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)

You are being invited to take part in a research study. Before you decide on participating, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with friends, relatives or your GP if you wish. It tells you about the study, will answer some questions that you may have, and it gives you detailed information about the conduct of the study. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide if you would like to take part.

What is the purpose of the study?

Venous leg ulcers (VLUs) affect approximately 400,000 UK people/year mostly over the age of 65. These are caused by inadequate blood flow through the veins, causing pain, difficulties moving around and social isolation. Compression (bandages/stocking) is used to treat VLUs, although healing rates are good, up to 69% of ulcers return within 12 months. Meaning that supportive therapies to compression are needed to reduce healing times and prevent recurrence.
Exercise may be an answer. We recently completed two small studies where we worked together with people with VLUs to develop and examine if we could use a 12-week, lifestyle programme based on aerobic exercises, alongside compression to treat VLUs either at home or in the community. In both settings the programme reduced healing times, was safe and participants enjoyed it.
Having proven that our intervention can be used as a supporting healing treatment we would like to see if it can also be used as a recurrence-prevention tool, before embarking to a bigger study.

Why have I been invited to take part?

You have been invited because according to our information, you have a recently healed venous ulcer.

Do I have to take part?

It is up to you to decide whether to take part. A decision not to take part will not affect the standard of care you receive or count against you in any way. If you decide to take part, you can withdraw from the study at any point without giving any reason. If you withdraw, unless you object, we will keep records relating to your participation, as this is valuable to the study.

What will happen if I take part?

If you are eligible for the study and are happy to take part we will arrange a baseline visit: either a member of our research team will visit you at home or a visit can take place at Sheffield Hallam University. During this appointment you will have the opportunity to ask any questions, and we will ask you to sign a consent form agreeing to take part and provide you with a copy of the form to keep. We will then look at medical history and assess your exercise capacity, quality of life, and general health (Described in greater detail below). The visit will take up to 40 minutes. Following that appointment, you will be randomly assigned to one of two groups. The group in which you are placed depends on chance and is rather like tossing a coin.

If allocated to Group A you will be invited to undertake an exercise programme that involves at least 2 self-managed sessions per week and have compression for 12 months. At the start you will be shown how to perform the exercises and given a booklet with instructions and pictures of each exercise. The sessions can be performed either at home or in the community, and you will receive face-to-face (every three-to-four weeks) and telephone (bimonthly) support from our facilitators. Group-B will only receive compression and standard clinical advice.

Participants in both groups will complete four assessments: at baseline, and then at 3-,6-and 12-months post-recruitment, in which we will repeat baseline tests and collect evidence for potential new ulcers. We will then talk to participants, nurses and facilitators about their programme experience.

Visit 1: Medical screening and baseline assessments (up to 40 minutes in total), Sheffield Hallam University (Collegiate Crescent) or at your home.

During the first 15 minutes of this visit, we will discuss the study with you in detail, ask you to sign a consent form, and conduct a basic medical assessment to confirm your suitability for the study. We will need to record your current medications, so please bring a list of all the medications that you are taking.

If you are suitable for the study, the remaining 25 minutes will involve completing various assessments of your health and fitness.
Firstly, you will be asked to complete some questionnaires about your health and quality of life.
Then, we will assess your physical fitness using three simple tests:
(1) 2-minute step in place test. Here you will be asked to march on the spot lifting your knees up to a point that's midway between the kneecap and top of the hip for two minutes.
(2) 30-second chair-stand test. Starting from a seated position, we will record the number of times you can stand up fully in 30 s with your arms folded across your chest;
(3) Sit and reach test. Starting from sitting at the edge of a chair, with your legs out straight in front, we will ask you to reach as far forward as possible towards your toes. These fitness tests might make you feel tired for a few minutes.
In the final part of the session, you will receive instructions on how to complete a brief ulcer diary which we will give you. The information you provide in this diary will allow us to follow healing/regression and how your ulcer related symptoms change over time.

Visits 2-4: (3-, 6- and 12-months after Visit 1): Follow-up assessment (30 minutes), Sheffield Hallam University or at your home.

During these visits, you will be asked to repeat the assessments that were completed in the first visit (i.e. questionnaires and physical fitness tests). You will also be asked to have your ulcer diary in-hand so that we can take a copy of it.

Participant interview

After the 12-month follow-up visit, 12 participants will have the opportunity to take part in a one-to-one interview (up to an hour) which will be led by an experienced member of the research team. The interview will explore participants experiences of the intervention to help us understand what worked, for whom and in what context. The interview will be conducted face-to-face or via telephone and recorded on Teams or a dictaphone depending on participant preference. Interviews will be stored on a password protected database and only specific members of the research team will have access and be responsible for transcription. All identifying information will be removed during the transcription process and interviews will be deleted 30 days after transcription.

Arrangements at the end of the trial

At the end of the intervention, if participants are interested, they will be given information about local exercise programmes that they could take part in. Subjects will be informed of this arrangement prior to agreeing to participate.

What are the possible advantages of taking part?

You may or may not benefit directly from this study. People who undertake regular exercise training often become fitter, healthier and improve their quality of life so you might experience this if you are allocated to the exercise group. The trial will also aid the development of a possible recurrence-prevention tool for venous ulcers which could be of benefit to others in the future.

What are the possible disadvantages of taking part?

The procedures that we are using in this research are all well-*established* techniques which have been used in other patient groups in numerous research studies without any significant side effects being reported.

Are there any expenses or payments involved?

You will receive £40 in vouchers at 6 months and £40 at 12 months if you travel to the university or a clinic to do an assessment. Participants who decide to take part in the one-to-one interview at the end of the exercise programme will receive £20. You will also receive some basic training equipment, if necessary, which will be loaned to you for the duration of the project (12 months). Additionally, we will arrange a free permit for on-site parking should you choose to drive to an assessment taking place outside your home.

How will we use information about you?

We will need to use information from your medical records for this research project.
This information will include your name, contact details, and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Sheffield Health and Social Care NHS Foundation Trust is the sponsor of this research. The research team will be using information from your medical records in accordance with the Study's Sponsors instructions and will act as the data controller for this study. This means that the research team will keep all information about you safe and secure by:

- Storing it on password protected computer databases.
- Limiting access to identifiable data to specific members of the research team. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.
- Storing paperwork in locked filing cabinets in a secure and continuously monitored building.
- Anonymising data by replacing participant names with an identification number.
- Publications will not contain any identifiable personal data.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Sheffield Hallam University and Sheffield Health and Social Care NHS Foundation Trust will keep identifiable information about you for 7 years after the study has finished. The study data will then be fully anonymized and securely archived or destroyed.

To protect your safety, rights, wellbeing and dignity all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. Therefore, this study has been reviewed by an NHS Research Ethics Committee. The research study has also been approved by Sheffield Hallam University Research Ethics Committee. Further information can be found at: https://www.shu.ac.uk/research/ethics-integrity-and-practice.

International transfers

Your data will not be shared outside the UK.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you decide to withdraw, we may ask you to consider attending one final assessment, but this is entirely optional. You can choose to leave the study at any time without having any further assessments.
- A decision not to carry on with the study will not affect the quality of care you receive in any way.

- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- our leaflet
- by asking one of the research team
- by sending an email to Professor Markos Klonizakis: m.klonizakis@shu.ac.uk or ringing us on 0114 225 5697
- the link: www.hra.nhs.uk/patientdataandresearch
- by sending an email to DPO@SHSC.NHS.UK
- by writing to:

  Data Protection Officer
  Information Department
  Sheffield Health and Social Care NHS Foundation Trust
  Wardsend Road North
  Sheffield
  S6 1LX

What will happen to the information from the study?

It is anticipated that the results of the study will be presented at scientific meetings and published in a scientific journal. The overall results will be available to you; however, it will not be possible to provide you with an individualised report of your performance.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. You can use the normal Trust complaints procedure or contact Ms Faye Mellors, PALS Advisor, Sheffield Health and Social Care NHS Foundation Trust, Tel 0114 275 8956, who will be able to provide some independent advice on the study.

Who is organising and funding the research?

This study is being funded by the Research for Patient Benefit programme of the National Institute of Health Research. Sheffield Hallam University and Sheffield Health and Social Care NHS Foundation Trust are responsible for the conduct of the study. The investigators of this study will not receive any payment for conducting this research.

Thank you for taking the time to read this information sheet and to consider this study.