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Prehab FAI - Prehabilitation for patients undergoing arthroscopic hip surgery for Femoroacetabular impingement syndrome

Submission date
07/03/2023

Recruitment status
No longer recruiting

Registration date
09/03/2023

Overall study status
Ongoing

Last Edited
01/07/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Femoroacetabular impingement syndrome (FAI) is where extra bone grows on the bones that form the hip joint, giving it an abnormal shape. This condition is common in young adults (aged 16–50) and can lead to damage of the lining of the hip joint (labrum) and cartilage and in some cases cause early onset of osteoarthritis. Majority of patients with FAI experience pain and problems with movement affecting their daily life as well as their physical and mental wellbeing. Two large scale research studies have demonstrated that correction of FAI via keyhole surgery (hip arthroscopy - which is looking at the affected area using a tiny camera inserted through a keyhole incision), can improve quality of life in the shorter term. However, not all patients benefit equally and the road to recovery can be long and difficult. Problems occur because of the pre-existing deficits in muscle strength, length of time muscles are not functioning, and also because of damage to muscles and tissues during surgery.

One possible solution to this problem is to prepare the patient prior to surgery by helping them with education, psychological support, exercises and pain management. This is called ‘prehabilitation’. There has not been much research investigating prehabilitation for FAI specifically in the NHS. The aim of this study, therefore, will be to assess if a prehabilitation programme is feasible in an NHS care setting for patients undergoing hip arthroscopy. This study will then be able to inform a future larger study to test if prehabilitation for FAI can improve patient outcomes.

My plan is to perform a feasibility study which addresses the following issues:
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.

Who can participate?
All patients referred to Cambridge Young Adult Hip service (aged 16-50 years), undergoing hip arthroscopy for Femoroacetabular Impingement Syndrome.

What does the study involve?
There are 2 parts to the study described below. Participants will be invited to take part in just the first or both parts of the research.

Part 1:
Our study is a randomised, controlled, single-blinded, two group parallel study. Participants will be assigned to either one of the two programs (the intervention program or control program) by a randomised method. Participants allocated to the intervention group 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 individual capabilities. They 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 their clinical or surgical pathway.

Part 2:
Participants may be asked to attend one focus group session which may last up to 2 hrs. This is to understand their 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 their standard clinical visits.

What are the possible benefits and risks of participating?
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.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust in collaboration with Anglia Ruskin University, Cambridge (UK)

When is the study starting and how long is it expected to run for?
April 2022 to March 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Mr Anuj Punnoose, anuj.punnoose@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
293927

Protocol serial number
CPMS 53203, NIHR302117, IRAS 293927

Study information

Scientific Title
Prehabilitation for patients undergoing surgery for Femoroacetabular Impingement Syndrome - a feasibility study

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2023, East of England - Cambridge Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 207 104 8286; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0024

Study design
Interventional randomized controlled pilot and feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Femoroacetabular impingement syndrome

Interventions
Current interventions as of 09/04/2024:

Randomisation & Blinding

Once patients are allocated to one of the two groups (prehabilitation or standard care), all baseline data will be obtained. This will be uploaded to a secure database known as REDCap (Research Electronic Data Capture) and all study personnel will be blinded to the allocation sequence ensuring adequate concealment. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

Blinding participants and clinicians delivering interventions will not be possible as both will be aware of the intervention and allocation. However, the content of the programme will only be known to participants in the intervention group thereby reducing the risk of cross contamination between groups. Physical outcome measures will be measured by 2 blinded assessors who will be trained by the PI to ensure standardisation and improve reliability of the assessment.

Interventions

All participants will receive standard peri & post-operative care. A record of their analgesia consumption will be noted during their follow-up appointments in a logbook by a member of the research team.

Prehabilitation intervention

The intervention will be delivered over a period of 8 weeks prior to surgery and will target 5 domains- muscle strength, range of motion, balance, cardiovascular fitness and addressing co-existing pathologies. Literature suggests high prevalence and poorer outcomes of depression and anxiety in people with FAI, and the intervention will therefore also include an in-person educational session delivered by the PI to provide greater understanding of the surgery to alleviate anxiety and help manage patient expectations. The intervention will include at least four in-clinic face-to-face sessions (once a fortnight) with an experienced physiotherapist (>2 years' experience in treating musculoskeletal conditions including FAI) followed by six to eight remotely monitored sessions (once a week) using a telehealth system (Physitrack). The number of sessions will be determined based on physiotherapist assessment and intensity and complexity of exercises will be gradually increased depending on each participant's individual progress. Due to the wide variation of patient characteristics within the FAI population (e.g. sedentary or athletic) interventions will be tailored according to individual participant's capabilities.

Pre-op education sessions will be delivered virtually via Zoom/MS Teams: This is to reduce the impact on patient travel and reduce the need for additional resources e.g. room availability in the hospital.

Training of Physiotherapists delivering the prehabilitation intervention

The prehabilitation intervention will be delivered by experienced physiotherapists as described above. All of the rehabilitation components are standard clinical therapies familiar to a trained physiotherapist. The physiotherapists will undergo training (by PI) on how to deliver these components together as per the protocol for this study. A representative from Physitrack will be invited to deliver training on the use of the app.

Use of Physitrack app and Telehealth system:

The participants will use Physitrack which provides photos and videos of the prescribed exercises and those unable to use the app will be provided with paper-based instructions. Additionally, patients will be asked to complete their exercises at home twice weekly. Physitrack provides exercise information and videos via websites and apps. The dosage and

frequency of the exercises can be selected, and patients will be encouraged to record the completion of the exercises enabling the physiotherapist to measure adherence via the app. Physitrack has been found to improve adherence and patient confidence and is utilised across several NHS Trusts in the UK. Additionally, the use of Physitrack's telerehabilitation would enable physiotherapists and patients to interact with each other via video providing reassurance of the correct exercise techniques and progression.

Usual care intervention
As per the host hospital's current clinical guidelines, the usual care intervention consists of advice to continue with normal activities and no prehabilitation therapy.

Qualitative component
An embedded qualitative component will be utilised to answer specific trial objectives and to refine and adapt the design prior to the full RCT. Prior to participating in the qualitative study, participants will be provided with an information leaflet and an opportunity will be given to raise any questions to the researchers regarding the processes.
Consent from all participants will be obtained prior to commencement. All qualitative data will be recorded and transcribed verbatim. Transcripts will be returned to participants for review and edited prior to analysing the data.

Physiotherapists
In-depth face-to-face semi-structured interviews will be used to evaluate the views of the Physiotherapists (n=4) regarding the feasibility, suitability and acceptability of the intervention, outcome measures as well as the Physitrack app in an NHS setting as described below. The interviews will be conducted by the PI within 1 year of the commencement of the study to gather qualitative data. Appropriate questions for the interviews will be developed by the PI and the supervisory team. A patient and public involvement group will review the questions for clarity and appropriateness.

Research participants
A focus group with research participants will be conducted following the 6 months assessment point to evaluate the research objectives. A purposive sample of 6-8 patients at different points of their research pathway (pre-op & post-op) will be included as recommended in the literature. A predetermined topic guide developed by the PI and reviewed by the PPI panel will be used for the focus group. The focus group will be conducted by 2 researchers; the PI (facilitator) and a supervisor (observer).

Focus groups with patients: The researchers would like to conduct two or more focus groups (8-10 participants) as needed. This is to improve data quality and may achieve data saturation in a robust manner improving the overall quality of the study. This will only be implemented with the participant's explicit consent.
The focus group will be conducted either face to face or on occasions virtually using online software such as MS Teams or Zoom. The flexibility will promote inclusivity for all research participants and reduce burden on the participants especially for the ones who does not live close to the hospital.

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Previous interventions:

Randomisation and blinding
Following baseline evaluation, participants will be randomly allocated to one of the two groups

(prehabilitation or usual care) by the Investigator using a random numbers table. Opaque sealed envelopes will be utilised for participant group allocation concealment.
Blinding participants and clinicians delivering interventions will not be possible as both will be aware of the intervention and allocation. However, the content of the programme will only be known to participants in the intervention group thereby reducing the risk of cross-contamination between groups. Physical outcome measures will be measured by a blinded assessor who will be trained by the PI to ensure standardisation and improve the reliability of the assessment.

Added 22/08/2023:
Following baseline evaluation, participants will be randomly allocated to one of the two groups (prehabilitation or usual care) by the PI using a computer-generated simple random allocation sequence. This will be uploaded to REDCap and all study personnel will be blinded to the allocation sequence ensuring adequate concealment.

Interventions
All participants will receive standard peri & post-operative care. A record of their analgesia consumption will be noted during their follow-up appointments in a logbook by a member of the research team.

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Intervention Type
Behavioural

Primary outcome(s)
The iHOT-12 is a patient-reported outcome of Quality of Life (QoL) and will be the planned primary outcome measure for this study. This will be measured at baseline, Pre-op (after prehabilitation), 6 weeks, 6 months and 12 months post-op.

Added 22/08/2023:
Study follow-up points will be +/- 4 weeks to accommodate flexibility in clinic appointments within the NHS: Upon further consideration of the current situation and waiting times within the NHS, having a rigid follow-up point would not be feasible. Therefore, the follow-up points are kept flexible, but within a reasonable duration, so this does not affect the quality of the study. Patient-reported outcome measures will be completed digitally via online surveys at baseline and all other follow-up points (at pre-op, 6 weeks,6 months and 12 months post-op) using REDCap. A link to the online outcome measures survey with instructions will be emailed to participants for completion at the above follow-up points. If participants forget to complete the outcome questionnaire on the required day, a reminder to complete it will be sent on two more occasions after the deadline to facilitate compliance.

Key secondary outcome(s))
1. Hip muscle strength using a handheld dynamometer will be measured at baseline, Pre-op (after prehabilitation), 6 weeks and 6 months post-op.
2. The Star excursion balance test is a reliable measure to assess dynamic postural control and proprioception and will be measured at baseline, Pre-op (after prehabilitation), 6 weeks and 6 months post-op.
3. Pain will be measured using Brief Pain Inventory-short form (BPI) and will be measured at baseline, Pre-op (after prehabilitation), 6 weeks, 6 months and 12 months post-op.
4. Anxiety and depression will be measured using Hospital Anxiety and Depression Scale (HADS) at baseline, Pre-op (after prehabilitation), 6 weeks, 6 months and 12 months post-op.
5. Patient's Global Impression of Change (PGIC) will be used to gather a patient's perception of change after intervention and will be measured at baseline, Pre-op (after prehabilitation), 6 weeks, 6 months and 12 months post-op.

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Completion date
01/03/2027

Eligibility

Key inclusion criteria
All patients referred to Cambridge Young Adult Hip service (aged 16-50 years), undergoing hip arthroscopy for Femoroacetabular Impingement Syndrome.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
50 years

Sex
All

Key exclusion criteria
1. Previous hip disease such as Perthe’s, Slipped upper femoral epiphysis or avascular necrosis
2. Participants who are unable to give full written consent.
3. Pre-existing neuromuscular conditions like Motor neuron disease or Multiple sclerosis.
4. History of any previous hip surgery
5. History of any previous hip arthroscopies

Date of first enrolment
21/04/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

Added 22/08/2023:
The REDCap database will be used to collect and store the data for the study and will therefore be more secure and will strictly follow all UK and GDPR guidelines. Both the PI and CI are part of the direct clinical team and routinely collect and review data regarding patient demographics, clinical examination details and details of any investigations done for their care. The above details will be collected and utilised for the purpose of the study. This information is mentioned on the current PIS, however not explicitly and covering all the above terms mentioned. This will be stored securely in the hospital computers and REDCap database as mentioned above. If a need arises to share data or present at meetings for dissemination, this data will be anonymised, and no patient identifiable details will be presented.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/04/2024	12/04/2024	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version 2.1	10/02/2023	08/03/2023	No	Yes
Protocol file	version 2.4	18/03/2024	09/04/2024	No	No