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Protocol

Accelerometer-based facilitated walking program in addition to usual care for the management of patients with low back pain at medium or high risk of chronicity: a randomised controlled trial protocol

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ABSTRACT

Background: The lifetime prevalence of low back pain (LBP) has been reported to be as high as 84% worldwide. Around 23% of the population has chronic non-specific LBP. Despite the potential health benefits of walking, few studies have investigated its effectiveness in people with non-specific LBP. The primary objective is to examine the efficacy of a Fitbit facilitated walking intervention in people with LBP with medium or high risk of chronicity in reducing disability and pain. The secondary objective is to investigate the efficacy of a Fitbit facilitated walking intervention in increasing physical activity levels in people with LBP.
Methods: This prospective, randomised controlled trial will involve 68 participants. This study will recruit participants who are aged 18 years or over, have been diagnosed with non-specific LBP with medium or high risk of chronicity and classified as physically inactive. Participants will be randomised into two groups: usual physiotherapy care (n=34) and usual physiotherapy care plus Fitbit facilitated walking intervention program (n=34). The treatment duration will be 8 weeks. Primary outcomes for this study are disability and pain. Secondary outcomes include physical activity level and walking steps, depression, fear of movement and pain catastrophising. The outcomes will be assessed at baseline, post-intervention and 26 weeks post-randomisation follow-up.
Conclusions: The results of this study will provide empirical evidence on the efficacy of a Fitbit facilitated walking intervention program, when added to usual care, in a clinical setting for improving disability and pain, and other clinical outcomes in people with LBP.
Trial Registration: Australian New Zealand clinical trials registry (Number ACTRN12617001404314).

Keywords: Low back pain, Physical activity, Walking, Fitbit, Randomised controlled trial, Protocol

INTRODUCTION

Low back pain (LBP) is one of the most common conditions presenting to health professionals and is a major health problem globally.[1] The lifetime prevalence of LBP is reported to be as high as 84% worldwide.[2] Around 23% of the population has chronic non-specific LBP.[3] The risk of developing chronic LBP has been associated with various individual, psychosocial (e.g. depression, fear of movement and pain catastrophising) and occupational factors; leading to high levels of

disability and imposing high costs to the individual and the community.[1,2,4-10]

To improve the effect and cost-effectiveness of interventions provided for people with LBP, the STarT Back screening tool was developed to stratify patients, according to the presence of modifiable physical and psychosocial prognostic variables, for targeted treatment.[11] The tool categorizes patients as being at low risk of developing persisting LBP, medium risk (which indicate the presence of physical and low level of psychosocial prognostic factors), or high risk (which indicate the presence of high levels of psychosocial prognostic factors, with or without the presence of physical factors). People categorised as having medium or high risk of chronicity are more disabled with their pain and more likely to have a poor outcome than those having low risk.[12] Since people at low risk have a good prognosis and highest probability of recovering spontaneously, a minimal intervention (i.e. education and self-management) is highly recommended.[13,14] According to the current clinical guidelines, none of the available treatments were found to be clearly favourable in treating people at risk of chronicity; however, most of these guidelines recommend treating people at risk with multimodal therapy.[15,16]

According to the fear avoidance model, people with chronic LBP presenting with higher levels of fear of movement are more likely to develop avoidance behavior, leading to greater disability.[17-19] A recent meta-analysis reported that people with chronic LBP who have high levels of disability are likely to present with lower levels of physical activity.[20] Promoting a physically active lifestyle by increasing the daily walking steps might therefore improve the psychosocial factors and reduce disability.

The health benefits of physical activity in improving overall health status and reducing risk factors for non-communicable diseases are well documented.[21] Additionally, encouraging people to participate in physical activity has benefits beyond health, including social and economic benefits.[22] Walking is one of the simplest and preferred types of physical activity as it is functional, safe, accessible, cost-effective and does not require any special equipment.[23] A published meta-analysis in 2016 of five RCTs found that walking as effective as exercise in reducing pain, disability and fear of movement, and improving quality of life at short-, intermediate-, and long-term follow-up in people with chronic LBP.[24] Yet, the study did not make a firm recommendation about the appropriate amount of walking due to the small number of included studies. Therefore, the authors recommended a need for further research investigating different types and dosages of walking in the management chronic LBP. Another recent meta-analysis included nine studies and found walking interventions to be as effective in reducing pain and disability as other interventions (e.g. education and physiotherapy) in patients with chronic LBP at both short- and intermediate-term follow up.[25] However, that review found the majority of the included studies failed to report intervention adherence which may have confounded the results. The authors therefore recommended further research to investigate the influence of adherence to walking interventions in improving the management of chronic LBP. They also recommended using objective self-monitoring devices to measure the total physical activity level and also to encourage people to increase their daily walking steps by providing immediate feedback on their progress.

Lack of compliance with the intervention is one of the challenges which may affect the success of walking programs. Poor compliance may be due to lack of individual motivation, goal setting, or inadequate program prescription. There is emerging evidence that physical activity interventions are more effective when they include technology that allows self-monitoring of target behavior.[26,27] Current wearable accelerometers such as the Fitbit devices have features that include monitoring daily physical activity, providing feedback and motivating messages, and setting up goals. The wearable Fitbit devices have been shown to be valid for measuring step counts and have also demonstrated potential to improve a person's adherence to a programme and motivation.[28-30] However, to the best of our knowledge no study has previously investigated the effect of the Fitbit device as a facilitator of a walking intervention in addition to usual care for the management of people with LBP.

Therefore, the objective of this study is to examine the efficacy of a Fitbit facilitated walking intervention, in addition to usual physiotherapy care, in 1) reducing disability, pain, and other LBP-related outcomes, and 2) increasing physical activity levels (i.e. daily walking steps), in people with LBP with medium or high risk of chronicity.

This trial will test the following hypothesis: people who have received Fitbit facilitated walking intervention in addition to usual physiotherapy care will have significantly better LBP-related outcomes and increased physical activity levels compared with those who have received usual physiotherapy care only.

METHODS

Design

The study design will be a randomised controlled trial. Participants will be randomised into two groups; Group 1/Experimental Group: usual physiotherapy care plus a Fitbit facilitated walking intervention, and Group 2/Control Group: usual physiotherapy care alone. The study flowchart is displayed in Figure 1. This protocol was developed to adhere with the guidelines of the standard protocol items: recommendations for

interventional trials (SPIRIT) and was reported to comply with the 25-item consolidated standards of reporting trials (CONSORT) statement on trial reporting.[31] This protocol has been registered at the Australian New Zealand clinical trials registry (registration number ACTRN12617001404314) and approved by the Human Research Ethics Committee from the University of Sydney (project number 2017/842).

Eligibility criteria for participants

Participants will be included in this study if they:

- are diagnosed with non-specific LBP by a physiotherapist;
- are aged 18 years or over;
- are categorized as being at medium or high risk of chronicity using the STarT Back Screening Tool;[11]
- are classified as insufficiently physically active (those who engage in less than 150 minutes/week of moderate intensity, or less than 75 minutes/week of vigorous intensity or an equivalent combination of the two intensities of physical activity) as determined by International Physical Activity Questionnaire (IPAQ);[32]
- have internet access;
- are ready and able to participate in physical activity as determined by The physical activity readiness questionnaire (PAR-Q).[33] Those deemed not fit to participate in physical activity by the PAR-Q or aged over 69 years, will need a clearance from their medical practitioner before engaging in the walking intervention.

Participants will be excluded if they have any:

- contraindications to physical exercise (cardiovascular diseases e.g. myocardial infarction, embolism, or uncontrolled diabetes; orthopaedic impairments; balance problems);
- serious spinal pathologies (e.g. fractures, tumours or inflammatory diseases such as ankylosing spondylitis);
- neurological compromise (e.g. spinal nerve compromise or cauda equina syndrome);
- pregnancy.

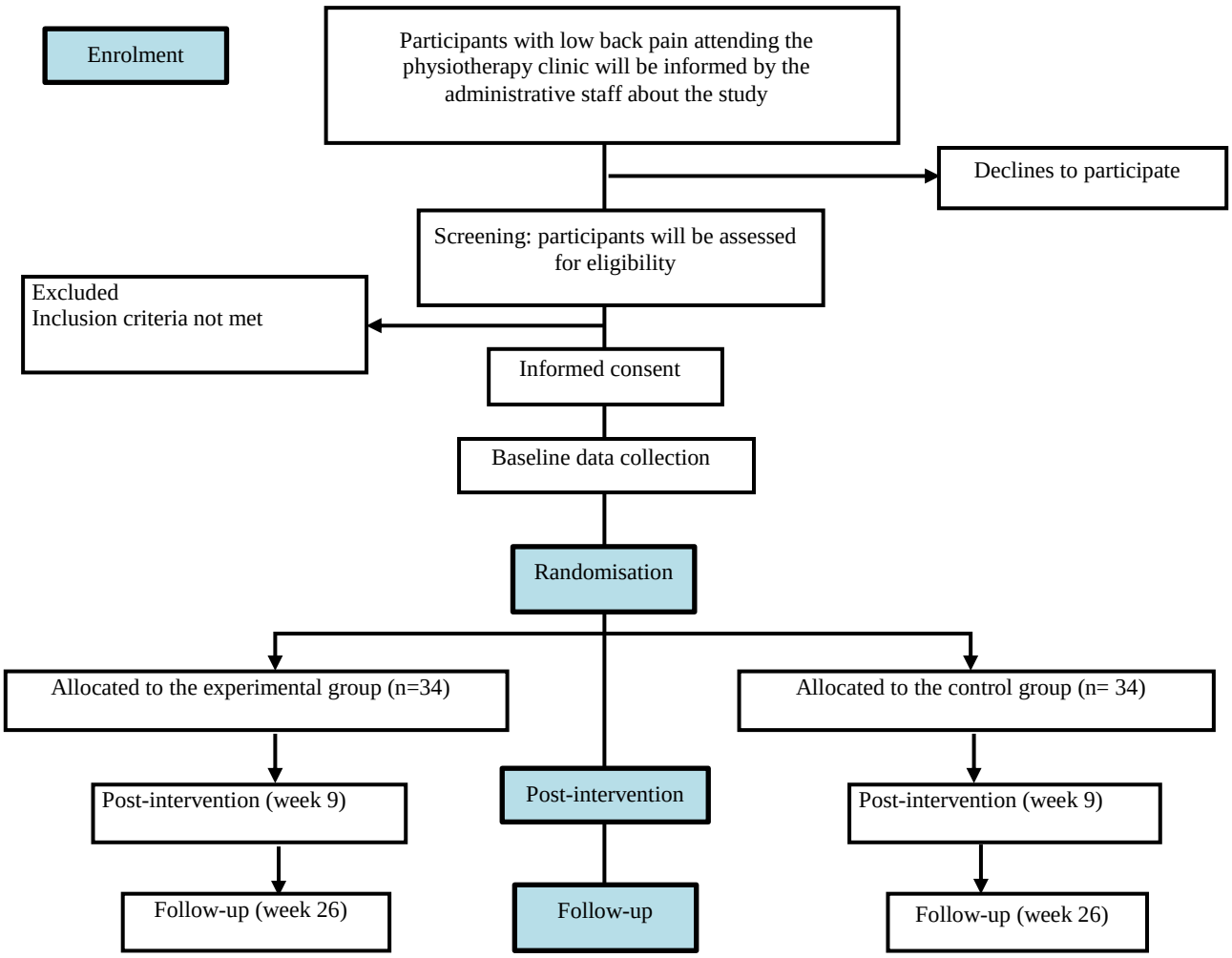

Figure 1: Flow of participants through the trial.

Table 1: Outcome measurement tools and time-points.

	Outcome	Measurement tool	Measurement points
Primary outcomes	Disability	Oswestry LBP Disability Questionnaire	Baseline, post-intervention, follow-up (week 26)
	Pain	Visual Analogue Scale	Baseline, post-intervention, follow-up (week 26)
Secondary outcomes	Habitual physical activity level + Habitual daily walking steps	Axivity AX3	Baseline, post-intervention, follow-up (week 26)
	Depression	Beck Depression Inventory II	Baseline, post-intervention, follow-up (week 26)
	Fear of movement	Tampa Scale for Kinesiophobia	Baseline, post-intervention, follow-up (week 26)
	Pain catastrophising	Pain Catastrophising Scale	Baseline, post-intervention, follow-up (week 26)

LBP=low back pain.

Sample size

The sample size was calculated using a similar method to that of a published study with a similar design which investigated the effects of high-intensity aerobic exercise on pain, disability, anxiety and depression in people with chronic LBP.[34] That study reported a mean post-intervention (12 weeks) disability score of 15.8 (SD=12.7) (measured by Oswestry LBP Disability Questionnaire) in the experimental group and 30.6 (SD=16.9) in the control group. The aim is to achieve 90% power to observe a significance level of 0.05 using a two-tailed t-test. To allow for a 20% drop-out, the sample size was estimated to be 68 participants (34 participants in each group). The sample size calculation was performed using Sealed Envelope calculator (Sealed Envelope, Trojan House, London, UK).[35]

Setting and recruitment

Participants will be recruited from the physiotherapy outpatient departments of public and private hospitals or private physiotherapy practices in Sydney, Australia. Participants referred to the clinic will be informed about the study by the administrative staff who will also seek the approval of potential participants to pass their contact details to the associate investigator. Recruitment flyers will also be left in the waiting room or will be passed out by the staff to interested participants visiting the clinics. The investigator will contact participants via email and/or phone and provide more details about the study, check for the eligibility criteria and administer the surveys. A meeting will be arranged with the participating physiotherapists to explain the study protocol and agree on the research procedures.

Enrolment

Interested people with LBP will be assessed for eligibility to participate in the study by the therapist and investigator. Eligible people will receive information about the study protocol and written informed consent will be obtained. Also, the investigator will explain the protocol verbally and answer the participants' questions before obtaining written informed consent. Participants who sign the informed consent will be included in this study.

Randomisation

After confirmation of eligibility and signed informed consent is obtained, baseline outcome measurements will be collected (Table 1). After that, participants will be randomly allocated to one of the two groups. The randomisation process will be performed using computer-generated random numbers. The allocation sequence will be concealed from the investigator screening participants for inclusion and contained in sequentially, numbered, opaque and sealed envelopes. Stratified block randomisation will be used to ensure fidelity and balance of the usual physiotherapy care given to participants in both groups at each participating clinic, and also to ensure equal sample sizes. Usual physiotherapy care will be provided to participants by their treating physiotherapists who will determine the treatment pragmatically based on clinical reasoning. Participants may receive different treatment modalities as their usual care depending on their physiotherapist and clinical presentation.

Interventions

Control group

Participants allocated to the control group will receive usual physiotherapy care provided by their treating physiotherapist. Also, they will be given instructions to maintain their usual physical activity level during the treatment period.

Experimental group

Participants in the experimental group will receive a Fitbit walking intervention provided by the investigators

in addition to usual physiotherapy care provided by their treating physiotherapist.

During the baseline period, participants will be requested to wear a physical activity monitor (Fitbit Flex wearable device) for seven continuous days, to measure the total number of habitual walking steps per week. The baseline average daily walking steps for participants will be calculated by dividing the total number of habitual walking steps per week by seven (total walking steps per week/7). During the intervention each participant's average daily walking steps will be progressed each week by a minimum of 10%. To comply with current physical activity guidelines, participants will be asked to walk the prescribed number of steps at a moderate intensity (i.e. brisk walking, 100 steps/min).[36-39] When using the rate of perceived exertion (RPE), moderate intensity can be considered between 12 and 14 or 'somewhat hard'.[40] Participants will be asked to partake in the prescribed walking program at least five days per week for 8 weeks.

Participants in the experimental group will attend a training session delivered by the investigator to: 1) install and set up the Fitbit wearable device and account, 2) register the participant in the 10,000 Steps website (www.10000steps.org.au) and synchronise the device with the Fitbit account, and 3) provide the participant with instructions of using the device and account including monitoring step counts as well as other features.[41] Additionally, participants will receive a handbook detailing all of the instructions provided from the training session.

"Fitbit Facilitated Walking Intervention" conceptual basis and development

The Fitbit facilitated walking intervention was developed for patients with LBP, using physical activity guidelines in order to assist them maintain their usual activities, and to improve their compliance with the prescribed therapeutic exercise.[42,43] The intervention consists of: 1) Fitbit wearable device, 2) 10,000 Steps website, and 3) progressive walking program.

The Fitbit device will enable participants to monitor their progress in meeting the target number of steps. Further, the Fitbit wearable device will act as a motivational feedback tool providing immediate information on activity levels. The 10,000 Steps website is a non-profit promotion web-based platform that was developed to increase the physical activity level of the general community and it can be connected and synchronised with the Fitbit account. We are using this website to encourage participants to use the Fitbit device, track and monitor the daily steps progress and share it with other participants. Also, it enables the investigator to monitor and track the participants' progress and keep in contact with them. The website has high levels of usability.[44]

Participant's adherence to intervention and motivation

The following steps will be taken to enhance participant's adherence and motivation:

- The participants' and investigator's accounts will be connected using the "Fitbit friends" feature, which allows for Fitbit users to share and compare stats with each other for motivation.
- The data will be synchronised periodically to the Fitbit account from the wearable Fitbit device. The Fitbit application uses a Bluetooth low energy technology to synchronise with the Fitbit wearable device. Every time the participant opens the application, the data will be synchronised if the wearable device is nearby. However, if the computer does not have a Bluetooth, the participants will be instructed to plug the wireless synchronisation dongle into the computer.
- The participants' data will be monitored by the investigator using the 10,000 Steps website.
- Participants can log in to the Fitbit account and the 10,000 steps website and track their progress, and contact the investigator via the 10,000 Steps website.
- The investigator will have the list of participants' names with their information so that he/she can track the patients' adherence and progress, and provide feedback (i.e. achieved daily walking steps) by email, text message or telephone call during the treatment period every week.
- Participants will receive daily motivational messages from the Fitbit wearable device.
- Adherence to the walking intervention will be measured using the Fitbit device by assessing the duration of walking, and number of steps attained, and so intensity of walking (walking steps/walking duration).

Measures

Sociodemographic data

At the initial assessment demographic information including age, gender, employment status, level of education, health condition, height, weight, smoking and LBP history (duration of current LBP, previous episodes of LBP, previous surgery for LBP and previous LBP treatments received) will be collected. Data on types of usual physiotherapy care provided by physiotherapist to participant will also be collected during the study.

STarT back screening tool

The STarT back screening tool has been designed to help clinicians categorise participants with LBP into low, medium or high risk according to their risk of chronicity, developing persistent disabling pain.[11] It is composed of 9 questions about distribution of pain, disability, fear, anxiety, pessimistic thoughts, depression and bother-someness in the last two weeks. Participants will be asked

to choose either agree (0 point) or disagree (1 point) for each question except Question 9 which uses Likert scale comprising 5 possible options (Not at all=0, slightly=0, moderately=0, very much=1 and extremely=1). The total score (1-9) and the psychosocial sub score (5-9) will be calculated. A Score ≤3 point (≤3/9) indicates low risk. Scores ≥4 points (≥4/9) but ≤3 points on the psychosocial sub score **(**≤3/5) indicates medium risk. Scores ≥4 points (≥4/9) but ≥4 points on the psychosocial sub score **(**≥4 /5) indicates high risk. Therefore participants with a score above 3 will be eligible to join the study. The STarT Back Screening Tool has been shown to be valid in identifying subgroups of participants with LBP.[11]

Fitbit flex wearable device

The physical activity level and average number of walking steps per day for participants in the experimental group will be measured by Fitbit flex wearable device.[45] The Fitbit flex is a wristband activity monitor that contains a tri-axial accelerometer. The data can be uploaded to the Fitbit website which will be synchronised with 10,000 Steps website. This device has been shown to be accurate and valid in measuring physical activity and quantifying steps.[28,29,46]

Walking intervention adherence

Participants' adherence to the walking intervention will be determined using the 10,000 Steps Website and Fitbit Flex device during the treatment period (8 weeks).

Primary outcomes

Disability

Disability will be measured by the modified Oswestry Disability Index (ODI).[47] The modified ODI is an important tool used by researchers and clinicians in measuring functional disability in participants with LBP. It is a self-administered questionnaire consisting of 10 sections designed to evaluate the activities of daily living. Each section contains six statements scored from 0 (minimum difficulty in performing activity) to 5 (maximum difficulty). The total score is presented as a relative values (participant score/total possible score x 100). The modified ODI is valid, reliable and responsive to change in disability in participants with LBP.[47,48]

Pain

The worst pain intensity in the past 24 hours will be measured by the Visual Analogue Scale (VAS).[49] The VAS is one of the most commonly used scales in measuring pain intensity, providing a numerical rating ranging from 0 (no pain) to 10 (worst pain). The VAS has been shown to be valid and reliable for assessing pain in participants with LBP.[50]

Secondary outcomes

Habitual physical activity level and walking steps

Habitual physical activity level (light, moderate and vigorous) and walking steps in both groups will be measured objectively by the Axivity AX3 (Newcastle upon Tyne, UK; product website: http://axivity.com/product/ax3) for seven continuous days. The Axivity AX3 is a tri-axial accelerometer that can be worn on the wrist, thigh, hip, lower back, or upper back. The device is waterproof, small, light and is ideal for collecting longitudinal movement data. This device has been shown to be accurate and valid in assessing physical activity and measuring walking steps.[51-55] Participants in this study will be informed to wear the Axivity AX3 on the wrist.

Depression

Depression will be measured by the Beck Depression Inventory (BDI).[56] It is one of the most commonly used psychological tests for assessing the symptoms of depression. The BDI is a 21-item self-administered questionnaire; each item contains 4 statements ranging from 0 to 3 based on severity of each item. A higher total score (29-63) indicates severe depression. This tool has a good internal consistency and good content validity.[57]

Pain catastrophising

Participants' thoughts and feelings about pain will be measured by the Pain Catastrophising Scale (PCS).[58] The PCS is a 13-item self-administered questionnaire, each item consists of a 5-point scale ranging from 0 (not at all) to 4 (all the time). The PCS has been shown to be reliable and valid.[59,60]

Fear of movement

Fear of movement will be measured by the Tampa Scale for Kinesiophobia (TSK).[61] This tool is widely used in clinical practice to assess the fear of movement resulting from feeling of vulnerability to re-injury in participants with pain. It is a 17-item self-administered questionnaire, with four-point rating scale (1=strongly disagree, 2=disagree, 3=agree and 4=strongly agree). The TSK has a good validity and reliability.[19,62]

The primary and secondary outcomes measurement tools and time-points are described in Table 1.

Study timeline

The duration of the intervention will be 8 weeks. The outcomes will be assessed at baseline (week 0), post-intervention (week 9) and post-randomisation follow-up (week 26). See Table 1 for more details about the measurement tools and assessment schedule.

Safety and adverse events

Walking programs are generally safe; however, it is possible that participants may experience some unforeseen problems such as muscle soreness, falls or other injuries.[63] Participants will be closely monitored to keep track of any unwanted effects or any problems. If there are any unwanted effects the program may be stopped and the reasons will be discussed with the treating physiotherapist and investigator. In case of a serious adverse event (e.g. acute myocardial infarctions), participants will be advised to seek immediate medical assistance.

Data collection

The subjective data (disability, pain, depression, fear of movement and pain catastrophising) will be collected online using Research Electronic Data Capture (REDCap).[64] REDCap is a web-based software tool used to capture data for clinical research, create databases and projects, and administer electronic questionnaires.

Data management

The information collected from participants will be coded to be non-identifiable to staff involved in the trial, and stored securely into a secure server. Only the principal investigator will have access to the code. The results of this project will be published and/or presented in a variety of forums. No information about individual participants will be reported in any publication and/or presentation.

Statistical analysis

Data will be analysed using Statistical Package for Social Sciences (SPSS) version 22. Sociodemographic variables, physical activity and clinical characteristics will be described by means, standard deviations and frequencies. Generalised linear models will be used to evaluate the effect of the treatment on the primary and secondary outcomes. The statistical analysis will follow the intention-to-treat principle in which all participants will be analysed in the groups to which they were randomised, regardless of whether they withdraw from their allocation.[65] However, if participants withdraw from their randomised group, attempts will be made to obtain permission to collect outcome data at the follow-up time points. The statistical analysis will be conducted by an investigator who will be blinded to the subject's intervention group.

A sensitivity analysis will be conducted by excluding individuals in the control group who increased their activity level to assess their influence on the overall effect.

DISCUSSION

We have presented the rationale and design of this trial. This trial will investigate the efficacy of a wearable physical activity monitoring-based intervention to increase walking in addition to usual care provided by a physiotherapist. We will be able to determine the effect of a progressive walking intervention in the management of LBP. Results from this study will inform clinical practice by providing evidence about the efficacy of this program in reducing disability and pain, increasing physical activity levels, and improving functional and psychological status in participants with LBP at medium or high risk of chronicity.

Exaggerated fear of movement and re-injury, painful experience, and catastrophic feelings and thoughts may lead to fear of pain, to avoidance of movement, and eventually to reduced daily activities and then increased dependence.[9,66-69] Furthermore, in the long term, avoidance behavior results in physical deconditioning (due to disuse), disability and psychological changes (e.g. depression).[70,71] A recent mete-analysis found that people with chronic LBP presenting with high levels of disability have low levels of physical activity.[20] Low levels of physical activity can further lead to chronicity and persisting disability.[72,73] Research has shown that people at risk of chronicity benefit from increasing physical activity. Engaging inactive people in a tolerable and graduated physical activity (e.g. progressive walking program) can suppress that negative feelings and thoughts and encourage them to participate in physical activity.[74] Promoting a physically active lifestyle by increasing the daily walking steps might therefore improve the physical and psychosocial factors, and speed up recovery.

Strengths of the current study include: 1) measuring the change in physical activity level and daily walking steps for participants objectively using the Axivity AX3 device; 2) prescribing a progressive walking program that is tailored to each participant which enhance self-efficacy in inactive people and encourage them to increase their activity level; and 3) measuring the participants' adherence to the intervention objectively using the Fitbit device.

This study has a few methodological limitations. Firstly, participants meet the inclusion criteria for the study if they are classified as inactive using the IPAQ as an initial screen for level of physical activity. As the IPAQ is a questionnaire it may be subject to recall bias.[75] However, once admitted to the study baseline physical activity will be measured with an accelerometer. Secondly, although participants in the control group are instructed to maintain their usual activity level during the study, they may undertake more physical activity than normal throughout the study which may confound the results. However, sensitivity analyses will be performed to

include only those who maintained their normal physical activity level if required.

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Conflict of interest: None declared
Ethical approval: The study was approved by the The University of Sydney Human Research Ethics Committee

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