Department of Health Professions
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Chief Investigator's / Supervisor's Name & Title: Professor Mark Hancock

Participant Information and Consent Form

Name of Project: WalkBack: Preventing Recurrence of Low Back Pain

You are invited to participate in a study comparing the effectiveness and cost-effectiveness of two different approaches to preventing future low back pain in people who have recently recovered from an episode of low back pain. One approach involves participants meeting with a physiotherapist either in person in a physiotherapy clinic, or via telehealth to receive an individualised walking and education program, aimed at preventing recurrences of low back pain. Telehealth refers to using technology to facilitate meetings between participants and clinicians without being physically present (i.e. video calling). The second approach involves managing your back as you feel is appropriate after recovering from your recent episode (usual care) but does not involve any study treatment. The purpose of this study is to investigate which of these two approaches is better and more cost-effective at preventing or delaying future recurrences of low back pain.

The study is being conducted by Professor Mark Hancock (ph.: (02) 9850-6622, email: mark.hancock@mq.edu.au) of the Department of Health Professions, Faculty of Medicine and Health Sciences.

If you decide to participate and meet all inclusion criteria for the study, you will be provided with an electronic link to complete an online baseline questionnaire. This will take approximately 15 minutes to complete and asks about demographic characteristics, general health, work status, history of back pain, and psychological factors. You can also choose to complete this questionnaire over the phone if that is your preference. You will then be randomly allocated (like the flip of a coin) to one of the two study groups (walking and education group, or usual care). You will have a 50% chance of being allocated to either study group. You will not be able to choose the treatment group you are allocated to. The study is conducted this way to ensure that the information obtained is reliable.

Participants allocated to the usual care group will not receive any trial intervention as part of their involvement in this study. Participants allocated to the walking and education group will be required to attend 3 face to face or telehealth sessions and 3 over the phone sessions over a 6-month period with a physiotherapist. You will be able to select from one of approximately 25 physiotherapy clinicians across greater Sydney and south-east Queensland to provide the intervention. The face to face/telehealth sessions will last approximately 40 minutes for the initial session and 20-30 minutes for the subsequent sessions. If you are allocated to the walking and education group, you will have the choice of accessing the sessions face-to-face in a clinic or via telehealth (this may be guided by the locations of available clinic, COVID-related restrictions or personal preference). The over the phone sessions will be approximately 15 minutes each. The physiotherapist will ask some questions about daily activities and previous back pain, do a simple assessment of your walking capacity and then provide a home walking program and education which aim to prevent future back pain.

All participants will be contacted each month by email and asked if they have had a recurrence of low back pain. Responding to this should take only 1 minute. The monthly follow-ups will continue either until you have a recurrence of back pain, or for between 12 months and 36 months depending on when you entered the study (the first participant enrolling in the study will be followed for up to 36 months while the last participant will be followed for 12 months). If you do not respond to monthly email or text messages within 48

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hours, you will be contacted by phone. At 3, 6, 9 and 12 months after entering the study you will be asked to complete a short questionnaire about any low back pain, other interventions or adverse events over the previous 3-months. This can either be done as an online survey or over the phone depending on your preference and will take approximately 15 minutes to complete.

All participants (whether allocated to the walking and education group, or usual care), will be asked to wear a physical activity monitor for 7 consecutive days, approximately 3 months into the project. These monitors will provide us with accurate information about your levels of physical activity over a one-week period. These monitors are small, light and worn around the waist. You will be provided instructions on how to care for these devices and are able to contact the research team if you are having any difficulties.

The known risks of this study are minimal. If you are allocated to the walking and education program then like all physical activity, there is a small risk of injury. Temporary soreness, muscle strain or the chance of a fall are potential risks that may arise. Before enrolling you in the study you will be screened over the phone by one of the researchers to make sure you are appropriate for the study. If there are any concerns, you will be asked to get permission from your GP before enrolling in the study. The physiotherapist will also tailor the treatment to your ability to minimise any risk.

You will not be paid to participate in the study; however, if you are allocated to the walking and education group, all sessions with the physiotherapist involved in this trial will be free of charge. The physiotherapist will be paid directly by the research team at standard rates.

Any information or personal details gathered in the course of the study are confidential, except as required by law. No individual will be identified in any publication of the results. The data collected in this study may be made available to other researchers, in a de-identified form, for future Human Research Ethics Committee approved research projects. A summary of the results of the data can be made available to you on request. If you would like to be provided with this summary, please email Prof Mark Hancock (email: mark.hancock@mq.edu.au).

Participation in this study is entirely voluntary: you are not obliged to participate and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence.

☐ Yes, I consent to participate in this study. I have read or had read to me and understand the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this research, knowing that I can withdraw from further participation in the research at any time without consequence.

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone (02) 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

(PARTICIPANT'S COPY)