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TOPS: Trial of Prevention Strategies for Low Back Pain
2015/728

PARTICIPANT INFORMATION STATEMENT

Invitation

You are invited to participate in a research study examining the effects of exercise and education in preventing recurrence of back pain. It is believed that guiding people to improve their physical activity levels may be effective in reducing the risk of future recurrences of back pain. At present there are no definitive studies that have tested whether a Back Care Booklet or an Exercise and Education Program are effective in preventing recurrence of back pain.

The study is being conducted by:

- Chris Maher, Professor, The George Institute for Global Health;
- Jane Latimer, Professor, The George Institute for Global Health;
- Rachelle Buchbinder, Professor, Monash University;
- Christine Lin, Associate Professor, The George Institute for Global Health;
- Mark Hancock, Associate Professor, Macquarie University; and
- Matthew Stevens, PhD Student, The George Institute for Global Health.

The study is part of an international collaborative study coordinated by Prof Chris Maher at The George Institute for Global Health

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose is to investigate whether a group-based exercise and education program or a back care booklet is more effective for preventing recurrence of back pain.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you have recently recovered (within 3 months) from an episode of low back pain.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. There are no consequences of withdrawal from the study. However, it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

Although extremely unlikely you may be removed from the study if your doctor or treatment provider deems it unsafe for you to continue.

4. 'What does this study involve?'

This study will be conducted over 4 years and potentially involve 1482 participants from across NSW.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form and complete a simple questionnaire to collect information about you (eg age, gender, work status) and your history of back pain (eg how many episodes you have suffered). You will then be randomly allocated (like the flip of a coin) to one of two treatment groups:

1. Exercise and education program
2. Back care booklet

You will have a 50% chance of receiving the exercise and education program and a 50% chance of receiving the back care booklet. 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 exercise and education group will be asked to attend a group-based exercise & education program for 12 weeks. Prior to joining the program participants will undergo an individual assessment by a physiotherapist. This information will be used to guide your participation in the classes. Classes will include physical retraining focusing on strength, movement and posture re-education and aerobic conditioning. Education will be integrated within each class and comprise information on back pain, efficient use of the back during daily activities (e.g. sitting, walking and bending) and self-management of back pain. Participants allocated to the back care booklet group will receive a booklet which includes advice on self-management and prevention of back pain.

Participants will be contacted each fortnight by email or text message (based on the participant's preference) and asked if they have had a recurrence of back pain. If a participant reports a recurrence they will be contacted by a research assistant and a detailed description of the episode will be obtained. The follow-ups will continue for a minimum of 12 months and until the study finishes. This means you may be followed-up from between 12 to 48 months depending upon when you are enrolled into the trial.

In addition we will measure (i) beliefs about back pain; and (ii) physical activity at the start of the study, at 6 months and 12 months. Beliefs about back pain will be measured using the one page Back Beliefs Questionnaire. Engagement in physical activity will be assessed with an Actigraph: a non-invasive, small, lightweight device (4.6 x 3.3 x 1.5cm, 19 grams) that is worn during waking hours for 7 consecutive days on the right hip. It records activity counts and steps taken, which are converted to time spent in sedentary, light, moderate, and vigorous intensity physical activity.

5. 'How is this study being paid for?'

We have secured funding for the study from WorkCover NSW. We are also seeking funding from the National Health and Medical Research Council and the Defence Health Foundation.

None of the researchers have any conflicts of interest that will impact upon the conduct of this study. Matthew Stevens' scholarship is partly funded by monies from the WorkCover NSW grant.

6. 'What are the alternatives to participating in this study?'

If you decide not to participate in this study, and you wish to learn more about prevention of recurrence of back pain, you may still receive the standard treatment available. It is important that you discuss the alternatives to participating in this study with your treatment provider

7. 'Are there risks to me in taking part in this study?'

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

Both the program and booklet encourage physical activity and some participants may experience some temporary muscle soreness following exercise. This is a normal response to unaccustomed exercise and should resolve quickly within a day or so. The booklet and program being trialled in this study are used by physiotherapists every day to help patients reduce their risk of future low back pain. Therefore the risks associated with this study are similar to those associated with receiving physiotherapy to prevent future low back pain. There may also be risks associated with this trial that are presently unknown or unforeseeable.

8. 'Will participating in this study affect my plans to start a family?'

This study should not affect any plans to start a family as physical activity is generally encouraged before and during pregnancy. However, If at any time you think you may be pregnant it is important to discuss this with your treatment provider.

9. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact your doctor or the study physiotherapist as soon as possible, who will assist you in arranging appropriate treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the study treatment, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

10. 'Will I benefit from the study?'

This study aims to further medical knowledge and may reduce recurrence of low back pain, however it may not directly benefit you.

11. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything, nor will you be paid. As a study participant, you will receive the intervention free of charge. If you are allocated to the exercise and education program you may

be asked to purchase some exercise equipment and if this occurs you will be reimbursed up to \$50 to pay for this equipment.

12. 'How will my confidentiality be protected?'

Only the named researchers, your treatment provider and their administrative staff need to know whether or not you are participating in this study. With your permission, we will also notify your regular doctor and/or your referring doctor/employer. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above your treatment provider and their administrative staff will have access to your details and results that will be held securely at the treatment providers and the research study office. Only non-identifiable information will be sent off site. This will only occur when necessary and the provisions of Australian privacy law will be complied with.

13. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss/publish the results in peer-reviewed journals and presentation at conferences or other professional forums. In any publication or presentation, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

14. 'What happens to my treatment when the study is finished?'

The treatment is for a defined period and aims to teach you to continue the program independently.

15. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on phone: 02 9657 0346 or email: TOPS@georgeinstitute.org.au

16. 'Who should I contact if I have concerns about the conduct of this study?'

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney 2015/728. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**