Protocol and SAP

"Are baseline factors associated with persistent pain in people with Femoral Acetabular Impingement Syndrome after a physiotherapy-led rehabilitation programme?"

Document date 8th January 2026

FAIR

Study: **F**emoral-**A**cetabular **I**mpingement **R**ehabilitation **O**utcomes

Study Title: Are baseline factors associated with persistent pain in people with Femoral Acetabular Impingement Syndrome after a physiotherapy-led rehabilitation programme?

Internal Reference Number / Short title: Do patient characteristics associate with poor outcomes who have FAIS?

Ethics Ref: 25/YH/0258

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There are no actual or potential conflicts of interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

Study Title: Are baseline factors associated with persistent pain in people with Femoral Acetabular Impingement Syndrome after a physiotherapy-led rehabilitation programme?
Protocol Date and Version No: 2.0_SW8January2026

Protocol signature page

The undersigned has read and understood the trial protocol detailed above and agrees to conduct the trial in compliance with the protocol.

Simon Wood		Nufffield Orthopaedic Centre	15th January 2026
Principal Investigator (Please print name)	**Signature**	**Site name or ID number**	**Date**

Following any amendments to the protocol, this page must be updated with the new protocol version number and date and re-signed by the site PI.

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1. KEY CONTACTS

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2. LAY SUMMARY

The hip joint is a ball and socket joint where the ball inserts into the socket. The ball shape is round but sometimes the ball has a bony bump on it. When the ball moves in the socket, the bump can hit the edge of the socket causing pain in movements like squatting or kicking a ball. Repeated hitting of the bump in the socket can cause hip pain, damage, and arthritis. This is called hip impingement and is found in 10-15% of young adults.

Does Physiotherapy treatment work? Exercises from a physiotherapist make the muscles stronger around the hip joint which alters the way the ball moves. This stops the bump hitting the socket and this can help reduce the pain. However, an experiment found only 32% of people doing exercises got better. So, why after strengthening the muscles are some people still in pain? Is there another source of pain?

Other causes of pain? We know things like people's emotions such as 'feeling down' can affect pain. An experiment I did found neuropathic pain in people with hip impingement. This pain is caused by a disease of the nerves that provide information about your body. This can be a cause of pain even if your muscles are strong. In both situations, strengthening your muscles may not be the best choice. We need to know more about types of pain in people with hip impingement to give better treatment.

Aim: To look at causes of hip impingement in people before they have physiotherapy treatment, to see if we can find a reason why some people don't get better after strengthening their muscles.

What does the study involve?

I will review the research to see if people with hip impingement may feel for example, sad, anxious or scared of moving their hip, which could be a reason why some people don't get better after doing their strengthening exercises. I will invite 175 adults with hip impingement who have been referred for

routine standard NHS physiotherapy treatment to join this study. They will have 2 research appointments, 45minutes for assessment involving measuring hip movement and collection of baseline information and the second appointment will be 30 minutes at 4 months after starting the Physiotherapy-led rehabilitation to collect further information. The first one before the start of their physiotherapy treatment, the second one will be at 4 months from starting the physiotherapy treatment. At both appointments they will complete special questionnaires designed to explore emotions and causes of pain. I will compare the results of the questionnaires which will give me more information about the causes of pain and how people view their pain. This will give me a better understanding why strengthening exercises may not be the best treatment.

Study Title	Are baseline factors associated with persistent pain in people with Femoral Acetabular Impingement Syndrome after a physiotherapy-led rehabilitation programme?
Internal ref. no. / short title	Can patient characteristics associate with poor outcome in patients with FAIS after physiotherapy treatment?
Study registration	N/A non-interventional study. A study summary will be registered on the HRA Research Summaries once REC approval has been given
Sponsor	University of Oxford Research Governance, Ethics and Assurance Joint Research Office Boundary Brook House Churchill Drive Headington Oxford OX3 7GB
Funder	National Institute of Health Research
Study Design	A multicentred cohort study
Study Participants	• Patients aged between 18 to 55 with a formal diagnosis of Femoral Acetabular Impingement Syndrome with absence of Osteoarthritis (OA). • Diagnosis confirmed from clinical assessment, symptoms and radiographical imaging (MRI and/or X-Ray and/or CT). Imaging is optional as part of usual care pathway. • Undergoing a physiotherapy-led rehabilitation program
Sample Size	175

<table>
<tr><td>Planned Study Period</td><td colspan="3">Total length of study is 24 months (planned from 31st January 2026 to 31st January 2028)
Baseline data at start of physiotherapy-led rehabilitation including PROMS.
Final data collection for PROMS at 4 months after commencing physiotherapy-led rehabilitation.
The physiotherapy-led rehabilitation data collection point from baseline to follow up will be 4 months.
If treatment is required beyond 4 months, no further data will be collected
It is up to the treating physiotherapist to determine the frequency and number of treatments as this study has no influence over the physiotherapists management. The conclusion of this study is at 4 months after commencement of treatment. There are two appointments expected. The first appointment is gathering the baseline measurements at the time of the hip clinic as part of routine care (allowing for up to 1 hour). The second appointment to collect the outcome measure at 4 months if the participant is undergoing treatment where either the physiotherapist or research assistant directs the participant to the QR code to complete the questionnaire, or a paper copy is given to the participant (allowing for up to half an hour). If the participant is no longer under the care of physiotherapy, they will be automatically sent via email or post a copy of the questionnaires. It is estimated that total duration from recruitment to conclusion of the study is 8 months for each participant.</td></tr>
<tr><td>In the Planned Recruitment period</td><td colspan="3">31st January 2026 to 31st January 2028</td></tr>
<tr><td></td><td>Objectives</td><td>Outcome Measures</td><td>Timepoint(s)</td></tr>
<tr><td>Primary</td><td>To compare baseline and post treatment functional outcomes</td><td>International Hip Outcome Score 33 (iHOT33)

Average pain over 4 weeks</td><td>At Baseline

Post treatment</td></tr>
<tr><td>Secondary</td><td>To measure baseline characteristics prior to starting a PLR</td><td>• NPSI Questionnaire
DN4-Interview Questionnaire
• Widespread pain index
• Tampa scale of Kinesiophobia
• Hospital Anxiety and Depression scale (HADS).
• Pain Catastrophising Scale (PCS)
• Average pain over 4 weeks
• Credibility/Expectancy Questionnaire (CEQ
• Treatment Expectation Questionnaire (TEX-Q)</td><td>At Baseline</td></tr>
</table>

		• Hip range of movement	
Intervention(s)	This is a non-interventional study and is purely observational. The treatment is routine, pragmatically applied usual standard of care physiotherapy-led rehabilitation program. The treatment will be based on the clinical assessment and reasoning of the treating physiotherapist. **This study will not affect or influence the PLR.**		
Comparator	No comparator		

3. ABBREVIATIONS

Define all unusual or 'technical' terms related to the project. Maintain alphabetical order for ease of reference.

AE	Adverse event
Alpha angle	Measure of sphericity of the femoral head
BMI	Body mass index
CI	Chief Investigator
CEQ	Credibility/Expectancy questionnaire
CRF	Case Report Form
CT	Computerised Tomography
CTRG	Clinical Trials & Research Governance, University of Oxford
DN4	Douleur Neuopathique 4
FABER	Flexion Abduction External Rotation (Hip impingement test)
FADIR	Flexion Adduction Internal Rotation (Hip impingement test)
FAIS	Femoral acetabular impingement
FAIT	Femora Acetabular Impingement Trial
FASHIoN	Hip arthroscopy versus best conservative care for the treatment of femoroacetabular impingement syndrome (UK FASHIoN): a multicentre randomised controlled trial
FSC	Fibromyalgia survey criteria
GCP	Good Clinical Practice
GP	General Practitioner
HADS	Hospital Anxiety and Depression scale
HRA	Health Research Authority
IASP	International Association of the Study of Pain
ICF	Informed Consent Form
iHOT33	International hip outcome score 33

IMD	Index of multiple Deprivation
Kellgren-Lawrence	Staging system of classification of OA graded from 0: no X-Ray findings to 4: large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends.
MRI/A	Magnetic Resonance Imaging/Arthrogram
NeP	Neuropathic pain
NPSI	Neuropathic Pain Symptom inventory
NHS	National Health Service
NIHR	National Institute of Health Research
OA	Osteoarthritis
PCS	Pain catastrophising scale
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
PLR	Physiotherapy-led rehabilitation e.g. routine physiotherapy treatment
PROMS	Patient reported outcome measure e.g. validated questionnaires and pain scores measuring treatment outcomes
QoL	Quality of Life
QR (code)	Quick Response code
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
REDCap	Secure web-based data collection platform
RES	Research Ethics Service
ROM	Range Of Movement (of a joint measured in degrees)
SAE	Serious adverse event
SOP	Standard Operating Procedure
STROBE	Strengthening the Reporting off Observational Studies in Epidemiology.
TEX-Q	Treatment Expectation Questionnaire
TSK11	Tampa scale on kinesiophobia 11
VAS	Visual analogue scale (0= no pain to 10, worst pain imaginable)
WPI	Widespread pain index

4. BACKGROUND AND RATIONALE

What is the problem being addressed?

Femoral acetabular impingement syndrome (FAIS) is characterised by abnormal morphology of the proximal femur (Cam) and/or the acetabulum (Pincer) resulting in premature contact between the femoral head or neck and the acetabulum during hip flexion and internal rotation. This repeated microtrauma causes progressive joint degeneration, culminating in hip osteoarthritis (OA). It is a common cause of hip pain in young adults, occurring in 10-15% of the population and is associated with impaired quality of life (QoL) [1] and disability[2]. The associated financial burden affects both the individual, the NHS and the wider economy as pain and disability frequently impact on the individual's ability to work. Current recommended first line management of FAIS is physiotherapy-led rehabilitation (PLR), aiming to strengthen the muscles around the hip correcting abnormal movement patterns. Physiotherapy treatment regimens may include a combination of activity modification, education, hip muscles strengthening, joint mobilisation and soft tissue mobilisations [3-5]. If this is unsuccessful, then surgery should be considered to correct abnormal morphology [6]. PLR has been shown to be associated with statistically significant improvements in both pain and function and to be more effective at producing these improvements than intra-articular steroid injection [7]. However, two recently completed, well powered UK multicentre RCTs have compared surgery and PLR directly, rather than only assessing the efficacy of surgery in those who have failed physiotherapy [8, 9]. Both found surgery to be the most effective treatment, and this is also in line with the findings of a recent systematic review analysing the results of 6 RCTs comparing surgery to conservative therapy (1187 patients, 598 in conservative therapy arm and 589 in the arthroscopic arm) [10]. Specifically, in the Femoral Acetabular Impingement Trial (FAIT), Palmer et al. [8] showed that after 8 months follow-up of those participants receiving PLR (n=88) 68% did not achieve a minimal clinically important difference (MCID) in the Hip Outcome Score, (a validated patient reported outcome measure for arthroscopic hip procedures) compared to 49% with surgery (n=100). Whilst in the FASHIoN Trial, Griffin et al.,[9], using the iHOT-33 score (a validated hip quality of life (QoL) questionnaire) found a mean adjusted difference of 6·8 points in favour of hip arthroscopy at 12 months. Importantly, however, PLR is time consuming for the individual but is a low-risk and low-cost treatment whilst surgery is associated with significant risk and markedly higher cost. The FASHIoN Trial [9] (undertaken in 23 centres across the UK) reported adverse events in 73% of the surgery arm and 60% of the physiotherapy arm, where serious adverse events were much more common in the surgery arm (6 vs 1 respectively). The adverse event in the PLR group was not related to treatment. Moreover, a cost utility analysis for the FASHIoN trial calculated the mean incremental cost for FAI surgery ranged from £2047 to £5628 and concluded that this was not cost effective compared to physiotherapy [11]. There is therefore an urgent need to determine which patients are **not** likely to benefit from physiotherapy for FAIS, in order to rationalise allocation of surgery. The pain construct for FAIS is traditionally understood to be nociceptive, arising from the damaged hip joint itself. The International Association of the Study of Pain (IASP) defines nociceptive pain as 'pain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors' (sensory neurons that respond to damaging or potentially damaging stimuli). Current treatment modalities aim to modify these nociceptive pain drivers. However, it is well established that other types of pain exist and the presence of these pain mechanisms in subgroups of patients with FAIS could be a plausible explanation for the limited response to standard treatments. In support of this hypothesis, it is recognised that morphological appearances of the hip do not correlate with pain intensity [12, 13]. Neuropathic pain (NeP) is defined by IASP as 'pain caused by a lesion or disease of the somatosensory system' and there is increasing awareness that a neuropathic component occurs in many conditions traditionally considered nociceptive including OA hip/knee, ankylosing spondylopathies and tendinopathies [14]. NeP is characterised by abnormal pain qualities: burning, tingling or prickling;

mechanical and thermal hyperalgesia and often radiation to other areas. Griffin *et al.,* consensus paper on FAIS [15] highlights the wide variation in clinical characteristics of FAIS pain. The secondary analyses of the FAIT trial undertaken during my NIHR pre-doctoral clinical academic fellowship (Wood *et al)*., [16] showed that 12% of the patients included in this trial had neuropathic pain (NeP) and 19% had mixed-neuropathic component identified by the PainDETECT questionnaire (PDQ). Moreover, those identified as having NeP reported higher levels of anxiety, average pain over 4 week, and poorer hip function. This agrees with findings in a variety of other conditions including Osteoarthritis[17] and endometriosis [18]. Unfortunately, the FAIT trial was not geared towards investigating other pain phenotypes or characteristics and therefore lacked the measures to explore these. Further investigation of other mechanistic causes for pain and characteristics may explain why traditional PLR which focuses on the nociceptive pain driver may have limited effect. If relevant pain phenotypes and patient characteristics can be identified at initial presentation to physiotherapy, then a personalised treatment regime addressing the drivers of pain could be developed, potentially improving the outcome of PLR and reducing referrals for surgery.

Rationale for the study: Primarily this study aims to explore the baseline characteristics in patients prior to starting a routine standard care NHS provided PLR to see if these characteristics affect the treatment outcome after PLR. The aim is to ultimately improve the outcomes of a PLR by providing in the future, a PLR treatment program tailored to the individual patient.

How will this be done: Firstly, we will recruit patients who are aged between 18 and 55 who have a formal diagnosis of FAIS and fulfil the inclusion/exclusion criteria and have been referred to a PLR. We aim to gather psychometric information in the form of validated questionnaires in the form of Patient Reported Outcome Measures (PROMS) to determine the baseline characteristics of patients presenting at the beginning a PLR program and gather further information by measuring hip range of movement for each participant.

We will then collect psychometric information at the conclusion of the PLR program and analyse the data to see if baseline characteristics associate with poor outcome.

This is an observational cohort study with no perceived risk to patients or the physiotherapist. Physiotherapy-led rehabilitation has been proven to be a low-risk treatment, and the intervention will be routine standard of care.

5. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**

Primary Objective To compare baseline with post treatment functional outcomes	**Primary outcome measure** **Quality of life measurement:** international Hip Outcome Score 33 (iHOT33). The iHOT 33 is a validated patient-derived, patient reported Quality of Life outcome measure for non-arthritic hip pain. The iHOT33 consists of four domains: symptoms and functional limitations; sports and recreational, activities; job-related concerns and social, emotional and lifestyle concerns [15] The iHOT33 provides a 100-point score with 100 representing no pain and perfect function, and a lower scores indicating pain and poorer function. The iHOT33 has a minimal clinically important difference of 6.1 points [19] The iHOT33 is a preferred self-reported outcome measures to assess hip-related pain and function in young and middle-aged patients.[15] **Average Pain intensity over 4 weeks** Visual Analogue Scale	**At baseline and at 4 months**
Secondary Objectives To measure baseline characteristics prior to starting a PLR These questionnaires are designed to collect data on pain phenotypes, e.g., neuropathic pain, distribution of pain, fear of movement, emotional components and thoughts and perception of feeling pain	**Secondary outcome measures** Data collected at the start of the PLR and at conclusion of the study) **Pain Phenotyping**: Neuropathic Pain Symptom Inventory (NSPI)[20] Douleur Neuropathique 4 (DN4)[21] Widespread pain index (WPI)[22] **Psychometric measurements**:	**At Baseline (all questionnaires)** A cap of up to 4 months has been chosen for two reasons: Firstly, this reflects routine standard care in a physiotherapy department and secondly there is a

	Tampa scale of Kinesiophobia (TSK-11) [23] • Hospital Anxiety and Depression scale (HADS)[24] • Pain Catastrophising Scale (PCS)[25] • Credibility/Expectancy Questionnaire [26] • Treatment Expectation Questionnaire [27] **Quality of life:** iHOT33 [15] **Average Pain intensity over 4 weeks** Visual Analogue Scale **Hip range of movement**	time limit for this study. At conclusion of PLR **Baseline**+ Conclusion of PLR (up to 4 months) Baseline hip range of movement

6. STUDY DESIGN

Title: Are baseline factors associated with persistent pain in people with Femoral Acetabular Impingement Syndrome after a physiotherapy-led rehabilitation programme?

The study design is shown in Figure 1 (**Appendix A)** which summarises the study.

Patients will be invited to participate in this observational prospective cohort study.

Setting: Participants will be screened from 4 tertiary hospital sites recognised for the management and treatment for FAIS, allowing for a broad range of demographics. The hospital locations were chosen to cover a diverse population ranging from urban to rural locations and offering a broad range of backgrounds and culture according to the ONS Census of Population. Four centres have been selected from existing clinical and research networks and are expected to comprise in principle: Birmingham: Royal Orthopaedic Centre, Leeds: Chapel Allerton Orthopaedic Centre, Oxford: Nuffield Orthopaedic Centre and Exeter: Royal Devon University Hospital. Across hospital involvement will reduce spectrum and selection bias. All participants will be approached prior to attending their PLR with a diagnosis of FAIS at the specialist orthopaedic hip clinics. However, alternative centres are available should the situation change at any of these between application and study onset.

Participants: will be recruited from relevant hip clinics and from the hospital that they are attending data bases They will be approached by a research assistant including a study information pack after identified by a clinician. Participants who have a formal diagnosis of FAIS by an orthopaedic doctor/registrars or physiotherapists will be screened for eligibility.

Consent: Patients with mental capacity who have a proven understanding of the English language will be approached. The consent form, questionnaires and information pack will be accessible on-line via a QR code linked to a free secure web-based data collection platform (REDCap). An information pack including a letter of invitation, Patient Information Sheet explaining the nature of the study and an informed consent form will be included in paper form. If participants would prefer, a printed copy of the questionnaires will be issued, and the results manually inputted.

- **Outcome measures**: Baseline physical hip characteristics will be collected from MRI or Xray findings: Cam size (alpha angle), OA (Kellgren Lawrence staging of OA), and radiological co-morbidities on MRI (e.g., gluteal tendinopathy) Pain Phenotyping • • Douleur Neuropathique 4 [20] Widespread Pain Index (35) Neuropathic Pain Symptom Inventory Psychometric measurements • Tampa scale of Kinesiophobia (TSK-11)(36) • Hospital Anxiety and Depression scale (HADS)(37) • Pain Catastrophising Scale (PCS) (38) Credibility/Expectancy Questionnaire[26] Treatment Expectation Questionnaire [27] Quality of Life • International Hip Outcome Tool (iHOT33). • Visual analogue scale for pain (39), Hip range of movement

Two additional outcome measures in the form of questionnaires (CEQ and TEX-Q) have been included based on feedback from the **PPIE group**. For participants unable to access the QR code, a paper copy of the questionnaires will be provided with a self-addressed stamped envelope.

Data collection: Baseline data will be collected and include patients mobile number, postal code, landline number and email address, cross checked with the patient to confirm correct contact details. Participants demographics: age, sex, ethnicity, weight, height, BMI, duration of symptoms, smoking history, laterality of the hip pain, level of education, marital and social status, work status, medication, patient expectations of PLR, hospital location and comorbidity data. Alpha angles calculated by consultant radiologists and other features from the MRI e.g. gluteal tendinopathy (to document potential confounders) and other characteristics identified from the systematic review. The results of the patient reported questionnaires will be collated and anonymised and recorded electronically.

Sample size calculations: I have based the sample size calculations on the primary purposes of the data analyses exploring the strength of the relationships between variables. I plan for 9 variables identified from the questionnaires and ongoing systematic review where the number of participants required per variable for a multivariable linear regression model is 10-15. Allowing for 15 participants per variable and a 30% attrition rate lost to follow up, an *a priori* power analysis indicated that a minimum sample size of 175 patients would provide 80% statistical power with an alpha set at 0.05 based on the primary purposes of the data analyses. Power calculations will be crossed checked with a statistician.

Statistical analyses:

I will undertake descriptive analysis of the data and will document counts, means, standard deviations or medians and interquartile ranges where appropriate. A Multiple Regression analyses will be performed

exploring the association of the baseline variables and Correlational statistics will be used to explore the relationships between the variables.

Data management: All data will be recorded on REDCap which is a secure web-based data collection platform. Clinical data will be stored separately from patient identifying data. All data will be password and firewall protected. All paper records will be kept in a secured locked room in locked filing cabinets used to store patient data at the Physiotherapy Research Unit (Nuffield Orthopaedic Centre).

Participants will be issued appropriate questionnaires **after 4 months from commencement of their PLR program**. This will be done via either paper copy of the questionnaires or via a QR code that is linked to REDcap secured database or emailed automatically by REDcap.

Aim and objective. **To identify whether pain phenotypes, psychological, social and demographics associate with poor outcomes after a PLR programme as defined by ongoing pain and/or hip stiffness and limited range of hip movement.**

The questionnaires along with patient characteristics identified from the systematic review will be collected to determine if there is an association between the variables and poor outcome.

Recruitment and retention strategy. Clinical staff will be notified of the study via presentations in governance meetings, posters in clinic rooms and waiting areas and emails and a clear effective line of communication will be available for clinical staff to contact me. The posters are aimed to recruit the patients but will remind clinicians of the study. Regular visits are planned for the 4 sites to ensure a close working relationship with clinical staff and to monitor the recruitment process is on target and address any issues. Ongoing communication with the Patient and Public Involvement Engagement group to discuss strategies they identify which could be implemented to assist in recruitment and retention. Furthermore, strategies will be used for recruitment and retention using methods identified [28] by including:

- Information on nature of the study, participants requirements detailing potential benefits and follow up.
- Create project identity and logo on all study correspondence.
- Contact and scheduling methods.
- Non-financial incentives including a letter of appreciation.
- Providing reminders to complete the questionnaires and self-stamped addressed envelopes for return of post.
- Obtaining multiple contacts for each participant

Data collection time points from baseline to 4 months): Prior to starting PLR, the research assistant will measure hip range of movement (flexion, extension, abduction, adduction, internal rotation and external rotation, and two impingement tests (FADIRS/FABERS). The participant will be given the study Questionnaires: iHOT33 (Health related QoL) and Visual Analogue Scale (VAS) for pain intensity, TSK, WPI, HADS, PCS, DN4, NPSI, CEQ and TEX-Q.

At 4 months after commencement of treatment the participant will be given the iHOT33 questionnaire and pain intensity score (VAS). No other measurements will be taken.

A standard routine physiotherapy-led rehabilitation and follow up (PLR) provides routine care that is provided in an NHS setting. A personalised hip therapy programme including (i) an individualised and progressive exercise program, (ii) education and its management, and (iii) advice regarding pain relief and avoiding positions of discomfort and activity are key features to the intervention, individualisation, progression and supervision. A treatment log will be kept documenting clinical treatment type, progression and exercise prescription with sets and repetitions. Fidelity will be checked by randomly selecting 10 sets of Physiotherapy notes to ensure routine standard care physiotherapy as detailed above is adhered to. Four months will mark the duration of the study from commencement of PLR to follow up irrespective whether the participant is still undergoing PLR. At the beginning of PLR the patient's pain, function and hip range of movement will be documented.

At 4 months, the physiotherapist will direct the patient to the QR code (or a paper copy if required) to complete the questionnaires if still undergoing PLR or REDcap will automatically email the questionnaires if the participant has finished their PLR. Working closely with the PPIE group will ascertain preferred methods of filling out the questionnaires whether electronically or paper format and to advise on retention strategies. It is planned that non responders will be contacted via a follow-up telephone call and letter and email if data is still missing but this will be reviewed on feedback from the PPIE group. After three attempts contacting the participant, no further attempt will be used to contact the participant. Paper copies of the questionnaire will be posted with a self-addressed stamped envelope if requested by the participant.

Flowchart of the participant through the study and for the project are in Figure 2 (**Appendix B)**

7. PARTICIPANT IDENTIFICATION

7.1. Study Participants

Adult male or female participants with a formal diagnosis of FAIS who meet the inclusion criteria.

7.2. Inclusion Criteria

Inclusion criteria include:

- Participants aged between 18 and 55 years
- Diagnosis of symptomatic FAIS following a formal clinical assessment
- Appropriate imaging: MRI/Arthrogram, and /or Xray and/or CT (secondary care pathway for diagnosis but this is optional).
- Awaiting PLR
- No previous surgery to the index hip
- Have capacity to give informed consent
- English as a spoken language

7.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Presence of hip dysplasia, femoral stress fracture, synovitis or other inflammatory arthropathy (psoriatic arthropathy)
- Kellgren-Lawrence grading of Osteoarthritis ≥2 (to exclude moderate OA which could be a confounding influence on pain)
- Avascular necrosis of the femoral head
- Previous surgery to index hip
- Previous physiotherapy treatment to the index hip in the past 6 months
- Current pregnancy
- Perthes disease
- Involved in a current research study involving the hip

8. PROTOCOL PROCEDURES

8.1. Recruitment

Four centres have been selected from existing clinical and research networks and are expected to comprise in principle: Birmingham: Royal Orthopaedic Centre, Leeds: Chapel Allerton Orthopaedic Centre, Oxford: Nuffield Orthopaedic Centre and Exeter: Royal Devon University Hospital. The hospital locations were chosen to cover a diverse population ranging from urban to rural locations and offering a broad range of backgrounds and culture according to the ONS Census of Population. These centres have been identified as tertiary referral centres for management of hip conditions.

Patients will be identified when attending hip clinics at their participating hospital. Following a clinical assessment by the clinician (Consultants, Registrars in Orthopaedics or Sports and Exercise Medicine or advanced practitioner physiotherapist working in the hip clinic) and appropriate imaging/referral for imaging and formal diagnosis of FAIS, patients will be introduced to the study by the assessing clinician. The initial sites for this study are the 4 sites mentioned above. The Orthopaedic and Sports and Exercise Medicine team will be informed of the study by formal meetings and posters in clinic rooms to remind them of the study and to identify potential participants.

If the patient expresses an interest in the study, they will be introduced to a research assistant. The research assistant will provide an information pack with a QR code to scan which will provide more details of the study. A paper information pack will be given upon request. If the patient agrees to register for the study and participate, then the research assistant will use a clinic room and collect baseline data and consent the patient to the study. Clinicians will not be asked to obtain consent due to the nature of the busy clinics.

8.2. Screening and Eligibility Assessment

Screening for participants will principally take place in the hip clinics. These clinics are undertaken by orthopaedic consultants and registrars or advanced physiotherapy practitioners. Typically, these patients will have been referred via their GP if previous conservative treatment has been ineffective. The participant will, upon agreeing to participate in the study, be screened by a research assistant using a

checklist for the inclusion and exclusion criteria. If the criteria for inclusion into the study is met, and the exclusion criteria cleared, the research assistant will gain written consent and collect patient demographics including age, gender at birth, height, weight, BMI calculation, smoker, employment status, postcode, duration of hip pain and educational status. The participant information pack has a QR code, which will direct the participant to the PROMS and provide further information on the study. The patients will also be screened to determine if they have had appropriate imaging in respect of MRI and/or Xray/and or CT as part of their pathway of care.

This study **does not** include a referral for imaging as a part of the inclusion criteria. It is presumed that imaging will form part of a routine clinical pathway whilst attending a specialist hip clinic. However, in the unlikely event of seeing any concerning structural abnormalities on a scan, the scan will be checked by a clinical specialist i.e., a radiologist. If the specialist feels that the abnormality was medically important, they will contact the referring doctor to discuss the implications. This can then be discussed with the participant and arrange for further investigations as necessary. Patient will not be informed unless the doctor considers the finding has clear implications for their current or future health. The participant may be withdrawn from the study pending a diagnosis from imaging that fulfils the exclusion criteria for e.g. if the imaging confirms a diagnosis that meets the exclusion criteria e.g. femoral stress fracture.

If a member of the research team is unavailable in the hip clinics to speak to potential participants, the clinical care team will obtain verbal consent and document this in the patients' medical notes for the patient to be contacted by the study team by telephone and send an information pack if requested. They will be contacted by telephone by the study team within the following week to discuss the recruitment process.

A physical examination carried out by the research assistant as part of the study on the day of recruitment will measure passive hip range of movement for the index and asymptomatic hip: flexion, abduction, internal/external rotation, extension and adduction with range and pain response documented. Two tests for hip impingement will be performed: Flexion, adduction internal rotation (FADIRS) and Flexion, abduction external rotation (FABERS) which are two tests that are specific to FAIS. Pain and restriction in these tests will be documented.

The estimated time for screening, obtaining consent, including physical examination and collection of baseline PROMS will be between 45 minutes to 1 hour. The consent form (e-Consent), and PROMS can be obtained and completed at the participants convenience via the QR code (or paper copy) if they are unable to stay for the duration of the screening process. However, the consent process and completion of the PROMS will be encouraged to be completed on the day of recruitment to reduce recall bias.

If participants agree to complete the questionnaires electronically, we will use the e-consent framework established on REDCap. By using the QR code the participants will be taken to the participant information sheet and the consent form which will be completed including initials, name, data and e-signature as on the paper version but without the researcher's signature. Only if the participant has completed and signed the e-consent will they be taken to the electronic questionnaires. The e-consent will be stored in REDCap as per routine practice but will not be exported with other data. Participants will receive an electronic copy of their consent.

8.3. Informed Consent

The participant must personally sign and date the latest approved version of the Informed Consent form either in an electronic form or written hard copy (if requested by the participant) before any study specific procedures are performed.

Written, verbal or electronic versions of the Participant Information Sheet and Informed Consent will be presented to the patient, detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The patient will be allowed as much time as required to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent in the form of paper consent will then be obtained by means of participant-dated signature and dated signature of the person (research assistant**)** who presented and obtained the Informed Consent. If the participant is unable to stay for the duration of the assessment, then an e-consent can be obtained but if the participant would prefer consent may be obtained via phone call. The research assistant will be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site. E-consent forms will be stored electronically in the patients notes. Clinicians will not be asked to obtain consent.

8.4. Enrolment

No randomisation is required for study. Enrolment will be registered electronically via REDCap which is a secure web application for building and managing online surveys and databases. Consent will be gained either by electronic means via a QR code or by paper format. Enrolment will be obtained by a research assistant with paper copies kept on-site in a secured room and electronic copies kept securely on-line via REDCap.

8.5. Blinding and code-breaking

This study does not require the participant or research assistant to be blinded

8.6. Description of study intervention(s), comparators and study procedures (clinical)

The participants will be referred to a PLR as part of the 'routine standard care' pathway following the diagnosis of FAIS and is not part of the study. This study is purely observational and no treatment intervention or comparators. A treatment log will be kept documenting treatment type, progression and exercise prescription with sets and repetitions. Fidelity will be checked by randomly selecting 10 sets of Physiotherapy notes to ensure routine standard care physiotherapy as detailed above is adhered to.

There is no comparator in this study design.

8.6.1. Description of study procedure(s)

Physical examination:

At the recruitment and screening process the research assistant will collect baseline demographics and will do a physical examination measuring the following movements via a goniometer:

Passive hip range of movement in all planes in supine: flexion, abduction and adduction and hip internal and external rotation in supine with the hip at 90 degrees flexion. Hip extension will be measured in prone lying.

Two hip impingement tests will be performed in supine: FABERS and FADIRS which are validated tests for FAIS. The pain response will be documented.

These measurements are planned to be completed after attending the hip clinic on the same day.

Questionnaires:

We will use a battery of validated questionnaires to evaluate patient's characteristics. These questionnaires are commonly used in research.

Quality of life questionnaire:

- International Hip Outcome Score33 (iHOT33): this is a validated hip quality of life questionnaire for FAIS. The iHOT33 provides a 100-point score with 100 representing no pain and perfect function, and a lower scores indicating pain and poorer function. The iHOT33 has a minimal clinically important difference of 6.1 points

Pain Phenotyping:

- Neuropathic Pain Symptom Inventory (NPSI) is a self-administered validated screening tool designed to assess diverse symptoms of neuropathic pain. The NPSI has 5 clinical domains assessing superficial spontaneous pain, Deep spontaneous pain, Paroxysmal pain, Evoked Pain and Dysethesia/Parasthesia. Douleur Neuropathique 4 [21] is a validated questionnaire which can differentiate between neuropathic and non-neuropathic pain, which is self-administered, quick and easy to complete. It contains 7 questions with a cut off of ≥3 for assessing neuropathic pain.
- Hospital Anxiety and Depression scale (HADS): This is used as a screening tool in non-psychiatric hospital clinics. The HADS is used for multiple chronic pain conditions and has good concurrent validity and reliability. There are 7 items relating to anxiety and 7 items relating to depression with each item scored on a 4-point Likert scale from 0 to 3 with a maximum score for depression and anxiety of 21 respectively [24].
- Widespread pain index (WPI). The WPI is a questionnaire that fulfils three conditions, Widespread Pain Index, Symptom Severity Score where symptoms have been present for more than 3 months, and lastly, the patient does not have another disorder that may explain ongoing chronic pain. This measure constitutes the Fibromyalgianess Scale and can be applied to every disease [22].

Psychometric measurements:

- Pain Catastrophising Scale (PCS): is a validated questionnaire that measures how an individual experiences pain and includes three subsections: Ruminating, magnification and helplessness. The PCS was therefore developed to quantify the individuals pain experience. It is a valid and reliable tool with adequate to excellent internal consistency with a coefficient alpha of 0.87 to 0.93[25]

- Tampa Scale of Kinesiophobia (TSK11): is a commonly used self-reported questionnaire that quantifies the fear of movement or re-injury. The TSK shows a high level of internal consistency and demonstrated moderate construct validity. The concurrent validity is moderate ranging from *r =0.33 to 0.59* [29]
- **Credibility/Expectancy Questionnaire (CEQ):** A validated questionnaire which is a quick and easy-to-administer that measures patient expectations for improvement. The CEQ measures two constructs; cognitively based credibility and affectively based expectancy. The CEQ measures how a patient 'thinks' treatment will help and what they 'feel' the treatment will help.

Treatment Expectation Questionnaire (TEX-Q): A validated multidimensional questionnaire which assess patients' treatment expectations measuring the impact of different expectations across conditions and treatments which investigates the relative impact and predictive role of expectations for treatment outcomes.

Pain intensity measurement:

- **Visual Analogue Scale (VAS):** Is a unidimensional measure of pain intensity and is a widely used outcome for pain in the adult population for conditions such as chronic pain, rheumatic diseases etc. It is measured on a 100 mm line with an anchor point at 0 mm for 'no pain' and 100 mm representing severe pain. The participant is asked to mark on the 100 mm line their current pain intensity. The pain score is calculated using a ruler to measure along the 100 mm line where the mark on the scale lies.

Evaluation of Imaging data

This study will include results from imaging as part of the participants routine standard care (if available), but imaging **will not be ordered as part of the inclusion criteria**. It is presumed that any participant attending a secondary care hip clinic for an orthopaedic consultation will fulfil a criterion for further investigations in the context of X-ray, MRI/A or CT.

8.7. Baseline Assessments

Specified in 8.6.1

8.8. Subsequent Visits

The participants may have completed their PLR or may still be undergoing treatment. The follow up period is 4 months after starting the PLR irrespective of whether the participant is still undergoing PLR or not. This is part of usual care and not related to this study.

It is planned that the Research assistants will follow the patient up after 4 months from commencement of PLR and collect the PROMS whilst in the physiotherapy department. If a research assistant is not available, then the physiotherapist can direct the participant to the QR code with a link to the questionnaires. Furthermore, REDcap can automatically email the two questionnaires if the participant is not present in the hospital. If the participant has finished their PLR prior to 4 months, then REDcap will automatically email the PROMs to the participant. If the participant is still undergoing PLR, then tthe PROMS will be collected either by either QR code or the participant will be given a paper copy of the PROMS. However, if this is not possible then the research assistant will contact the participant via telephone and collect the PROMS or by post or electronically via email if requested. Reminders to participants will be sent to attempt to gather the PROMS in a timely fashion to reduce the risk of recall bias and prevent non-responder and lost-to-follow-up bias.

Clinical measurements will be taken from the individual treating physiotherapist notes at the final treatment session in the format of hip range of movement and impingement test. In the event of missing data from the questionnaires, the participant will be contacted by the research assistant. Missing information from the questionnaire can be gathered from a telephone consultation.

Treatment compliance will be gathered from the physiotherapist's notes, noting how many missed appointments (did not attend, DNA, or unable to attend, UTA) and the number of visits and compliance of the rehabilitation program.

It is planned that the participant will attend as part of their usual care two hospital visits. The first visit will be in the hip clinic where baseline measures will be taken. The second visit at 4 months will collect information from the two questionnaires. If the participant is no longer under the care of the physiotherapist, then REDcap will automatically send out the questionnaires. **The visits to hospital will be part of the usual care for the participant i.e. attending their hip clinic appointment and their PLR appointment.**

8.9. Sample Handling

No samples will be obtained from the participants.

8.10. Early Discontinuation/Withdrawal of Participants

During the course of the study a participant may choose to withdraw early from the study at any time. This may happen for several reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse event (AE)
- Inability to comply with study procedures

Participant decision:

- Participants may choose to stop the clinical treatment and/or study assessments but may remain on study follow-up.
- Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. In the case of withdrawal from both clinical treatment and active follow up the following options for a tiered withdrawal from the study will be made implicit at the consent stage and be covered in the patient information sheet.
- According to the design of the study, participants may have the following three options for withdrawal.

i. Participants may withdraw from active follow-up and further communication but allow the study team to continue to access their medical records and any relevant hospital data that is recorded as part of routine standard of care, i.e., Imaging, disease progression data etc.

ii. Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

iii. Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis. (Any limits to this type of withdrawal where, for example analysis of their data or samples has already been integrated into interim results, should be explained in the participant information sheet).

In addition, the Investigator may discontinue a participant from the study treatment at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Pregnancy
- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Clinical decision

Participants that did not attend (DNA) their treatment will be contacted to determine the reason i.e., a change in social circumstances, forgetting to attend the appointment or treatment has resolved the hip pain or worsened the symptoms. Participants will be contacted via telephone or by letter as appropriate. If symptoms are worse because of the PLR, then an opportunity for the patient to come back to the hip clinic will be offered or further contact from the PI or treating physiotherapist until the adverse event has resolved. In the event that a change of social circumstances or purely forgetting the appointment was a reason for the DNA, then a further appointment will be offered.

If the participant withdraws from the study, then clarification with the participant will be obtained whether the existing data can be used for analyses or not.

If the participant consents for the information to be used, then the data will be included as an intention-to-treat analyses. Further analyses using per protocol analyses will also be performed as a sensitivity analysis to determine the effect of missing data.

If the participant does not permit existing data to be used for analyses, then this will be deleted from the data base.

Owing to time restrictions to this DPhil, it may not be possible to further recruit to replace the participant, but this will be closely monitored.

The type of withdrawal and reason for withdrawal will be recorded in the CRF.

8.11. Definition of End of Study

The end point for this study concludes after the last recruited participant has had their last visit with the physiotherapist and their PROMS collected on achieving the target of 175 participants. However, this study will also conclude after 26 months of recruiting if the target of 175 participants fails to be reached, whichever comes first, and all queries have been resolved.

9. SAFETY REPORTING

There are no expected serious adverse events expected from completing the questionnaires or measuring hip range of movement which is a standard routine component of a physiotherapy assessment. Therefore, we will not be reporting on associated adverse events.

Adverse Event Definitions

9.1. Definition of Serious Adverse Events

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect.

Other ‘important medical events’ may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Reporting Procedures for Serious Adverse Events

A serious adverse event (SAE) occurring to a participant will be reported to the REC that gave a favourable opinion of the study where in the opinion of the CI the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to that procedure. Reports of related and unexpected SAEs will be submitted within 15 working days of the CI becoming aware of the event, using the HRA report of serious adverse events form (see HRA website).

10. STATISTICS AND ANALYSIS

We will summarise the flow of participants for this study using the STROBE checklist.

Data analyses: We will use descriptive statistics including frequencies and percentages for discrete variables; and mean, standard deviation, and range for normally distributed continuous variables. Data will be checked for normality as describe below. Bivariate analysis involving unpaired Student's t-test or analysis of variance for comparing continuous and discrete variables and Pearson correlation for continuous variables will be used. Data will be tested for multicollinearity and after adjusting for multicollinearity each independent variable will be entered into a multivariate regression analysis. The Index of Multiple Deprivation 2015 (IMD) will be used to form a relative rank for social deprivation

10.1. Statistical Analysis Plan (SAP)

The statistical aspects of the study are summarised here with details fully described in a statistical analysis plan that will be available from the time that the first participant is recruited. The SAP will be finalised before any analysis takes place.

- **Data Description**

Demographic data will be collected by a research assistant after consent obtained.

- **Baseline characteristics**:

Sex, Age, Height, Weight, BMI, Hip laterality, work status, postcode, type, educational status, back pain, hip symptom duration, pain intensity, GP visits

- **Objective measurements**:

Pre and post treatment passive hip range of movement and questionnaires.

  - **Patient reported outcome measures:** International hip outcome tool 33 (iHOT33).

This is a patient self-reported questionnaire measuring 4 domains of function: Symptoms and functional limitations, sports and recreational activities, job related concerns and social, emotional and lifestyle concerns. The iHOT33 uses a Visual Analogue Scale for each question in each domain. The scale is 0mm for 'Extremely Difficult' to 100mm representing 'Not difficult at all'. The iHOT33 is calculated as a mean of all VAS scores. The meaningful clinical important difference is the iHOT33 is 6.0 [19] A total score of 100 is no pain and full range of movement and no functional limitation, thus the higher the score, the better the hip function.

- Average pain over 4 weeks.

This is measured from the data collection sheet. This outcome is a unidimensional patient reported numerical pain rating scale. The respondent selects a whole number (integers 0–10) that best reflects the intensity of pain, The anchors are 0 = no pain and 10 = maximum pain. Average pain over 4 weeks is used because this acknowledges the fluctuations of pain intensity over time. The MCID for the numerical pain rating scale is a 2-point change. (Ostelo & de Vet 2005)

Definition of poor outcome: Patients not reaching an MCID of 6 points on the iHOT33 or MCID of 2 points on Average pain over 4 weeks.

- **Variable category**

Variable	**Category**
Sex	Nominal
Employment status	Nominal
Educational status	Nominal
Hip Laterality	Nominal
Back pain	Nominal
Postcode	Nominal
Back pain duration (years)	Continuous
Hip pain duration	Continuous
Age (years)	Continuous
Height (cm)	Continuous
Weight (kg)	Continuous
BMI (kg/m^2)	Continuous
Hip range of movement (degrees) at Baseline	Continuous
iHOT33	Continuous

Average pain over 4 weeks (VAS)	Continuous
Questionnaires: TSK, HADS, PDQ, WPI, PCS, CEQ, TEX-Q	Continuous

- **Statistical Methods**

Continuous measurements will be described using by the means and standard deviations (or median and interquartile range, as appropriate). Nominal and ordinal data will be described as counts and percentages.

Statistical analysis

Objective	**Parametric test**
Quantify the correlation baseline data with the outcome	Pearson correlation
Explore the unadjusted association of baseline factors on the outcome	Linear regression
Explore the adjusted association of baseline factors on the outcome	Multiple (linear) regression
Predictor	Independent t-test
Comparing nominal data with iHOT33	Independent t-test One-way ANOVA

Results will be reported with 95% confidence intervals, and statistical testing performed at the significance level of 0.05.

- **Data Management**

The FAIT database is stored on two password electronic devices. The first device is on the hard drive of a password NDORMS Dell computer, and the second device is a password protected memory stick.

Data cleaning of the FAIT database will be completed and formatted Excel version 2503.

STATA version 19.5 will be used to analyse the data with graphical representation and tables where appropriate.

10.2. Description of the Statistical Methods

Statistical analyses:

All data sets will be tested for normality using the K-S test and Shapiro-Wilks test and the Q-Q plot will be visually inspected for distribution. This will inform the decision to use non/parametric statistical tests. I

will undertake descriptive analysis of the data and will document counts, means, standard deviations or medians and interquartile ranges where appropriate. An alpha value of 0.05 will be used for hypothesis testing and statistical significance with 95% confidence intervals documented. A Multiple Regression analyses will be performed exploring the association of the baseline variables and Correlational statistics will be used to explore the relationships between the variables.

10.3. Sample Size Determination

I have based the sample size calculations on the primary purposes of the data analyses exploring the strength of the relationships between variables. We are planning 9 variables identified from questionnaires where the number of participants required per variable for a multivariable linear regression model is 10-15. Allowing for 15 participants per variable and a 30% attrition rate lost to follow up, an a priori power analysis indicated that a minimum sample size of 175 patients would provide 80% statistical power with an alpha set at 0.05 based on the primary purposes of the data analyses.

10.4. Analysis populations

All eligible participants that enrolled and registered into the study at baseline who underwent a PLR will be included in the study. Participants who fail to complete the PLR program will be included into the statistical analyses using intention-to-treat to account for missing data. Furthermore, it is anticipated a *per-protocol* analysis will be performed to evaluate all participants that received and completed the PLR.

10.5. Decision points

An interim analysis will be scheduled once all baseline data has been collected. These analyses will form part of the cross-sectional study and provide a description of the population. The final analyses will be completed at the conclusion of the study once either the last patient has completed their PLR, or the duration of the study has been reached, and all follow up PROMS have been collected. The reporting of the results will follow the STROBE statement and checklist.

The data sets will be available to the supervisory team, myself and the supervisory team: Professors Karen Barker, Steve Gwilym, Sion Glyn Jones, Gary Collins and Katja Weich. Furthermore, the research assistants will have access to the data base to allow for data entry. Decisions based on the results of the study will be discussed within the supervisory team and agreed by consensus.

10.6. Stopping rules

Participant recruitment will be closely monitored. If recruitment levels fall behind expected predicted numbers, then the recruitment strategy will be reviewed. This study will be registered with the Research Delivery Network to facilitate further recruitment centres if the recruitment levels fall behind target. Other sites for recruitment may become available to provide extra opportunities for recruitment.

However, if after consideration, that the study demonstrates futility or lack of power then the supervisory group will meet to discuss the future of the study, and a decision will be made.

Futility: It is expected that treatment efficacy will not be an issue because standard routine PLR has been shown to be effective.

10.7. The Level of Statistical Significance

An alpha *P* value level of significance is set at 0.05

10.8. Procedure for Accounting for Missing, Unused, and Spurious Data.

We will perform a complete case analysis of observed data. Given the overall size of the study and the anticipated level of data expected to be available, no imputation of data is planned.

10.9. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

No secondary analyses are planned

10.10. Health Economics Analysis

Not applicable

11. DATA MANAGEMENT

The plan for the data management of the study is outlined below. There is not a separate Data Management document in use for the study.

Description of data
Type of study A prospective cohort study identifying baseline characteristics that are associated with a poor outcome after a physiotherapy -led rehabilitation programme with patients with femoral acetabular impingement. There are 2 types of categorical data to be collected: Continuous: • Baseline demographics and PROMS: Age, Height, weight, BMI, hip passive range of movement, hip pain duration, average pain over 4 weeks, iHOT33, TSK11, pain VAS, NPSI, DN4, FM widespread pain index, HADS, PCS, CEQ and TEX-Q Nominal: • Gender, work status, work type, hip laterality, postcode, level of education Imaging data (if available) • MRI scans

Data collection/generation
Baseline demographics and data generated by questionnaires will be stored on REDcap. REDcap is a secure online data capture system designed and developed for clinical research and hosted by the University of Oxford servers. Data on REDcap will be exported onto non-propriety structured formats. Study data in paper form will be stored on the participating NHS hospital sites in locked cabinets in a secure area accessed by the research team only. All data generated will meet the FAIR Guiding Principles for scientific data management and stewardship. SITU will support methodology and conduct of the study. **Data quality and standards.** Questionnaire data and consent forms will be collected on each patient and will be stored in REDCap allowing data capture to be standardized using a prepared database or log files.
Managing, storing and curations
The electronic data will be stored in line with the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) information security policy. Data will be stored at the University of Oxford on secure fileservers managed by Medical Sciences Division (MSD) IT Services, following the MSD IT Services security policy, which is compliant with the University's Information Security Policy. MSD IT virtual servers are imaged daily, allowing for fast recovery to ensure disaster recovery and long-term storage. Data will be organised and integrated in formats that allow future retrieval and usage. Data curating will be managed by the principal investigator, following the FAIR Guiding Principles for scientific data management and stewardship. **Data preservation strategy and standards.** All data will be retained for the lifetime of the project as specified above and for three years following completion to allow any questions regarding publications to be answered.
Data Sharing and access
Suitability for sharing The data collected during this study is suitable for sharing in aggregated, de-identified form immediately after the research article publication. Strictly no data will be shared that could identify participants. **Discovery by potential users of the research data** Potential users can find out about the data from publications in journals, conference presentations. **Governance of access** The project will adhere to the NDORMS Information Security Policy which defines general rules for the securing access of data. The PI will be responsible for decisions on whether to supply non-identifiable research data to potential new users **The study team's exclusive use of the data** We expect to adopt the policy that the research team should have exclusive use of the data until the data is published. Aggregate, de-identified data may be shared with named collaborators during this time. **Restrictions or delays to sharing, with planned actions to limit such restrictions**

There will be restrictions to data sharing due to participant confidentiality. We will be able to share anonymised data. **Regulation of responsibilities of users** Where we engage with any collaborators, and where appropriate, we reserve the right to share the data and analysis under Non-Disclosure Agreement. Access to study data by external users will be bound by a data-sharing agreement, which will address handling of intellectual property, publication, authorship and acknowledgement.
Responsibilities
The CI will take overall responsibility for data management, documentation, curation, metadata creation, and quality assurance of data. The Medical Sciences Division IT and NDORMS IT Support teams will take responsibility for data security, storage, back-up and access. Information security advice will be provided by NDORMS Information Governance Manager.

Relevant institutional, departmental or study policies on data sharing and data security	
Data Management Policy and Procedures	http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-data-supporting-research-outputs/
Data Security Policy	https://www.infosec.ox.ac.uk/guidance-policy https://www.ndorms.ox.ac.uk/information-security-policy
Data Sharing Policy	https://researchdata.ox.ac.uk/home/sharing-your-data/
Institutional Information Policy	http://www.admin.ox.ac.uk/dataprotection/policy/

11.1. Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). A QR code will be used to gather PROMS and electronically downloaded to REDCap as additional source data. All CRF documents will be stored safely in confidential conditions and the electronic source data will be secured on the REDCap secure database. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

11.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

11.3. Data Recording and Record Keeping

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Data collection and entry: All study data will be anonymised as soon as possible and will be entered directly into a secure REDCap database by the participant or a member of the study team during data collection. Participant identifiable data will be stored securely in accordance with SITU Standard Operating Procedures (SOPs).

All trial data will be entered on paper CRFs and REDCap which is a secure web application that employs encryption-at-rest on mobile devices to protect the data from unauthorised access.

The participants will be identified by a unique trial specific number and/or code in both the CRF and on the REDCap database. The name and any other identifying detail will NOT be included in any trial data electronic file, with the exception of the electronic consent forms.

Paper CRF will be held in a secure environment and stored in locked filing cabinet or equivalent or in an office which is locked or attended only by authorised staff at each participating centre. If documents including paper consent forms are taken off-site this will be for shortest time possible, and with authorisation from the line manager. The documents will be kept securely in a document holder and not left unattended.

No identifiable, personal data will be retained centrally (i.e. by the sponsoring organisation), but rather this will be held at individual sites **only**.

After the conclusion of the study, all data will be kept for 5 years and stored on University of Oxford secured servers and firewall and password secured computers. In compliance with the University of Oxford Data Protection Checklist, with consideration to: Transparency, Data minimisation and Security. It is not planned for the data to be shared with other organisations outside the scope of this study but if required to do so, written legal agreements will be obtained. Further information can be obtained from the Information Governance Policies below.

Information Governance Policy:
https://researchsupport.admin.ox.ac.uk/policy/data/practical
https://researchsupport.admin.ox.ac.uk/policy/data/checklist
Information Governance and confidentiality - Oxford University Hospitals
Information%20Governance%20Policy/Information%20Governance%20Policy%20v9.2%20FULL.pdf
Privacy Notice: https://www.ouh.nhs.uk/privacy/default.aspx

12. QUALITY ASSURANCE PROCEDURES

Fidelity of the PLR is planned, and 10 randomly selected physiotherapy notes will be inspected to ascertain if the PLR is appropriate, progressive and all data points are being recorded.

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

12.1. Risk assessment

A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

12.2. Study monitoring

This is a low-risk study and regular monitoring by the research team will be performed according to the study specific Monitoring Plan. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents as these are defined in the study specific Monitoring Plan. Following written standard operating procedures, the monitors will verify that the clinical study is conducted, and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

MRI results will be accessed at part of the routine care pathway after a radiologist has formally reported the results. This study does not involve referring for imaging therefor the ownership of the results of the MRI lay with the referring clinician and radiologist.

12.3. Study Committees

Management committee: This study is small, logistically simple and low risk therefore the DPhil supervisory team will manage and oversee the study with regular meetings with ad hoc meeting as required. The meetings will discuss issues of recruitment, participant retention, effective and accurate data gathering and fidelity of the study. Furthermore, we will involve a member of the PPIE group to advise on matters arising and to ensure that information to participants is appropriate and accurate.

Th frequency of meeting will be planned for every three monthly or more frequently if required. The composition of the meetings will include Professors Barker, Gwilym, Glyn Jones, Collins and Weich with Professor Barker as chair.

13. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file. SITU SOPs will be followed for the procedure of identifying non-compliances, escalation to the central team and assessment of whether a non-compliance/deviation may be a potential serious breach

14. SERIOUS BREACHES

A “serious breach” is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

15. ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Declaration of Helsinki (2024)

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

15.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice. All investigators and research assistants will be up to date with their GCP training.

15.3. Approvals

Following Sponsor approval, the protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

15.4. Other Ethical Considerations

This study will only include participants who are able to understand verbal and written instructions in English and have capacity to fulfil the treatment regime. Participants are expected to follow written instructions provided by a physiotherapist for the progression of their rehabilitation independently and at home which forms part of the treatment regime. The nature of the questionnaires are designed to collect information about pain perception and effects of pain on activities of daily living. If there are questions that the participant finds upsetting, then they can leave the questions blank and are under no obligation to answer all questions. For some questions there are options to choose ‘not applicable’.

This study does not involve ordering imaging. If structural anomalies or pathologies are detected that are clinically significant, then the referring clinician is responsible for feeding back the results to the participant, and the appropriate medical management required, if appropriate.

15.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the host organisation and funder (where required). In addition, an End of Study notification and final report will be submitted to the REC Committee, HRA, host organisation, Sponsor and funder (where required).

15.6. Transparency in Research

This study will be registered with the HRA and a summary of the study will be published in the HRA Research summaries

15.7. Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s), with the exception of consent forms where the full name will be included and where participant initials may be added. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

15.8. Expenses and Benefits

It is planned that baseline and follow up data will be obtained during hospital visits as part of routine care. There will be no reimbursement for participants as it is planned that data will be gathered during the routine hospital visits.

16. FINANCE AND INSURANCE

16.1. Funding

The study will be funded through an NIHR grant (HFT000240) as costed on the SoECAT

16.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

16.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

17. PUBLICATION POLICY

The results of the study will be disseminated to the PPIE group who advised and was involved in the planning of the study. The Investigators and supervisory team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by The National Institute of Health research (NIHR). Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

18. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

19. ARCHIVING

After completion of the study, all essential documents will be retained for 5 years. Documents will be retained in a lockable filing cabinet at the Physiotherapy Research Unit at the Nuffield Orthopaedic Centre.

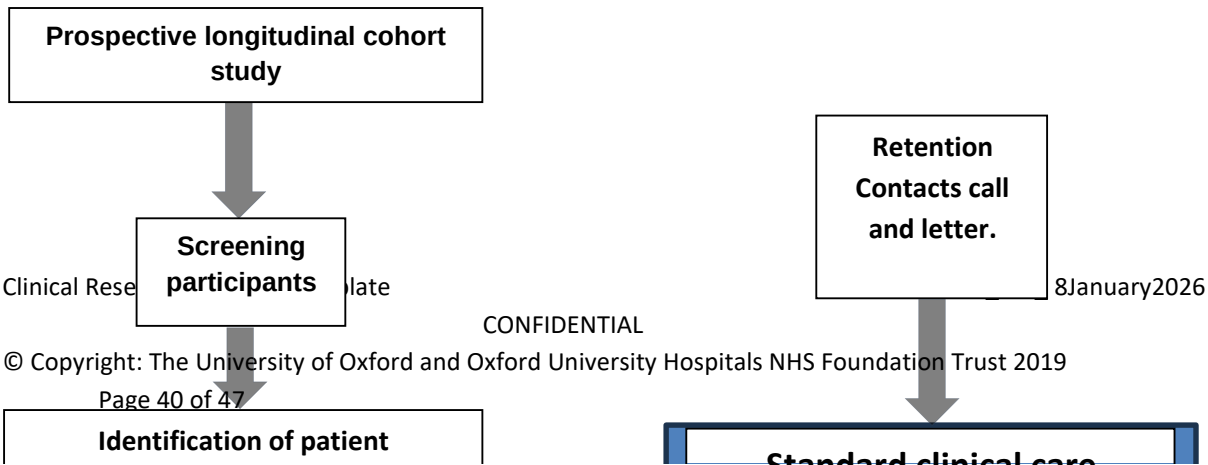
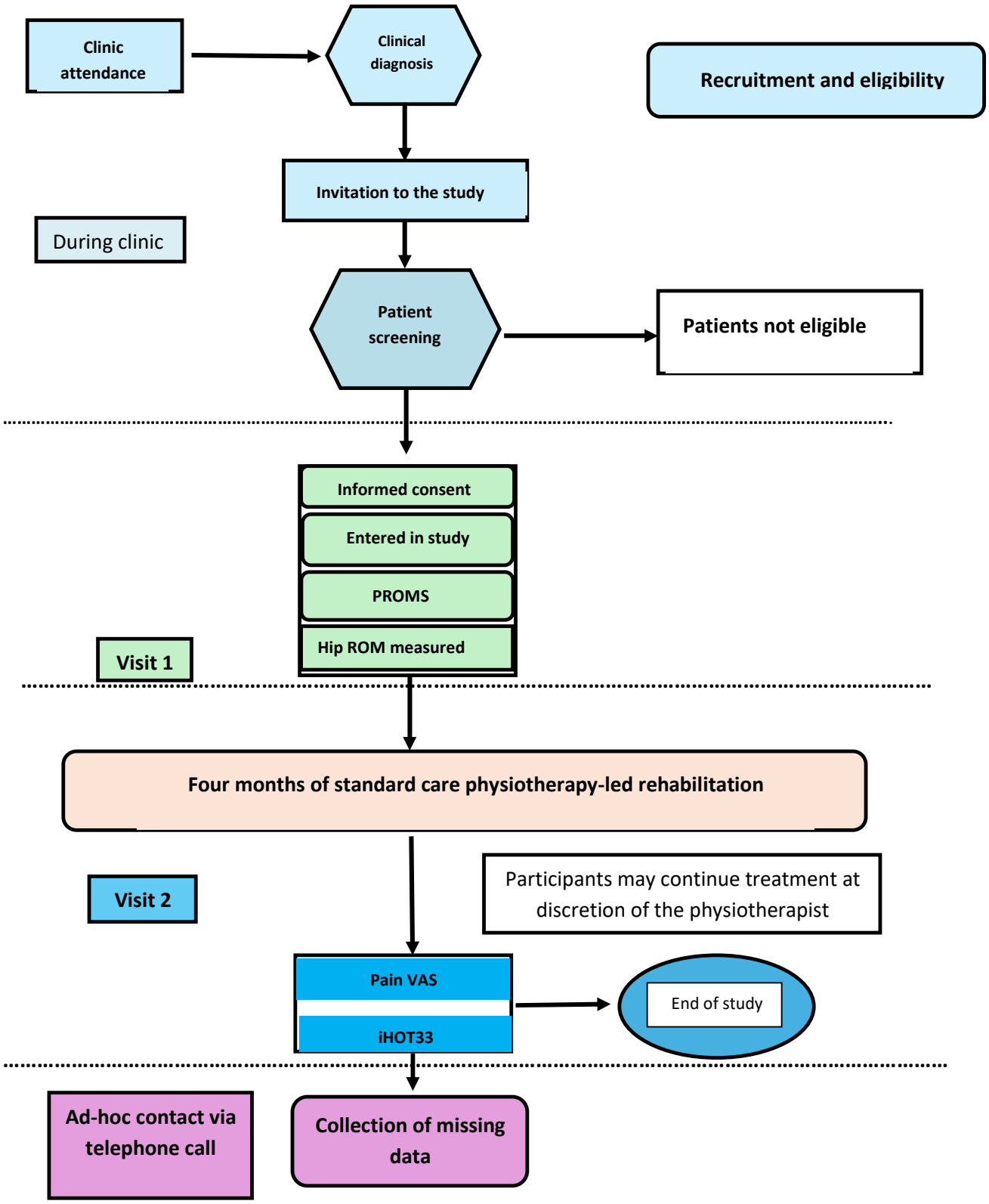


Figure 1 APPENDIX A: Study design

Abbreviations: CEQ: Credibility/Expectancy Questionnaire, **DN4**: Douleur Neuropathique 4, **iHOT33**: International Hip Outcome Score 33, **HADS**: Hospital Anxiety and Depression Scale, **NPSI**: Neuropathic Pain Symptom inventory, **PCS**: Pain Catastrophizing Scale, , **PLR**: Physiotherapy-Led Rehabilitation,: **TSK11**: Tampa Scale if Kinesiophobia 11, **TEX-Q**: Treatment Expectation Questionnaire, WPI: Widespread Pain Index

20. Figure 2 APPENDIX B: Flow of the participant through the study



21. APPENDIX C: SCHEDULE OF STUDY PROCEDURES

Procedures	**Clinic day**	**F*ollow up on discharge***	**Further assessment**	
	Screening/Baseline	Follow up assessment	Collection of missing data (either face to face of telephone)	
Informed consent	☑			
Demographics	☑			
Medical history	☑			
Physical examination	☑			
Eligibility assessment	☑			
Baseline Questionnaires	☑			
Follow up Questionnaires		☑	☑	
Adverse event assessments	To monitor and arrange a follow up if necessary			

22. APPENDIX D: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	0.2	3/2/2026	Simon Wood	Change in statistician, Added 2 questionnaires: TEX-Q and CEQ as planned from PPIE feedback Added two pain questionnaires: DN4 and NPSI Removed painDETECT questionnaire. Change duration of follow up from 6 treatments to 4 months after starting PLR

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee and HRA (where required).

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