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A physiotherapist-led exercise and education program for preventing recurrence of low back pain: a randomised controlled pilot trial

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Abstract

Background Before beginning a large and complex trial it is considered good practice to run a pilot study to assess the feasibility and acceptability so that quality is maintained and resources are not wasted.
Objective To assesses the feasibility and acceptability of procedures for TOPS: Trial Of Prevention Strategies for low back pain.
Design Randomised controlled pilot trial.
Methods This is a trial of an 8 week, physiotherapist-led group exercise and education program for preventing recurrence of low back pain (LBP) in those recently recovered from LBP. We assessed the feasibility of recruitment and data-collection procedures, acceptability of the trial interventions and loss-to-follow up.
Results The feasibility of recruitment, acceptability of the intervention and feasibility of physical activity data-collection procedures were all below anticipated levels. We enrolled 12 participants over 44 weeks, the adherence rate for the intervention group was 63% and valid physical activity data were obtained for 67% of the measurements. Follow-up methods for collection of LBP recurrence were successful with this information able to be collected for 100% of participants.
Conclusion In response to the pilot, modifications were made to the main trial protocol. We will increase recruitment by relaxing inclusion criteria and expanding recruitment sites to include workplaces, community centres and via social media. We will facilitate compliance by expanding treatment sites to provide more options for participants to access the program and we will limit missing data by checking the validity of baseline physical activity measures prior to enrolment.

Trial registration: The study was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ref: ACTRN12614000706673).

Keywords: Physiotherapy; Pilot trial; Low back pain; Exercise; Prevention

Introduction

Despite low back pain (LBP) being the leading cause of disability burden worldwide [1], robust research evaluating interventions to prevent LBP is lacking. The latest systematic review [2] on the topic suggests only exercise alone or in combination with education is effective for preventing LBP. However as the trials in the review were generally small and of low methodological quality, there is still some doubt as to the effectiveness of these interventions. Also, as none of the included studies assessed cost-effectiveness, health policy makers are unable to judge whether exercise programs to

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prevent recurrences of LBP represent value for money and are a wise investment. In order to provide this information we will conduct a large, high quality randomised controlled trial assessing the effectiveness and cost-effectiveness of a physiotherapist-led exercise and education program for the prevention of recurrent LBP [3].

Before beginning a large and complex trial it is considered good practice to run a pilot study in order to assess the feasibility and acceptability of the study so that resources are not wasted [4–7]. Aspects that need to be considered are: the integrity of the study procedures, the feasibility of recruitment and the acceptability of the intervention and data collection [8]. For example, if planned recruitment methods are not able to achieve the necessary recruitment rate, limited funds may necessitate the early stoppage of the trial before the required sample size has been achieved. Pilot studies can minimise these problems through early identification of such issues and allowing for modification of the protocol before commencement of the main trial.

In this study we assessed the feasibility and acceptability of procedures for TOPS: Trial Of Prevention Strategies for low back pain [3]. More specifically we assessed the feasibility of recruitment and data-collection procedures, the acceptability of the trial interventions and the expected loss-to-follow up. This information will facilitate the successful running of TOPS and provide valuable information for external researchers considering the use of similar procedures in future trials.

Methods

This study is a randomised controlled pilot trial to assess feasibility and test procedures for TOPS. TOPS is a pragmatic randomised controlled trial to assess the effectiveness and cost-effectiveness of a physiotherapist-led group exercise and education program, compared to a minimal intervention control, in preventing recurrence of LBP in those recently recovered from an episode of LBP [3]. The pilot study was based in the Sydney metropolitan area, Australia. Ethics approval was obtained from the University of Sydney Human Research Ethics Committee (ref: 2014/238). The study was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ref: ACTRN12614000706673).

Participant recruitment and enrolment

Potential participants were identified upon presentation to their primary care practitioner (general practitioner or physiotherapist) with an episode of low back pain and, with their permission, their details were passed through to the researchers. Potential participants were then pre screened by the researchers using the inclusion/exclusion criteria to identify those who would become eligible for the study upon their recovery from LBP. Potential participants who passed the pre screen were then followed by the researchers once a month for up to 3 months with those who recovered in this time assessed against the complete eligibility criteria and, if eligible, arranged to be enrolled into the trial.

Enrolment was conducted on site by a researcher at the physiotherapy clinic that would be providing the intervention. At the enrolment participants' understanding of the study was confirmed and informed consent obtained. Eligibility for the study was then re-checked and baseline data (participant demographics, history of back pain, beliefs around back pain and physical activity data) obtained. Randomisation occurred after completion of the enrolment.

Inclusion criteria

Participants were included if they met the following inclusion criteria:

- Recovered from a previous episode of non-specific LBP within the last month. Non-specific LBP was defined as pain in the area between the 12th rib and buttock crease not attributed to a specific diagnosis such as sciatica, ankylosing spondylitis, vertebral fracture etc. The date of recovery is defined as the 30th consecutive day with pain no greater than 1 on a 0 to 10 scale.

Exclusion criteria

Participants were excluded if they had any of the following:

- Previous spinal surgery.
- Any co-existing medical condition that would severely restrict or prevent participation in the exercise program. (e.g. uncontrolled hypertension, severe osteoarthritic pain, loss of limb) [9].
- Inadequate English to complete outcome measures.
- Currently participating in a structured exercise program similar to the TOPS exercise program. (e.g. a structured moderate intensity aerobic exercise of at least 150 minutes/week, or a structured strength training exercise program of at least 2 times/week.)

Randomisation and blinding

Microsft Excel 2013 was used to develop the randomisation sequence utilising simple randomisation to assign participants to either a minimal intervention or a group exercise and education program at a 1:1 ratio. Consecutively numbered, sealed, opaque envelopes were used to conceal randomisation. These envelopes were stored at the research office and given to the intervention provider (physiotherapist) upon completion of the enrolment to be opened after the researcher had departed. Blinding of participants and the physiotherapists providing the intervention was not possible. Participants were told that the trial was comparing two methods for preventing recurrence of back pain and that it was unknown which was more effective. Staff conducting