

REC Reference: 13/SC/0154

# Femoroacetabular Impingement Trial (FAIT)

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## **Patient Information Leaflet**

We would like to invite you to take part in a research study called FAIT.

The study is looking at the treatment of hip pain.

Before you decide whether to take part or not, we would like you to understand why the research is being done and what it would involve for you.

One of our team will go through this information sheet with you and answer any questions you have. We anticipate that this will take about 30 minutes.

## **PART 1: INFORMATION REGARDING THE PURPOSE OF THE STUDY**

### **1a What is the purpose of the FAIT?**

The aim of the FAIT study is to find out the best way to treat hip pain and prevent the development of long-term disease such as arthritis.

### **1b Why have I been invited to take part in FAIT?**

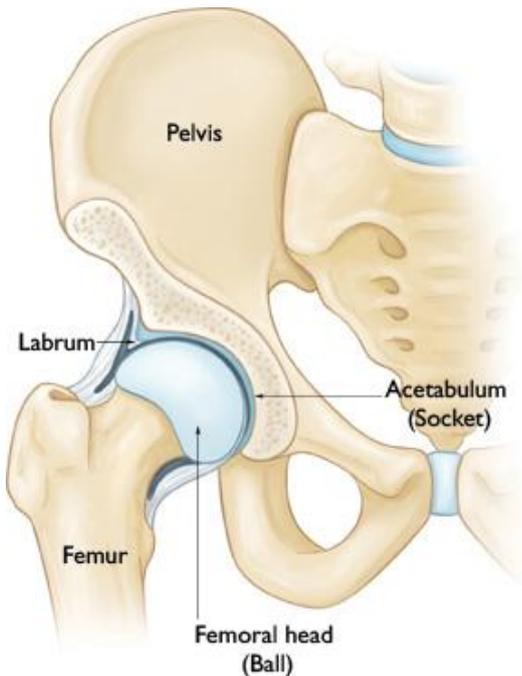
You have been invited because you have been diagnosed with a condition called femoroacetabular impingement (FAI). We are hoping to recruit 120 patients into our study.

### **1c What is femoroacetabular impingement (FAI)?**

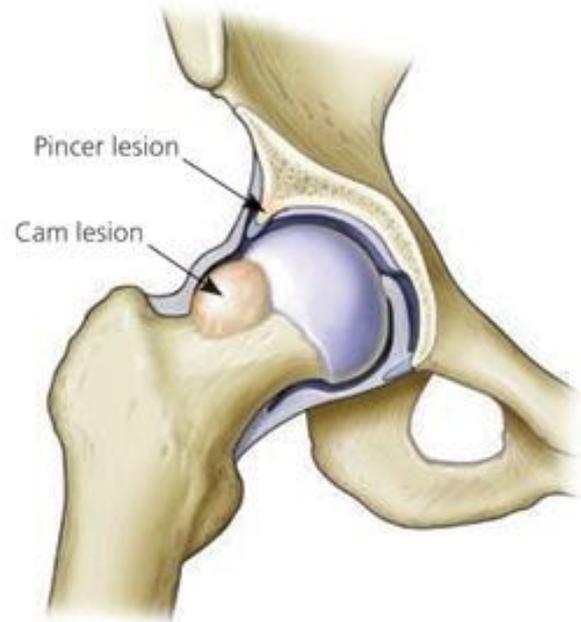
FAI describes a condition where there is abnormal contact between the ball and the socket of the hip joint due to the shape of the bones (see images on next page). In some patients this gives rise to pain and may increase the risk of developing future arthritis.

We know relatively little about this condition including its causes and also how we should best treat it. Two current options are physiotherapy and surgery. The use of physiotherapy for this condition has been the traditional treatment, while surgery, on the other hand, is a relatively new option. Both these treatments have been shown to improve symptoms in the short-term, but this study will also look at the longer-term benefits of each treatment.

### Normal Hip



### Hip with Femoroacetabular Impingement



#### 1d. What will happen to me if I take part in the study?

You will have your hip assessed and will be asked to complete some questionnaires relating to your pain. If you then decide to take part in FAIT you will undergo one of the following:

- Physiotherapy Programme  
This involves regular physiotherapy sessions under the care of clinicians who specialise in this condition. In these classes, you will work on improving the strength of different muscles to modify the way you move your hip. You will also be asked to work on some exercises at home, and a key element to this regime is avoiding activities that may make your condition worse, such as certain sports. This programme lasts a minimum of 26 weeks and the number of sessions will depend on your individual needs.
- Key-hole surgery  
This is carried out under general anaesthetic, and patients go home either the same day, or the day following surgery. During surgery, the hip joint is assessed and any cartilage damage is treated. Extra lumps of bone that may be causing pain are also removed. As with any surgical procedure there is a small risk of complications.

All patients participating in this study will be seen again at regular intervals by members of your Consultant's clinical research team over a period of 3 years. We will ask you to complete some questionnaires via post and on other occasions we will ask

you to come to the clinic for us to assess your hip. These hip assessments will involve having MRI scans and X-rays. We will also perform a fasting blood test and ask you to bring a sample of urine to your assessment. Prior to these appointments we shall send you a urine specimen collection pot in the post.

At the end of the study, we will compare outcomes in the two groups to see which treatment is the best for hip pain and preventing future arthritis.

**1e Which of these groups will I be in?**

We don't know yet. Allocation to these groups is random (like a lottery). We are advising this because it is the best way to allow a fair comparison between treatments. Dividing people into groups in this way is what is called a "randomised controlled trial". Whatever group you are in, you will still be under the care of your Consultant Surgeon and followed up regularly. If you are allocated to physiotherapy and your symptoms do not improve within 6 months, you will be allowed to have surgery if you and your Consultant Surgeon agree this could be beneficial.

**1f Do I have to take part?**

No, taking part in a research study is always optional. We will describe the study and go through this information sheet with you. You do not have to decide straightaway. Please feel free to take the information sheet home with you and discuss your participation with friends, family or your own GP. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

**1f What is the treatment if I don't participate in the study?**

If you were not involved in the study, your surgeon would inform you of your choices for treatment. At your hospital the choices available are the same as the treatments in the study. At many other hospitals, physiotherapy is the standard treatment for this type of hip pain, although there is some evidence to suggest that surgery may be beneficial. If this study proves that one treatment is more effective than the other, then this treatment may become standard care.

**1g Will taking part involve extra visits to the hospital?**

Yes. After your initial assessment we would like to see you at 6 months, 12 months, 24 months and 36 months. The visits at 6 and 12 months are part of routine care but the others are extra.

**1h What will these visits involve?**

Each visit should take about 90 minutes and will be made at a time convenient to you. At each visit a member of your Consultant's clinical research team will see you to discuss the study requirements. These involve:

- **Questionnaires** - consist of questions about your hip pain and function and also how it affects your activities of daily living. Questionnaires will take about 20 minutes to complete. Ones posted to you will need to be returned to the study office in Oxford in a prepaid envelope that will be provided.
- **Blood and Urine samples** are taken to determine how the pain progresses.
- **MRI scans** are used to assess the condition of your hip joint. MRI is safe and does not involve radiation. An MRI safety questionnaire will be asked to identify any reasons why you should not have the scan such as having a pacemaker implanted or being claustrophobic. Some of the MRI scans are part of routine care and others are additional as part of the study.
- **X-rays** are also necessary to examine the condition of your hip joint, but measure different aspects to MRI. Some of the x-rays required for FAIT are performed routinely while others are additional as part of the study.
- **Hip Examinations** look at how your hip moves and feels.

Please see the table below detailing what is involved at each visit; (*italics denotes routine care*)

When you first see the surgeon	<i>Hip examination, questionnaire, X-ray, MRI, urine collection, blood test</i>
6 weeks later (for surgical patients only)	Hip examination
3 months after entry into the study	Questionnaires – posted to you
6 months after entry into the study	<i>Hip examination, questionnaire, MRI, urine collection, blood test</i>
9 months after entry into the study	Questionnaires – posted to you
12 months after entry into the study	<i>Hip examination, questionnaire, X-ray, MRI, urine collection, blood test</i>
18 months after entry into the study	Questionnaires – posted to you
24 months after entry into the study	<i>Hip examination, questionnaire, X-ray, MRI, urine collection, blood test</i>
30 months after entry into the study	Questionnaires posted to you
36 months after entry into the study	<i>Hip examination, questionnaire, X-ray, MRI, urine collection, blood test</i>

## 1i Expenses and Payments

There is no payment to people taking part in the study but reasonable travel expenses to the hospital for your follow up appointments can be reimbursed. Ask the local research team for further details about this.

## 1j What are the possible disadvantages and risks involved of taking part?

If you are randomised to the surgical option there are the usual risks associated with surgery and anaesthetics. Steps are always taken to ensure that these risks are minimised. Your surgeon will be able to tell you about the risks and complication rates in your own local hospital. Occasionally patients are advised to use crutches for a few weeks following their operation.

The assessments for this study do include x-rays, which involve exposure to radiation. The number of x-rays and radiation doses are within the recommended guidelines and has been approved by experts in this area. In fact, the radiation dose involved is less than the exposure a person living in Cornwall receives every year (from the granite).

There are no known side effects associated with having an MRI scan. Some people find that the scanner makes them feel uncomfortable or claustrophobic. If you know that you are claustrophobic, you may wish to discuss this with the researcher beforehand.

It may not be safe to have a scan if you have metal or a pacemaker in your body. This is because of the strong magnetic field in the scanner room. For your safety you will be asked to fill out a MRI Safety Screening Questionnaire, and to remove any metallic items (e.g. jewellery, coins) before you enter the scanner room.

## 1k What are the possible benefits of taking part?

We cannot guarantee any benefit to patients who take part. Either one of the treatments we are comparing would be an appropriate treatment for you. Until we have completed the study we cannot be sure which is best. The main benefit from taking part will be the information we gain from this study, which should help us to improve the future treatment of patients with hip pain. You will also be followed-up more closely than in routine care, and during these follow-up appointments you will have one-to-one consultations with an experienced clinical researcher who may be able to help with any problems that arise relating to your hip.

## **PART 2: DETAILED INFORMATION ABOUT THE CONDUCT OF THE STUDY.**

### 2a. What happens when the research study stops?

Any hip related care required beyond this time should be arranged in the usual way via your GP.

### 2b. What if there is a problem?

Taking part in the study will not affect your legal rights. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact your local principal investigator:

Or

FAIT trial co-ordinator at the central office in Oxford at [FAIT@ndorms.ox.ac.uk](mailto:FAIT@ndorms.ox.ac.uk) or on (01865) 737643.

Or

You may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email [ctrg@admin.ox.ac.uk](mailto:ctrg@admin.ox.ac.uk).

NHS indemnity operates in respect of the clinical treatment with which you are provided. In addition, in the unlikely event you were harmed by participation, the University of Oxford has appropriate insurance-related arrangements in place in respect of the University's role as Research Sponsor of this study.

**2c. Will taking part be kept confidential?**

Yes. All patient information will be stored on password protected computer databases or in locked filing cabinets. You will be allocated a study number and staff not directly involved with your care will know you only by this number. All study information will be collected and analysed at the University of Oxford. When the results of the study are reported, individuals who have taken part will not be identified in any way. Responsible members of the University of Oxford or your NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with research regulations.

Your scans and x-rays, once made anonymous, may be sent to collaborators working outside of the EU. Colleagues abroad may help us to interpret the images of your hips that we acquire during the course of the study.

**2e. What if relevant new information becomes available?**

Any information relevant to the treatment of hip pain will be considered in relation to its effect on your care. If new information arises that suggests one of the study treatments is more effective or less harmful than the other, allocation of this treatment will stop. Should this occur, the research team will contact you to discuss the situation further.

**2f. What will happen if I don't want to carry on with the study?**

If you decide to withdraw from the study, your standard of care will not be affected. You will still be asked to attend the usual follow-up clinics required by your surgeon and hospital, but these will not be part of the study. Any information you have already provided will still be considered as part of the final study outcome.

**2g. Will my GP be informed about my participation in the study?**

With your consent we will notify your GP about your participation in this study.

## 2h. What will happen to the results of the research study?

At the end of the study, patients who participated will be offered a report detailing the study findings. This will also be made available on the study website. We plan to publish the results in a medical journal so that others can read about our findings and learn from the results.

## 2i. What will happen to any samples I give?

During surgery for femoroacetabular impingement, abnormal bone and overlying cartilage are removed. Whereas we normally dispose of this tissue, we may collect it at the time of surgery and store it with an anonymous form labelled only with your given study number. Blood and urine samples collected will be also be stored anonymously. These samples will be stored in the Oxford Musculoskeletal Biobank and analysed at a later date to help determine the effectiveness of each treatment, and to better understand the disease process. Samples will be considered a gift to our on-going research at the University of Oxford.

## 2i. Who is organising and funding the study?

The study is organised by a team of surgeons, nurses, physiotherapists, patient representatives, health economists and statisticians working with Mr Sion Glyn-Jones. The team are based at the Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences (NDORMS) at the University of Oxford.

FAIT is funded by Arthritis Research UK, a registered charity specialising in research into treatments for patients with musculoskeletal problems. You can access information about them on their website [www.arthritisresearchuk.org.uk](http://www.arthritisresearchuk.org.uk)

## 2j. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and approved by the Berkshire Research Ethics Committee. (Reference 13/SC/0154).

The UK Comprehensive Research Network, the Research and Development Committee/Department in each hospital, and your local Orthopaedic Consultant have also reviewed and approved this study

## 2k. Further information

If you require further information about this study, please contact the Oxford FAIT team via e-mail at [FAIT@ndorms.ox.ac.uk](mailto:FAIT@ndorms.ox.ac.uk) or on the telephone number provided in section 2b. Alternatively, information about the study is available on the NDORMS website ([www.ndorms.ox.ac.uk](http://www.ndorms.ox.ac.uk)).

The clinical research team at your hospital are also available to be contacted if you have any questions. Their details are provided below: