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Development and feasibility-testing of a home-based exercise training and compression hosiery intervention for people with venous ulceration

Submission date
28/10/2019

Recruitment status
No longer recruiting

Registration date
30/10/2019

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Venous leg ulcers (VLUs) affect almost 400,000 people over the age of 65 in the UK. These are triggered by inadequate blood flow through the veins, causing pain, mobility restrictions, devastation and social isolation. Each VLU costs about £2k/year to the NHS, while annual healthcare costs are about £400 million. Compression therapy (most commonly stockings or bandages) are used to treat VLUs: although healing rates are good, ulcers often return. Moreover, many remain open for up to 1 year, needing about 50 visits to heal. Consequently, supportive therapies to compression are needed to reduce healing times. Exercise may provide an answer. The researchers recently examined if it was possible to use a 12-week, community-based exercise programme, along with compression therapy, to treat VLUs. The programme was safe, participants enjoyed it and were attending their sessions. The programme also offered reduced healing times and savings to the NHS of up £875/ulcer. Nevertheless, the programme wasn't accessible by people who are house-bound and could otherwise do the programme exercises. Therefore, the researchers need to design and explore the practicality of a home-based exercise programme, which would be offered to patients who cannot travel. This is worth trying, as findings indicate that 74% of house-bound people with VLUs would willingly try such a programme.

Who can participate?
Patients aged 18 and over with at least one VLU

What does the study involve?
In Phase 1, patients help design the home-based exercise programme. In Phase 2, patients are randomly allocated to one of the two study groups to receive home-based exercise and standard care, or standard care only, for 12 weeks with an extra 3 weeks to allow for missed sessions. Patients are assessed at 3 and 6 months to explore any changes that might take place in the lower leg physiology and quality of life. Finally, in Phase 3 the researchers talk to Phase 2 participants to hear about their study experience and refine the programme further.

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

Where is the study run from?
Sheffield Hallam University (UK)

When is the study starting and how long is it expected to run for?
December 2018 to January 2023

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS: 42699

Study information

Scientific Title
Development and feasibility-testing of a home-based exercise training and compression hosiery intervention for people with venous ulceration

Acronym
FISCU II

Study objectives
Current hypothesis as of 13/07/2022:
Venous leg ulcers (VLUs) affect almost 400,000 people over the age of 65 in the U.K. These are triggered by inadequate blood flow through the veins, causing pain, mobility restrictions, devastation and social isolation. Each VLU costs about £2k/year to the NHS, while annual healthcare costs are about £400 million. Compression therapy (most commonly stockings or bandages) are used to treat VLUs: although healing rates are good, ulcers often return. Moreover, many remain open for up to 1 year, needing about 50 visits to heal. Consequently, supportive therapies to compression are needed to reduce healing times. Exercise may provide an answer. The researchers recently examined if it was possible to use a 12-week, community-based exercise programme, along with compression therapy, to treat VLUs. The programme was safe, participants enjoyed it and were attending their sessions. The programme also offered reduced healing times and savings to the NHS of up £875/ulcer. Nevertheless, the programme wasn’t accessible by people who are house-bound and could otherwise do the programme exercises. Therefore, the researchers need to design and explore the practicality of a home-based exercise programme, which would be offered to patients who cannot travel. This is worth trying, as findings indicate that 74% of house-bound people with VLUs would willingly try such a programme. In Phase 1, people with VLUs will help to design the home-based exercise programme. In Phase 2, the researchers will recruit people with VLUs in Sheffield, who although house-bound, can do some exercises (flexibility, stretching and chair-aerobics) and are mentally healthy. The researchers will have the intervention tested and explore any changes that might take place in the lower leg physiology and quality of life. Finally, in Phase 3 the researchers will talk to Phase 2 participants to hear about their study experience and refine the programme further.

The main research question for this study is: Can we develop and pilot test a home-based, exercise intervention for home-bound people with VLUs?
Phase 1: The primary aim of Phase 1 will be to develop, with the support of people with VLUs in specially-arranged focus groups and interviews, a home-based, exercise intervention, modelled on the exercises delivered on the successful FISCU community-based exercise programme. Specific objectives will include: a) the definition of the regularity/mode/type of support offered by the intervention facilitators to participants, b) the choice of exercises implemented in the home-based programme (based on exercises that are appropriate to meet the programme's targets), c) the adaptation of materials and resources provided to participants and d) the retention/adherence promotion strategy/monitoring followed during home-based delivery
Phase 2: The primary aims for Phase 2 are to estimate the rates of compliance and retention for a definitive trial. Specific objectives include: i) to assess the ease of data collection required for each potential primary outcome (including participant burden and impact of participant's cognition, assessed via qualitative data). ii) to evaluate quantitatively (i.e. compliance) the proposed exercise intervention
Phase 3: The primary aims for Phase 3 will be to conduct post-intervention interviews with participants and using the obtained information to refine the design and delivery of the home-based programme. The specific objective for Phase 3 will be to evaluate qualitatively (i.e. direct patient experience of the interventions) and then carry out the intervention refinement task.

Sub-study:
We will recruit 6-8 people with VLUs with an early stage neurodegenerative disease (e.g., Alzheimer's disease, Parkinson's disease), which will support us to further adapt the intervention developed in Phase 1 of the study, in order to make it appropriate for this group of people. Participants will engage in face-to-face interviews or focus groups and will support the adaptation of the intervention.
Once the co-design phase is completed, these participants will take part in a 1-month implementation of the intervention, to assess its feasibility in real terms. Participants will have to undertake the same assessments and complete the same paperwork as all Phase-2 participants of the main study.
Upon completion of the 1-month intervention period, participants will be invited to take part in another round of face-to-face interviews or focus groups, with the view to share their experiences on the intervention.
Family members, friends and carers of the sub-study participants will be encouraged to be present at the interview and assessment sessions and to support the participants in carrying out their exercise sessions.

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Previous hypothesis:
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exercises. Therefore, the researchers need to design and explore the practicality of a home-based exercise programme, which would be offered to patients who cannot travel. This is worth trying, as findings indicate that 74% of house-bound people with VLUs would willingly try such a programme. In Phase 1, people with VLUs will help to design the home-based exercise programme. In Phase 2, the researchers will recruit people with VLUs in Sheffield, who although house-bound, can do some exercises (flexibility, stretching and chair-aerobics) and are mentally healthy. The researchers will have the intervention tested and explore any changes that might take place in the lower leg physiology and quality of life. Finally, in Phase 3 the researchers will talk to Phase 2 participants to hear about their study experience and refine the programme further.

The main research question for this study is: Can we develop and pilot test a home-based, exercise intervention for home-bound people with VLUs?
Phase 1: The primary aim of Phase 1 will be to develop, with the support of people with VLUs in specially-arranged focus groups and interviews, a home-based, exercise intervention, modelled on the exercises delivered on the successful FISCU community-based exercise programme. Specific objectives will include: a) the definition of the regularity/mode/type of support offered by the intervention facilitators to participants, b) the choice of exercises implemented in the home-based programme (based on exercises that are appropriate to meet the programme's targets), c) the adaptation of materials and resources provided to participants and d) the retention/adherence promotion strategy/monitoring followed during home-based delivery
Phase 2: The primary aims for Phase 2 are to estimate the rates of compliance and retention for a definitive trial. Specific objectives include: i) to assess the ease of data collection required for each potential primary outcome (including participant burden and impact of participant’s cognition, assessed via qualitative data). ii) to evaluate quantitatively (i.e. compliance) the proposed exercise intervention
Phase 3: The primary aims for Phase 3 will be to conduct post-intervention interviews with participants and using the obtained information to refine the design and delivery of the home-based programme. The specific objective for Phase 3 will be to evaluate qualitatively (i.e. direct patient experience of the interventions) and then carry out the intervention refinement task

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/04/2019, London Surrey Research Ethics Committee (Tel: +44 (0)20 7104 8222; Email:
NRESCommittee.SECoast-Surrey@nhs.net), ref: 18/LO/1983

Study design
Randomised; Both; Design type: Treatment, Process of Care, Complex Intervention, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

Current intervention as of 14/07/2022:
Following baseline measurements, participants (n=40) will be randomised remotely to one of the two study groups (Group A: home-based exercise with embedded behavioural support and standard care, n=20; Group B: standard care only, n=20) by the 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. Stratification will be on the basis of ulcer size (e.g., ulcer size greater than 3 cm or between 1 and 3 cm in any direction).

Total duration of treatment: 12 weeks with an extra 3 weeks to allow for missed sessions
Follow-up for both groups: assessment at 3 months and 6 months after baseline

Sub-study: Following the interviews and focus groups and after the intervention is co-developed with people with VLUs and at an early stage of neurodegenerative disease, all participants will follow the new intervention for 1 month. The primary outcome of the sub-study will be to develop a lifestyle exercise intervention tailored for people with VLUs living with an early-stage neurodegenerative disease.

Previous intervention as of 13/07/2022:
Following baseline measurements, participants (n=40) will be randomised remotely to one of the two study groups (Group A: home-based exercise with embedded behavioural support and standard care, n=20; Group B: standard care only, n=20) by the 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. Stratification will be on the basis of ulcer size (e.g., ulcer size greater than 3 cm or between 1 and 3 cm in any direction).

Total duration of treatment: 12 weeks with an extra 3 weeks to allow for missed sessions
Follow-up for both groups: assessment at 3 months and 6 months after baseline

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Previous intervention:
Following baseline measurements, participants (n=40) will be randomised remotely to one of the two study groups (Group A: home-based exercise and standard care, n=20; Group B: standard care only, n=20) by the 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. Stratification will be on the basis of ulcer size (e.g., ulcer size greater than 3 cm or between 1 and 3 cm in any direction).

Total duration of treatment: 12 weeks with an extra 3 weeks to allow for missed sessions
Follow-up for both groups: assessment at 3 months and 6 months after baseline

Intervention Type

Other

Primary outcome(s)

1. Recruitment rates measured as rate of invited participants who are eligible and consenting and reported in Consolidated Standards of Reporting Trials (CONSORT) flowchart
2. Acceptability of procedures assessed by examining reasons for drop-out in discontinuing participants and comparing attrition between groups
3. Suitability of measurement procedures evaluated by completion rates and reasons for missing data
4. Attrition rates established as discontinuation of intervention and loss to follow-up measurement
5. The acceptability of the exercise programme assessed by using session compliance data and participant feedback via one-to-one, semi-structured interviews conducted after the 3-month follow-up visit
6. Exercise safety assessed by exploring reasons for drop-out from the intervention and the number and type of adverse events that occur in each group
7. Group contamination assessed by the number of people in the control group who take up exercise as a result of their study participation

Key secondary outcome(s))
1. Health-related quality of life assessed using EQ-5D-5L and VEINES-QOL at baseline and at 3 and 6 months
2. Physical fitness assessed using Senior Fitness Test at baseline and at 3 and 6 months

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. Are at least 18 years of age
2. Have at least one venous leg ulcer of primarily venous aetiology (determined by a clinician) with a maximum diameter ≥ 1 cm
3. Have an ankle brachial pressure index (ABPI) ≥ 0.8 (recorded within the previous 3 months)
4. Are able/willing to tolerate lower-limb compression

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Are unsuitable/unable to exercise (determined by a clinician at screening or baseline)
2. Are unable/unwilling to tolerate lower-limb compression
3. Have insulin-controlled diabetes mellitus
4. Are pregnant
5. Have coexisting skin conditions, vasculitis, deep venous occlusion or malignant/atypical ulceration (if suitable otherwise, participants may be re-considered at a later stage)
6. Require major surgery within 3 months from eligibility assessment
7. Have a leg ulcer with a maximum diameter ≤1 cm
8. Have had an ulcer at the same site within the previous 3 months
9. Are unable or do not wish to consent to participation in the trial

Date of first enrolment
01/09/2019

Date of final enrolment
30/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lifestyle, Exercise and Nutrition Improvement (LENI) Research Group
Department of Nursing and Midwifery
Sheffield Hallam University
Collegiate Campus
Collegiate Crescent
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United Kingdom
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Sponsor information

Organisation
Sheffield Health & Social Care NHS Foundation Trust

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0418-20021

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to these being used for consecutive grant applications following the end of the current one and lack of relevant ethical approval.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Focus group/interview data analysed through thematic analysis	08/03/2025	12/02/2025	Yes	No
Results article		11/10/2023	13/02/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes