

Using exercise as a prevention tool for venous leg ulcers

Submission date 01/07/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/08/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

254648

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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