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Tailored physiotherapy rehabilitation after revision total hip replacement

Submission date
03/07/2025

Recruitment status
Recruiting

Registration date
08/07/2025

Overall study status
Ongoing

Last Edited
08/07/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study aims to find out if it is possible to do a large trial to compare two types of physiotherapy after revision total hip replacement (THR) surgery: physiotherapy designed around the patient that includes tailored exercises and education, and physiotherapy that a patient would normally have after surgery. As large trials are expensive, the research team is first running a smaller study to find out whether they are able to get enough people to take part, what people think about the treatment, and if they are likely to stick to it.

Who can participate?
Adult patients ≥ 18 years undergoing a single- or final-stage revision THR and independently mobile (with or without an assistive device).

What does the study involve?
Participants will be involved in the study for approximately 9 months. After surgery, participants will be randomly assigned to one of two groups:
1. THRIVE intervention will involve a physiotherapy assessment and 5-8 additional follow-up physiotherapy appointments (in person or remote) over a 12-week period involving exercise and education tailored to the participant. There will also be two follow-up calls at 5 and 7 months.
2. Usual Care will involve a physiotherapy assessment and up to 2 additional follow-up physiotherapy appointments (in person or remote) over 12 weeks.

In addition to having physiotherapy, all participants will attend three additional research sessions. One session will take place before surgery, and two sessions will take place after surgery (4 months and 8 months post-surgery). These sessions will be 60-90 minutes. During each session, participants will complete questionnaires about their hip, overall function, quality of life, physical activity level and self-efficacy, and their balance, strength, and walking speed.

What are the possible benefits and risks of participating?
Findings from this study may mean that a larger trial can be conducted in the future to find out which type of physiotherapy treatment is better following revision THR. National guidelines recommend people undertake a home exercise programme after undergoing a THR, so regardless of the group participants are allocated to, their treatment will be in line with these

recommendations. In taking part in the study, participants will be helping patients in the future who are rehabilitating from revision THR surgery.

The physiotherapy exercises in this study are safe and part of standard care. When doing an exercise programme, there is always a risk that participants might feel sore afterwards, but this should not last longer than 3 days. Participants assigned to the THRIVE intervention group attend 5-8 physiotherapy follow-up sessions - this requires an extra time commitment.

Where is the study run from?
The Oxford University Hospitals NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
April 2025 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) Programme, UK

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
340762

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61084, NIHR207903

Study information

Scientific Title
Tailored physiotherapy rehabilitation after revision total hip replacement: a feasibility randomised controlled trial

Study objectives
To analyse (a) participant recruitment to the study and (b) participant retention in the study

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/06/2025, West of Scotland REC 4 (Research Ethics – Room 29, 2nd Floor, Administration Building, Gartnavel Royal Hospital, 1055 Great Western Road , Glasgow , G12 0XH , United Kingdom; -; ggc.wosrec4@nhs.scot), ref: 25/WS/0080

Study design
Multicentre parallel-group two-arm feasibility randomized controlled trial with an embedded qualitative acceptability study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal and orthopaedics; elective orthopaedic surgery; arthrosis

Interventions
Study design: A multicentre, parallel 2-arm feasibility RCT with an embedded qualitative study to explore acceptability.

Timeframe: The study duration will be 24 months. This will include site set-up, recruitment, intervention and follow-ups (final at 8 months post-surgery), participant and clinician qualitative interviews, data analysis, interpretation and report of findings, and preparation for a full, definitive trial if indicated. The study will start recruiting from Oxford University Hospitals Trust first, then a staged set-up of 3 other NHS sites.

Randomisation: Following the collection of baseline data and reconfirmation of eligibility and consent after total hip arthroplasty (THA) operation, eligible patients will be randomised in a 1:1 ratio between the intervention and usual care groups using a web-based centralised randomisation database (SealedEnvelope™), which will be managed by the trial manager. Stratified permuted blocks will be used, with the following stratification criteria: sex and site. The blocks will be of random sizes.

Setting: Secondary care NHS hospitals.

Study participants: The study aims to recruit at least 60 participants (30 in each arm), which is the recommended sample size for a feasibility trial. The target population is adults undergoing a single-stage or final-stage revision of THA.

Participant involvement duration: Participants will be involved in the trial for approximately 9 months. This includes a pre-operative screening and recruitment, pre-operative baseline assessment, 4-month and 8-month post-operative assessments for all participants. Participants in the THRIVE intervention arm will receive an initial physiotherapy evaluation and 5-8 visits over 12 weeks, plus 2 follow-up phone calls. The Usual Care arm will receive an initial physiotherapy evaluation and up to 2 visits over 12 weeks. A subset of participants from both arms will be asked to take part in a qualitative interview. In addition, a subset of physiotherapists who deliver the THRIVE intervention will be asked to take part in a qualitative interview.

Study data collection: Three research assessments (baseline, 4 months and 8 months) will be conducted in person and will include both questionnaires and physical outcome measures. The qualitative interviews, guided by an interview schedule, will be conducted in person or remotely and will be recorded and transcribed.

Patient and public involvement: During the trial design process, input was sought from patients who have undergone revision surgery. This has informed elements of our intervention and our patient information. They will continue to be part of the trial going forward.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Recruitment to the study is measured using screening logs at one time point, and numbers eligible, consented and randomised at screening
2. Retention in the study is measured using logs of data collected at baseline, 4 and 8 months

Key secondary outcome(s))

1. Adherence with the intervention is measured using physiotherapy session attendance, retention rate and qualitative interviews
2. Intervention fidelity is monitored by completion of treatment logs and qualitative interviews upon completion of the intervention and interviews.
3. Evaluation of the outcome measures for a full trial is by assessment of completion rate of the patient-reported outcome measures and performance-based outcome measures, and qualitative interviews from patients and physiotherapists, at the end of the study
4. To confirm a definitive primary outcome for a full trial, the completion rate of the expected primary outcome for a future full trial (Oxford Hip Score) will be assessed at the end of the study
5. The experience of participants in the trial and clinicians delivering the intervention will be assessed using qualitative interviews conducted at the end of the intervention period.

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Undergoing a single-stage rTHA or the final stage of a multi-stage rTHA
4. Independently mobile (with or without an assistive device)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Planned lower limb surgery within 8 months
2. Conditions or comorbidities that make participation in an exercise programme unsafe (e.g. severe acute or unstable cardiovascular or pulmonary disease,or undergoing radiotherapy or chemotherapy for cancer treatment)
3. Other neurological or medical conditions that would prevent physical measures from being collected

Date of first enrolment
01/08/2025

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD

Study participating centre
St Georges Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Northern General Hospital
Herries Road
Sheffield
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S5 7AU

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes