La Trobe Sports and Exercise Medicine Research Centre

LTU ethics approval number HEC17-080

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

Investigators: Dr Joanne Kemp, Sally Coburn, Denise Jones, Dr Anthony Schache, Dr Benjamin Mentiplay
Associate Professor Dr Steven McPhail, Professor Kay Crossley

Participant Information Statement

We invite you to participate in our project: "The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy to reduce pain and improve function for hip impingement."

We would like to give you some background information to explain why we think this project is important and describe what we would like you to do if you decide to join us in this research.

What is the purpose of this study?

Femoroacetabular (hip) impingement is a painful condition that commonly affects healthy active younger adults. It can limit their ability to continue playing sport and perform normal daily activities. It can be related to extra bone formation at the hip joint known as a cam deformity. Physiotherapy is one treatment people may use to reduce their symptoms and improve their function. We would like to compare the benefits of two different physiotherapy treatments to find the best way to manage this condition. Funding for this project has been provided by La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, an Arthritis Australia State/Territory Affiliate grant and a National Health and Medical Research Council Early Career Fellowship grant to Dr Kemp.

Who can participate in this study?

- People aged 18 to 50 years
- People with hip or groin pain aggravated by activity some of the time for more than 6 weeks
- People with signs of hip impingement when the hip is tested by a physiotherapist
- People with x-rays showing you have a 'cam deformity'

You are not eligible to participate in this study if:

- You cannot understand written or spoken English
- You have had physiotherapy in the past three months
- You have had hip surgery before
- You are not able to commit to a
    - **12-week physiotherapy program**
    - **a subsequent 12-week gym program, where you attend three times per week**
    - **baseline** (beginning) physical assessment
    - **follow-up** (24 weeks - after all treatments) physical assessment

- You are unable to have an x-ray of your pelvis (both hips at once) eg. You are pregnant or breastfeeding/unwilling

What does the project involve?

1. *Screening assessment (10 mins)*

You will be asked some questions about your hip over the phone to ensure you are eligible for the study. You will be asked to provide details of where any previous x-rays of your sore hip were taken for assessment of the digital copy to see if you have a 'cam deformity'. If you don't have x-rays we will organise a free hip (pelvic) x-ray for you at an x-ray clinic convenient to you (Imaging at Olympic Park, 60 Olympic Blvd, Melbourne or at Lake Imaging, Howitt St, Ballarat) if you are willing and able. The x-ray assessment will take about 30 minutes.

2. *Physical testing of your hip and questionnaires – Baseline (45 mins)*

If your movement tests and x-rays indicate you are eligible, we will ask you to attend an appointment at a mutually convenient time at La Trobe University, Melbourne, or at Lake Health Group, Ballarat, to undergo baseline measurement of your hip movements and strength. These baseline tests will take about half an hour.

Following the assessment we will ask you to complete several questionnaires online, and will be provided with instructions for access to the website. If you prefer you may complete a paper version of the questionnaires instead. The questionnaires will ask you questions about your hip/groin pain, other hip-related symptoms and your levels of physical activity and take about 15 minutes to complete.

3. *Biomechanical assessment of your movement (60 minutes)*

If you are willing to, we will undergo biomechanical assessment of your movement patterns after your physical testing described above. This testing will occur at La Trobe University, Melbourne. You will be asked to wear shorts (either you can bring some or we will provide you will shorts) and a singlet whilst you perform a series of tests including walking, running, squatting, jumping, and going up/down stairs. Reflective skin markers will be placed over your upper and lower body. Testing should take no longer than 60 minutes to complete. Participation in this section of the research is optional.

4. *Collection of activity data using Fitbit Flex 2™*

If you are willing to participate in this portion of the research, you will be given a Fitbit flex™ to wear on a daily basis for 14 consecutive days. It is important that you are able to wear the device every day on the wrist of your dominant hand. You will also need access to a computer so that you can set up and upload the information from the device. You will be given a password and email address that will be linked to the device you are given. Participation in this section of the research is optional.

Once the device is set up you will have access to your own Fitbit™ interface (called a dashboard), the same as any other user. This interface is accessible only by yourself (although you do have the option to share with your friends should you chose to do so).

Once the Fitbit™ is linked to your computer, the information from the Fitbit™ will be automatically synched to the computer via a USB dongle.

When data is uploaded from your Fitbit™, it is stored by Fitbit™ on an online server. The information collected by the research team will be gathered from that server using a program that will remotely log in and download the data. The research team will not need to log into your account through the Fitbit™ web page and will not access the personal dashboard and information that you set up.

5. *A free MRI of your hip (45 mins)*

If you are willing to participate in this portion of the research, we will investigate your hip joint structure in detail via a magnetic resonance imaging (MRI) scan at Imaging at Olympic Park, 60 Olympic Blvd, Melbourne. Parking is free and parking instructions are on the referral. The MRI will take place prior to the intervention period as well as after to examine any changes in your hip joint. You may not be able to participate in this section of the testing if you have a pacemaker, metal implants, or claustrophobia. Participation in this section of the research is optional.

6. *Physiotherapy treatment (12 weeks)*

After the first assessment and completion of the questionnaires, you will be randomly allocated to one of the physiotherapy treatment groups. Both treatments are used regularly by physiotherapists. You will then be asked to attend one of three physiotherapy clinics in Melbourne (or at Lake Health Group in Ballarat). Your treatment will comprise two phases which is provided free of charge and includes physiotherapy treatments and a 3 month gym membership.

In Phase 1, you will receive 6 free physiotherapy treatments over a period of twelve weeks. Each fortnightly treatment will last 30 minutes and will be performed by an experienced and project-trained physiotherapist. You will also be asked to perform a gym-based exercise program once per week in the gym at the same clinic. There are also exercises to complete at home twice per week. All treatments and any use of gym equipment will be provided at no cost to you.

7. *Gym membership (12 weeks)*

In Phase 2, you will receive a free 3-month gym membership and continue the exercise program you received in Phase 1 three times per week. You will receive a further three free physiotherapist reviews to continue to monitor your progress.

8. *Physical testing of your hip and questionnaires – Follow-up (45 mins)*

You will then return to La Trobe University (or Lake Health Group, Ballarat) for a final physical assessment. This will take approximately the same amount of time as the first assessment (about 45 minutes) and will also include biomechanics assessment if you participated in this before the intervention (about 60 minutes). The examiner physiotherapist will not know which treatment you have received. We ask you not to discuss your treatment with the examiner. We will also provide the same follow-up questionnaires for you to complete again (15 minutes), on paper, or online, and will ask you some questions about your experience of the project.

You will not receive any payment for your participation, however you will have free x-ray (and MRI if applicable) and assessment of your hip problem and free comprehensive physiotherapy if you are eligible and choose to participate.

We will also give you a $100 gift voucher for attending the final 6-month assessment of your hip at La Trobe University, as your assessment provides data critical to the success of our study. You may also ask for a copy of your assessment results.

We also ask that if you are considering another treatment for your hip or another musculoskeletal condition, you discuss the impact this might have on the study with the project leader, Dr Joanne Kemp.

Are there any potential side-effects?

The impingement and movement tests represent usual examination by a physiotherapist. You may experience a small amount of discomfort in the joints or tiredness in the muscles during the movement

and strength testing and interventions. Please report any undue discomfort or pain experienced during the testing. If the pain or discomfort is deemed to be excessive by yourself or the examiner, testing or treatment will cease.

If you have not already had a hip xray and require one to determine if you may participate, you will be exposed to a very small amount of radiation. 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 this study is about 0.32 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. If you decide to participate in the MRI scans, there is no further exposure to radiation with MRI.

If required, emergency procedures will be used to deal with any medical event that arises during testing or physiotherapy treatments. La Trobe University and participating physiotherapy clinics and gymnasiums have documented procedures for emergencies. This includes annual first aid and CPR training and appropriate management of fire for all staff.

What if I have any concerns during the study?

This study is funded La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora, Arthritis Australia and National Health and Medical Research Council fellowship grant to Dr Kemp. This study adheres to the La Trobe University Human Ethics Guidelines and National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your initial participation in this study with the project coordinator (Sally Coburn ph: 0408 761 237), you may want to talk an officer of the University not involved with the study. If so, you may contact the Ethics Manager, Heidi Gaulke on ph: (03) 9479 1443. If you choose to participate, you are free to call the project chief investigator with any queries following the baseline assessment of your hip (Dr Joanne Kemp ph: 0484 776 536)

Can I withdraw from the study if I wish?

Your participation in the study is voluntary. If you do not wish to take part you are under no obligation to do so. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. You may also withdraw any unprocessed data previously supplied by you.

If you are a student of La Trobe University, your decision whether to take part or not to take part, or to withdraw, will not affect your affiliation with the university in any way.

If you are a patient of any of the investigators or project physiotherapists, your decision whether to take part or not to take part, or to withdraw, will not affect your relationship with the physiotherapy clinic or your future physiotherapy management in any way.

Will my details be kept confidential?

Our procedures require allocation of a code number to identify you and any data associated with your participation. This assures your anonymity as your name will not be used. You will be videoed performing a single leg squat but will be de-identified for analysis. No findings that identify you will be published and access to individual results is restricted to the investigators. Coded data will be stored for at least 5 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 La Trobe University Human Ethics Guidelines. However, you must be aware that there are legal limitations to data confidentiality.

What will happen to the results of the study?

Summaries of the study results will be sent to participants, if requested on the consent form. It is possible that results from this study will be presented at a local, national or international conference, or published in a peer reviewed journal. Results may also be used for teaching purposes and web-based translational material. All results are **de-identified**.

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 that concerns you, either now or in the future, do not hesitate to ask one of the investigators or project coordinator. Before deciding whether or not you should 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. A newsletter will be sent to update you during the project. A project summary will be available, on request via email/post at the conclusion of the study and will include no identifiable information.

About the investigators:

Prof Kay Crossley is a sports physiotherapist and professor at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Joanne Kemp is a sports physiotherapist and post-doctoral researcher at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Sally Coburn is a physiotherapist and research assistant at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Denise Jones is a physiotherapist and research assistant at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Anthony Schache is a physiotherapist and senior research fellow at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Benjamin Mentiplay is an exercise scientist and researcher at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

A/Prof Steven McPhail is a health economist at University of Queensland

Contacts:

Enquiries and eligibility:

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If you have commenced participation:

Dr Joanne Kemp

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