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A multicentre randomised research trial assessing the effectiveness and acceptability of a calf muscle exercise device for supportive treatment of venous leg ulcers

Submission date
02/05/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
24/08/2022

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
A venous leg ulcer (VLU) is a long-lasting open sore on the lower leg caused by increased pressure of blood in the leg veins. They are the most common type of leg ulcers, affecting 1-3% of the population over 60 years and this incidence is expected to increase with an aging population. There is some evidence to suggest that specific exercise of the calf muscle through for example plantar flexion movement with resistance (moving the front of the foot up and down, similar to what a drummer does when using the foot pedal of a drum) may improve the calf muscle pump function. This type of exercise has been shown to improve blood flow and endurance, at least in the short term. It is known that the return of blood to the heart from the legs (venous return) depends on an efficient calf muscle pump and adequate range of ankle motion. Whilst failure of these systems may contribute to the development of VLU, evidence suggests that exercise programmes designed to increase the strength of the calf muscle pump through resistance training would be feasible and effective in improving calf muscle pump function and ankle range of motion. However there is still a lot of uncertainty regarding the effects of this exercise on ulcer healing. The aim of this study is to find out whether it would be feasible to run a full scale study looking at the effectiveness of a plantar flexion pedal (developed by StepIt Ltd) will be of benefit to people with VLU in terms of improving the healing rate.

Who can participate?
Adult who have had a VLU for up to six months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual treatment only, which involves compression therapy (wearing tight stockings which squeeze the leg to improve circulation). Those in the second group receive usual treatment with the addition of the StepIt exercise programme for 12 weeks. Participants are be supplied with a pedal to use at home and are asked to exercise on the pedal for one minute, followed by a one minute rest,

repeated 10 times twice a day. The pace of the StepIt device is variable, but the desired tempo for this study would be a two second downwards and two second upwards motion, if achievable, by the participant. The resistance is approximately 6 kg when pushing downwards. Participants are asked to keep a diary recording how they use the pedal. At the start of the study and after 12 weeks, participants have their VLUs examined and complete assessments and questionnaires to see if their symptoms have improved. The number of participants who take part and remain in the study until the end are also recorded to see if a larger study would be possible.

What are the possible benefits and risks of participating?
Participants who use the StepIt device may benefit from improved VLU healing, however this has not yet been proven and established, and so there may be no benefit involved with taking part. There are no notable risks involved with taking part.

Where is the study run from?
1. Carleton Clinic (UK)
2. Spencer House GP practice (UK)
3. Cumberland Infirmary (UK)

When is the study starting and how long is it expected to run for?
March 2017 to March 2019

Who is funding the study?
StepIt System AB (Sweden)

Who is the main contact?
Mr Leon Jonker
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
34377

Study information

Scientific Title
PREVUE: PlantaR flexion Exercise for Venous Ulcer Evaluation, a multi-centre, controlled, prospective, randomized trial

Acronym
PREVUE

Study objectives
The aim of this study is to assess the feasibility of conducting a full-scale trial to determine if the use of a CE-approved plantar flexion pedal, developed by StepIt Ltd, will be of benefit to people with venous leg ulcers (VLUs) in terms of healing rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 1, 26/04/2017, ref: 17/WA/0103

Study design
Randomised; Interventional; Design type: Treatment, Device, Physical

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Dermatology, Primary sub-specialty: Dermatology; UKCRC code/ Disease: Cardiovascular/ Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified

Interventions
Following written consent patients will be allocated at random to the control or intervention group, using a non-restricted randomised sequence generated for the whole sample using a free ware randomisation programme, see https://www.randomizer.org/ . The randomisation will be stratified for VLU size, with one group being those with a PUSH score of 8 or lower and the other with a PUSH score of 9 or higher. Sequential envelopes with each next randomisation allocation will be used to achieve concealment. It is recognised that random selection does not guarantee representativeness but variables which may affect the outcome variable are more likely to be balanced out and reliability enhanced (Thomas 1990). As the study involves a self-administered intervention of necessity it is not possible to achieve blinding for the participants. Due to the pilot nature of this study, the researcher will not be blinded either to the subjects intervention, although this can be considered as part of a larger trial since it would further reduce any risk of

bias. However, the primary outcome measure, size of the VLU is a quantitative outcome measure which is less prone to bias than for example a patient reported outcome measure or a clinician reported outcome measure.

Control group: Participants receive treatment as usual, which involves compression bandaging if indicated and other types of dressings if indicated.

Intervention group: Participants receive treatment as usual plus StepIt pedal exercise for 12 weeks or until ulcer healing has taken place. Participants are issued with a StepIt Pedal to use daily for foot and ankle exercises. These exercises consist of resisted plantar flexion while seated, performed 2 times daily in the pattern of: 1 minute exercise / 1 minute rest, 10 times (participants may alternate legs as an alternative to merely resting both legs for 1 minute). The participants will be asked to keep an exercise diary to record their activity. At their discharge visits participants are asked to provide their opinion on trial participation.

After six and twelve weeks, participants in both groups complete questionnaires relating to their VLU and clinical assessments.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes:
1. Compliance is measured using an assessment of participant diary entries at the end of the trial intervention period at 12 weeks
2. Recruitment and attrition are measured using final consent numbers and lost at follow-up numbers at the end of the trial
3. Adequacy of duration of follow-up (e.g. in relation to VLU healing) is measured using the number of completely healed ulcers in comparison to the total sample size at the end of week 12
4. Fitness for purpose of data collection methods including across and between care settings is measured using completion of CRF data at the end of week 12 (comparing data for participants from different care settings and recruitment sites
5. Adverse events are measured using the total number adverse events recorded at week 12 for all participants

Key secondary outcome(s))
1. VLU size is measured with Convatec grid tool (outcome measure used for calculating potential power of this present study) at baseline, 6 and 12 weeks
2. Size and characteristics of VLU, determined with PUSH score at baseline, 6 and 12 weeks
3. Mobility is measured using the LifeSpace questionnaire score at baseline, 6 and 12 weeks
4. Ankle range of motion is measured using a goniometer at baseline, 6 and 12 weeks
5. Ulcer-related Pain is measured using the VAS pain scale at baseline, 6 and 12 weeks
6. Quality of life is measured using the Charing Cross Venous Ulcer Questionnaire at baseline, 6 and 12 weeks
7. Intervention compliance (StepIt arm patients) is measured using an exercise diary kept by participants throughout the study at the end of week 12
8. Participant opinion on trial participation is measured using a satisfaction questionnaire at the end of week 12
9. Patient withdrawal rates due to change in management (e.g. need for surgery) is measured

using data on loss to follow-up at baseline, 6 and 12 weeks
10. VLU infection rates are measured using clinical record data and microbiology result data at baseline, 6 and 12 weeks

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Over the age of 18
2. VLU* of less than 6 months duration
3. Tolerating compression bandaging
4. Able to give consent

*The case definition for VLU is any break in the skin on the lower leg that has been present for 2 weeks or more with a clinical venous aetiology and an ankle brachial pressure of ≥ 0.8 (NICE 2013).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Limited life expectancy, i.e. undergoing palliative care
4. Active infection in VLU

Date of first enrolment
30/05/2017

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Carleton Clinic
District Nursing Department and R&D Department
Cumwhinton Drive
Carlisle
United Kingdom
CA1 3SX

Study participating centre
Spencer House GP practice
St Paul’s Square
Carlisle
United Kingdom
CA1 1DG

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
Cumbria Partnership NHS Foundation Trust

Funder(s)

Funder type
Industry

Funder Name
StepIt System AB

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2020	07/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 4	11/11/2025	11/11/2025	No	Yes
Protocol file		12/12/2018	24/08/2022	No	No