ISRCTN12347290 https://doi.org/10.1186/ISRCTN12347290

Home-based blood flow restriction exercise in people with peripheral arterial disease

Submission date 16/06/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/06/2026	**Overall study status** Ongoing	
Last Edited 18/06/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Peripheral artery disease (PAD) is a common condition where narrowed arteries reduce blood flow to your limbs (usually the legs). According to treatment guidelines, patient care should include advice and treatment aimed at prevention of cardiovascular disease with referral to a supervised exercise training (SET) programme. However, SET programmes are affected by low availability and adherence.

Blood flow restriction exercise (BFR), where a tourniquet is used to reduce arterial inflow and block venous outflow, alongside resistance training, represents an innovative treatment approach for people with PAD. A feasibility study which delivered a supervised BFR programme demonstrated high adherence and excellent safety, as well as improvements in functional capacity, walking pain and quality of life. However, as implementation of a community-based intervention would be difficult, we need to coproduce a bespoke, home-based, self-managed BFR-based intervention.

The aims of this study are:

Phase 1: to produce a home-based intervention, modelled on our community-based BFR exercise programme.

Phase 2: to estimate the rates of recruitment, compliance, and retention for a definitive trial; to estimate the outcome completion rate at the follow-up visit; and to refine a cost-effectiveness analysis framework.

Phase 3: to conduct post-intervention interviews with participants to refine the intervention's processes.

Who can participate?

Patients with PAD with stable claudication (i.e., symptoms unchanged for 6 months)

What does the study involve?

Phase 1: We will conduct focus groups and/or additional interviews with patients to co-produce the intervention. Once the intervention is developed, a workshop will refine it.

Phase 2: Following baseline assessments, participants will be randomly allocated into one of two groups: Group A will follow the developed intervention (BFR-based exercise and health advice) and standard therapy; Group B will receive standard therapy only.

Although the intervention particulars will be defined in Phase 1, it will be self-managed, with

regular personal contact with a facilitator. Assessments will be repeated at 3 and 6 months. We will then interview participants (Phase 3) to hear about their programme experience.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Sheffield Health Partnership University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2026 to December 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
1. Prof. Markos Klonizakis, m.klonizakis@shu.ac.uk
2. Dr Tom Parkington, t.parkington@shu.ac.uk

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Prof Markos Klonizakis

Contact details
Collegiate Crescent Campus, Sheffield Hallam University
Sheffield
United Kingdom
S10 2BP
+44 (0)1142255697
m.klonizakis@shu.ac.uk

Type(s)
Public

Contact name
Dr Tom Parkington

Contact details
Collegiate Crescent Campus, Sheffield Hallam University
Sheffield
United Kingdom
S10 2BP
+44 (0)1142252262
t.parkington@shu.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
359782

Central Portfolio Management System (CPMS)
69032

National Institute for Health and Care Research (NIHR)
209640

Study information

Scientific Title
Exploring the feasibility of using home- and blood flow restriction-based exercise in combination with health coaching for the management of peripheral arterial disease

Acronym
CALIBRE-IC

Study objectives
The main hypothesis is that it is feasible to design and implement a lifestyle intervention based on blood flow restriction (BFR) exercise.

The study objectives are:
Phase 1 (co-production): to produce a home-based intervention, modelled on our community-based BFR exercise programme.

Phase 2 (feasibility):
1. To estimate the rates of recruitment, compliance, and retention for a definitive trial
2. To estimate outcome completion rate at follow-up visits
3. To refine a cost-effectiveness analysis framework

Phase 3: To refine the intervention's processes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/01/2026, East Midlands - Leicester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; leicestercentral.rec@hra.nhs.uk), ref: 25/EM/0278

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral arterial disease

Interventions
This is a three-phase study (comprising intervention design and feasibility), informed by the MRC complex interventions framework, using both qualitative (Phase 1: a participatory approach based on focus groups/interviews) and mixed methods (Phase 2: RCT; Phase 3: qualitative study). Total study duration will be 36 months.

Phase 1 (intervention co-production):
We will gather the views and opinions of pPAD in 3-4 focus groups and/or additional interviews, with the aim of co-designing the intervention format and content, as well as all relevant participant-facing material. Co-designing will be evidence-based; the home-based exercise programme will be centred on published evidence about exercises and on our successful BFR community intervention.
Once this information is collected, we will work collaboratively with our PPIE group to produce the intervention, therefore ensuring that the information collected is translated successfully into a practical tool, that participant burden is kept to a minimum and that the documents and resources' wording is appropriate. We will then conduct a workshop (n = 6) to pilot-test adapted ideas, tools, and resources.

Phase 2 (feasibility):
Following eligibility confirmation, an appointment will be made for baseline measurements to take place (VISIT 1; 60 minutes). Baseline measurements will be repeated at 3 months (visit 2) and 6 months (visit 3).
During follow-up visits, assessors will review participants' paper resource use diary, as used successfully in our previous feasibility trials. This will be completed by participants during the 6-month intervention, aiming to collect information on PAD-related healthcare visits and expenses to assist in the health-economic exercise. A decision on whether this will be paper- or online-based (alongside all other participant materials) will be made in Phase 1. On follow-up visits, we will also collect information on any exercise-related, non-study-prescribed activities that participants from both groups have taken part in. Participants will also be given information on how to access the study team in a study-related emergency (e.g., landline and/or study email) as well as the fact that they will retain their right to withdraw from the study at any point and without a reason (although giving one will be appreciated). A study debriefing of our findings will take place at the end of the study, in a mode and manner decided in Phase 1. All study participants will receive a "thank you" card at the end of their successful participation in the study.
Participants will be randomised remotely to one of two groups (Group A: intervention and standard care; Group B: standard care only) by our study statistician (to ensure allocation concealment), using a computer programme (nQuery Advisor
6.0, Statistical Solutions, Ireland) to generate stratified block randomisation with variable block size.

Home-based exercise intervention (Group A):
The full intervention details will have been co-designed in Phase 1. However, as it will be evidence-based, certain items will be predetermined.
Support materials and separate health coaching session(s) will also be offered to support long-term adherence, with content and mode to be decided in Phase 1.

Standard care (both groups):
In the wider Yorkshire region (as in most UK regions) there is no SET offer. Therefore, standard care will include regular monitoring as well as the provision of oral and written, tailored information about their condition and the need for making specific lifestyle adjustments (i.e., smoking cessation, diet, and exercise) to prevent secondary cardiovascular disease. Angioplasty, stenting, bypass surgery and/or medication (e.g., naftidrofuryl oxalate) may also be offered, according to participants' individual needs.

Phase 3 (qualitative evaluation/post-intervention interviews):
The aim of the qualitative component is to explore participants' acceptability of the intervention and study procedures. A sub-sample of 12 participants will be recruited by using purposive sampling (a mixture of genders and younger and older participants from both groups). Semi-structured interviews of up to 1 hour will be conducted with participants either face-to-face or via telephone (participants' preference) after the 3-month follow-up visit.

Transcripts will be analysed thematically by using framework analysis. An audio recording of the interviews will be made and then transcribed verbatim, and the five stages of framework analysis (familiarisation, thematic framework identification, indexing, charting, and mapping) will be followed.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rates measured using rate of consenting participants over those invited at 36 months

2. Acceptability of procedures measured using comparison of attrition rates between groups at 36 months

3. Suitability of assessment procedures measured using completion rates at 36 months

4. The acceptability of the lifestyle programme measured using session compliance data at the 3-month follow-up visit

5. Exercise safety measured using the number and type of adverse events that occur in each group at 36 months

Key secondary outcome(s)
1. Peripheral arterial disease severity measured using the Ankle Brachial Pressure Index (ABPI) at 3 and 6 months
2. Health-related quality of life measured using the EQ-5D-5L questionnaire at 3 and 6 months
3. CVD event history (since baseline) measured using patient recall of events at 3 and 6 months
4. Functional walking capacity measured using a 6 Minute Walking Test at 3 and 6 months

Completion date
31/12/2029

Eligibility

Key inclusion criteria

1. Patients with PAD with stable claudication (i.e., symptomatic presentation unchanged for 6 months)
2. Ankle–brachial index (ABI) ≤0.9

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. Stents in the artery system of the thigh; symptomatic presentation of rest pain, skin ulcers, or gangrene
2. Impaired walking by a non-PAD condition (e.g., hip or knee osteoarthritis) or cannot walk without a walking aid

Date of first enrolment
20/06/2026

Date of final enrolment
20/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Hallam University
City Campus
Pond Street
Sheffield
England
S1 1WB

Sponsor information

Organisation
Sheffield Health Partnership University NHS Foundation Trust

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
Fully anonymised, de-identified datasets will be available upon reasonable formal email requests for non-commercial requests only to bona fide researchers with a legitimate academic purpose, 3 years after the end of the study by Professor Markos Klonizakis (m.klonizakis@shu.ac.uk) for 4 years, to meet ethical approval constraints. A data sharing agreement will be developed, outlining permitted uses, security measures, and prohibition of onward sharing. The data use agreement will detail the agreed use and appropriate management of the research data to be shared, securing also appropriate acknowledgement of the significant contributions of all parties to creating new value through data sharing, including the researchers who generated the data and the original funder.

IPD sharing plan summary
Available on request