School of Allied Health
College of Science, Health and Engineering
La Trobe University

PARTICIPANT INFORMATION STATEMENT: PART A

Efficacy of footwear for patellofemoral osteoarthritis (FOOTPATH)

Investigators:

Prof Kay Crossley	School of Allied Health, La Trobe University	k.crossley@latrobe.edu.au
Prof Hylton Menz	School of Allied Health, La Trobe University	h.menz@latrobe.edu.au
Dr Natalie Collins	School of Health and Rehabilitation Sciences, The University of Queensland	n.collins1@uq.edu.au
Prof Trevor Russell	School of Health and Rehabilitation Sciences, The University of Queensland	t.russell1@uq.edu.au
A/Prof Anne Smith	School of Physiotherapy and Exercise Science, Curtin University	anne.smith@curtin.edu.au
Prof Bill Vicenzino	School of Health and Rehabilitation Sciences, The University of Queensland	b.vicenzino@uq.edu.au
Prof Terry Haines	Department of Physiotherapy, Monash University	terrence.haines@monash.edu
Prof Rana Hinman	Department of Physiotherapy, The University of Melbourne	ranash@unimelb.edu.au
Dr Shannon Munteanu	School of Allied Health, La Trobe University	s.munteanu@latrobe.edu.au
Ms Jade Tan	School of Allied Health, La Trobe University	jade.tan@latrobe.edu.au

We invite you to participate in our research project "Efficacy of footwear for patellofemoral osteoarthritis (FOOTPATH)", collaboration between La Trobe University and The University of Queensland. We would like to give you some background information on why we think this project is important, and what we would like you to do if you decide to participate.

What is this project about and why is it important?

Kneecap arthritis is a leading cause of knee-related pain, disability and health expenditure in the Australian community, and has no cure. Compared to general knee arthritis in elderly people, kneecap arthritis can also affect middle-aged adults, impacting on productivity and contribution to society, and resulting in more years of knee pain and disability across the lifespan. At this time, we know very little about effective treatments for kneecap arthritis. This project is investigating whether simple footwear interventions are an effective treatment for kneecap arthritis. The aims of this project are to: (i) determine whether footwear interventions can reduce pain and improve outcome in people with kneecap arthritis over 1 year; and (ii) evaluate whether specific footwear interventions are a cost-effective treatment for kneecap arthritis. This knowledge may provide evidence for a simple, effective, non-invasive treatment for kneecap arthritis.

What does the research involve?

If you are potentially eligible for the trial, you will be screened via telephone, and attend La Trobe University for a knee examination. If you are included in the trial, you will undergo baseline assessment at the same venue as your knee examination. For the first 3 months of the trial, we will monitor your knee condition using questionnaires. You will then be provided with a footwear intervention to take home and wear for 1 year, and be asked to complete a series of questionnaires online or via mail.

All assessments and footwear interventions will be provided at no cost to you.

At baseline, you will be asked to complete:

- Questionnaires, including:
    - Age, gender, occupational and sporting history, mechanism of injury, symptom duration, rehabilitation, medication use, and family history of arthritis
    - Your expectations and values regarding your condition and its management
    - Physical activity (type, frequency and dosage)
    - Knee-related pain, symptoms, function and quality of life
    - General health and self-efficacy
- Physical testing, including:
    - Height, weight and waist circumference
    - Movement and palpation of your knee
    - Foot and ankle mobility measures
    - Knee strength: The maximal strength of your leg muscles will be measured using a special device. The examiner will ask you to push against it, as hard as you can, in one direction.
    - Functional performance tests, including walking and hopping
    - Measures of pressure pain onset: The examiner will apply a pressure stimulus with a probe to 4 points around your knee, and one point at your elbow. As the pressure increases, you will be asked to press a button to indicate the precise moment that the pressure sensation changes to one of pressure and the first onset of pain. At this point the pressure will cease. Three measures will be taken at each site, and repeated on both knees and elbows.
- X-rays of your knee:
    - You will undergo the x-rays at a private radiology clinic that is convenient to your home or workplace. This will take approximately 30 minutes.

You will be invited to attend the La Trobe University Health Sciences Clinic, at the Bundoora Campus of La Trobe University, to undergo the baseline assessment. This will take approximately 2 hours of your time. You will first complete a series of questionnaires about your knee pain, as outlined above. You will then undergo the physical tests described above, including measures of foot and ankle motion, knee strength, and functional performance. For the physical tests, you will be asked to change into shorts. You may either bring your own shorts or we can provide some for you.

Your knee condition will then be monitored for 3 months, during which time you will receive no intervention. This is a novel and important part of this study, to learn more about the natural course of kneecap arthritis. At the conclusion of the 3-month observation period, you will be asked to repeat the same questionnaires that you completed at baseline.

You will then be contacted by a member of the study team, regarding your footwear intervention. At this time, they will explain in more detail what is involved, and will ask you to provide consent. You will then be given a footwear intervention to take home and wear for a period of 1 year. This may involve a sandal, or a special insole to wear in your own shoes. These be fitted by an experienced Podiatrist or Physiotherapist, and may require you to attend up to six appointments at a clinic that is convenient to your home or workplace. We will give you instructions on how to break the footwear intervention in safely. You will be encouraged to use the footwear intervention as much as possible (e.g. around 8 hours per day), whenever you are moving around (e.g. daily tasks such as cleaning, or exercise such as walking).

During this time, you may be provided with a diary where you can record your physical activity, how often you wear the footwear intervention, what other type of footwear you have used, whether you have experienced any adverse effects from wearing the footwear intervention, and whether you have had any other medical issues. At regular intervals during the 1-year intervention period, you will be asked to complete the questionnaires outlined above (via email or postal mail), as well as how your knee condition has changed overall since commencing the trial. This will take approximately 20-30 minutes to complete each time. You may ask for a copy of your assessment results. At the conclusion of the trial, you are free to keep the footwear intervention that you received. We will continue to monitor your knee symptoms, using the same questionnaires, at yearly intervals for 5 years.

We may also ask your consent to obtain data about your health care from Medicare and Pharmaceutical Benefits Scheme (PBS) databases. This data is important for us to determine which footwear intervention is most cost-effective. This type of analysis is commonly conducted alongside intervention studies such as this. We will provide you with a separate information sheet specifically outlining details of this process.

During the study, you may be eligible for reimbursement of a proportion of your travel costs.

Use of pain-relieving medications and other forms of treatment during the trial period
During the 1-year trial period, we recommend that you use paracetamol (e.g. Panadol®), up to 4 grams/day, as a pain-relieving medication if it is necessary. You must attempt to not use any other treatment for your knee pain during the study period. However, if you do not obtain sufficient pain relief with this approach, you are free to use other treatments or take other medication as you require. It is possible that limiting the amount of (or altering) pain medication or treatment may cause an increase in your knee pain.

Why were you chosen for this research?
You can participate in this project if you are 50 years of age or older, and have experienced symptoms indicative of kneecap arthritis for at least 3 months. This may include a gradual onset of knee pain that is aggravated by activities that load the knee (e.g. stair climbing, squatting, prolonged sitting).

You are not eligible to participate in this project if you: (i) are not fluent in written and spoken English; or (ii) have another significant knee, hip or lower back condition; or (iii) have had recent treatment for your knee pain (e.g. knee injections or shoe inserts within the previous 3 months); or (iv) have recently commenced physiotherapy treatment for your knee pain; or (v) have any foot condition precluding the use of footwear interventions; or (vi) have had any major surgery to your knee or hip (e.g. total joint replacement or osteotomy) or are planning to have surgery to your knee or hip; or (vii) have any neurological or systemic arthritis conditions; or (viii) are not suitable to have an x-ray of your knee (e.g. pregnancy, breastfeeding).

Consenting to participate in the project and withdrawing from the research
Before you can participate in the project, you will be asked to read this participant information statement and sign a consent form indicating you have understood what the project is about and that you agree to participate. You have a right to withdraw from further participation at any stage without disadvantages, penalties or adverse consequences. You may also request to have your data withdrawn from the project by contacting the investigators, or by sending a withdrawal form within 4 weeks of completing the project. This will not impact upon any relationships with La Trobe University and/or affiliated clinics or sporting clubs.

You will also be asked to indicate if you agree to your data being used for future studies. Your data would identify you only by a code (and not your name), but your data would be potentially identifiable (i.e. we could break the code to access your name and personal details in case we needed them. An example of when this might arise would be if we needed to contact you at any stage).

What are the possible risks of participating in this project?
X-ray: You will be asked to have an x-ray of your knee. This involves exposure to a very small amount of radiation from x-ray imaging. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from the x-rays of your knee is less than 0.015 mSv. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The risk is believed to be very low.

It is important to be aware that with any imaging investigation, there is a small chance of a previously unknown medical condition being detected. In the unlikely event that this occurs, we will contact you directly and inform you of the findings. Should you require further medical review, we will also organise a referral to your chosen GP. It must be emphasized that the purpose of this study is to investigate your knee pain and not to identify other

potential medical conditions. While we will ensure that you are made aware of any incidental findings reported on by the consulting radiologist, neither the investigators, the radiologist, nor the Universities involved, will be held accountable if a medical condition exists that is not detected during the process.

Physical testing: The physical tests are routinely performed by Physiotherapists and Podiatrists, and are not associated with any risks. You may experience a small amount of discomfort in your joints or muscles during the physical examination or testing procedures. Please report to the researcher any undue discomfort or pain experienced during the testing. If the pain or discomfort is deemed to be excessive by yourself or the investigators, testing will cease.

If required, emergency procedures will be used to deal with any medical event that arises during the testing. The La Trobe University Health Sciences Clinic and on-call security have documented procedures for emergencies. This includes annual St John's ambulance CPR training and appropriate management of fire for all staff.

Footwear intervention: You may feel some discomfort in your feet or knees when starting to use the footwear intervention. Occasionally, footwear interventions can cause some skin irritation, pressure points under the feet, or an increase in knee pain. If you experience any continued pain or discomfort in your knee or leg muscles, please contact the researchers. These problems are usually quickly and easily resolved with modifications to the footwear intervention and/or wearing time.

What are the possible benefits of participating in this project?
Although you may experience some improvements in your knee pain after wearing the footwear intervention, there may be no direct benefits in completing this project. However, your participation will provide evidence for a simple, effective, non-invasive treatment for kneecap arthritis, and inform researchers and clinicians regarding optimal design of footwear interventions for kneecap arthritis.

What will happen to the results?
The results of this project may appear in journal publications and in conference presentations, but you will not be able to be identified in any of these reports. Data may also be used by members of this research team in future projects to compare with results from similar studies that have used the same testing procedures.

Results from the project will be confidential and only accessible by the researchers named above. No one other than the investigators will have access to the data. No findings that could identify you will be published and access to individual results is restricted to the investigators. All data and results will be handled in a strictly confidential manner, under guidelines set out by the *National Health and Medical Research Council*. Data will be kept in a password protected computer located at La Trobe University Health Sciences 3 building, gait laboratory. Hard copies of questionnaires will be kept in a locked filing cabinet in the office of Prof Kay Crossley (room 521; 5th Floor, Health Sciences 3) at La Trobe University.

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Data will be stored for at least 5 years after completion of the project in the Health Sciences storage vault, Building 3, level 1.

At the conclusion of the project, results of the project and your personal data will be made available to you upon request. This may entail mailing your results to your home residence, or if you prefer, a discussion with one of the investigators in person. Please direct requests for this information to Prof Kay Crossley (Phone: 03 9479 3902; Email: k.crossley@latrobe.edu.au).

Funding

Funding for this project has been kindly provided by the *National Health and Medical Research Council of Australia (NHMRC)*.

Who can I contact if I have any questions?

Questions concerning the procedure and/or rationale used in this investigation are welcome at any time. Please ask for clarification of any point, which you feel is not explained to your satisfaction. Your initial contact is the person conducting the experiment (Professor Kay Crossley, 03 9479 3902 or k.crossley@latrobe.edu.au).

Complaints

If you have any complaints or concerns about your participation in the project that the researcher has not been able to answer to your satisfaction, you may contact the Senior Human Ethics Officer, Ethics and Integrity, Research Office, La Trobe University, Victoria, 3086 (Phone: 03 9479 1443, Email: humanethics@latrobe.edu.au). Please quote the project reference number S15/286.

Thank you,

Prof Kay Crossley, Prof Hylton Menz, Dr Natalie Collins, Dr Shannon Munteanu,

Ms Jade Tan

(on behalf of the research team)