The FOOTPATH Study

(FOOT inserts for PAtellofemoral osteoarTHritis):

A randomised controlled trial

Participant Handbook
Please bring this manual to every appointment

1 Disciplines of Podiatry and Physiotherapy
La Trobe Sport and Exercise Medicine Research Centre (LASEM)
2 School of Health and Rehabilitation Sciences at The University of Queensland
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1. PROJECT OUTLINE

**SCREENING & OBSERVATION**

- Screening
- Consent
- Observation (3 months)
- 3-month follow-up

*If suitable for RCT (pVAS ≥ 3/10):*

- Participant makes appointment with study practitioner
- Practice reception staff notify Jade (phone/email)
- Jade randomises participant to foot orthoses or flat inserts
- Jade sends intervention supplies to practitioner (post/courier)

**INTERVENTION**

- WEEK 1: 1 x appointments with practitioner
- WEEK 2: 1 x appointment with practitioner
- WEEK 3-4: appointment with practitioner (as needed)
- WEEK 6: 1 appointment with practitioner (as needed)

**FOLLOW-UP**

- Phone call (6 weeks)
- Questionnaires (3 months)
- Phone call (6 months)
- Phone call (9 months)
- Questionnaires (12 months)

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Appointment with practitioner (if applicable)

Appointment with practitioner (as needed)
2. GENERAL INFORMATION

Patellofemoral joint osteoarthritis (PFJ OA) is associated with considerable pain and disability. The study will look at how shoe inserts can assist pain levels and improve function in people with PFJ OA.

**Osteoarthritis**

Knee osteoarthritis (OA) is a consequence of ageing for many Australians, and often affects both knees. OA is a leading cause of pain and disability in our community. OA is a chronic local joint disease where the cartilage lining the joint breaks down and leads to other changes in bone and soft tissue. Cartilage that covers the end of each bone acts as a cushion or shock absorber between the thigh and leg bones in the knee joint. When the cartilage breaks down, the bones grind together and thicken, causing pain, stiffness, muscle weakness and difficulty with everyday tasks such as walking, climbing stairs, and getting up and down from chairs.

These symptoms can limit participation in daily activities, regular exercise and social engagement, which has implications for general health, mental health, and quality of life. The knee joint contributes substantially to the burden of arthritic disease in the community, costing an estimated $11.2 billion per annum in Australia.

OA is not life threatening but can cause considerable pain and disability. Management strategies for knee OA have traditionally focused on alleviating symptoms, primarily with drug therapies or surgery.
Although effective, drug therapies are expensive, have side effects, and demonstrate limited long-term efficacy. Although knee OA clinical guidelines recommend that non-invasive treatments should be the first-line strategy for optimal management of OA, there is very little evidence to support this. Therefore, the aim of the FOOTPATH Study is to determine if the use of simple shoe inserts can decrease pain and improve function in people with PFJ OA.
### 3. MEET THE FOOTPATH STUDY TEAM

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<tr>
<th>Name</th>
<th>Position and Affiliations</th>
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<tr>
<td><strong>Professor Kay Crossley</strong></td>
<td>Physiotherapist, director of the La Trobe University Sport and Exercise Medicine Research Centre (LASEM)</td>
<td><a href="http://www.latrobe.edu.au/school-allied-health/about/our-staff/profile?uname=KCrossley">http://www.latrobe.edu.au/school-allied-health/about/our-staff/profile?uname=KCrossley</a></td>
</tr>
<tr>
<td><strong>Professor Hylton Menz</strong></td>
<td>Podiatrist, Senior NHMRC Research Fellow at La Trobe University Sport and Exercise Medicine Research Centre (LASEM)</td>
<td><a href="http://www.latrobe.edu.au/she/staff/profile?uname=hmenz">http://www.latrobe.edu.au/she/staff/profile?uname=hmenz</a></td>
</tr>
<tr>
<td><strong>Dr Natalie Collins</strong></td>
<td>Physiotherapist, Post-Doctoral Research Fellow in the School of Health and Rehabilitation Sciences at The University of Queensland</td>
<td><a href="http://researchers.uq.edu.au/researcher/12040">http://researchers.uq.edu.au/researcher/12040</a></td>
</tr>
<tr>
<td><strong>Professor Trevor Russell</strong></td>
<td>Physiotherapist and Professor in the School of Health and Rehabilitation Sciences at The University of Queensland</td>
<td><a href="http://researchers.uq.edu.au/researcher/891">http://researchers.uq.edu.au/researcher/891</a></td>
</tr>
<tr>
<td><strong>Associate Professor Anne Smith</strong></td>
<td>Physiotherapist, Research Fellow and Senior Lecturer in the School of Physiotherapy at Curtin University</td>
<td><a href="http://oasisapps.curtin.edu.au/staff/profile/view/Anne.Smith">http://oasisapps.curtin.edu.au/staff/profile/view/Anne.Smith</a></td>
</tr>
<tr>
<td><strong>Professor Bill Vicenzino</strong></td>
<td>Physiotherapist and Professor in the School of Health and Rehabilitation Sciences at The University of Queensland</td>
<td><a href="http://researchers.uq.edu.au/researcher/53">http://researchers.uq.edu.au/researcher/53</a></td>
</tr>
<tr>
<td><strong>Professor Terry Haines</strong></td>
<td>Physiotherapist, Professor in the Division of Physiotherapy at Monash University</td>
<td><a href="http://www.med.monash.edu.au/physio/staff/thaines.html">http://www.med.monash.edu.au/physio/staff/thaines.html</a></td>
</tr>
<tr>
<td><strong>Professor Rana Hinman</strong></td>
<td>Physiotherapist, Professor in the Department of Physiotherapy and Centre for Health, Exercise and Sports Medicine at The University of Melbourne</td>
<td><a href="http://findanexpert.unimelb.edu.au/display/person5913#tab-overview">http://findanexpert.unimelb.edu.au/display/person5913#tab-overview</a></td>
</tr>
<tr>
<td><strong>Dr Shannon Munteanu</strong></td>
<td>Podiatrist and head of the Discipline of Podiatry at La Trobe University</td>
<td><a href="http://www.latrobe.edu.au/she/staff/profile?uname=se2munteanu">http://www.latrobe.edu.au/she/staff/profile?uname=se2munteanu</a></td>
</tr>
<tr>
<td><strong>Jade Tan</strong></td>
<td>Podiatrist, PhD candidate in the La Trobe University Sport and Exercise Medicine Research Centre (LASEM)</td>
<td><a href="http://www.latrobe.edu.au/she/staff/profile?uname=j5tan">http://www.latrobe.edu.au/she/staff/profile?uname=j5tan</a></td>
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**Project Podiatrists and Physiotherapists**

26 project podiatrists and physiotherapists have been selected to participate in this project. Their selection is based on their clinical experience and demographic location of their practice. This also makes it easier for you to attend your appointments for fitting of your shoe inserts!
4. PROJECT METHODS

160 people with kneecap arthritis (PFJ OA) will be recruited for this project. Prospective candidates are screened by project examiners in Victoria (Jade) and Queensland (Anthony, Gearoid). Volunteers will attend La Trobe University or The University of Queensland for baseline assessments, and will be assigned to a Project Podiatrist or Physiotherapist for treatment. Jade will reassess participants over the phone at 6 weeks, 6 and 9 months, and be responsible for sending you your questionnaires to complete at the 3 month, 6 month, 9 month and the 1-year mark. All participants will receive a copy of their x-rays and report, in addition to a summary of the study findings once published in a peer reviewed journal.

**Concurrent treatments**
You will be requested (where possible) to refrain from seeking other forms of treatment (other physical modalities, natural therapies etc.) during the project. If you are currently taking medication related to your knee pain, you must record this information in the questionnaires that you will receive.

**Bilateral symptoms**
If you have pain in both knees, your the most symptomatic knee will be the focus of this FOOTPATH study. Where both knees are equally symptomatic, then the right knee will be the nominated knee. However, the treatments that we are evaluating will be worn in both shoes, and so you may experience effects in both knees.

**Restriction of activity**
You should never exercise with or through pain or swelling. If in doubt, contact your project podiatrist or physiotherapist.
Your knee is formed by three bones. The thigh bone (femur) and shin bone (tibia) form a hinge joint. The kneecap (patella) sits over the thigh bone in a special groove that helps to hold it in place. Because of the shape of the groove, and the fact that it is quite shallow, the kneecap has a tendency to shift towards the outside of the knee during bending. The ligaments and muscles around the knee have an important role in controlling this outwards shift and keeping the kneecap within the groove.
The position and movement of your kneecap is influenced by the alignment of your thigh and shin bones. Interestingly, their alignment is very much dependent on the shape and movements of your foot. This is particularly so when you are doing weight bearing activities such as walking, running and hopping.

As the foot flattens when weight is taken onto it, the thigh and shin bones turn in towards the opposite leg. Normally, the kneecap remains within the groove while the thigh and shin bones turn.

In people with pain at the front of their knee, the foot tends to flatten more than normal. Often, this happens when doing more vigorous activities such as jogging, hopping and squatting.
This means that the thigh and shin bones turn inwards more.

The kneecap tends to remain behind, gliding slightly out of the groove towards the outside of the knee.

The change in position is not usually visible, but is significant enough to change the contact surfaces on the back of the kneecap, which results in pain at the front of the knee when load goes through the kneecap.

The magnitude of this pain increases as the knee bends further and more load is put through the kneecap.

For example:
- half of your body weight goes through your knee cap when you walk
- 3-4 times your body weight goes through your knee cap when you go up and down stairs
- 7-8 times your body weight goes through your knee cap when you squat.

It is no wonder then that stairs and squatting are often the most difficult activities for people with this type of knee pain.

Early information from researchers suggests that shoe inserts can assist foot movement and help to assist with absorbing shock to the knee, thereby reducing knee pain. Of course, shoe inserts are only effective while they are being worn in the shoes.
6. HOW TO GAIN MAXIMUM BENEFIT FROM YOUR SHOE INSERTS

As a participant in the FOOTPATH Study, you will be provided with shoe inserts to wear in your everyday shoes and your sports shoes. The shoe inserts will be fitted by your podiatrist or physiotherapist using a special procedure.

The most important thing about your shoe insert treatment is your diligence with wearing them. Remember that:

- The shoe insert will **only** have an effect on your knee pain while you are wearing them.
- To gain relief from your knee pain, you need to wear the shoe insert as much as possible throughout the day.
- This includes when you are at work, at home, going out, and when exercising.
When the shoe inserts are in your shoes, you may notice a little pressure under the sole of your foot. It is essential, though, that the pressure is comfortable. If the shoe inserts are not comfortable, they will not have their desired effect. Your podiatrist of physiotherapist is aware of the importance of comfort, and will modify the shoe insert using various techniques until they are comfortable.

Initially, the shoe insert may feel unfamiliar in your shoes. This is because your body is adjusting to the new position and movement of your foot and leg. This sensation should disappear after a short time as your body adapts. If it lasts longer than two weeks, please let your podiatrist or physiotherapist know.

Because you will have measures taken at 6 weeks, 3 months, 6 months, 9 months and 12 months, it is important that you keep wearing the shoe insert for the entire 1-year period. This will give you the maximum benefit from the treatment, and ensure that all measures taken are accurate.

If at any time you have any problems with the shoe inserts, please contact your podiatrist or physiotherapist as soon as possible.
7. WEARING YOUR SHOE INSERTS: A SUMMARY

You should:

- Have all shoes that you commonly wear fitted with the shoe inserts
- Wear shoes with shoe inserts for the entire day
- Avoid going barefoot
- Wear the shoe insert continuously for the entire 12 months
- Tell your podiatrist or physiotherapist if the shoe inserts are not comfortable
8. FURTHER INFORMATION ABOUT YOUR TREATMENT

You will visit your podiatrist or physiotherapist for an initial appointment (approx. 30 minutes) where they will fit your shoe inserts into shoes that you wear most often. You will then have a follow up appointment (approx. 30 minutes) one week later to assess how your inserts are going, and fit shoe inserts to other shoes that you commonly wear. It is important you attend this second appointment and inform your treating practitioner how the inserts are going.

We encourage you to continue your normal activities for the duration of the study, provided that the shoe inserts are worn during the activity, and that the activity does not provoke your knee pain.

You should never train through pain or swelling in your knee, as this will aggravate your condition.

If you experience pain or swelling during an activity, you should stop the activity immediately and contact your podiatrist or physiotherapist. If your podiatrist or physiotherapist is unavailable, please contact:

Jade Tan: 03 9479 2768 (Victoria)
9. CONTACT INFORMATION

Your podiatrist/physiotherapist is:

Name: __________________________________________________________________________

Clinic: __________________________________________________________________________

Address: __________________________________________________________________________

Phone number: ______________________________________________________________________

If you have any questions or concerns about your shoe inserts, please contact:

Your podiatrist or physiotherapist listed above

If you have any general questions about the study, please contact:

Jade Tan
Podiatrist, PhD Candidate
Disciplines of Podiatry and Physiotherapy
La Trobe University
Phone: (03) 9479 2768
Email: jade.tan@latrobe.edu.au
Thank you for your participation