

# Tailored physiotherapy rehabilitation after revision total hip replacement

<b>Submission date</b> 03/07/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/07/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/07/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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  $\geq 18$  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?

Dr Erin Hannink, erin.hannink@ouh.nhs.uk

## Contact information

### Type(s)

Public, Scientific

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Principal Investigator

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

340762

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital, Internet/virtual, Telephone

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **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 measure**

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

### **Secondary outcome measures**

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.

### **Overall study start date**

01/04/2025

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 60; UK Sample Size: 60

## **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**

England

United Kingdom

### **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  
United Kingdom  
S5 7AU

# Sponsor information

## Organisation

Oxford University Hospitals NHS Trust

## Sponsor details

John Radcliffe Hospital, Headley Way, Headington

Oxford

England

United Kingdom

OX3 9DU

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not@available.com

## Sponsor type

Hospital/treatment centre

## Website

<https://www.ouh.nhs.uk/>

## 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, RfPB

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer-reviewed journal

## Intention to publish date

31/07/2028

## 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