

Rehabilitation after revascularisation surgery: a study to improve recovery

Submission date 12/03/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 19/03/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 19/03/2026	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Peripheral artery disease (PAD) affects over 236 million people globally and is expected to rise in prevalence in Europe and the UK, as well as internationally, by 50% until 2045. The severity of PAD ranges from intermittent claudication (IC), presenting as exertional pain when walking, to the most severe manifestation, chronic limb-threatening ischemia (CLTI), which presents as lower limb rest pain or tissue loss. CLTI represents up to 11% of all PAD (25 million globally), especially in individuals from lower socio-economic backgrounds, those with diabetes and ethnic minorities such as South Asians.

CLTI is associated with high rates of limb loss and mortality, equating to a 50% mortality and amputation rate over two years in recent NHS-wide studies, as well as high costs of care. Those with CLTI require urgent surgery (revascularisation) to restore blood flow to the lower limbs. However, despite revascularisation, individuals with CLTI are still at great risk, with 1- and 3-year mortality ranging up to 50%, major adverse cardiovascular events (MACE) at 42% and 1-and-3-year amputation rates reaching 20%.

People with CLTI have limited or no walking capacity, low levels of fitness, a sedentary lifestyle, and a poor quality of life (QoL). Indeed, poor QoL, low fitness, and frailty are all independent predictors of mortality and morbidity. Furthermore, individuals with CLTI often develop anxiety and depressive disorders post revascularisation. Post surgery and without a secondary prevention strategy, these clinical outcomes will only further decline, leading to dependence on others. Therefore, this population urgently requires evidence-based rehabilitation to stop their physical decline, whilst reducing the risk of mortality or amputation.

A supervised and home-based exercise and education programme is known to help those with cardiovascular disease after they have had a heart stent or bypass surgery, but no studies have investigated if this also benefits those who have had stents or bypass surgery to help blood flow to the legs. The results of this study will help us to understand if an exercise and education programme is beneficial and if we can improve patient care in the future. This study aims to test the feasibility of a rehabilitation intervention that has been co-created for individuals with CLTI post revascularisation surgery.

Who can participate?

Patients ≥ 18 years of age diagnosed with CLTI who have undergone open, endovascular, infra-inguinal, and/or hybrid surgery ≥ 4 weeks ago but within the last 3 months.

What does the study involve?

The study is multi-site, and participants will attend whichever centre is most convenient to them. The study involves taking part in an initial baseline assessment before the commencement of a 12-week rehabilitation programme. The rehabilitation programme involves attending in-person exercise sessions once per week and the completion of a home-based exercise prescription. CLTI education sessions will also be provided bi-weekly. At 12 weeks, a final assessment is required to assess improvements in mobility, health, and quality of life. Finally, participants will be invited to participate in an informal interview about their experience in the programme (optional).

What are the possible benefits and risks of participating?

Benefits:

This research project may not offer any direct benefit at the time of participation. If any of the study measurements discover anything abnormal with your health, participants will receive prompt and appropriate medical care and attention.

Participants will be eligible to claim up to £60 reimbursement for travel expenses to and from the intervention site during their time on the study. Participants who complete the main HOPE intervention (12-week programme) will receive a £50 voucher as a "thank you" for taking part.

Risks:

The study mainly involves information gathering and non-invasive measurements. No significant risks to the participants have been identified. Exercise testing carries a very small risk of complication; participants may experience common effects such as breathlessness. Exercising with CLTI may result in some lower leg pain, which is common. Participants may also experience muscle discomfort as a result of exercise. This is a normal response and will be minimised with a thorough warm-up and cool down. To minimise risk, only members of the research team who have had appropriate training and experience will conduct the tests and supervise the exercise intervention.

During the interview, participants may be encouraged to talk about experiences which could be upsetting. However, if this occurs, the study team will stop the recording. If participants wish to discuss anything further, they can discuss with the interviewer, and would be encouraged to chat to a friend, family member or GP.

Where is the study run from?

The Manchester Royal Infirmary (Manchester) and Heartbeat (Preston), UK.

When is the study starting and how long is it expected to run for?

Recruitment aims to commence in March 2026, and the study will run until April 2027.

Participant involvement in the study will take place for 12-weeks, plus an optional interview following programme completion.

Who is funding the study?

National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?

Dr Stefan Birkett, s.birkett@mmu.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)

335894

Central Portfolio Management System (CPMS)

59364

National Institute for Health and Care Research (NIHR)

207175

Study information

Scientific Title

Rehabilitation for individuals with chronic limb-threatening ischemia post revascularisation: a co-created feasibility trial (HOPE)

Acronym

HOPE

Study objectives

To assess feasibility in terms of eligibility and recruitment rates, levels of adherence, tolerability, safety, attrition, and acceptability of the intervention.

To assess any changes in physical function and quality of life resulting from the intervention.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 28/01/2026, HRA and Health Care Research Wales (HCRW) (Health and Care Research Wales, Floor Four, North Welsh Government Offices, Cathays Park, King Edward VII Avenue, Cardiff, CF10 3NQ, United Kingdom; +44 02920 230457; HCRW.approvals@wales.nhs.uk), ref: 26/PR/0002

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Treatment

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Cardiovascular, Primary sub-specialty: Cardiovascular; Health Category: Cardiovascular, Musculoskeletal; Disease/Condition: Diseases of arteries, arterioles and capillaries

Interventions

The intervention:

Participants will take part in a 12-week rehabilitation programme (as advised by NICE guidelines for PAD patients). Participants will be expected to come to either study site (MFT Manchester or HeartBeat Preston) once per week for the duration of the study. During the study visits, participants will take part in an exercise and education session. The exercise portion of the session will last approximately 1 hour and the education portion of the session will run for up to 20 minutes.

During the exercise sessions, participants will take part in aerobic and resistance training exercises. The intensity of the exercise programme was informed by national guidelines obtained from the Association of Physiotherapists in Cardiovascular Rehabilitation (ACPICR). Therefore, participants will perform aerobic exercise at an intensity of 40-70% HRR, 11-14 RPE for 20-60 minutes. Resistance training will be performed at 1-3 sets, 8-10 repetitions, 11-13 RPE, incorporating all major muscle groups.

Following the supervised exercise, the CLTI education session will take place (a total of six education sessions will be provided and will be delivered on a bi-weekly basis). This session will involve a presentation delivered by a member of the research team. A digital recording will be available online after the session. Written leaflets will also be disseminated online and in the

session to summarise the presentation content. The education topics to be covered in these sessions will include:

- Introduction to physical activity and CLTI
- The condition and what causes it
- Medical conditions and risk factors related to CLTI
- Outcomes and what happens if nothing is done
- Types of surgery and what it achieves
- Medication and pain management

Participants will also undertake a large proportion of their rehabilitation programme at home. Elements of the programme which will be home-based include walking, balance, and breathing /relaxation exercises. Strength (resistance training) and aerobic exercises will initially be conducted under supervision at the venue (Heartbeat, Preston or Manchester Royal Infirmary, Manchester). However, once the research team is confident that a participant can perform the exercises with correct technique and has sufficient experience under supervision, the participants will be sent home with resistance bands to increase the frequency of this training modality. Activities performed at home will be monitored using activity diaries, telephone check-ins (once per week) and activity monitors.

Outcomes:

At baseline and 12-weeks a suite of outcomes will be assessed to evaluate the success of the HOPE Rehabilitation Programme. During the screening/baseline assessment, participants will be asked to provide informed consent, demographic data, relevant medical history, height, weight, waist measurements, BMI, pain-free walking distance, handgrip strength, and questionnaire completion. Post-intervention at 12 weeks, all of this data will be recollected (apart from informed consent and medical history). On a weekly basis, the following information will also be recorded:

Tolerability - whether the participant is able to reach and maintain the prescribed exercise. Reasons for stopping the exercise sessions will be recorded as free text e.g. leg pain, fatigue or breathlessness.

Attendance at each of the 12 exercise sessions.

Adherence to home-based exercise sessions.

Attrition - Whether the participant discontinued the intervention or was lost to follow-up.

Safety - The collection and reporting of data on adverse events and serious adverse events will be in accordance with ICH GCP and the Research Governance Framework 2005.

All source data (recruitment information, exercise diaries, AE/SAE report forms etc) will be recorded/ uploaded to the electronic medical record (as per sponsor policy) and subsequently recorded in the study database. Paper documentation will be stored on-site once the data is extracted/transcribed.

The participants will also be invited to attend an optional interview post-intervention. The interview will involve an informal conversation with a member of the research team to discuss the participant's experience/opinion of the programme. Participants who were identified as eligible and chose not to take part, as well as those who chose to leave the programme, will also be offered an interview to gather their opinions on the rehabilitation programme. The estimated

time for each interview is 30-45 minutes (maximum 1 hour) and will be conducted in person or via telephone.

Finally, a focus group will be run with clinicians and rehabilitation staff who were involved in the recruitment of participants and delivery of the programme. One focus group will be run at the Manchester Site and one at the Preston Site. A consent form will be provided alongside the PIS on initial approach of the clinical staff, but the consent form will be signed in-person on the day of the focus group meeting.

The focus group will run for a maximum of 3 hours. The questions will be focused on staff interaction with the service/patients, including roles and responsibilities in the delivery of programme, interactions with patients, training needs and any improvement suggestions.

Intervention Type

Behavioural

Primary outcome(s)

1. Feasibility, defined by recruitment: number recruited / number eligible measured using data collected weekly in a recruitment log at weekly in-person study visits, home-based exercise diaries, and weekly phone calls with a member of the study team
2. Feasibility, defined by eligibility: number eligible / number screened measured using data collected weekly in a recruitment log at weekly in-person study visits, home-based exercise diaries, and weekly phone calls with a member of the study team
3. Feasibility, defined by adherence: number of sessions attended measured using data collected weekly in a participant's exercise diary at weekly in-person study visits, home-based exercise diaries, and weekly phone calls with a member of the study team
4. Feasibility, defined by tolerability: the number of participants able to achieve the set exercise prescription measured using data collected weekly in a participant's exercise diary at weekly in-person study visits, home-based exercise diaries, and weekly phone calls with a member of the study team
5. Feasibility, defined by safety: number and type of adverse events (AEs) and serious adverse events (SAEs) measured using data collected weekly in an AE/SAE report form at weekly in-person study visits, home-based exercise diaries, and weekly phone calls with a member of the study team
6. Feasibility, defined by attrition: number who discontinued the intervention or were lost at follow-up measured using data collected weekly in a recruitment log at weekly in-person study visits, home-based exercise diaries, and weekly phone calls with a member of the study team
7. Qualitative measure: Acceptability measured using information collected during semi-structured interviews (participating patients and non-participating patients) and focus groups (clinician stakeholders) at one time point and recordings will be transcribed for thematic analysis. Participant interviews will take place at the end of the 12-week intervention period for those who complete the programme. For patients who are eligible but chose not to participate OR enrolled onto the programme and decided to leave, interviews will take place at their earliest convenience. Clinician focus groups will take place at the end of the study once all patients have completed the intervention.

Key secondary outcome(s)

1. Maximal walking distance measured using Maximum Walking Distance (MWD) assessed via a graded treadmill test using the Gardner Skinner protocol at baseline and 12 weeks
2. Pain-free walking distance measured using the Pain-Free Walking Distance (PFWD) assessed via a graded treadmill test using the Gardner Skinner protocol at baseline and 12 weeks
3. Hand grip strength measured using a hand-held isometric dynamometer endorsed by The European Society For Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO) at baseline and 12 weeks
4. Physical function measured using a short physical performance battery (SPPB) at baseline and 12 weeks
5. Health-related quality of life measured using a 5-component scale questionnaire (EQ-5D-5L) and Medical Outcomes Short-Form-36 version 2 questionnaire at baseline and 12 weeks
6. Anxiety and depression measured using the Hospital Anxiety and Depression Score (HADS). at baseline and 12 weeks

Completion date

30/04/2027

Eligibility**Key inclusion criteria**

Rehabilitation programme:

1. ≥ 18 years of age
2. Diagnosed with CLTI
3. Undergone open, endovascular, infra-inguinal, and/or hybrid surgery ≥ 4 weeks ago but within the last 3 months
4. Physically able to take part in the rehabilitation programme
5. Able to consent to study activities, participants' must be compos mentis and able to understand spoken English

Focus group:

1. Involvement in recruitment for the HOPE study OR delivery of the rehabilitation programme
2. Ability and availability to attend an in-person focus group

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Additional surgery pending (including any surgical procedure, not only CLTI-related)
2. Unhealed surgical wounds on the legs or feet

Date of first enrolment

31/03/2026

Date of final enrolment

30/04/2027

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Heartbeat (Preston)**

Sir Tom Finney Way

Preston

England

PR1 6PA

Study participating centre**North West RRDN**

Cobbett House

Oxford Road

Manchester

England

M13 9WL

Sponsor information**Organisation**

Manchester University NHS Foundation Trust

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

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

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The data will be stored on the Manchester Metropolitan University (MMU) RDS system. Participants will be provided with a study ID for the duration of their study enrolment. Participant identifiable data will only be accessible to the study team who work directly for MMU. Pseudonymised data will be shared with the entirety of the study team for review and analysis, as required. The RDS system is not accessible without an MMU-managed computer system, therefore any data to be sent to external members of the study team will be transferred via the Manchester University NHS Foundation Trust (MFT) Secure Portal. If the individual doing the analysis does not require a pseudonymised dataset or is not involved in any data checks, they will be given access to a fully anonymised dataset only. When the pseudonymised/ anonymised data is shared with the study team, a read-only copy will be provided to ensure that no edits to the original data can be made. All documents will also be password-protected to ensure data security.

Interview and focus group recordings will be shared with McGowan Transcriptions Limited. The service uses Global Lounge for all recording and documentation data transfer. Global Lounge utilises third-party McAfee Secure scans and AES 256-bit encryption with SSAE 16 certification for data security. Recordings and transcripts will be removed from the individual transcriber's system 10 days after receipt via secure deletion. McGowan transcriptions limited do not retain

audio or text files of completed projects beyond 95 days of the delivery of the project. The statistical approach for this study has been signed off on by the MFT Statistician (Catherine Fullwood). The analysis software to be used will include SPSS and NVivo. The trial will be reported in accordance with the CONSORT 2010 statement extension to feasibility and pilot trials. Descriptive statistics will be reported for our proof of feasibility outcomes, patient recruitment rates, intervention uptake, quality of data collection and intervention delivery. Categorical data will be summarised as frequency and 95% binomial confidence intervals, and continuous data as mean and standard deviation, or median and interquartile range. Interviews/focus groups will be audio recorded (with participants' permission) and transcribed verbatim (by McGowan Transcriptions Limited). Interviews and focus group data will be pseudonymised before dissemination to the wider study team. Data will be analysed using thematic analysis.

Following full completion of this study, all data will be analysed, formally reported, and submitted to a high-impact open-access peer-reviewed journal. The results from this study will also be presented at prestigious international scientific meetings.

Archiving of study documentation will be authorised by the sponsor (MFT) following submission of the end-of-study report. When all data is collected, analysed, and reported, Manchester Royal Infirmary (MRI) will be responsible for archiving the trial master file and associated study documents. The site file and study documents from HeartBeat will be transferred to MMU for storage on study completion. All essential documents will be archived for 10 years after completion of the study. Manchester Metropolitan University will then destroy the essential documents (paper and electronic) after 10 years from study completion when authorisation for destruction has been received by the sponsor.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 1.0	06/10/2025	17/03/2026	No	No