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Using exercise as a prevention tool for venous leg ulcers

Submission date
01/07/2025

Recruitment status
Recruiting

Registration date
07/07/2025

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Venous leg ulcers (VLUs) are painful wounds that happen when blood doesn't flow properly through the veins in the legs. Around 400,000 people in the UK are affected each year. These ulcers can cause pain, limit mobility, and lead to social isolation. Treating them costs the NHS up to £920 million a year. Compression therapy (like bandages or stockings) helps ulcers heal, but unfortunately, up to 69% of them come back within a year.

Researchers have developed a 12-week exercise and lifestyle programme to support healing and possibly prevent ulcers from returning. Early studies showed the programme is safe, enjoyable, and well-attended. The new study, called FISCU-III, will test whether this programme can help stop ulcers from coming back after they've healed.

Who can participate?
People living in Sheffield who have recently had a venous leg ulcer that has now healed may be able to take part.

What does the study involve?
Participants will be randomly placed into one of two groups:

Group A will follow the 12-month exercise and lifestyle programme alongside compression therapy.
Group B will receive compression therapy only.
Everyone will have tests at the start, and again at 3, 6, and 12 months. These tests will look at fitness, flexibility, quality of life, ulcer history, and any new ulcers or falls. Participants will also be asked about their experience in the programme. The programme is self-managed, but participants will get regular support through face-to-face and phone contact with trained facilitators.

What are the possible benefits and risks of participating?
Taking part may help prevent ulcers from coming back and improve overall health and wellbeing.

The programme has already been shown to be safe and enjoyable. As with any physical activity, there may be a small risk of discomfort or minor injury, but participants will be supported throughout.

Where is the study run from?
Sheffield Health and Social Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2025 to February 2029.

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

Who is the main contact?
Professor Markos Klonizakis, heartresearchuk@shu.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
254648

Central Portfolio Management System (CPMS)
57094

Study information

Scientific Title
Exploring the feasibility of using an exercise-based, self-managed, lifestyle intervention for venous leg-ulcer prevention in adults with a venous leg-ulcer history (FISCU III)

Acronym
FISCU III

Study objectives

1. Estimate the rates of recruitment, compliance and retention for a definitive trial
2. Estimate the outcome completion rate at follow-up visits, to identify any potential completion differences between study groups
3. Refine a framework to facilitate conducting a cost-effectiveness analysis
4. Conduct post-intervention interviews with participants to refine the design and delivery of the FISCU intervention
5. Define relevant "stop/go" criteria for the pilot phase of the definitive trial

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/02/2025, Health Research Authority (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 208200300; approvals@hra.nhs.uk), ref: 24/LO/0909

Study design
A single-phase study informed by the MRC complex interventions framework using mixed methods (randomized feasibility with a nested qualitative process evaluation)

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Venous leg ulcers

Interventions
Exercise lifestyle intervention: 12 months of self-managed exercise programme with embedded behaviour support, followed twice per week.

Standard treatment: Compression bandages or hosiery as prescribed by treating clinician.

Follow-ups for both groups at 3,6,9 and 12 months.

Randomisation: Participants will be randomised remotely to one-of-two study groups (Group A-FISCU lifestyle intervention and compression, Group B - compression only) using a computer programme (nQuery Advisor 6.0, Statistical Solutions, Ireland), to generate stratified block-randomisation with variable block-size. Stratification will be based on where VLU care was received (e.g., home-based or at a community/hospital clinic).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Recruitment rates will be measured as rate of invited participants who are eligible and consenting by 12 months since the start of the project.
2. Attrition rates will be established as discontinuation of intervention and loss to follow-up measurement until the end of follow up at 12 months.
3. Suitability of measurement procedures will be evaluated by completion rates and reasons for

missing data at the end of follow up at 12 months.
4. The acceptability of FISCU Intervention will be assessed by using session compliance data at the end of follow up at 12 months.
5. Exercise safety will also be assessed by exploring reasons for drop-out from the intervention and the number and type of adverse events that occur in each group at the end of follow up at 12 months.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/02/2029

Eligibility

Key inclusion criteria
1. Recently (e.g. 3-months) healed from a leg ulcer of primarily venous aetiology (e.g. with ankle brachial pressure index (ABPI) >= 0.8)
2. Able/willing to tolerate lower-limb compression

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Do not have the cognitive ability to complete the study assessments (clinician’s judgement)
2. Pregnant
3. Require major surgery within 3 months from eligibility assessment

Date of first enrolment
01/08/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust

ROR
https://ror.org/05cn4v910

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 the current study will be available upon request from Professor Markos Klonizakis (m.klonizakis@shu.ac.uk), four years after the end of FISCU III, upon reasonable request and following the removal of any identifiable information, for non-commercial purposes.

IPD sharing plan summary
Available on request