Footwear for self-managing knee osteoarthritis symptoms: the Footstep Trial

Centre for Health, Exercise and Sports Medicine
Physiotherapy, Melbourne School of Health Sciences

THE UNIVERSITY OF MELBOURNE

Plain Language Statement

We are pleased to invite you to participate in our research study into treatment for knee osteoarthritis. The purpose of this research is to compare the effects of different shoes on knee osteoarthritis symptoms.

This Plain Language Statement tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Plain Language Statement to keep.

What is the purpose of the study?

The purpose of this research is to compare the effects of different shoes on knee osteoarthritis symptoms.

Background information

Knee osteoarthritis is a major problem in Australia and there is no cure for the disease. Non-drug strategies that help people to self-manage the condition are needed. Different types of shoes influence forces acting across the knee joint. We know that increased knee forces can contribute to the knee pain associated with knee osteoarthritis, and that high forces can increase the risk of the disease worsening over time. It is recommended that clinicians provide advice on "appropriate" footwear for people with knee osteoarthritis. However, there is little evidence from clinical trials to determine which shoes are best for self-managing knee osteoarthritis.

We are conducting a research study to compare two classes of readily available off-the-shelf shoes on knee osteoarthritis symptoms. To do this, we will allocate people via a random process into two different groups. Participants in each group will be provided with 2 pairs of different shoes to wear daily for 6 months. To ensure that this is a fair and unbiased evaluation, we will not disclose the differences in the shoe classes between the two groups until the end of the study. There will be an equal number of participants in each group, and participants will not be able to choose which group they are in.

The findings of this study will help determine which shoes are best for people with knee osteoarthritis and will guide clinicians in providing appropriate evidence-based footwear advice for their patients. The findings of this study will be published in medical journals and be presented at conferences.

Why have I been invited to participate in this research?
You can participate in the study if you are aged over 50 years, have moderate to severe knee osteoarthritis on x-ray (in the inner knee compartment) and currently have knee pain on most days. You are not eligible if you have arthritis predominantly on the outside part of your knee, have had an injection into your knee in the past 3 months, have had knee surgery in the past 6 months or plan to have an injection or surgery within the next 6 months, you have a systemic arthritic condition, have had a knee joint replacement or high tibial osteotomy in the past, have other muscular, joint or neuromuscular condition that affects your walking, you currently use prescribed shoe insoles or a knee or ankle brace, you currently use a gait aid such as a walking stick, or have a significant muscular, joint or neurological condition in either leg.

If you are staff or a student of the University, your decision about whether or not to participate will not affect your relationship with the University or your grades in any way.

What does the participation in this research involve?
The study involves two screening steps to confirm your suitability: (1) initial screening over the internet and/or phone (which you may have already completed) and (2) x-ray screening. If you pass screening, you will be invited to take part in this 6 month study. If you decide to take part, you will be asked to sign the Consent Form (either on paper or online). You will then be allocated to receive one of two classes of footwear.

This type of study is known as a "randomised trial". To ensure the two groups in the study are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the researchers nor the study participant can decide which treatment the participant receives. As there are two shoe classes being compared in this study, you have equal possibility (a one in two chance) of receiving shoes from either class.

We are most interested in knowing the longer-term effects of the footwear on your knee pain and function so we would like to ask you to commit to the research until your 6 month follow-up measures are completed. It is very important from the research that information is collected at 6 months so that we can analyse your data as part of the project.

X-ray screening
If you have not had x-rays of your knee in the past 12 months, you will firstly be asked to attend a participating 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 you have a suitable x-ray of your knee taken within the past 12 months, the researchers will send you a stamped addressed envelope to send the x-rays in to the University for assessment. Once this has been done the researchers will send the x-rays back to you.

Laboratory assessment
We will call you when we have the x-ray results. If the x-ray shows you have moderate to severe knee osteoarthritis predominantly on the inside of your knee you will be eligible to take part in the study. If you are deemed suitable to take part, you will then attend the University of Melbourne, Department of Physiotherapy Human Movement Laboratory to undergo the baseline assessment, which will take approximately 75 minutes. It will involve completing a set of questionnaires which ask about your personal details, knee pain and function, your medications usage, previous knee treatments, physical activity levels and quality of life.

Foot assessment
One of the researchers will also perform some assessments of the posture and mobility of your feet while you stand barefoot in a normal stance.

Shoe assessment
The researchers will ask you to bring with you to the University appointment your 3 most commonly worn pairs of shoes. The shoes will be assessed for style and structural characteristics. You can take your shoes home with you afterwards.

Walking assessment
You will be asked to perform a walking assessment in your own shoes. The walking assessment will involve putting some thin insoles inside your shoes that have pressure sensors inside them, which are attached to a belt worn around the waist. You will be asked to perform 6 walks of an 8 metre walkway at your usual pace.

Group allocation
You will then be randomly allocated to receive shoes from one of two shoe classes using a computer program. You have a 50% chance of being allocated to either group. You will choose two pairs from a selection of 3 different styles of shoes (including shoes appropriate for recreational, casual or dress wear). You should choose a combination of shoes that you believe you will be able to wear for at least 6 hours per day for the following 6 months. It does not matter if you wear one pair more than the other. All shoes are readily available off-the-shelf shoes, rather than medical/orthotic shoes designed specifically for medical conditions.

To ensure that this is a fair and unbiased evaluation, we will not disclose the differences in the shoe classes between the two groups until the end of the study. We would prefer you to avoid starting any treatments for your knee pain if possible during the study. However you continue to take any regular medications you may

be using. If you do undergo new treatments or begin taking new medication, you will have the opportunity to report these to the researchers in the questionnaire at the 6 month mark.

Log Books

Over the 6 months, you will be asked to complete a short log book for one week each month. In the log book you will indicate how many hours you wore the study shoes for each day of that week. The log books will be provided with a stamped addressed envelope to return them in the mail.

Follow-up questionnaire

Six months after being given your study shoes, you will be sent a follow-up questionnaire to complete at home (either online or on paper where we will provide a stamped addressed envelope). These questionnaires will be the same as those completed at baseline about level of knee pain and symptoms, medications usage, physical activity levels, quality of life. You will also answer questions about any adverse effects you experienced, and answer questions about the study shoes such as about comfort and likeability.

Debriefing

Following the completion of the entire study, participants will be contacted by email or mail to inform them of the class of shoes they were provided, and information about the specific hypotheses the study was testing, as well as the main study findings.

Reimbursement for participation

After you complete the final questionnaire booklet at the 6 month time point, we will send you a $50 Coles Myer gift voucher to compensate you for your time and effort in wearing the shoes and completing our questionnaire and log-books. You can also keep the shoes that you were provided with as part of the trial.

Are there any costs for me?

The knee x-ray and shoes are provided at no cost to yourself, but all of your travel or other costs associated with attending the x-ray appointment and University are your own responsibility. We will provide you with free parking when you come in for testing at the University of Melbourne if you need it.

What are the possible benefits of taking part?

This study aims to further medical knowledge and may improve future management of knee osteoarthritis; however it may not directly benefit you. Your participation in this study will also help us to find out whether particular shoe styles are an effective management strategy for people with knee osteoarthritis.

Are there any potential side effects?

X-rays: Participation in this trial involves exposure to a small amount of radiation if you need to a knee x-ray as part of the screening process. 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.

How is this research funded and are there any disclosures?

This project is funded by the National Health and Medical Research Council (project number: 1124418) for $590,532. No shoe manufacturers or retailers are involved in the funding, design or interpretation of results of this study.

What if I have any concerns during the study?

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.

The Principal Investigators will be available throughout the study if you have any questions. This project has been approved by the Radiation Safety Program of the Victorian Government Department of Human Services.

Can I withdraw from the study if I wish?

Your participation in this study is 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 information 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 my details 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 limited 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.

How do I get more 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.

Will I be given the results of the study?
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.

About the researchers:

Prof Rana Hinman is a research physiotherapist who has conducted 20 randomised controlled trials in musculoskeletal conditions, most in knee osteoarthritis. She is the Chief Investigator of this trial.

Prof Kim Bennell is a research physiotherapist and Director of the Centre for Health, Exercise and Sports Medicine.

Dr Kade Paterson is a podiatrist and musculoskeletal researcher at the Department of Physiotherapy at the University of Melbourne.

Mr Tim Wrigley is a biomechanist and Director of the Centre for Health, Exercise and Sports Medicine gait laboratory.

Ms Penny Campbell is a Research Scientist, who will take on the role of Trial Co-ordinator. This will include participant recruitment, administration of questionnaires and scheduling of participant appointments.

Dr Jessica Kasza is a biostatistician from the Department of Epidemiology and Preventative Medicine at Monash University.

Prof Andrew Forbes is a biostatistician from the Department of Epidemiology and Preventative Medicine at Monash University.

Mr Ben Metcalf is a Research Scientist, who will help develop the study protocol and study documents. He will also collect laboratory baseline data, randomise participants to treatment group and fit allocated shoes.

To contact any of the researchers, please telephone (03) 9035 5702