

PLAIN LANGUAGE STATEMENT

CENTRE FOR HEALTH, EXERCISE AND SPORTS MEDICINE
DEPARTMENT OF PHYSIOTHERAPY



Title: The PEAK Study: **Physiotherapy, Exercise and physical Activity for Knee osteoarthritis**

Responsible Researcher: Prof Rana Hinman

Co-investigators: Prof Kim Bennell, Prof Trevor Russell, Prof Nadine Foster, Dr Jessica Kasza, Prof Anthony Harris, Mr Alexander Kimp, Mrs Penny Campbell

Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

What is this research about?

People with knee osteoarthritis often consult a physiotherapist for management of their knee problems. Physiotherapy management typically involves the delivery of a structured strengthening exercise program, and advice about how to manage and increase physical activity levels. We wish to evaluate the effectiveness of how physiotherapy is delivered to people with knee osteoarthritis. Physiotherapy may be delivered in any number of ways, including:

- Face-to-face consultations
- Consultations in public/private hospital settings
- Consultations at private practices
- Consultations at rehabilitation centres
- Video consultations over the internet
- Group-based classes
- Telephone consultations
- Consultations in community health centres
- Home-based visits from a physiotherapist
- Shared consultations with other health professionals

This study is comparing two different methods of delivery of physiotherapy for people with knee osteoarthritis. We cannot disclose exactly which methods of delivery we are comparing, as it is important participant responses on questionnaires are not unduly influenced by their knowledge of what each study group is receiving. Research shows that if people know that they are allocated to a certain treatment under investigation, they tend to overestimate the benefits of that treatment. The best way to evaluate the effectiveness of the different delivery methods is to randomly allocate volunteers to the different treatment groups. That means, by participating in

the study you will have an equal chance of being in one of the two groups. You can't choose or change groups along the way, and you will be expected to follow the advice of the physiotherapist you speak to in whichever group you are allocated to.

Although we can't tell you about how the physiotherapy will be delivered in each group, we can tell you that both groups will receive quality care by a physiotherapist based on the best current research evidence. This will involve 5 consultations with a physiotherapist over a 3-month period, including an individualised strengthening exercise program and physical activity plan. Participants in both groups will receive detailed educational information about osteoarthritis and its management, resistance bands for exercising and a wearable activity tracker to help with increasing physical activity.

Why do we want to do this research?

Osteoarthritis of the knee is a common condition in adults. It often causes pain and reduces quality of life. We know that many Australians with knee osteoarthritis are unfortunately not receiving accurate information and guidance about physical activity and exercise and are having trouble managing their knee condition on their own.

Consulting a health professional, such as a physiotherapist, can be helpful in discussing more specific information about osteoarthritis and for obtaining personalised guidance and support around a knee exercise strengthening program and physical activity plan. Physiotherapy is currently delivered in many different settings and via many different methods.. We will examine the clinical effectiveness and cost-effectiveness of physiotherapy under different delivery methods.

This study will help us better understand how different methods of physiotherapy delivery affect people, by using questionnaires to monitor their knee pain and their ability to carry out functional activities. Findings from this study will inform physiotherapists and health service providers about the most effective methods of delivering physiotherapy services to people with knee osteoarthritis.

Who can participate?

You can participate in the study if you are aged over 45 years; have had knee pain for 3 months or more; have had pain in your knee on most days for the past month; have difficulty with walking or climbing stairs; have access to the internet; willing and able to travel to physiotherapy locations in an area most convenient to you (if required) and can commit to participating in the study for 9 months.

There are several reasons that this study may not be suitable for you. These will be covered during screening and include:

- have already had a knee joint replacement on your painful knee
- on a waiting list for knee surgery or have had knee surgery in the past 6 months
- have a diagnosis of rheumatoid arthritis or other inflammatory arthritis
- have participated in a strength training program for your leg muscles in the last 6 months

- have had physiotherapy treatment for your knee pain in the last 6 months
- any neurological condition affecting your legs
- are unable to read and write English

What will I be asked to do?

Step 1: Screening

By the time you read this information you may have already completed this step.

First, we will ask you to answer some questions online to check if you are suitable for the study. This should take around 5 minutes to complete. If you complete the online questions and are suitable for further screening, the trial coordinator will telephone you and discuss the study in more detail to confirm if you are eligible to participate. This phone call will take around 10-20 minutes. If you don't feel comfortable completing the initial screening questions online, you can instead telephone a researcher directly to complete the entire screening process over the phone. Depending on your health conditions, you may be asked to obtain medical clearance from your doctor before you can be involved.

Step 2: Baseline Assessment

If you are eligible and decide to take part, you will be asked to complete a consent form prior to completing a questionnaire about yourself, your pain, difficulties with daily tasks, physical activity levels, and quality of life. The purpose of this questionnaire is to record how your knee osteoarthritis affects you before you start the study. Answering the questions can take some time (up to 45 minutes to complete) and may seem repetitive but every question is there for a reason and all the information you give us is valuable. The questionnaire can be completed online or via post, depending on your preference.

Step 3: Physiotherapy consultations:

You will be asked to consult with a physiotherapist on 5 occasions over 3 months. The trial coordinator will arrange an appointment for your first consultation at a time that suits you during business hours on Monday-Friday and in accordance with the physiotherapist's availability. Subsequent consultations will be arranged between the physiotherapist and yourself at mutually convenient times. You will receive an individualised strengthening exercise program and physical activity plan to perform at home over 9 months. You will also receive, via the post, detailed educational information about osteoarthritis and its management, resistance bands for exercising and a wearable activity tracker to help with increasing your physical activity.

Before your first consultation, we will ask you to complete a brief pre-consultation questionnaire that will ask questions about your knee pain symptoms, previous treatments, activity levels and personal goals. The pre-consultation questionnaire will be forwarded to your treating physiotherapist prior to your first session. The physiotherapist will record brief notes about their consultations with you and this information will be used as part of the analysis in this study. The consultations will also be audio and/or video recorded by the research team for analysis. Your identity will not be revealed in the final report or any publication or presentation that arises from the study.

Step 4: Log Book:

You will be asked to complete a short travel log book throughout the first three months of the study. In the log book you will be asked to record details about travel to and from your physiotherapy sessions and modes of transport (if required), in addition to keeping a record of your physiotherapy session schedule. Your physiotherapist's details will also be listed in the log book. The log book will be provided to you with a stamped addressed envelope to return in the mail upon completion of the five physiotherapy sessions.

Step 5: Follow-up assessments:

3 months after you complete your physiotherapy consultations, you will be asked to complete a second questionnaire (45 mins). A shorter questionnaire will be completed at 6 months (15-20 mins) and a final longer questionnaire at the 9-month point (45 mins). The questionnaires can be completed and returned via email or post.

What are the possible risks?

Some of the questionnaires you will be asked to complete require you to consider your pain, how this pain affects your daily tasks, and other health problems you may have. It is possible that some people could find these questions difficult emotionally, although we have not found this to be a problem in other similar studies. If you feel uncomfortable about any of the questions, you can discuss this with one of the researchers (see contact details below). If we identify from your answers that you experience depression and have not been treated for it, the trial coordinator will contact you to recommend you seek guidance from your GP.

Whilst we expect that people following an appropriate exercise plan would experience improved pain levels and greater ability to do their daily tasks, there is a small risk that you may experience a transient flare up of pain in your knee or in other parts of your body due to changing your usual exercise and/or physical activity levels. To minimise this, you will be given clear information about how to gradually increase your exercises. If you experience any problems, you should discuss them with the physiotherapist during your consultations, who will help you to modify your exercise and physical activity program

What are the possible benefits of taking part?

This study aims to improve healthcare knowledge and may change future methods of delivering physiotherapy treatment for people with knee osteoarthritis. You may find that the exercise program helps with your pain and ability to do your daily activities, however, it may not directly benefit you. By participating in this study, you will be helping us understand the most effective methods of delivering physiotherapy care to people with knee osteoarthritis.

Do I have to take part?

Your participation in this study is completely voluntary. If you do not wish to take part, you are under no obligation to do so. Also, if you decide to take part but later change your mind, you are

free to withdraw from the study at any stage. You may also withdraw any unanalysed data previously supplied by you. Your decision about whether to participate or continue in the study will not affect your relationship with the researchers or the University of Melbourne. The researchers are not involved in any other aspect of your health care. Your decision to participate or not, or to withdraw, will be completely independent of your dealings with your usual doctor(s) and/or other health professional(s).

Will I hear about the results of this study?

Once all study participants have completed the study and we have analysed the data, we can send you a summary of the overall study results if you wish. Depending on when you enrol in the study, the results may not be available for some time after you finish your final questionnaires, as the study will take several years for all participants to complete.

What will happen to information about me?

We intend to protect the confidentiality of your responses fully, and comply with the law. Information that could identify you, such as your name and address, must be obtained to allow research staff to stay in touch with you over the course of the study. This information will be kept in a password-protected computer file separate from any data that you supply. Your identity will not be revealed in the final report or any publication or presentation that arises from the study. The study data will be kept securely in the Department of Physiotherapy at the University of Melbourne for 15 years, before being destroyed.

How is the research funded?

This study is being funded by a National Health and Medical Research Council (NHMRC) Project Grant (#1157977).

Where can I get further information?

If you would like more information about the project or have any concerns during the study, please do not hesitate to contact the trial coordinator, Penny Campbell, via phone on 03 9035 5702 or via email at penelope.campbell@unimelb.edu.au.

Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Office for Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.

About the researchers:

Professor Rana Hinman is an experienced Physiotherapist in the Centre for Health, Exercise and Sports Medicine in the Department of Physiotherapy at The University of Melbourne.

Professor Kim Bennell is an experienced Physiotherapist and Director of the Centre for Health, Exercise and Sports Medicine in the Department of Physiotherapy at The University of Melbourne.

Professor Trevor Russell is a Professor in the Division of Physiotherapy within the School of Health and Rehabilitation Sciences at the University of Queensland and co-directs the Centre for Research in Telerehabilitation at the University of Queensland.

Professor Nadine Foster is a National Institute of Health Research Professor of Musculoskeletal Health in Primary Care and Director of Keele Clinical Trials Unit at Keele University, UK.

Professor Anthony Harris is a Director of the Centre for Health Economics at Monash University.

Mr Alexander Kimp is a physiotherapist and research scientist, experienced in developing study protocols and study documents.

Mrs Penny Campbell is a research scientist, experienced in the co-ordination of physiotherapy trials for knee osteoarthritis.