Plain Language Statement - x-ray required

CENTRE FOR HEALTH, EXERCISE AND SPORTS MEDICINE
SCHOOL OF PHYSIOTHERAPY

THE UNIVERSITY OF MELBOURNE

Project: Optimising exercise outcomes for knee OA: The TARGET study.

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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?

Osteoarthritis of the knee is a common condition in adults. It affects the lining of the joints giving rise to pain and stiffness. Many patients experience progressive worsening of their symptoms as time goes by. It is known that exercise is beneficial in reducing pain and disability in people with knee osteoarthritis. However, research indicates that people who have higher body weights may respond differently and more favourable to certain types of knee exercise.
This project will specifically compare the effects of two different exercise programs for individuals with knee osteoarthritis who are overweight and evaluate if people respond differently to either of the exercise programs.

It will also investigate strategies aimed at helping people stick to a prescribed exercise programs in the long term, after contact with a physiotherapist has ceased.

This study will help develop treatment programs that better target the right type of exercise program to the right person and develop strategies to encourage people to adhere to their exercise program over time.

Who can participate?

We require people diagnosed with osteoarthritis on the inner aspect of their knee. You can participate in the study if you are aged over 50 years; have knee joint osteoarthritis (which has been diagnosed by X-ray); have had knee pain on most days for the past month, and are overweight.
You are not eligible if you have had knee joint surgery in the past six months; have had a knee or hip joint replacement or are on the waiting list for surgery; have participated in a regular exercise program in the past 6 months; have a history of severe hip or back trouble or unable to walk without a stick or frame.

What will I be asked to do?

Should you agree to participate you will be required to complete the study tasks below;

1) *Screening to participate.* Your eligibility to participate in the study will be assessed by;
   a) *Online and phone screening* – where you will be asked several questions about your knee pain, your past medical history and your availability. You may already have undergone screening by the time you read this.
   b) *Consent* – If online and phone screening indicates that you may be suitable to participate you will be sent a copy of this Plain Language Statement and a consent form (either by mail or email dependent on your preference). You will be required to read this information and complete the consent form if you wish to participate further in the research project.
   c) *X-ray screening* – Finally, you will be asked to attend a radiology centre for a knee x-ray to determine if you are eligible for the study. These centres are located at the Epworth Hospital, Richmond, Blackburn South Radiology and Brunswick Diagnostic Imaging. You may attend the centre that is most convenient to you. The x-ray will take around 15 minutes and involves a small amount of radiation. There is no cost to you for this x-ray. If the results of your x-ray identify that you have osteoarthritis on the inner surface of your knee you will then be invited to participate in the study

2) *Baseline assessment.* If you are deemed eligible for the study, you will undergo baseline testing in the department of Physiotherapy, which will take around 1 to 1.5 hours. You will be provided with car parking at no charge to yourself when you come for the tests. The measures taken at this test session will include:
   a) completion of questionnaires on a computer about your knee pain and disability, how you feel about your knee pain, your physical activity levels and your medications.
   b) two tests of your thigh and hip muscle strength. The maximal strength of your thigh muscle will be measured in sitting using a special machine which you are strapped into. You will be asked to push against an ankle pad as hard as you can a few times. Your hip muscles will also be measured in lying as you push into a device held by the examiner.
   c) assessment of your function. You will be asked to climb up and down 6 steps which will be timed with a stopwatch, you will be asked to stand up from a chair while you are timed and asked to walk 40m at a fast paced while timed. You will also be asked to perform an assessment of your balance.

   You must report to the investigator any undue pain or discomfort during any of the testing procedures.
   For the measurements at the University of Melbourne, you will be required to wear clothing you are able to exercise in. You may either bring your own or we can provide you with suitable shorts if required.

3) *Study treatment – 5 x Physiotherapy sessions and a home exercise program over 12 weeks.* After baseline assessment you will be allocated to receive one of the two exercise programs. There is a 50% chance of being allocated to either exercise program. Both exercise programs have been used in our previous research and are beneficial for reducing knee pain caused by osteoarthritis. Participants in both groups will then select a project physiotherapist of their choice from the list of trained study physiotherapists provided by the research team. You may choose to attend the location that is most convenient to you and you will have a range of appointment times to choose from. You will then attend your appointments with the physiotherapist where they will teach you the exercises for the program you have been allocated to and will monitor you and progress the exercises as you improve. You will be provided with exercise equipment to take home. **You will see the physiotherapist to check and progress your exercises 5 times during the first 12 weeks of the study. It is very important that you attend all of the sessions and that you**

undertake the exercises the physiotherapist prescribes you at home, 4 times a week during this period.

4) *Follow-up testing.*
   a) After the first 12 weeks of the study, you will be asked to again attend The University of Melbourne for follow-up assessment. You will complete the questionnaires and undergo all the tests which you completed at baseline, this will take approximately 1-1.5 hours in total.

5) You will then be required to perform the exercises at home for a further 6 months, 3 times per week. You will be given a training diary where your can record how often you do your exercises and monitor your symptoms during this time. You may also receive text messages to help encourage you to continue your exercise regularly and you may be asked and expected to reply to these text messages regarding your exercise progress.

6) Completion of the study. At 36 weeks, the completion of the study, you will be asked to complete your final study questions, they will be the same questions you were asked at baseline and 12 weeks. You will not be required to complete any physical testing. You can complete the questions on a computer at home or can post a hard copy back to the study co-ordinator at The University of Melbourne.

What costs are involved and what is being covered by the study?

The study will cover the costs of parking at the Department of Physiotherapy for your testing sessions, the 5 physiotherapy exercise sessions and the required exercise equipment. At the completion of the study, you will be permitted to keep the exercise equipment provided to you. The only costs you are required to cover are your transportation costs to the university for your two assessments, transportation costs to the physiotherapist and any costs associated with receiving or replying to possible text message reminders during the study.

What are the possible risks?

Participation in this trial involves exposure to a small amount of radiation (if you have not already had your own knee x-ray in the past 12 months). This arises from the knee X-ray. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The additional effective dose you will receive from entering this trial is approximately 0.04 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. Studies suggest any risk is minimal.

You may experience increased knee or hip pain while you are performing the strength measures in the laboratory or you may experience increased knee or hip pain the next day. You should notify the tester if this occurs. The investigators are all trained in first aid and the Department of Physiotherapy has emergency procedures in place. Therefore if any medical event arises during the testing, the investigators will be able to deal appropriately with it.

It is also possible that you may experience an increase in knee, hip or back pain with the exercises, especially at the beginning of the program. To minimise this, you will be given clear instructions by the physiotherapist to gradually increase your exercises. You should telephone the physiotherapist if your pain increases. There is also the slight possibility of falling and perhaps injuring yourself if you are prescribed balance exercises. You will be asked to perform these exercises near a wall or sturdy object.

Do I have to take part?

No. Participation 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 project at any stage. You may also withdraw any unprocessed data previously supplied by you. Your decision about whether or not to participate or to continue in the study will not affect your future medical care in any way.

Will I hear about the results of this project?

Once we have completed testing all participants and 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 several years after you finish your measurements as it is anticipated that the study will take approximately three years to complete.

What will happen to information about me?

Your details will be kept confidential. The anonymity of your participation is assured by our procedure, in which a code number and not your name will identify you. No findings that could identify you will be published and access to individual results is restricted to the investigators. Coded data will be stored for 15 years. All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The chief investigator is responsible for maintaining this confidentiality. This project is subject to the requirements of the Human Research Ethics Committee of the University of Melbourne. However, you must be aware that there are legal limitations to data confidentiality.

Where can I get further information?

You should ask for any information you want. If you would like more information about the study, or if there is any matter about it that concerns you, either now or in the future, do not hesitate to ask one of the researchers. Before deciding whether or not to take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this.

If you would like more information about the project, please contact the researchers;
Professor Kim Bennell 03 8344 4135, or Study co-ordinator Alex Kimp 03 8344 3109

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.