ISRCTN10205425 https://doi.org/10.1186/ISRCTN10205425

Feasibility of an Exercise Intervention in Patients with Venous Ulcers

Submission date
08/05/2014

Recruitment status
No longer recruiting

Registration date
08/05/2014

Overall study status
Completed

Last Edited
26/11/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Chronic venous insufficiency (CVI) is a medical condition where the veins cannot pump enough blood back to the heart, and usually affects the legs. Some patients develop leg ulcers, which can cause pain, social isolation, inability to move, and reduced quality of life. Treatment of venous ulcers places a huge financial burden on the National Health Service. Compression stockings are often used to treat venous ulcers. While they work very well, ulcers frequently come back. Some patients can also benefit from venous surgery, but ulcers frequently come back and many patients are reluctant to undergo surgery. Different therapies are therefore needed. Supervised exercise training might be useful in addition to compression therapy in the prevention and treatment of venous ulcers. Exercise is a low-cost, low-risk, and effective strategy for improving physical and mental health. However, little is currently known about the practicality and usefulness of supervised exercise training used in combination with compression in patients with venous ulcers. We have designed a study to find out the possible benefits of supervised exercise training and compression stockings in patients with venous ulceration, to see if a larger study would be possible.

Who can participate?
Eighty patients with new venous ulcers can take part in this study.

What does the study involve?
Patients will be randomly assigned to either receive usual care (i.e., wear compression stockings), or to take part in a 12-week exercise programme and wear compression stockings. Exercising participants will undertake three sessions of supervised exercise each week (a combination of walking, cycling and leg strength and flexibility exercises). Patients will be followed-up until 1 year after completing the study.

What are the possible benefits and risks of participating?
Possible benefits to be explored include improved healing rate and time, reduced complications and higher quality of life. This is a low risk study, as all participants will be screened before the exercise programme and the programme includes a fully-supervised, moderate-intensity exercise.

Where is the study run from?
The study is run from Sheffield Hallam University in association with the Sheffield Health and Social Care NHS Foundation Trust (UK). Additional recruitment is undertaken by University of Lincoln in association with Lincolnshire Community Health Services NHS Trust (UK).

When is the study starting and how long is it expected to run for?
May 2014 to May 2017.

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

Who is the main contact?
Dr Markos Klonizakis
m.klonizakis@shu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Emma McIntosh

Contact details
The Centre for Sport and Exercise Science
Faculty of Health and Wellbeing
City Campus, Howard Street
Sheffield
United Kingdom
S1 1WB
-
E.mcintosh@shu.ac.uk

Additional identifiers

Protocol serial number
16665

Study information

Scientific Title
Exploring the Feasibility of Implementing a Supervised Exercise Training and Compression Hosiery Intervention in Patients with Venous Ulceration

Acronym
FISCU

Study objectives
Is a randomised controlled trial comparing supervised exercise training and compression therapy versus compression therapy only feasible in patients with venous ulceration?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber; ref. 14/YH/0091

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Patients are randomised to two groups:
1. Usual care : Compression stockings
2. Excercise programme: Low-to-medium term intensity exercise. Thirty six sessions over a period of 3 months.; Follow Up Length: 12 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The main outcomes of the study are the ones that are going to define if this feasibility study should proceed to a larger randomised controlled trial. These will be:
1. The definition of an appropriate primary outcome variable
2. Compliance of participation of patients randomized to the exercise group
3. Loss to follow-up
4. Patience preferences in regards to the randomization group

These will be defined at the trial end (12 months).

Key secondary outcome(s))
1. Time to reference ulcer healed (clinical report - time of healing)
2. Proportion of patients healed (clinical report - assessed at 3, 6 and 12 months post-randomisation)
3. Percentage and absolute change in ulcer size (clinical measurement - measured at baseline, 3, 6 and 12 months post-randomisation)
4. Proportion of time patients are ulcer free (clinical report)
5. Recurrence data will be collected at 3, 6 and 12 months post-randomisation)
6. Health-related quality of life (assessed at baseline, 3, 6 and 12 months post-randomisation

using the EQ-5D-5L and VEINES-QOL)
7. Lower-limb cutaneous microvascular function
8. Microvascular assessments using Laser Doppler Fluximetry and Iontophoresis at baseline, 3 months, 12 months post-randomisation
9. Physical fitness Senior Fitness Test (physical assessment, at baseline, 3 months and 12 months post-randomisation)

Completion date
18/05/2017

Eligibility

Key inclusion criteria
1. Patient has at least one new venous leg ulcer with a maximum diameter =1 cm
2. Patient has an ankle brachial pressure index (ABPI) =0.8 (taken within last 3 months)
3. Patient is able and willing to tolerate high compression
4. Patient is aged =18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient is unsuitable or unable to exercise (nurse/doctor judgement)
2. Patients who are not tolerant of high-level lower-limb compression delivered by compression stockings or multilevel bandaging
3. Patients with insulin-controlled diabetes mellitus
4. Pregnant women
5. Patients with coexisting skin conditions, vasculitis, deep venous occlusion or malignant /atypical ulceration
6. Patients who require major surgery
7. Patients with leg ulcers with a maximum diameter of <1 cm
8. Patients who have had an ulcer at the same site within the previous 3 months (updated 30/07 /2015: was previously 6 months)
9. Patients are unable or do not wish to consent to participation in the trial

Date of first enrolment
21/07/2014

Date of final enrolment
21/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Hallam University
Sheffield
United Kingdom
S1 1WB

Study participating centre
University of Lincoln
Lincoln
United Kingdom
LN6 7TS

Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust (UK)

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

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

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	results	01/05/2018		Yes	No
Protocol article	protocol	06/10/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes