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

## Participant Information Statement

Project Title: **FEMOROACETABULAR IMPINGEMENT AND EARLY OSTEOARTHRITIS.**

Investigators:

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We invite you to participate in our research project "Femoroacetabular impingement and early osteoarthritis". This project is collaboration between La Trobe University, The University of Queensland and The University of Melbourne. We would like to give you some background information on why we think this project is important and on what we would like you to do if you decide to participate.

### What is this study about and why is it important?

Femoroacetebular impingement (FAI) is a common cause of hip and groin pain in active young adults and affects up to 25% of the general population. It is characterised by extra bone formation at the edge of the hip and is known as a cam-deformity. During motion, the cam deformity can cause further damage to the hip. The aims of this study are to (i) evaluate changes in hip joint structure over 2 years; and (ii) determine if factors such as hip joint force, hip muscle strength and hip joint range predict worsening of hip structure over 2 years in people with FAI. This knowledge may help to develop targeted intervention strategies for managing this condition in the future.

### What does the research involve?

Once screened for eligibility, you will have an X-ray and MRI of your pelvis and hip and attend either La Trobe University or The University of Queensland for your baseline clinical assessment. This assessment process will be completed again 2 years later (excluding the x-ray). At the completion of each testing session, you will be partially reimbursed for time and travel expenses. The total time commitment will be approximately 4hrs at base line and 3-4hrs at the follow up assessment. In addition, you will be asked to complete a series of mini questionnaires each month. These will be sent via text or email and will be less than 5minutes in duration.

The baseline and follow-up assessment will be performed at no cost to you. Both consist of:

- Questionnaires, including:
  - Age, gender, occupational and sporting history, mechanism of injury, symptom duration, rehabilitation, medication use, and family history of osteoarthritis~~OA~~.
  - Previous treatment for hip pain including (i) use of treatment modalities to increase joint range (may include massage, other soft tissue treatments, joint mobilisation, acupuncture and dry needling); (ii) exercise programs to improve hip muscle strength (may include home programs, gym programs or other).
  - Your expectations and values regarding your condition and its management.
  - Physical activity (type, frequency and dosage)
  - Age that you started playing sport
  - Type and level of sport you have played previously
  - Hip-related pain and quality of life.
- Physical testing- Tests of hip muscle strength and range of motion

- The maximal strength of your lower limb muscles will be measured using a special hand-held device. The examiner will ask you to push against it, as hard as you can, in up to eight directions. Following the assessment, you will be asked via email to complete the questionnaires outlined above. You may ask for a copy of your assessment results.

- Biomechanics testing- Measures of hip joint force
  - Measurements of hip joint force during tasks such as walking, jogging, squatting, going up and down steps will be taken. For the measurements, you will be required to change into shorts and singlet. You may either bring your own shorts or we can provide you with some. Reflective skin markers and electrodes will be attached to your skin at various sites such as the ankle, knee, hip and trunk as well as over the muscles of your leg, and will aid in the visualisation of joint movement while you walk. You may be videoed during these tasks.
- Magnetic resonance imaging (MRI) and X-ray scans:
  - You will undergo the x-ray and MRI assessment at Imaging at Olympic Park (Melbourne) or Queensland X-Ray (Brisbane). This will take approximately one hour of your time. The X-ray will be completed at baseline only.

The physical and biomechanical testing will be completed at the physiotherapy department of either La Trobe University in Melbourne, or the University of Queensland in Brisbane. These measures will be completed at baseline and the 2-year follow up, and will take approximately 2-3 hours of your time.

**Why were you chosen for this research?**

You can participate in this study if you are aged between 18 and 50 years of age, have symptoms indicative of impingement, which may include gradual onset of hip pain (may radiate to outside of your leg or groin), that is aggravated by prolonged sitting or hip movements (such as squatting, twisting, stair climbing, running).

You are not eligible to participate in this study if you (i) are not fluent in written and spoken English; or (ii) have planned to have lower-limb surgery in the following 2 years (e.g. arthroscopy); or (iii) have another significant hip condition (e.g. trauma, rheumatoid arthritis, congenital dislocation of the hip Perthes disease, subluxation, osteochondritis dissecans, fracture, septic arthritis, bursitis or tendinitis); or (iv) have any contraindications to magnetic resonance (MR) imaging; or (v) have a physical inability to undergo physical testing procedures; or (vi) are pregnant, might be pregnant or are breast feeding (as you will need to have an X-ray).

**Consenting to participate in the project and withdrawing from the research**

Before you can participate in the study you will be asked to read this participant information statement and sign a consent form indicating you have understood what the study 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. Specifically, this is will not impact upon any relationships with the University or and affiliated clinics/sporting clubs.

**What are the possible risks of participating in this study?**

*X-ray*- You will be asked to have an X-ray of your hip to confirm eligibility. 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 hip is about 0.7 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.

*MRI*- There is a side effect related to the use of MRI in individuals with some metal in their body. Thus it is imperative that you inform the investigator of your full medical history and of previous surgical procedures and any metal implants. You will be given a safety screening form to complete to ensure that it is safe for you

to be scanned by the MRI machine. If the practitioner who is assessing your MRI scan believes that you have an abnormal finding that is potentially significant, you will be notified and referred to an appropriate practitioner for further management and investigation. There is no exposure to radiation with MRI scans.

*Physical and biomechanical testing*- The physical tests are routinely performed by physiotherapists and are not associated with any risks. You may experience a small amount of discomfort in the joints or muscles during the physical examination. 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 physiotherapy departments 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.

**What are the possible benefits of participating in this study?**

There are no direct benefits in completing this study. However your participation will inform researchers and clinicians of possible risk factors that may predict deterioration of this condition. This information can be used to direct targeted treatment in future.

**What will happen to the results?**

The results of this project will appear in journal publications and in conference presentations, but you will not be able to be identified in any of these reports. With the participants consent, still and video images may be taken during aspects of the biomechanical and physical testing procedures. These images may be used in future for professional training purposes at Universities, or presentations at conferences related to the testing procedures used in this study. All images will be edited to prevent facial recognition for de-identification purposes. Data may also be used by members of this research team in future projects to compare with results from similar studies relating to the same testing procedures.

Results from the study 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; 5$^{th}$ Floor, Health Sciences 3) at La Trobe University. Data will be stored for at least 5 years after completion of the study in the Health Sciences storage vault, Building 3, level 1.

Furthermore, results of the experiment will be made available to you upon request. This may entail a mailing of results to your home residence, or if you prefer, a discussion with one of the investigators in person. If a participant choses to withdraw from the study they may opt to have their data deleted, irrespective of the timing of their withdrawal.

*"I (the participant) have read (or, where appropriate, have had read to me) and understood the **participant information statement and consent form**, and any questions I have asked have been answered to my satisfaction. I understand that even though I agree to be involved in this project, I can withdraw from the study at any time, up to four weeks following the completion of my participation in the research. Further, in withdrawing from the study, I can request that no information from my involvement be used. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used."*

**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?**

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

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, 9479 3902 or k.crossley@latrobe.edu.au).

**Complaints**

If you have any complaints or queries that the researcher has not been able to answer to your satisfaction, you may contact the Ethics Liaison Officer, Faculty of Health Sciences Ethics Committee, La Trobe University, Victoria, 3086, (ph: 94791443, email: humanethics@latrobe.edu.au). FHEC reference number

Thank you

**Prof Kay Crossley, Dr Adam Semciw, Dr Joanne Kemp, Prof Marcus Pandy, Dr Anthony Schache**