NIHR | National Institute for Health and Care Research

Cambridge University Hospitals NHS
NHS Foundation Trust

PARTICIPANT INFORMATION SHEET

Pre-operative interventions for patients undergoing keyhole surgery of the hip for Femoroacetabular Impingement Syndrome (FAIS)

We would like to invite you to take part in our research study. The study forms a part of a PhD research fellowship funded by the National Institute for Health and Care Research. Participation in this research study is entirely voluntary. Before you agree to participate, it is important that you understand why the research is being done and what it involves. Please take time to read this information and discuss it with your family and/or friends if you wish. Please do not hesitate to ask us if you need any further information about this research study.

Why is this research important?

Keyhole surgery (hip arthroscopy) which is looking at the affected area using a tiny camera inserted through a small incision, can improve quality of life and improve function for patients with FAIS. However, the road to recovery can be long and difficult for patients. Problems occur because muscles often weaken as a result of the damage, the length of time muscles are out of action, and also because of damage to muscles and tissues during surgery. One possible solution to this problem is to prepare the patient before surgery by helping them with exercises and patient education. This is called 'prehabilitation'.

My plan is to conduct a feasibility study to address the following issues before progressing to a full trial in the future:

1. Is the study feasible in an NHS setting? Specifically: Will we have enough participants for the study? What difficulties may arise during the study?

2. To determine if the intervention is acceptable to both patients and Physiotherapists.

Why have I been invited?

You have been invited to take part in this study because you have been placed on the waiting list for hip arthroscopy at Addenbrooke's Hospital.

Do I have to take part?

Taking part in this study is entirely voluntary. If you do agree to participate, you can withdraw at any time, without giving a reason. However, we will keep information about you that we already have. You will have the option to take part in future research using your data saved from this study. Withdrawing from the study will not affect your clinical care.

I am already participating in another research study. Could I still volunteer to take part in this study too?

The hospital is a very research active site and there is a possibility that you might be invited to participate in several research studies at the same time. If this is to occur, it is important that you notify a member of the research team. Although participating in studies is your decision, it is important to understand the burden it may place on your commitments and time. We also have to ensure that participating in this study does not adversely affect your health and wellbeing and safety.

What will happen to me if I decide to take part?
There are 2 parts to the study described below. We invite you to take part in just the first or both parts of the research. Please speak to the study team if you would like more information or to undertake only a particular part of the research:

Part 1:
Our study is a randomised, controlled, single-blinded, two group parallel study. You will be assigned to either one of the two programs (the intervention program or control program) by a randomised method. This means that you are put into a group by chance and neither you nor the researchers can choose the group you will be in. This method is chosen so every participant in the study gets equal chances of being assigned to a particular group. This method can ensure that any differences we observe between the two groups are due to the study intervention and nothing else.

If you are allocated to the intervention group, you will be asked to attend one educational session and up to 8 to 10 treatment sessions pre-operatively. The sessions will be a combination of face to face and also via videoconferencing or telehealth systems. The exercise intervention will be delivered and supervised by an experienced Physiotherapist and will be tailored to your capabilities. You will be given instructions to carry on the exercises at home and record the completion via an app called Physitrack.

As per the hospital's current clinical guidelines, the control group will be advised to continue with normal activities and will not receive any prehabilitation therapy. Participants from both groups will receive standard post-operative care and physiotherapy. Participating in this research study will not alter your clinical or surgical pathway.

Part 2:
You may be asked to attend one focus group session which may last up to 2 hrs. This is to understand your opinions about the contents of the exercise programme, it's delivery, use of Physitrack app and whether the outcome measures used were appropriate. The focus group discussion will be audio recorded to ensure we don't miss anything important that

you tell us. Data from the focus groups will be used to develop a training manual at the end of the study.

Additionally, regardless of allocation to groups, all participants in the study will be asked to complete a set of outcome measures which will enable the research team to assess the possible benefits of prehabilitation. This will include some objective measurements (e.g. muscle strength) and some self-reported questionnaires. Participants will be required to travel the hospital site for undertaking the objective measurements. However, necessary steps have been taken to ensure that this is kept to a minimum as these measures will be performed during your standard clinical visits.

When do I have to decide if I want to participate in the research?
One of the research team members will contact you after 1 week of you receiving this study information.

What are the advantages and disadvantages of participating in this study?
Previous research suggests some benefits of prehabilitation before surgery. Therefore, we anticipate some benefits of exercises if you are allocated to the treatment group. You may find the experience of taking part in the focus group with other patients interesting and informative and the information you give us may also help develop a programme for people like you in the future.

You will have to consider giving up your time to attend the prehabilitation programme and the focus group if you are allocated to the treatment group.

There an no added risks being involved in this study. The exercises and treatment delivery in the study has been well developed by the research team in collaboration with international experts and a Patient and Public Involvement panel. Exercises will be prescribed and progressed by an experienced Physiotherapist according to your individual capabilities. However, exercises can induce pain and discomfort in which case the Physiotherapist will re-evaluate and adjust the dosage or frequency.

If you are randomised to the control group, you will receive the same standard of care that you would get if you were not in the study. Therefore, we do not anticipate any increased risk due to participation.

Will I be reimbursed for taking part?
You will not receive any payments for taking part in this study. However, travel expenses maybe claimed if the visit to the hospital falls outside of your standard clinic visits or follow-ups.

What if there is a problem?

Any complaint you have about participating in this research project will be addressed appropriately. Please discuss this with a team member in the first instance or use the contact details below. If your issue has not been dealt with following this process, you can contact the Patient Advice and Liaison (PALS) service to take this further.

What is Physitrack and how is this useful?
Physitrack provides exercise information and videos via website and apps. If you are randomised to the intervention group, your Physiotherapist will select the exercises for you and he can share this with you via the Physitrack app, so you can easily follow them by watching the videos or photos on the app. You can also complete the self-reported outcome measures or questionnaires via Physitrack. Additionally, you can record your exercise completion on the app, so your Physiotherapist can measure your adherence of the exercise programme. As a patient, the app is completely free to use and is available to use on both IOS and Android devices.

Is it mandatory to use Physitrack?
No, it is not compulsory to use Physitrack. However, it is easier to follow the exercises by watching high resolution videos on the app compared to using a paper copy. If yo do not have access to a smart phone, please inform your Physiotherapist.

What if new information becomes available?
You will be advised of any new information during this study that may affect your wish to continue in the study. If more effective techniques become available, they will be offered to you.

What information will be gathered and stored?
We will need to use the information about you from your medical records for this research project. The hospital's audit department may use this information to check if the research is being done properly. The information will include your name and contact details, age, gender, employment status, your current physical activities, medications, past medical history etc.

Will my GP or other healthcare professionals be informed of my participation in the study?
Yes. A letter with details regarding the study will be send out to all healthcare professionals involved in your care provided you have consented for this to happen.

Will my taking part in the study be kept confidential?
Your data will be stored on secure hospital computers and will be only accessible to the research team. We will ensure that all aspects of your participation in this study is confidential. Moreover, the data collection, handling and storage will comply with the General Data Protection Regulation (GDPR). If any of your information is shared with

researchers outside the hospital then it will have your name and address removed so that you cannot be recognised from the data. Some of your information (anonymised) might also be shared with other researchers inside or outside the UK. They must follow our rules about keeping your information safe.

What will happen to the results of the study?
The information you provide during the focus group will be used to develop or refine the prehabilitation programme for a larger study in the future . The process used to develop this programme, including the findings from each stage will be presented at academic conferences and published in academic journals. No patient identifiable data will be used for these purposes ensuring strict confidentiality. The research is also part of PhD project and therefore anonymous data will be submitted as part of a final thesis.

What will happen if I don't want to carry on with the study?
Your participation in this study is voluntary and you can decide to withdraw at any stage by informing the research team. If you choose not to take part, this will in no way affect your routine follow up appointment or any of your future care.

Who is organising and funding the study?
This study is part of Doctoral Research Fellowship funded by the National Institute for Health and Care Research, UK. The study is being done by a post graduate student researcher and supervised by 3 experienced academic supervisors. The study sponsor will be Addenbrookes Hospital, Cambridge in collaboration with Anglia Ruskin University, Cambridge.

Who has reviewed the study?
This study has been reviewed and given approval by the Health Research Authority for East of England, UK.

Raising concerns
If you have a concern about your care or treatment, or about any of our services, please talk to the member of staff; they will be as helpful as possible and may be able to resolve your concerns straight away. For immediate help, advice and support contact the Patient Advice and Liaison Service by email cuh.complaints@nhs.net or telephone 01223 216756

Contacts for further information
If, at any time, you would like further information about this research study you can contact the research team at cuh.prehabfaistudy@nhs.net

Thank you for reading this information sheet.