Study Title:

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

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No potential conflicts of interest to declare.

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.

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1. KEY CONTACTS

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2. LAY SUMMARY

Hip replacement surgery is usually a success. However, some people will need another surgery on their hip. This is called *revision* surgery. After revision surgery, people often need to stay in hospital longer and may find it difficult to get back to activities they did before. We know a lot about how to help people

recover after their first hip replacement, but we do not know enough about the best way to help recover after revision surgery.

We want to compare two types of physiotherapy for revision surgery: (1) comprehensive physiotherapy designed around the patient that includes exercise and education, and (2) physiotherapy that a patient would routinely get after surgery; and (b). As large trials are expensive, we will run a small study first. We want to find out if we can get enough people to take part; what people think about the treatment; and if they likely to stick to it?

We will include sixty people from NHS hospitals who are about to have revision hip surgery. After surgery, we will randomly assign each person into one of the treatments. Each person will either get:

(1) A tailored physiotherapy programme: an exercise, walking and education programme with 5-8 follow-up appointments over 12 weeks, and two follow-up phone calls at 5 and 7 months after surgery; or

(2) Routine treatment: advice, an exercise programme from a physiotherapist to do at home, and up to 2 follow-up appointments over 12 weeks.

We will take regular measurements to track progress, including hip strength, activity level, and quality of life. We will measure before and after surgery (at 4 months and 8 months). We will also talk to participants and physiotherapists to find out about their experience in this trial.

Our findings will help us plan a larger trial.

3. SYNOPSIS

Study Title	Tailored physiotherapy rehabilitation after revision total hip replacement: a feasibility randomised controlled trial
Internal ref. no. / short title	THRIVE trial
Study registration	
Sponsor	Oxford University Hospitals NHS Foundation Trust Joint Research Office First Floor, OUH Cowley, Unipart House Business Centre Garsington Road, Oxford, OX4 2PG
Funder	NIHR (Research for Patient Benefit, ref: 207903) Mr Jack Finn Programme Manager Grange House, 15 Church Street, Twickenham, TW1 3NL Email: jack.finn@nihr.ac.uk
Study Design	Multicentre, 2-arm, parallel feasibility randomised controlled trial
Study Participants	Adults ≥ 18 years undergoing a single stage or final stage revision total hip arthroplasty.
Sample Size	n=60; THRIVE intervention n=30; Usual care n=30 Embedded qualitative study: n = 24 participants and 8 clinicians

Planned Study Period	Project duration: 24 months Duration of participant involvement: 9 months
Planned Recruitment period	10 months

	Objectives	Outcome Measures	Timepoint(s)
Primary	To analyse (a) recruitment to the study and (b) retention in the study.	(a) Screening logs, eligible consented, and randomised. (b) Logs of data collection (retention rate)	(a) Screening (b) Baseline, 4-months, 8-months
Secondary	To appraise adherence to the intervention.	Participant adherence to the physiotherapy programme will be assessed by measuring physiotherapy session attendance, retention rate and qualitative interviews.	Completion of intervention and qualitative interviews
	To evaluate intervention fidelity.	Delivery of all three main components of the intervention (exercise progression, gait re-training and education) as monitored on Treatment Logs and qualitative interviews.	Completion of intervention and qualitative interviews
	To evaluate outcome measures for a full trial.	Assessment of completion rate of the patient-reported outcome measures and performance-based outcome measures, and qualitative interviews with patients and physiotherapists.	End of study
	To confirm a definitive primary outcome for a full trial.	Completion rate of expected primary outcome for future full trial: Oxford Hip Score (OHS)	End of study
	To explore the experience of participants in the trial and clinicians delivering the intervention.	Qualitative interviews	Completion of qualitative interviews

Intervention(s)	The intervention will involve targeted progressive strengthening, gait re-training, and education, plus integrated exercise adherence strategies. It will comprise of a physiotherapy evaluation and 5-8 follow-up sessions over a 12-week period, and two follow-up calls (5- and 7-months post-operatively).

Comparator	Usual care will comprise of a physiotherapy assessment with home exercise programme and up to two follow-up sessions within 12 weeks.

4. ABBREVIATIONS

CI	Chief Investigator
COM-B	Capability-Opportunity-Motivation model of Behaviour
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OUH	Oxford University Hospitals NHS Foundation Trust
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust Research & Development Department
REC	Research Ethics Committee
RES	Research Ethics Service
rTHA	Revision total hip arthroplasty
SOP	Standard Operating Procedure
THA	Total hip arthroplasty
TMG	Trial Management Group

5. BACKGROUND AND RATIONALE

Total hip arthroplasty (THA) operations are highly successful, associated with considerable improvements in health-related quality of life, joint function and patient satisfaction (1); however, THAs have a finite lifespan and some fail early due to a complication such as infection or fracture, requiring revision surgery. With an ageing population, over the past two decades the number of revision total hip arthroplasty (rTHA) operations have increased and are projected to continue the upward trend (2). In 2022 more than 6700 revision THA operations were performed in the UK (3).

People who have rTHA surgery have a higher in-hospital mortality rate, longer hospital length of stay, are at higher risk of re-revision surgery (4), and have worse physical and mental health outcome measures compared to primary THA (5-7). Recovery trajectories after rTHA have been shown to plateau at 3 months post-operative in self-reported functional outcomes (pain and function) and gait speed, yet the

same measures continue to improve after primary THA (6). In addition, rTHA surgeries impose a considerable financial burden on the health system (8, 9).

Experiencing a THA is biopsychosocial process. A patient with elevated pre-surgical anxiety and depression is more at risk for poor hip function after primary THA surgery (10). However, the beliefs which a patient holds about their THA surrounding duration, consequences, control and coherence are more strongly associated with functionality post-surgery than their emotional representations (e.g. anxiety and depression) (11). To add to the complexity of this experience, rTHA patients often have more comorbidities, general deconditioning, and fixed flexion deformity (12-15) and have expectations based on a failed primary THA that influence rehabilitation after revision surgery (16).

To incorporate this biopsychosocial complexity into the management of adherence to rehabilitation physiotherapy post-rTHA we draw upon the Capability-Opportunity-Motivation model of Behaviour (COM-B) (17). This model can suggest the mechanisms which mediate or moderate rTHA patients' adherence to post-surgical physiotherapy rehabilitation and identify suitable behaviour change techniques which can target these mechanisms. A panoramic meta-analysis of interventions to increase adherence to physiotherapy in adults identified moderate certainty of evidence to support implementing certain behaviour change techniques in order to increase adherence to physiotherapy (18).

Clinical practice in primary THA rehabilitation has evolved in the past decade with evidence supporting the discontinuation of hip precautions after surgery (19); however, this is not the case for rTHA where variable precautions, contraindications and weight bearing status are often directed by individual surgeons based on the complex nature of revision surgery. Considering the poorer functional status and complexity of rTHA surgery, physiotherapy provision after rTHA varies widely across the UK (12). Sometimes patients are treated identically to a primary THR, receiving self-directed home exercise or no rehabilitation, leading to large variation and possibly to inadequate provision (12, 13).

Most clinicians rely on the National Institute for Health and Care Excellence (NICE) guidelines, based on evidence from primary THA rehabilitation, which recommends self-directed rehabilitation at home, or supervised outpatient rehabilitation depending on operation type and specific needs (20). More recent systematic reviews also support self-directed exercise after primary THA (21, 22). However, both reviews highlight lack of research on supervised physiotherapy for subgroups of patients with lower baseline functional status (21, 22), which is often the clinical population for patients undergoing rTHA.

In addition to the quantitative evidence, qualitative research amplifies this blind spot in rehabilitation evidence. Patients who are indicated for revision surgery have preconceived expectations around their surgery and recovery (23), and post-operatively they do not always feel supported (13, 15). In part due to their prior experience, the biopsychosocial involvedness of rehabilitation, and the complexity of surgery, patients are likely to benefit from a tailored approach to maximise engagement and adherence (15). This research resonates with findings from our own qualitative study of patients after rTHA which highlighted the desire for full information/education and the need for both physical and psychological support after surgery (24).

A review of the literature revealed scarce evidence investigating rehabilitation after rTHA (25, 26). The available evidence emphasises the importance of comprehensive, tailored physiotherapy rehabilitation that can be adapted and delivered flexibly with the establishment of regional revision networks. We

hypothesise that delivering a tailored physiotherapy intervention will improve and sustain greater functional outcomes and health-related quality of life compared to standard protocols currently in place.

6. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective		
To analyse (a) recruitment to the study and (b) retention in the study.	(a) Screening logs, eligible consented, and randomised. (b) Logs of data collection (retention rate)	(a) Screening (b) Baseline, 4-months, 8-months
Secondary Objectives		
To appraise adherence with the intervention.	Participant adherence to the physiotherapy programme will be assessed by measuring physiotherapy session attendance, retention rate and qualitative interviews.	Completion of intervention and qualitative interviews
To evaluate intervention fidelity	Delivery of all three main components of the intervention (exercise progression, gait re-training and education) as monitored on Treatment Logs and qualitative interviews.	Completion of intervention and qualitative interviews
To evaluate outcome measures for a full trial.	Assessment of completion rate of the patient-reported outcome measures and performance-based outcome measures, and qualitative interviews from patients and physiotherapists.	End of study
To confirm a definitive primary outcome for a full trial.	Completion rate of expected primary outcome for future full trial: Oxford Hip Score	End of study
To explore the experience of participants in the trial and clinicians delivering the intervention.	Qualitative interviews	Completion of qualitative interviews

7. STUDY DESIGN

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

Setting: Trial sites will be secondary care NHS hospitals.

Some trial sites may operate a hub-and-spoke model for delivery of the usual care arm, whereby the recruiting 'Lead Trial site' acts as the hub and collaborates with other NHS or community providers ("spokes") to deliver usual care in line with established local pathways, and the protocol. In these cases, the hub site will retain responsibility for participant identification, consent, randomisation, and overall trial governance. The spoke site staff will be trained by the central THRIVE study team and a delegation log maintained to record responsibilities delegated by the hub site PI.

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. Participants in 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. See flow chart in Appendix A.

Study data collection: Research assessments will be conducted in person and will include both questionnaires and physical outcome measures (see section 9.7 for full description). The qualitative interviews, guided by an interview schedule, will be conducted by a Qualitative Researcher from the central study team. These will be recorded and transcribed, checked for accuracy, and pseudonymised.

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Target population: Adults ≥ 18 years undergoing a single stage or final stage revision total hip arthroplasty.

8.2. Inclusion Criteria

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

8.3. Exclusion Criteria

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

- Planned lower limb surgery within 8 months.

- 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).
- Other neurological or medical condition (e.g. Parkinson's disease, multiple sclerosis, cerebral palsy, conditions causing ataxia) that would prevent physical measures being collected.

9. PROTOCOL PROCEDURES

9.1. Recruitment

Potential participants will be identified from the pre-operative lists and a pre-operative clinician (e.g. nurse, physiotherapist, or occupational therapist) will send potential participants a patient information sheet (PIS) (with covering invitation letter, reply slip and prepaid return envelope), or give them a PIS during their face-to-face pre-operative clinic appointment. After reading the PIS, if the patient expresses interest in participation and is willing to proceed (as indicated by a reply slip or contact with the site research study team), they will be phoned by a site research team member where eligibility will be confirmed and appointment arranged for the pre-surgery baseline and consent visit. If no reply has been received, one reminder letter will be sent. Where possible, this visit will be arranged to coincide with the patient's routine pre-admission appointment to reduce the burden on the patient. During this appointment with the site research clinician, informed consent, enrolment and the baseline research assessment will be completed. We will record the reasons for any exclusion at each step to meet our feasibility objectives.

9.2. Screening and Eligibility Assessment

There will be no exceptions made regarding eligibility criteria for inclusion in the study. After rTHA surgery, eligibility to continue to randomisation will be confirmed by medical notes to ensure their surgery was single stage or final stage revision operation. All patients who undergo screening will be recorded on the screening log. Reasons for ineligibility and declining to participate will be recorded.

9.3. Informed Consent

A study researcher will take informed consent before rTHA surgery. The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures take place.

Participant Information and Informed Consent will be presented to the participants 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 participant will be allowed as much time as they need 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 will then be obtained by means of participant-

dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must 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, and a copy kept in their medical notes. The original signed form will be retained at the study site.

9.4. Randomisation

Following collection of baseline data and reconfirmation of eligibility and consent after rTHA 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
- Site

The blocks will be of random sizes.

By the nature of the intervention, patients and clinicians cannot be blinded to treatment once allocation has occurred. However, the data analysis will be conducted in a blinded fashion.

Participants from both arms will complete the standard post-surgical care pathway, then will be allocated to the treatment arm they were randomised to and scheduled for an outpatient physiotherapy appointment approximately 2-3 weeks after discharge from hospital (within 4 weeks of operation). All timings of questionnaires and outcome assessments will be from the date of randomisation and will be in weeks. A letter will be sent informing the GP about their patient's involvement in the study and the treatment they have been allocated.

9.5. Blinding and code-breaking

By virtue of the design, it is not possible to blind participants or the physiotherapists delivering the intervention. The trial assessors conducting baseline and follow-up research assessments will be blinded to allocation. Physiotherapists will be instructed not to give indication to the trial assessor as to which group the patient has been allocated. Participants will be asked, and reminded, not to disclose their treatment group to the trial assessor at follow-up appointments.

As participants and treating clinicians are not blinded to their allocated treatment it is not necessary to have a code-breaking procedure.

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

9.6.1. Description of study intervention(s)

Our tailored physiotherapy rehabilitation (THRIVE) programme will involve targeted progressive strengthening, gait re-training and education. The delivery of the physiotherapy elements will be underpinned by the COM-B model and include evidence-based behaviour change techniques to encourage adherence. Due to the complexity of the patient group, who will present with multiple co-

morbidities and environmental factors to account for, the intervention will be delivered flexibility while maintaining the primary tenets of the intervention (27). The THRIVE programme will comprise of an in-person physiotherapy evaluation (60 minutes) and 5-8 follow-up sessions (30 minutes each) delivered in-person or remotely over a 12-week period. Additionally, there will be 2 follow-up phone calls (15 minutes each) at 5 and 7 months post-operation. The duration of the intervention is particularly important to allow for strengthening adaptations (21).

Targeted progressive strengthening

Targeted progressive strengthening will focus on hip muscle strengthening and core stability to improve functional activities (28). Due to de-conditioning before surgery compounded by the physical damage to tissues during surgery, post-operative strengthening is critical (14, 29). Improving strength involves both neuromuscular adaptations (improving the signal from the brain to activate the muscle) and muscle hypertrophy (increasing the size of the muscle fibres). In addition to restoring strength for functional activities such as getting in and out of bed, up and down from a chair, walking to the shops, gardening, and other physical recreation and hobbies, muscles around the hip joint provide active stabilisation which protects the prosthetic joint. Targeted progressive strengthening will be milestone-based progression, as opposed to strictly time-based progression which does not take into account individual patient presentation and complexities associated with a revision surgery.

Gait re-training

Working in conjunction with progressive strengthening tenets, gait re-training will aim to restore gait pattern, gait speed, and confidence. After rTHA surgery, fixed hip flexion and deficient hip abduction remain problematic, leading to gait instability (30). The physiotherapist will focus on re-training and stabilising gait as strength and range of motion improves. Progression will be tailored to the participant's goals and environmental needs.

Education

Concurrently with participants' physical rehabilitation, education delivered as part of the THRIVE programme will be evidence-based and individualised to address issues around rTHA, including any restrictions or precautions. In addition, advice will be provided for returning to physical activity and participant-specific activities identified in their rehabilitation goals.

Exercise adherence strategies

Importantly, integrated within the THRIVE programme will be exercise adherence strategies to support transition to self-management after the active 12-week intervention. An essential part of taking on an exercise programme during rehabilitation after major surgery is adhering to the programme.

We are asking our patients to make a significant health change by taking on an intensive exercise programme and performing exercises at home. Numerous factors impact on exercise adherence and engagement in people with long-term musculoskeletal health conditions such as hip osteoarthritis and joint arthroplasty. For example, people may feel uncertain about possible benefits or feel hesitant because they lack knowledge or skill; they may not feel confident in their physical ability due to comorbidities or may have negative views about treatment (fear of pain, dislocation or falling); there may also be financial barriers that impact engagement. (15, 31).

Guided by the COM-B model of behaviour change, we identified several proposed mechanisms that might mediate or moderate patient's adherence to physiotherapy. We identified an evidence-based mechanism of increasing self-efficacy (an individual's belief in their capacity to complete a task or achieve a goal) will improve adherence to the exercise programme (32-35). We have integrated several exercise adherence strategies aiming to enhance self-efficacy that are built upon behaviour change techniques (BCTs) to target common barriers and facilitators to exercise specific to our clinical population (15, 31). Our four approaches are:

[1] *Goal setting* – physiotherapists will discuss with participants to establish patient-led, values-based goals to guide and progress the physical intervention.

[2] *Education* – in addition to education being a central part of the physiotherapy intervention, it serves a dual purpose as a BCT by providing information about health consequences and instruction on how to perform the exercise programme.

[3] *Self-monitoring and feedback* – participants will use exercise diaries to monitor their exercise behaviour at home; these diaries will also guide the physiotherapist's feedback and progression during follow-up sessions.

[4] Social support – physiotherapists will complete two 15-minute follow-up phone calls after the 12-week intervention (5-months and 7-months) to support and motivate continued exercise adherence behaviour.

The approaches we have incorporated have been used in similar clinical populations and in physiotherapy intervention research (18, 36), therefore demonstrating their practicality and acceptability among clinicians and patients. Using multiple approaches at different points during the active intervention and follow-up periods will contribute to sustained adherence to the prescribed exercise programme, consequently improving and sustaining functional outcomes. In addition, these approaches will help tailor the physiotherapy programme and contribute to the holistic approach and *therapeutic alliance* which can improve adherence (18, 37). The therapeutic alliance, or 'the working relationship,' between patient and therapist will grow over the 12-week duration. Within musculoskeletal physiotherapy, a strong therapeutic alliance can facilitate exercise and physical activity adherence and has the potential to improve outcomes (37-39).

9.6.2. Description of comparator(s)

Having completed consultations with stakeholders within centres that perform revision operations, usual care has been standardised to comprise of an assessment by a physiotherapist with a home exercise programme (60 minutes) and up to two follow-up sessions (30 minutes) within 12 weeks, delivered in-person or remotely (depending on participant preference). This falls within the recommendation of the NICE guidelines for THA rehabilitation.

Where a hub-and-spoke arrangement is in place, the usual care provided by the spoke site will follow this same standardised usual care. The PI at the Lead Trial Site will have oversight of the trial at the spoke site. Spoke site staff will be trained by the central THRIVE study staff to deliver the usual care arm intervention and in safety and deviation reporting procedures.

9.7. Baseline Assessments (Research clinic assessment 1)

The baseline assessment visit will last up to 90 minutes. Participants will provide the following data (Table 1) with an experienced physiotherapist, nurse or researcher at the site, who has been trained in the protocol by central THRIVE study staff. The baseline assessment will be completed following eligibility screening and informed consent, prior to their surgery and randomisation.

Table 1. THRIVE study participant baseline data collection

OUTCOMES	OUTCOME MEASURES
Self-reported	
Demographic	Age, gender, ethnicity, socioeconomic factors (marital status, carer status, living situation, education level, employment)
Medical history	Previous lower limb surgeries, number and date of previous hip replacements, indication for previous hip replacements, indication for current rTHA
Mobility	Current walking distance, stair use, aid use
Comorbidities	Weighted Functional Comorbidities Index (w-FCI)
Disability	Oxford Hip Score (OHS)
Joint awareness after surgery	Forgotten Joint Score (FJS)
Health-related quality of life	EQ5D-5L
Physical activity level	UCLA activity scale
Self-efficacy barriers to exercise	Self-efficacy for exercise (SEE)
Clinician-completed assessment	
Demographic	Height and weight
Gait speed	4-meter walk test (4MWT)
Functional lower extremity strength	30-second chair stand test
Balance and walking ability	Timed Up and Go (TUG) test
Balance	Single leg stance test (SLST)
Grip strength	Hand grip strength

9.8. Intervention data collection

The following data will be collected during the intervention period, by the site physiotherapist who has been trained in the protocol by central THRIVE study staff. To maintain blinding, this will be done by someone other than the staff member conducting the site research clinic assessment. Where a hub-and-spoke arrangement is in place, spoke site staff will be trained by the central THRIVE study staff to deliver the usual care arm intervention and will complete the report form for the participants they treat.

Table 2. THRIVE study intervention data collection

DATA SOURCE	DATA RECORDED

For participants in the THRIVE intervention group	
Physiotherapist treatment log	Date, clinician details, session number, mode of delivery, session content
Physiotherapist follow-up phone call log	Date, clinician details, call number, tick-boxes of call content
Participant home exercise diary	Date, exercise(s) completed
For participants in the Usual Care group	
Physiotherapist report form	Date, mode of delivery of session, tick-boxes of session content: provision of aids, manual therapy, exercises, home exercise programme

9.9. Follow-up at 4 months post-randomisation (Research clinic assessment 2)

This applies to all participants (THRIVE intervention group and Usual Care group). All participants will attend a second research clinic assessment lasting up to 90 minutes. An experienced physiotherapist, nurse or researcher will collect the following data:

Table 3. THRIVE study participant follow-up data collection

OUTCOMES	OUTCOME MEASURES
Self-reported questionnaires	
Disability	Oxford Hip Score (OHS)
Joint awareness after surgery	Forgotten Joint Score (FJS)
Health-related quality of life	EQ-5D-5L
Physical activity level	UCLA activity scale
Self-efficacy barriers to exercise	Self-efficacy for exercise (SEE)
Healthcare resource use & family social support	Healthcare resource use diary
Clinician-completed assessment	
Gait speed	4-meter walk test (4MWT)
Functional lower extremity strength	30-second chair stand test
Balance and walking ability	Timed Up and Go (TUG) test
Balance	Single leg stance test (SLST)
Grip strength	Hand grip strength

9.10. Follow-up at 8 months post-randomisation (Research clinic assessment 3)

As in Research clinic assessment 2, this follow-up applies to all participants (THRIVE intervention group and Usual Care group) and will last up to 90 minutes. An experienced physiotherapist, nurse or researcher will collect the data described in Table 3 (see section 9.99.9).

9.11. Embedded qualitative study

The qualitative aspect of this study will explore the feasibility and acceptability of the experimental and control interventions from the perspective of the participants, and their experiences of taking part in the study (e.g. trial procedures, assessments). The qualitative study will also explore the feasibility and acceptability of the THRIVE intervention from the perspective of the physiotherapists delivering it. Questions will seek to explore participant opinion and experience of study recruitment, intervention content, timing, accessibility, and barriers and facilitators to adherence. Qualitative findings will be used to modify the content and delivery of a future definitive trial.

Participant interviews

Up to 24 participant interviews in total (up to 16 from the THRIVE intervention group and up to 8 from the Usual Care group) will be conducted with participants from each study site, by a qualitative researcher from the central study team. This sample is aligned with interpretive qualitative research methods which do not rely on statistical representation. There is no standardised sample size for qualitative research. Our sampling strategy will be influenced by the principles of Information Power (40) which is compatible with Braun and Clarke's reflexive thematic analysis (41).

All participants will be given a brief explanation of the interviews during the initial consent process. Those willing to be interviewed will indicate permission to be contacted by the qualitative researcher on the Consent form. It will be clarified that, although willing, not all participants may be required for the interview study.

Sampling will be purposive to include males and females, participants of different ages and baseline levels of function, and from a range of socio-economic contexts. The qualitative researcher will telephone the sampled participants and invite them to take part in an interview and answer any questions they may have about taking part. If the participant is interested, and agrees to take part (in principle), a time and date convenient to the participant will be arranged for an interview. A PIS will be sent to the participant. Interviews will be conducted over the telephone, by video call via Teams, or face-to-face if the participant is unable to communicate over the telephone or video call for an extended period, or prefers a face-to-face interview. Face-to-face interviews will take place within a hospital outpatient department or in the participant's own home, depending on which is most convenient for the participant. Interviews that take place face-to-face at a participant's home will be arranged following the OUH lone working policy.

Interviews will be conducted within four weeks of a patient participant's final contact with a physiotherapist as part of their allocated intervention. An experienced qualitative researcher will take Consent before undertaking the interview. A copy of the completed informed consent form will be given to the participant, by email or post. Interviews will be semi-structured, following an open-ended topic guide, lasting approximately 60 minutes. Interviews will be audio-recorded, independently transcribed verbatim, checked against the recording, and pseudonymised. Data will be analysed using Braun and Clark's reflective thematic analysis.

THRIVE physiotherapist interviews

Up to eight physiotherapists will be interviewed. Eligible physiotherapists who undertake training to deliver the THRIVE intervention will be given a participant information sheet at the time they undertake their study training, and invited to take part in the interview study. Physiotherapists who have delivered

the THRIVE intervention and agreed to be contacted regarding the interview study will be telephoned by a central THRIVE researcher within two weeks of delivering their last THRIVE follow-up call. During this phone call the exact nature of the interview study and what it will involve for the physiotherapist participant will be discussed. If the physiotherapist agrees to take part in principle, the qualitative researcher will arrange a suitable time for an interview via telephone or Microsoft Teams. Informed consent will be taken remotely by the researcher prior to commencing the interview. A copy of the completed informed consent form will be emailed to the physiotherapist. Each interview will take approximately 30-45 minutes, and will follow a semi-structured, open-ended topic guide with the opportunity for the physiotherapist to raise additional items for discussion. Interviews will be audio-recorded, independently transcribed verbatim, checked for accuracy, and de-identified. Data will be analysed using Braun and Clark's reflective thematic analysis.

9.12. Sample Handling

There will be no samples taken.

9.13. Early Discontinuation/Withdrawal of Participants

During the course of the study a participant may choose to withdraw early from the study treatment 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; or
- Participant decision.

Participants may choose to stop 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. According to the design of the study, participants may have the following two options for withdrawal:

1) 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.

2) 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.

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:

- 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

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

If the participant is withdrawn due to an adverse event, the Investigator will arrange for telephone calls until the adverse event has resolved or stabilised.

Withdrawn participants will not be replaced; however, withdrawals will be recorded to determine retention rate and used to assess the feasibility of the study.

9.14. Definition of End of Study

The end of study will be the date of the last visit of the last participant.

10. SAFETY REPORTING

An Adverse Event (AE) is defined as any untoward medical occurrence which a participant experiences to whom an intervention (control or experimental) has been administered, including occurrences which are not necessarily caused by or related to that intervention. AEs related to the intervention will be recorded using the Study AE form from randomisation to the completion of the allocated intervention, and thereafter at the 4-month and 8-month research assessments. AEs that are unrelated to the rTHA, intervention or treatment will not be reported. Given the age range of the participant population and the nature of physical interventions, foreseeable AEs that may occur during the study period which do not require specific time-critical reporting but may be collected as part of standard data collection are:

- acute infections (e.g. viral)
- medical instability (e.g. diabetic control – becomes hypoglycaemic, deterioration in control of heart failure)
- vestibular disorders and stroke
- fall-related injuries

However, if any of the above occur as the result of an incident during, or within two hours of completing the physiotherapy sessions or follow-on physical activities or are related to the intervention and categorised as an SAE according to section 10.1 then they should be reported to the Trial Management Group as a suspected SAE as per section 10.2.

We would also foresee that participants taking part in an exercise programme may experience delayed onset of muscle soreness (≤ 72 hours). If this fails to resolve in 72 hours, is assessed as being related to the study intervention, and is categorised as an SAE according to section 10.1 then it should be reported to the Trial Management Group as a suspected SAE as per section 10.2.

Under these conditions these events will be considered unexpected as they are more severe and longer lasting than what is expected. All reported AEs will be reviewed by the Study Team to determine whether they are related to the intervention or not. It will be left to the PI's clinical judgment, in liaison with CI if required, to decide whether an AE is of sufficient severity to require the participant's removal from the treatment provided by the study. A participant may also voluntarily withdraw from treatment if they perceive an AE to be intolerable. If either of these occurs, the participant will be given appropriate care under medical supervision until symptoms cease, or the condition becomes stable. Participants who withdraw from treatment will be encouraged to continue with the follow-up where possible.

10.1. Definition of Serious Adverse Events

A serious adverse event (SAE) 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.

10.2. Reporting Procedures for Serious Adverse Events

If an SAE arises in the period between randomisation and the final follow-up visit, that is deemed related to the trial interventions, the site will complete an SAE form and record the description, date of onset, end date, severity and assessment of relatedness to trial intervention. Where a hub-and-spoke arrangement is in place, if an SAE is identified at the spoke site, the clinician who identified the event will report the details to the Lead Trial Site (hub) at the time, using the SAE form. The Lead Trial Site will review the content and completeness of the SAE form, and the PI will assess causality.

For the purpose of safety recording for this trial, only unforeseeable SAEs potentially related to the intervention will be reported immediately to the central trial team. When the local research team becomes aware of an SAE in a participant, the PI will review the SAE locally and make a decision about the causality (i.e. likelihood of the event to be related/attributed to the intervention). Further details on the grades of causality are available in the SAE Reporting Guidelines document in the Investigator Site File. Following the assessment of causality the PI will assess any related events for expectedness. For any SAEs assessed as unexpected and potentially related, the details of the event will be entered on an SAE reporting form on the database, and the local research team will notify the central trial team via email or telephone within 24 hours of the PI becoming aware of the event. Once received, causality and expectedness will be confirmed by the CI or delegate (Nominated Person). In the event that consensus is not reached between the PI and Nominated Person about assessment of causality and expectedness, this will be escalated to the CI for further discussion. However, if no consensus decision is reached about expectedness after further discussion within one working day, and the SAE is judged to be unexpected by any one of either the PI, Nominated Person or CI, the event will be classified as an unexpected event. An SAE occurring to a participant should 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 those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the CI becoming aware of the event, using the HRA report of serious adverse event form (see HRA website). All such events will also be reported to the Trial Management Group at their next meeting.

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

The plan for the statistical analysis of the study is outlined below. There is not a separate SAP document in use for the trial.

11.2. Description of the Statistical Methods

Primary analysis will evaluate the feasibility of conducting the study. The feasibility outcomes (for example: recruitment rate, consent proportion, physiotherapy session attendance, and retention rate) will be described by randomisation group using frequency and proportions, and figures where appropriate.

We will use progression criteria to assess feasibility of a future definitive trial using a 'traffic light' system (42) (Table 4). These quantitative progression criteria will be considered in combination with qualitative findings to guide decision making and trial design. Green (Go) indicates feasible with the current procedures; Amber (Amend) indicates feasible if there is modification to one or more components of the protocol; and Red (Stop) indicates a definitive trial would not be feasible without significant changes to protocol.

Table 4. Progression criteria

CRITERIA	Green (GO)	Amber (AMEND)	Red (STOP)
Recruitment	**≥60** eligible participants recruited within 10 months	**45-59**	**<45**
Intervention fidelity	**≥75%** of participants receive allocated intervention per protocol	**50-74%**	**<50%**
Adherence	**≥75%** of THRIVE intervention participants have at least 5 follow-up sessions delivered	**50-74%**	**<50%**
Outcome data completion rate	**≥80%** of participants have 8-month outcome data	**≥60-79%**	**<60%**
Outcome measure use in full trial	**2 or more** outcomes suitable for full trial	**1 outcome** suitable for full trial	**No outcomes** suitable for full trial

Intervention implementation	Delivery of intervention judged **strongly feasible** by qualitative data	**Feasible**	**Possibly feasible**

The characteristics of the randomised groups will be described using mean and standard deviation, or frequency and proportions, as appropriate.

The outcome assessments, including patient reported outcome measures and performance-based measures, will be reported in a descriptive fashion, with no formal assessment of treatment effect between groups since this is a feasibility study. We will summarise outcomes overall and in each group. Completeness and variability of the outcome measures will be used together as a guide to help determine the best outcome for a future main study. We will visualise the change in outcomes over time within groups using plots.

11.3. Sample Size Determination

As this is a feasibility study which is not aimed to assess treatment effects, we have not undertaken a formal power sample size calculation. A minimum of 60 participants (≥30 in each arm) will be recruited, as recommended to estimate key design parameters in a feasibility RCT and to establish the study sample size for a definitive trial (43). The qualitative sub-study will include up to 24 participants from the main trial (up to 16 from the THRIVE intervention group and up to 8 from the Usual Care group). Additionally, we will interview up to 8 clinicians who delivered the THRIVE intervention. These qualitative samples are aligned with interpretive qualitative research methods which do not rely on statistical representation. Our sampling strategy will be influenced by the principles of Information Power (40).

11.4. Analysis populations

The intention to treat population will include all patient participants at baseline, 4-month and 8-month follow-ups in the randomised groups to which they were allocated regardless of the treatment they actually received.

11.5. Decision points

There are no planned interim decision points in this study. The Trial Management Group will review recruitment, completion of data collecting and monitor the safety of participants and the conduct of the study (see section 13.3.1).

11.6. Stopping rules

This is a feasibility study and there are no formal stopping rules.

11.7. The Level of Statistical Significance

For this feasibility study statistical significance will not be assessed. Comparative results will be presented using 95% CIs. These are expected to be wide due to the small sample size and care should be taken with any interpretation.

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

Missing data will be minimised by careful data management. Missing data will be described with reasons given where available. The number and percentage of individuals in the missing category will be presented by treatment arm. All data collected on data collection forms will be used, since only essential data items will be collected. No data will be considered spurious in the analysis since all data will be checked and cleaned before analysis.

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

Any changes from this SAP will be described and justified in the final report.

11.10. Health Economics Analysis

An economic evaluation would be an important component of a full trial, providing information on the value for money of tailored physiotherapy rehabilitation after rTHA compared to usual care. A within-trial cost-effectiveness analysis, taking an 8-month time horizon, from an NHS and personal social services perspective is envisaged. The main outcome measure for the economic evaluation would be quality-adjusted life years (QALYs), estimated using the EQ-5D-5L.

In this feasibility study, the aim of the health economics component is to test out the feasibility of gathering the resource use and outcome data required in a cost-effectiveness analysis to inform data collection for a future study. Resource use data will be collected from time of first physiotherapy appointment, rather than from randomisation, which will occur post-inpatient discharge. The time to first physiotherapy appointment will be monitored for any differences between groups. Data on resource use associated with the trial interventions will be captured on trial CRFs. All other health and social care resource use will be captured from participants at 4-months and 8-months post-randomisation using resource use diaries. To assess whether there are substantial costs to patients and their families, and whether a wider perspective should be considered in the full trial, we will also include questions on family social support in the resource use diaries. Participants will complete the EQ-5D-5L at baseline, 4-months and 8-months post-randomisation. The proportion of participants followed up at each time point and data completeness for resource use and outcomes at each timepoint will be reported descriptively.

12. 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.

12.1. 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). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code only, not by name.

12.2. 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.

12.3. Data Recording and Record Keeping

All trial data will be collected on paper CRFs, then entered and managed on REDCap (Research Electronic Data Capture) hosted at OUH. REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

The participants will be identified by a unique trial specific number and/or code in any database. The name and any other identifying detail will NOT be included in any trial data electronic file. The ID log will be stored in a separate password protected file on an OUH server accessible by the chief investigator and trial manager.

Data will be collected by the site researchers (baseline, 4-months and 8-months assessment), physiotherapists delivering the THRIVE intervention (treatment logs), physiotherapists delivering Usual Care (report forms) and participants (treatment diaries (THRIVE intervention only), assessment questionnaires at baseline, 4-months and 8-months assessment). All data requested on the CRF must be recorded. All missing data must be explained. All data will be sent to the central THRIVE team at OUH for entry into REDCap. Contact details will be stored for all participants (after receiving the consent to do so) to ensure 4 and 8-month questionnaires can be posted to participants who do not complete the in-clinic follow-up research visit, and so study results can be posted to participants. These details will be stored on the REDCap database with access limited to the trial manager and CIs only. Contact details will be deleted when no longer required as part of the study (following posting of the summary of study results). This will be within 12 months of the end of the study.

Qualitative interview data will be collected on an encrypted audio recorder by the central study team and immediately transferred from the recording device to be stored as password-protected files on an encrypted computer within the OUH network. Data will then be deleted from the original recording device. Audio files will be transferred to an independent transcription service via encrypted software. Transcriptions will be returned via the same means, and the transcription service will immediately delete the recording. After the transcript has been checked for accuracy, the audio recording held by the researcher will then be deleted. The transcription will be stored as a Word file on encrypted computers within the OUH network. The qualitative researcher will assign each transcript a unique study specific

code and remove all identifying information (i.e. names and locations) from the transcripts. Only this anonymised form of data will be used for analysis. To ensure compliance with the relevant Sponsor organisation's policy, data will be safely retained within the Nuffield Orthopaedic Centre (OUH) for five years and safely destroyed after this time.

13. QUALITY ASSURANCE PROCEDURES

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

13.1. 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.

13.2. Study monitoring

The planned monitoring activities will be based on the study specific risk assessment. Any SAEs that occur will be reviewed by the Trial Management Group. Quality control procedures will be undertaken during recruitment and data collection phases to ensure compliance with the protocol, Good Clinical Practice and ethics committee recommendations. The processes of seeking and recording consent, provision of information, randomisation, and provision of treatment will be monitored centrally. All CRFs and questionnaires will be monitored upon receipt for accuracy and completeness. Intervention delivery will be monitored to check fidelity. This will be done by checking Treatment Logs, and by conducting support telephone calls with site physiotherapists delivering the THRIVE intervention, using a checklist. We will provide relevant feedback to sites from quality assurance activities to help maintain and improve fidelity.

13.3. Study Committees

13.3.1. Trial Management Group

The Trial Management Group (TMG) will be responsible for the overall running of the study. The TMG will meet approximately monthly during the trial. A PPI representative will be an integral member of the TMG. The day-to-day management of the trial will be the responsibility of the CI, supported by the trial manager. It will also be the responsibility of the CI to ensure training of the research staff at each of the trial centres. The trial statistician and CI will be closely involved in setting up data capture systems, design of databases and CRFs. As this a low-risk feasibility study there will be no Data and Safety Monitoring Committee. The TMG will maintain robust oversight of trial conduct and safety issues.

13.3.2. Trial Steering Committee

A Trial Steering Committee will be established to provide independent oversight of the study. The committee will aim to meet at the start of the study and then at least annually.

14. 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 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. The identification and reporting of protocol deviations will be included in training delivered to site staff during set-up. Where a hub-and-spoke arrangement is in place, the same training will be delivered to spoke site staff who will be asked to return any completed protocol deviation forms to the Lead Trial Site.

15. 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 one working day. In collaboration with the CI, 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.

16. ETHICAL AND REGULATORY CONSIDERATIONS

16.1. Declaration of Helsinki

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

16.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

16.3. Approvals

Following Sponsor approval, the protocol, informed consent form, participant information sheet, and other patient facing study materials will be submitted to an appropriate Research Ethics Committee (REC), and Health Regulatory Authority (HRA) 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.

Where a hub-and-spoke arrangement is used for delivery of the usual care arm, appropriate information-sharing and governance arrangements will be in place to ensure participant safety, data protection, and protocol compliance. The lead trial site ("hub") will enter into a hub-and-spoke agreement with the

subcontracted “spoke” site. The addition of the spoke site will be recorded via an amendment to the Sponsor site agreement with the lead trial site.

16.4. Other Ethical Considerations

Participants who attend physiotherapy may experience muscle soreness after completing exercises. The physiotherapist will monitor this, and exercises will be tailored to an appropriate level. Additionally, potential participants will be approached, screened and informed about the nature of the study verbally by the clinical team and written consent will be taken prior to undertaking the intervention. The study team has considerable experience in recruiting pre-operative orthopaedic participants into physiotherapy trials of exercise and qualitative interview studies. As described earlier, testing of the study recruitment procedures and assessment of the intervention acceptability will be formally investigated within this study. Lastly, as part of the patient reported outcomes we are gathering, the EQ-5D-5L asks a question about the participant’s anxiety / depression. If a participant reports a high score, the trial research assessor who collects the questionnaire will raise this to their PI who can refer the participant to their GP or an internal psychology support service.

16.5. Reporting

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

16.6. Transparency in Research

Prior to the recruitment of the first participant, the trial will have been registered on a publicly accessible database. This will be updated throughout the study should any amendments be made. The CI or their delegate will upload results to the public registries within 12 months of the end of the trial declaration.

16.7. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be anonymised 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 or screening number only on all study documents and any electronic database(s). The exception to this is the consent form which will include the participant’s name. Contact details will be collected from participants with their consent, so that the participant can be contacted by the study team if required. Contact details will be deleted when no longer required as part of the study (following posting of the summary of study results). 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.

16.8. Expenses and Benefits

Reasonable travel expenses for any visits additional to normal care (baseline, 4-months and 8-months research assessments) will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

17. FINANCE AND INSURANCE

17.1. Funding

This study is a funded by the NIHR (Research for Patient Benefit, ref: 207903).

17.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances.

In exceptional circumstances an ex-gratia payment may be offered.

17.3. Contractual arrangements

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

18. PUBLICATION POLICY

The Investigators and PPI representatives 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 NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. A lay summary of the study outcomes will be posted to all study participants.

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

Ownership of IP generated by employees of the OUH vests in OUH. The protection and exploitation of any new IP is managed by the IP and Research Contracts Team at OUH unless it is generated in collaboration with Oxford University in which case this is led by the University's technology transfer office, Oxford University Innovations.

19. ARCHIVING

Data from the study will be archived for a period of five years after the end of study.

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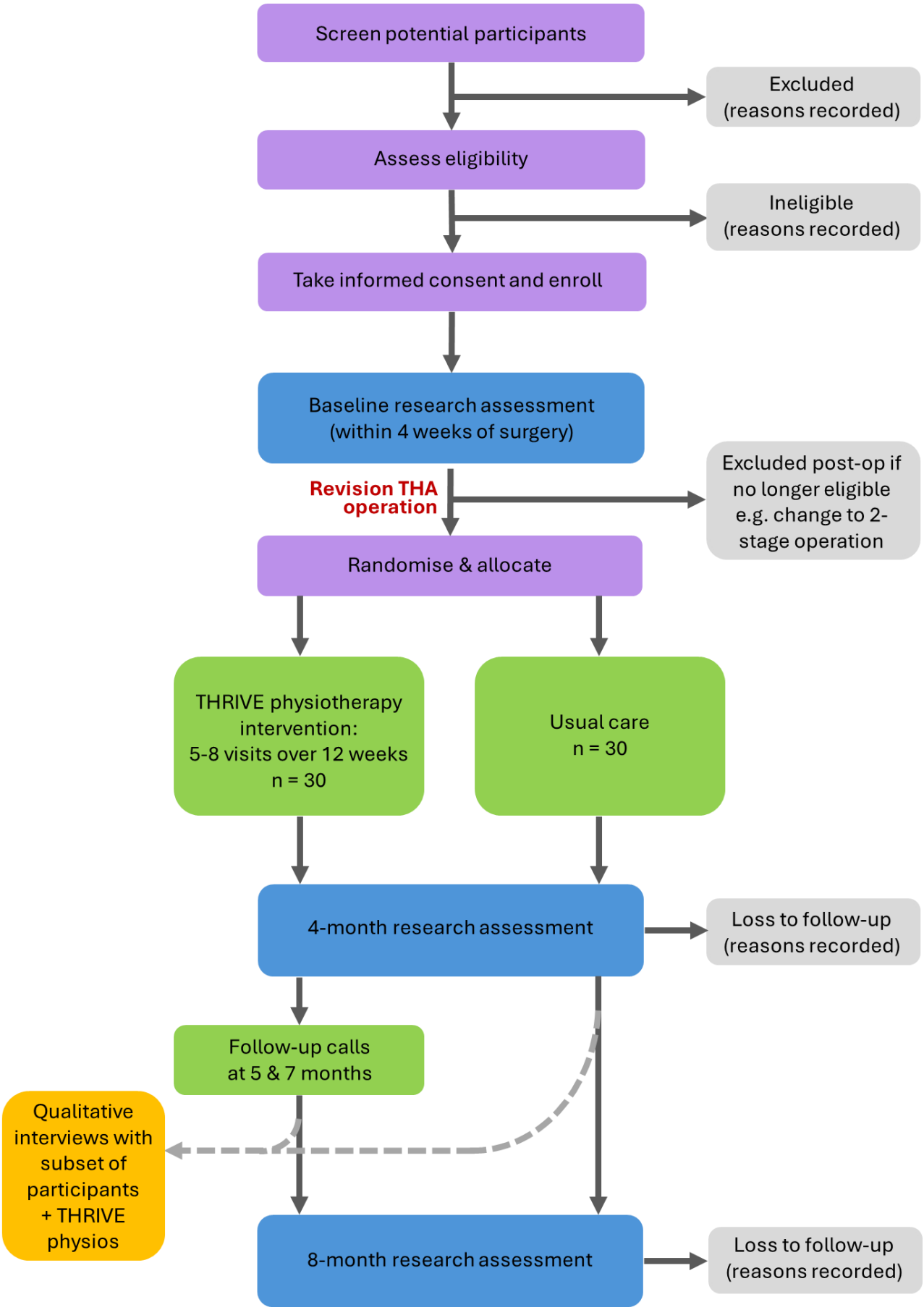
21. APPENDIX A: STUDY FLOW CHART



22. APPENDIX B1: SCHEDULE OF STUDY PROCEDURES

Procedures	Pre-enrolment	Pre-surgery baseline	Post-surgery		4-month follow-up	8-month follow-up	Post-intervention
	Screening	Visit 1	After operation	Intervention period	Visit 2	Visit 3	Qualitative interviews
Potential participant identification and screening	x						
Provision of PIS	x						
Eligibility assessment	x		x				
Informed consent		x					
Questionnaire completion		x			x	x	
Physical assessment by research staff		x			x	x	
Randomisation			x				
Letter sent to GP informing study involvement			x				
Referral to physiotherapy (based on allocated arm)			x				
Trial interventions delivered				x			
Treatment log completed by physiotherapist (THRIVE intervention)				x			
Treatment log completed by physiotherapist (Usual Care)				x			
Home exercise diary (THRIVE intervention)				x			
Additional treatments received (healthcare resource diary)				x	x	x	
Follow-up phone calls for THRIVE intervention				x			
Adverse events recorded				x	x	x	
Qualitative interviews with selected sample							x

23. APPENDIX B2: SCHEDULE OF STUDY PROCEDURES – PHYSIOTHERAPIST INTERVIEWS

Procedures	**At time of THRIVE intervention delivery training**	**Week following delivery of final THRIVE intervention**	**Within 4 weeks of delivering final THRIVE intervention**
Invitation to take part in interview study	x		
Provision of PIS	x		
Telephone call from central THRIVE study team to discuss interview study		x	
Remote informed consent completed			x
Qualitative interview conducted			x

24. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
3	V3.0	28Jan2026	Alana Morris	Inclusion of details regarding hub and spoke arrangements.
3	V4.0	24Feb2026	Alana Morris	Addition of clarifications around the training, roles and responsibilities of spoke site clinicians and safety reporting from spoke clinicians to hub PI.

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).