone and in combination with education were effective in reducing LBP episodes (35% and 45% risk reductions, respectively) for up to one year. However, the trials included in the review had a number of methodological flaws. The trials were typically small and unregistered and did not attend to trial features, such as concealed allocation, masking and intention-to-treat analysis (known to control against bias). Consequently, it is likely that these trials overestimated the prevention effects. Despite the favorable results, these exercise programs are relatively costly and time consuming often requiring people to attend many sessions. For example, in the Soukup et al, randomized controlled trial participants were required to attend 20 group sessions of exercise and education over a period of 13 weeks.[15]

Self-management programs aim to empower patients with skills that help them become more active and responsible in the management of their condition.[16] Previous studies have demonstrated that a self-management program has some beneficial effect on management of a number of conditions, such as asthma, arthritis, diabetes, and chronic LBP.[17,18] Thus, an effective self-management intervention in which the patient/participant is empowered with knowledge and skills to prevent future episodes of LBP would be ideal, reducing the cost and time burden for participants, and increasing the likelihood of large-scale implementation.

The McKenzie method–based self-management approach has several potentially important advantages over traditional group-based exercise approaches in preventing recurrence of LBP. The program involves very simple exercises that are quick to perform and can be done on a daily basis without the need to attend regular exercise classes. Exercises focus on balancing mechanical forces created by the postures or positions used by each individual throughout a typical day (ie, if a person spends most of the time in either a flexed or extended spinal posture, exercises will be focused on the opposite direction). For most people this involves lumbar extension to counteract the large amount of flexion activity typical of most people's lives either in sitting or performing manual tasks. Importantly, the McKenzie method-based self-management approach also provides simple strategies with the aim of allowing management of mild episodes without seeking care.

To our knowledge, there are no published studies that have evaluated the effectiveness of McKenzie method–based self-management approach in secondary prevention of a recurrence of LBP. A previous study by Larsen and colleagues[19] investigated prone extension exercises for the "prevention" of LBP. The study recruited military conscripts and randomized them to education and passive prone extension exercises done daily or a group that received no intervention (control). Significantly fewer people in the intervention group than in the control group reported back problems during the 1-year follow-up (33% and 51%, respectively). The main limitation of this study is that it recruited a heterogeneous population with and without current LBP, so assessment of the effect of the intervention on prevention is difficult, as approximately 25% of participants had pain at the start of the study. The study also had a fairly high dropout rate (21%). We believe it is important to test if the promising findings can be generalized to a broad population sample who have recently recovered from an episode of LBP.

Therefore, the aim of our randomized controlled trial is to compare the effectiveness of the McKenzie method–based self-management and educational approach with that of a minimal intervention control in preventing recurrence of LBP in people recently recovered from an episode of nonspecific LBP. We will also investigate whether the approach reduces the impact of back pain over 1 year, and establish the risk of adverse events during the follow-up period. A safe, low-cost, and effective intervention to prevent recurrences of LBP would be of enormous benefit to individuals and society.

Methods

Design Overview

The SAFE Trial is designed to be a pragmatic randomized controlled trial, where the outcome assessors and the statistician are masked. A total of 396 participants who have recently recovered from an episode of nonspecific LBP will be randomized to either the McKenzie method–based self-management approach or a minimal intervention group control. Participants will be followed-up from the day of randomization for a minimum of 12 months and up to 30 months, depending on when they enter the study. The primary outcome is days from randomization to a self-reported recurrence of activity-limiting LBP. The SAFE Trial design is illustrated in the Figure. The Pragmatic in

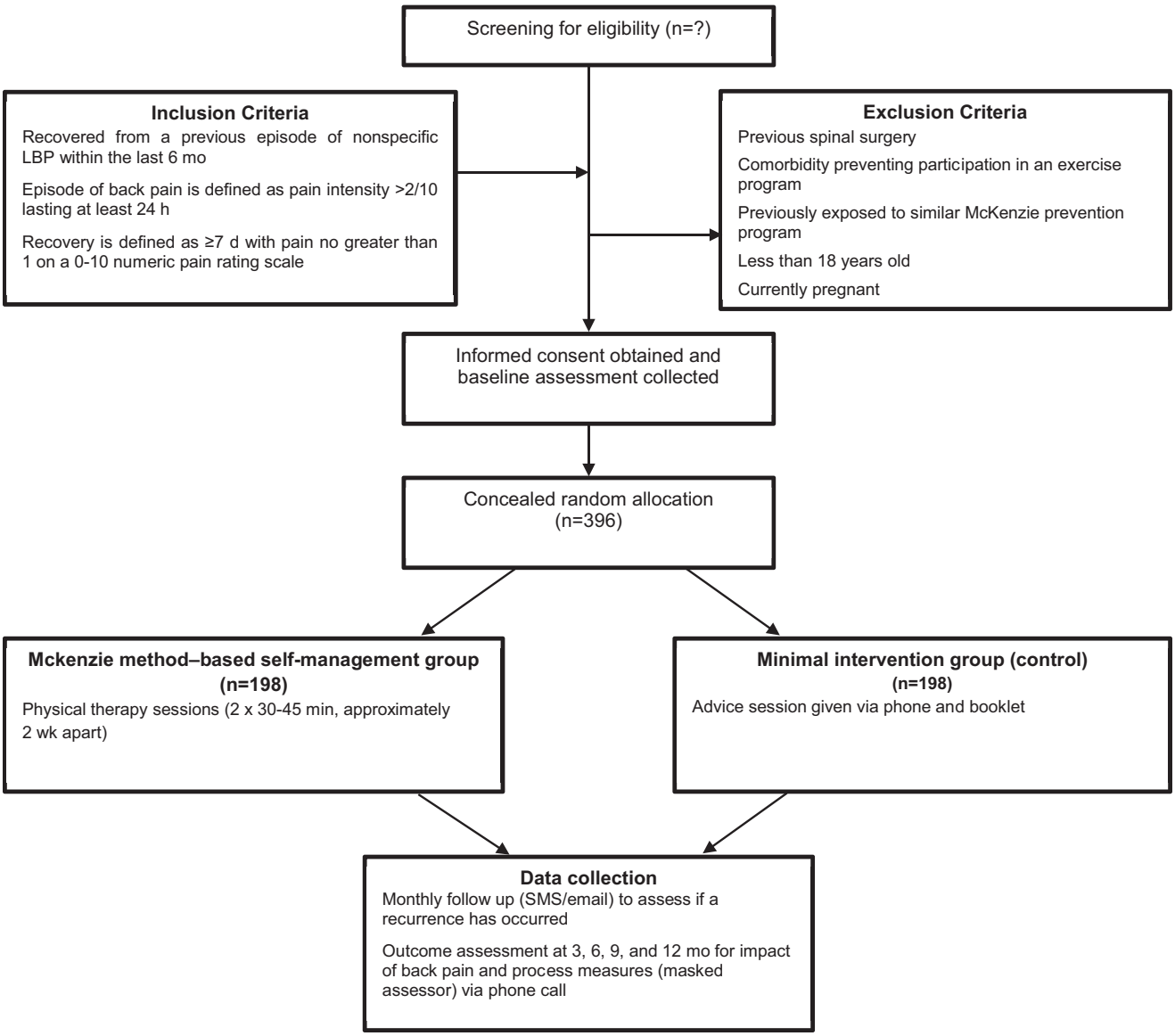

Figure.
Design of SAFE Trial study. LBP = low back pain, SMS = Short Message Service.

design, the SAFE Trial aims to determine the benefit of the intervention in a real-world clinical setting.[20,21] There are limited inclusion and exclusion criteria, treatment is tailored to the individual, and outcomes are directly relevant to participants.

Participant Eligibility and Recruitment

Eligibility. We will include 396 participants who are at least 18 years old and who have recently recovered (within the last 6 months) from an episode of nonspecific LBP (with or without leg pain). Nonspecific LBP is defined as pain in the area between the 12th rib and buttock crease[22] not attributed to a specific diagnosis, such as ankylosing spondylitis or vertebral fracture. Recovery is defined as having occurred after 7 consecutive days with pain no greater than 1 on a numeric pain rating scale (ratings = 0–10). Participants will be excluded if they meet any of the following criteria: previous spinal surgery; comorbidity restricting or preventing safe participation in exercise (eg, traumatic brain injury, psychological illness); inadequate English usage to complete outcome measures; previous exposure to the McKenzie method–based self-management approach as a method of preventing future LBP; or current pregnancy. Participants will be recruited from the community via advertisements (eg, public noticeboards, websites) and from primary care clinics (general practitioner, physical therapist, or chiropractor) in Sydney, Australia.

Recruitment procedure. The trial advertisements will direct members of the community interested in the study to contact the researchers. Also, patients being discharged from primary care clinics on recovery from an episode of nonspecific LBP will be informed about the study by their clinician. People interested in finding out more about the study can either contact the researchers directly (phone or email) or provide verbal consent for the clinician to forward their contact details to the researchers. The participant information and consent form will be posted or emailed to the participant. Potential participants referred to the study will be contacted by phone to explain the study in more detail and answer any questions they have. Potential participants who want to volunteer for the study will be screened to determine if they meet all study eligibility criteria.

Participants will be enrolled into the study over the phone without meeting one of the researchers in person. Therefore, the consent will be a verbal consent. We will gain verbal consent over the phone through the following process. After answering any questions the participant has about the study, the researcher will read the following statement: "By completing this questionnaire, you are indicating that you have read and understood the information in the participant information and consent form provided to you and any questions you have asked have been answered to your satisfaction. You agree to participate in this research, knowing that you can withdraw from further participation in the research at any time without consequence."

Baseline Assessment

After fulfilling the eligibility criteria, agreeing to participate, and providing verbal consent, participants will undergo a standardized baseline assessment over the phone. This will take approximately 10 to 15 minutes and will collect data on demographics, history of LBP and prognostic factors for recurrence. All baseline data will be entered directly onto a hard copy of the baseline assessment questionnaire and then entered into the electronic database at the first available opportunity.

Randomization

Immediately after completing the baseline assessment, participants will be randomly allocated into either the McKenzie method–based self-management approach group or minimal intervention (control) group. The researcher will open the next consecutively numbered, sealed, opaque randomization envelope to ensure concealed allocation. A randomization schedule—incorporating randomly permuted block sizes of 4, 6, and 8—will be generated prior to the commencement of the trial by an independent investigator not involved in participant recruitment, treatment, or follow-up, using a computer program. Randomization will be stratified by history of more than 2 previous episodes of LBP (dichotomised as "yes" or "no") as our previous research showed that this is the only known consistent predictor of recurrence.[13] Study participants will be considered enrolled into the study when the allocation envelope is opened and the participant is assigned to either the McKenzie method–based self-management approach or the minimal intervention group. They will receive a study enrollment number and this will be documented in the participant's clinical trial record and on all study documents.

Masking. Due to the nature of the trial, complete masking will not be possible. In an effort to mask the participants as much as possible to the trial research question, they will be told that the study is comparing 2 methods for preventing future recurrence of back pain, one delivered face-to-face and the other delivered over the phone. Also, it will not be possible to mask the treatment providers to group allocation. The statistician and the outcome assessors will be masked to group allocation.

Study Interventions

Minimal intervention group (control). Participants allocated to the minimal intervention (control) group will receive simple advice that is widely available about how to prevent back pain. This will be delivered over the phone by a physical therapist. The key points in this advice will be maintenance of regular exercise and education about lifting and handling objects safely, taking approximately 10 to 15 minutes. Participants in this group will be posted a copy of the "*Managing Back Pain – Get Back on Track*" booklet,[23] which was developed by Bupa Australia Pty Ltd (private health insurance company). This booklet includes general advice about back pain prevention and self-management. The company has given consent for the booklet to be used in this project. Participants will have the opportunity to contact the physical therapist who delivered the intervention on one further occasion, approximately 2 to 4 weeks after being randomized, by email or phone, if they require further clarification.

McKenzie method–based self-management approach group. Participants allocated to the McKenzie method–based self-management approach group will attend two 30- to 45-minute individual sessions with a trained physical therapist. These sessions will be approximately 2 weeks apart. In the first session, study physical therapists will assess participants using the McKenzie Institute Lumbar Spine Assessment Form.[24] The history will focus on developing a clear understanding of the previous episodes including causal or aggravating factors, and the daily mechanical and postural stresses for each individual. The physical examination will assess habitual postures and their relationship to symptoms, spinal movement loss, and any effect of repeated spinal movements on symptoms and mobility. This assessment will help the therapists to gather information that will guide prescription of an appropriate home prevention exercise program for each particular participant's circumstances. The participant will be provided with and educated about an individualized simple specific exercise program focusing on movements that balance/counteract the postures or positions habitually adopted throughout the day and on improving any existing movement loss. Because the intervention is individualized for each participant, the exercises to be completed at home will vary in frequency and duration, based on the judgment of the assessing physical therapist. Typically exercises

will be performed multiple times per day and be of short duration.

At the follow-up session, the physical therapists will perform a reassessment and obtain feedback from participants on how the program is going and any barriers to adhering to the program. Depending on this reassessment the physical therapist will then modify or progress the home exercise prevention program as needed. The therapist will emphasize the importance of continuing these exercises indefinitely as a prevention strategy for back pain recurrence. For most people the exercise program will involve lumbar extension to counteract the large amount of flexion activity typical of most people's lives (either sitting or performing manual tasks).

Follow-up

Participants will be followed up monthly by email or text message from the day of randomization into the study for at least 12 months and up to 30 months, depending on when they enter the study. To make maximum use of all available data, the usual practice in studies using survival analysis is to follow people until the study concludes. Because people enter the study at different dates, some participants will be followed for only 12 months and some will be followed for as long as 30 months. Participants will be asked whether they have had a recurrence of LBP of intensity greater than 2 on a numeric pain scale (ratings = 0–10) and lasting at least 24 hours within the past 4 weeks or since the last contact from the research team. If participants reply "yes" to this email or text message, a study researcher will contact them via phone call for further information about this recurrence. Participants who have not replied to the first text message or email within 2 days will be sent a second text message or email. Participants not responding to these 2 messages will be then contacted by phone. In addition to the recurrence data, outcome data will be collected at 3, 6, 9, and 12 months from randomization into the study by a phone call at these time points. Follow-ups will be conducted by a researcher masked to group allocation.

Outcome Measures

Primary outcome. The primary outcome will be the number of days from randomization to first self-reported recurrence of an episode of activity-limiting LBP (somewhat or greater activity limitation measured using an adaptation of item PI9 of the PROMIS item bank to measure pain interference).[25] Participants will be followed up for this outcome for between 12 and 30 months post-randomization, depending on when they are randomized into the study.

Secondary outcomes. One secondary outcome will be the number of days from randomization to first self-reported recurrence of an episode of nonspecific LBP (intensity > 2/10 on the numeric pain rating scale and lasting at least 24 hours).[26] Participants will be followed up for this outcome for between 12 and 30 months after randomization, depending on when they are randomized into the study.

Days from randomization to first self-reported recurrence of an episode of LBP leading to care seeking (with consultation to a health care provider) will be another secondary outcome. Participants will be followed up for this outcome for between 12 and 30 months after randomization, depending on when they are randomized into the study.

The personal impact of LBP over the first 12 months after randomization will be determined for all participants in the study. The impact of back pain will be measured with the Impact of Back Pain Questionnaire using 9 items of the 29-item PROMIS short form.[27] This measure was recommended in the recent NIH Task Force report on research standards for LBP.[27] These 9 items cover the domains of pain intensity, pain interference with normal activities, and functional status. The total score on the Impact of Back Pain Questionnaire ranges from 8 (least impact) to 50 (great impact). This outcome will be collected at the 3-, 6-, 9-, and 12-month follow-ups by asking about the impact of back pain over the past 3 months.

Process Measures

Additional process measures will also be collected. These measures will help better understand the study results and include:

Physical activity levels will be measured by the International Physical Activity Questionnaire (IPAQ).[28] This questionnaire estimates a participant's physical activity level over the past week. Physical activity measures will be collected at baseline and at the 3- and 12-month follow-up assessments.

Study program compliance will be monitored by recording attendance at the two physical therapist visits, asking physical therapists to rate their perception of participant compliance to the home exercise program between the participants initial and second visit (2-week period), and asking participants to rate compliance with home program using the Brief Adherence Rating Scale at 3-, 6-, 9-, and 12-month follow-ups.

Credibility/expectancy regarding treatment will be measured with a credibility/expectancy questionnaire modified from Devilly and Brokovec.[29] This questionnaire will provide information on the participant's beliefs about the intervention received. The credibility/expectancy scores will be collected at the 3-month follow-up assessment.

Adverse Events and Use of Co-interventions

Adverse events will be considered to be any health problems or complaint reported by the participants during the study. Adverse events will be collected by self-report at the 3-month and 12-month follow-up assessments after randomization. Data on use of any intervention for treatment or prevention of LBP, apart from the study program, will be collected at all follow-up assessments (3, 6, 9, and 12 months).

Physical Therapist Training and Treatment Fidelity

We will work with a small number of physical therapist clinicians (eg, 8-10),

who have undertaken, at least, training in the McKenzie Method of Mechanical Diagnosis and Therapy, Parts A and B, or are fully credentialed in the McKenzie method, around metropolitan Sydney. All study physical therapists will be trained in the study intervention procedures in a single session lasting approximately 1 hour. H.A.C. will be responsible for ensuring that clinicians are adequately trained to deliver the intervention and for assessing compliance with the study procedures. She will be in regular contact with the participating clinicians, to discuss any issues in delivering the intervention and provide reminders of the study procedures. She will attend some sessions to directly observe the fidelity of the intervention being delivered. Physical therapists will complete standardized assessment and prevention strategy notes for each session that will be collected by researchers after the participants' final sessions.

Data Analysis, Monitoring, and Auditing

Sample size calculation. The sample size was calculated for the primary outcome using PASS statistical software (NCSS Statistical Software, Kaysville, Utah), as described by Lakatos.[30] For a 2-sided log rank test with an alpha value of 0.05 we calculated that a sample size of 198 participants per group will provide 80% power to detect a 40% relative reduction in recurrence rates between the treatment group and the control group. These calculations are based upon 30% recurrence in 1 year in the control group. Higher rates of recurrence typically reported in the literature would increase power. Our sample size calculations are based on an 18-month accrual period and 12-month follow-up period. We have conservatively allowed for 1% loss to follow-up, and 1% treatment nonadherence per month in both groups.

Data integrity and analysis. All study data will be entered into an electronic database as soon as possible after being collected. Access to the data obtained in this research will be restricted to the researchers involved in the collection and analysis of the data. Participant confidentiality will be maintained through secure data storage, during and after the study. Data will be carefully monitored for any errors. We will use descriptive analyses to identify outliers and potential errors. All data being entered manually will be double entered by a second researcher and checked for any data discrepancy.

Data will be analyzed by a statistician who is masked to group status. The primary analyses comparing the groups will follow the intention-to-treat principle.[31] For the primary outcome, a P value of <.05 will be considered statistically significant. For the secondary outcomes, a P value of <.01 will be considered significant.

For the primary outcome analysis, we will assess difference in survival curves (days from randomization to first self-reported recurrence of activity-limiting LBP) using the log-rank statistic. Cox-regression will be used to assess the effect of treatment group on hazard ratios. We have stratified for the only known predictor of recurrence (previous recurrence).[13] We will treat prognostic factors for LBP[32,33] as potential confounders and, if these are unbalanced despite randomization, we will include them as covariates in the analysis. The proportional hazards assumption will be tested using the time-dependent covariate method.

For the secondary outcomes of days from randomization to first self-reported recurrence of either an episode of nonspecific LBP or an episode of LBP leading to care seeking, a survival analysis analogous to that of the primary outcome will be conducted. To investigate whether the intervention will have an influence on the impact of back pain over a 1-year period, we intend to use repeated-measures linear models; however, given that this is a new measure, we will explore the data distribution before making a final decision.

A secondary analysis will assess the presence of a limited number of baseline variables as modifiers of treatment effects. Variables to be investigated include age, body mass index, number of previous episodes, sitting time, perceived risk of recurrence, and frequency of exposure to heavy loads and awkward positions.

Ethics Approval

Ethical approval was obtained from Macquarie University Human Research Ethics Committee in April 2016 (ref. no. 5201600187). The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research 2007*.[34] Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected. The study protocol will be implemented and reported in line with the SPIRIT statement.[35] Also, the completed clinical trial and its results will be reported according to CONSORT[36,37] and TIDieR[38] guidelines. Study results will be disseminated at research conferences and as published articles in peer-reviewed journals.

Role of the Funding Source

This trial is funded by the International Mechanical Diagnosis and Therapy Research Foundation – USA. The funders will have no role in this study other than to provide funding.

Discussion

Potential Impact and Significance of the Study

Back pain places an enormous burden on individuals and society as demonstrated by the recent Global Burden of Disease Study reports.[2,3] Much of this burden is due to the recurrent nature of LBP. The great majority of trials in the back pain field evaluate treatment rather than prevention. A recent systematic review investigating all interventions for prevention of LBP found low-quality evidence supporting exercise as a strategy for preventing future back pain episodes. The lack of high-quality back pain prevention research limits the ability to provide clinicians and patients with strong recommendations about effective prevention approaches.

To our knowledge, this study will be one of only a few high–quality, large trials evaluating secondary prevention of recurrent LBP and the first evaluating the McKenzie method-based self-management approach, which aims to teach participants simple exercise focused on balancing mechanical forces or positions used during typical daily activities and improving mobility. The identification of a cost-effective method to prevent recurrences of LBP would be a major breakthrough and could make an enormous contribution to global health. If this self-management approach is found to be effective against recurrence of LBP, our research will have the potential to help prevent pain and disability for millions of people worldwide.

Strengths and Weaknesses of the Study

This trial was prospectively registered with the Australian and New Zealand Clinical Trial Registry, and the sample size was preplanned to provide robust evidence. We will use a stratified, blocked randomization process, concealed allocation, masked assessments, and an intention-to-treat analysis. Experienced physical therapists trained by the research team in the study process will be conducting the McKenzie method–based intervention, and the quality of the intervention will be monitored. Due to the nature of the interventions, it is not possible to mask the therapists and participants to the treatment allocation, but outcome assessors and statisticians will be masked.

Recruitment for clinical studies is typically difficult, but, we have designed the study to make this process as easy as possible. We will be recruiting participants for this study primarily through community advertisements, and also through primary care clinicians as needed. The role for the recruiting clinicians will be simply, as they need only pass on the study information to appropriate patients. The time commitment for patients will be relatively small, and all follow-up assessments will be done remotely. However, if we do struggle with these 2 recruitment strategies, we will increase the number of recruiting clinicians and investigate barriers to recruitment from all perspectives.

Contribution to the Physical Therapy Profession

High-quality evidence about prevention of LBP is very important for physical therapy, given that LBP and the associated recurrences are the most common condition presenting to musculoskeletal physical therapists. If we find evidence for the effectiveness of the McKenzie method–based self-management program, then this has the potential to influence the physical therapist management of many patients who could be provided with this program when they recover from an episode of LBP. Physical therapists could offer this program to people in the community who are not currently seeking care but who have recurrent episodes of LBP. The skills and training of physical therapists make them the ideal professionals to deliver evidence-based interventions for prevention of LBP.

Author Contributions and Acknowledgments

Concept/idea/research design: T.F. de Campos, C.G. Maher, H.A. Clare, M.J. Hancock
Writing: T.F. de Campos, C.G. Maher, H.A. Clare, T.M. da Silva, M.J. Hancock
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Project management: T.F. de Campos, C.G. Maher, H.A. Clare, M.J. Hancock
Fund procurement: C.G. Maher, H.A. Clare, T.M. da Silva, M.J. Hancock
Consultation (including review of manuscript before submitting): T.F. de Campos, C.G. Maher, H.A. Clare, T.M. da Silva, M.J. Hancock
M.J. Hancock, T.F.de Campos, C.G. Maher, and H.A. Clare will form the data management committee.

Funding

This trial is funded by the International Mechanical Diagnosis and Therapy Research Foundation – USA. The funders will have no role in this study other than to provide funding.

Clinical Trial Registration

This study is registered in the Australian and New Zealand Clinical Trial Registry (ANZCTR) (ACTRN12616000926437). Universal Trial Number (UTN): U1111-1184-9436.

Ethics Approval

Ethical approval was obtained from Macquarie University Human Research Ethics Committee on April 2016 (ref. no. 5201600187).

Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest. C.G. Maher's fellowship is funded by Australia's National Health and Medical Research Council. T.F. de Campos has a PhD scholarship from Macquarie University (Macquarie University Research Excellence Scholarship (MQRES) - Allocation No. 2016221. T.M. da Silva receives a scholarship from CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Ministry of Education of Brazil.

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