The effect of leg muscle stimulation on blood flow and quality of life of older adults with leg symptoms

What is this about?

We are inviting people to participate in our study titled:

"The effect of an eight-week treatment program using foot electrical muscle stimulator (EMS) on physical function, leg symptoms and leg blood flow in community dwelling older adults."

What is the aim?

The study aims to investigate the effects of non-invasive EMS on swelling, pain, cramps and any other leg symptoms among community dwelling older adults. We are comparing between three types of stimulators: two that will cause your leg muscles to contract, and the third that wouldn't cause any muscle contraction. The outcomes will be assessed using non-invasive measurement techniques and using brief questionnaires and interviews.

Who all can participate?

Eligible participants will be adults over the age of 65 years who suffer from one or more of the following symptoms:

- Swelling, mainly in the lower legs, feet and ankle(s).
- Heaviness in the leg(s).
- Cramps in the leg(s), mainly during the night or at rest.
- Aching in the leg(s).
- Tiredness in the leg(s).

However, please note that you are not required to have any specific diagnosis of a medical condition to be eligible for the study. The conditions such as severe diabetes mellitus with severe diabetic neuropathy and other conditions that might influence the results of this study, such as a significant injury to the leg(s) in the last six months are exclusions. Also, you are not eligible if you have active cancer for which you are currently receiving treatment, or if you are having any electronic implants in your body such as a pacemaker. Screening will be performed using a medical questionnaire prior to finalising recruitment and testing.

OK, I am participating... What happens next?

If you are suitable and decide to take part in our study, you will be involved in it for the next few weeks attending a minimum of three face-to-face sessions within a 12-week period, each lasting about two hours. you will be asked to attend the physiotherapy research laboratory in the Wright Building, College Lane Campus of the University of Hertfordshire to receive EMS treatment to your feet and allow some measurements to be taken from the

legs and feet before and after treatment. We will also work through some questionnaires together. Each session, which last around two hours, will include some paperwork, screening, treatment, and assessments. Please note, all these procedures are harmless, completely non-invasive and routinely employed in clinical practice and research.

How is the EMS applied?

You will be randomly allocated to one of the three study groups. Your group allocation will decide which type of EMS you receive. Of the three types of EMS, two will generate types of currents that will cause muscle contractions **(motor stimulation)**. The third type will cause skin sensation but will not cause muscle contraction **(sub motor/sensory stimulation)**. EMS will be delivered using **'Revitive'** (Actegy Health Limited, Bracknell, UK). This is a CE marked treatment device, which is already in use for several years and is available for over the counter purchase without prescription in the UK and many other countries. It is advocated for self-use where required, safely without the supervision of a clinician. You are expected to experience a 'harmless mild electric stimulation' in the Millivolt / Milliampere range that is typical to such stimulating devices. Depending on your group and the intensity of delivery you choose, you will either feel mild pins and needles or muscle contraction or both. You will be screened for your ability to provide clear feedback upon your sensation of the stimulation. The intensity can be adjusted according to your sensation of the stimulation.

What happens on the first visit?

On your first visit, after we both have signed a consent form, you will change to appropriate clothing (shorts or similar) and undergo some simple screening tests in your legs and thereafter height, weight and body composition measurements. After this you will undergo 'pre-treatment measurements' where the researcher will record your normal baseline measures (listed in the above section) from your legs, work through the questionnaires and then talk you through the experimental procedures, what to expect during the treatment and what to do if you have a problem. Subsequently, after 30 minutes of resting while you are in the lab the stimulation will be delivered for 30 minutes. If you feel any discomfort during the session you may ask the investigator to STOP the procedures. Localized application of EMS is safe and is not known to cause any significant effect elsewhere in the body. Hence, the chances of any injury are minimal. However, you will be given clear information regarding any potential hazard and the study will be terminated if you report any discomfort while receiving the treatment. If you are happy to continue with the study, you will be given a Revitive EMS machine to take home and use at the required intensity level for 30 minutes twice daily for the next eight weeks. You will return to the lab (second visit) after using the device for eight weeks and again after four weeks from the second visit (third and final visit) for a follow-up. All tests will be repeated on both revisits.

What do I gain from this study?

We cannot promise that the study will help you, but the information gathered from this study will help improve the knowledge base by providing a better understanding of the physiological mechanisms of action of EMS. The information we get from this study will also help us to plan the methodology for further research. There should be no harmful effects or disadvantages caused by participation in this study. You can always, at any moment, withdraw from the study if such a need arises. All the assessments are safe and have been used extensively in other research.

All information about you will be handled in confidence. If you join the study, some parts of your personal details and the data collected for the study may be looked at by authorized person(s) from the University of Hertfordshire (project management team) for monitoring purposes. All will have a duty of confidentiality to you and nothing that might identify you will be made public. Any information about you that leaves the university will have your personal identification removed so that you cannot be identified. We ask your permission to keep your name and contact details at the University of Hertfordshire so that we can contact you to make or change appointments should this be necessary. This information will only be available to the researcher involved in the study and will be kept in a locked filing cabinet and/or a password protected university computer.

Who has reviewed this study?

The University of Hertfordshire Health, Science, Engineering and Technology Ethics Committee with Delegated Authority has reviewed and approved this study.

Who can I contact if I have any questions?

If you would like further information or would like to discuss any details personally, please get in touch with us, in writing, by phone or by email:

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