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The effect of an 8-week treatment programme using foot electrical muscle stimulator (EMS) on physical function and leg symptoms in community-dwelling older adults

Submission date
05/06/2019

Recruitment status
No longer recruiting

Registration date
17/06/2019

Overall study status
Completed

Last Edited
15/08/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Foot Electrical Muscle Stimulators often claim to boost the blood circulation in the legs thereby reliving symptoms such as swelling, heaviness, cramps, tiredness and pain. This study aims to investigate the effects of non-invasive EMS on the above leg symptoms among community-dwelling adults over the age of 65 years. We are comparing between three types of stimulators: two that will cause 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 can participate?
Eligible participants will be adults over the age of 65 years who suffer from one or more of the following symptoms in one or both legs:
Swelling, mainly in the lower leg, ankle or foot.
Heaviness in the leg.
Cramps in the leg, mainly during the night or at rest.
Aching in the leg.
Tiredness in the leg.
Severe diabetes mellitus with severe diabetic neuropathy and any significant injury to the leg(s) in the last six months would make one ineligible. Also, active cancer and presence of any electronic implants (e.g. cardiac pacemaker) in the body are exclusions.

What does the study involve?
Participants will be involved in the study for 12 weeks attending a minimum of three face-to-face sessions, each lasting about two hours. They 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 their feet and allow some measurements to be taken from the legs and feet before and after treatment. They will also work through some questionnaires. Each session, which last around two hours, will include some paperwork,

screening, treatment, and assessments. All these procedures are harmless, completely non-invasive and routinely employed in clinical practice and research. Participants will be randomly allocated to one of the three study groups. The group allocation will decide the type of EMS received. 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. Recipients are expected to experience 'harmless mild electric stimulation' in the Millivolt / Milliampere range that is typical to such stimulating devices. Depending on the group and the intensity of delivery chosen, either mild pins and needles or muscle contraction or both will be experienced. Participants will be screened for their ability to provide clear feedback upon their sensation of the stimulation. The intensity can be adjusted according to the sensation of the stimulation. On the first visit, after signing the consent form, participants will change to appropriate clothing (shorts or similar) and undergo some simple screening tests in their legs and thereafter height, weight and body composition measurements. After this they will undergo 'pre-treatment measurements' where the researcher will record normal baseline measures from the legs, work through the questionnaires and then talk through the experimental procedures, what to expect during the treatment and what to do if they have a problem. Subsequently, after 30 minutes of resting while they are in the lab the stimulation will be delivered for 30 minutes. If they feel any discomfort during the session they 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, they will be given clear information regarding any potential hazard and the study will be terminated if they report any discomfort while receiving the treatment. If they are happy to continue with the study, a Revitive EMS machine will be given to take home and use at the required intensity level for 30 minutes twice daily for the next eight weeks. Participants 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 are the possible benefits and risks of participating?
There should be no harmful effects or disadvantages caused by participation in this study. The researcher will be near for the duration of the treatment and the tests to assist if necessary. The participants can always, at any moment, withdraw from the study. All the assessments are safe and have been used extensively in other research. On the other hand, it cannot be promised that the study will help the participants, 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. People in the past have reported benefits from using similar device, and the current study will help to measure any such potential benefits. The information gained from this study will also help to plan the methodology of further research.

Where is the study run from?
University of Hertfordshire, UK

When is the study starting and how long is it expected to run for?
August 2019 to October 2022

Who is funding the study?
Actegy Health Limited, UK

Who is the main contact?
Dr Binoy Kumaran,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
aHSK/SF/UH/03458(2)

Study information

Scientific Title
The effect of an 8-week treatment programme using foot electrical muscle stimulator (EMS) on physical function and leg symptoms in community-dwelling older adults: a randomised controlled trial

Study objectives
The use of foot electrical muscle stimulator improves symptoms and function among people suffering from symptoms of peripheral arterial disease or chronic venous insufficiency in their legs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/05/2019, Health Science Engineering & Technology Ethics Committee with Delegated Authority (ECDA) of the University of Hertfordshire (Governance Services Administrator (Ethics), Governance Services, University of Hertfordshire, Hatfield, AL10 9AB; +44 (0)1707 285568; hsetecda@herts.ac.uk), ref: aHSK/SF/UH/03458(2)

Study design
Single-centre interventional study with a single-blind randomised controlled design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Symptoms of leg discomfort

Interventions
Current intervention as of 03/03/2022:
Participants will be randomised to three groups, each receiving a different type of foot electrical muscle stimulation, EMS (Group 1: EMS Type 1 in a low sensory mode; Group 2: EMS Type 2 in a standard motor mode; Group 3: EMS Type 3 in a high motor mode). The randomisation will be performed with concealed envelopes, which will be prepared a priori using a computer-generated randomisation chart (IBM SPSS Statistics, Version 23) and blinded from the participants. Each group will self-administer the treatment at home for 30 minutes twice daily (total one hour per day) for eight weeks. A baseline assessment will be carried out at WEEK ZERO for all participants prior to the start of the 8-week intervention. A post treatment assessment will be carried out at week 8 at the end of the 8-week intervention period for all participants. All participants will again return for a 4-week post intervention follow-up assessment at week 12.

EMS will be delivered using Revitive™ machines (Actegy Health Limited). They will be administered in sitting position with the participants placing the soles of their feet on the rubberised foot plates. The machine is timed to run for 30 minutes continuously. The user can increase or decrease the intensity of treatment with a remote control. During the study all participants will continue with their normal life, activities, medications and diet with no restrictions attached.

Power and sample size calculation:
At the time of protocol development, neither the anticipated effect of the EMS Type 1 intervention (Sham device) nor the effect of EMS Types 2 & 3 interventions (Standard & Vigorous devices) on the primary outcome (the Canadian occupational performance measure) was well understood. To inform response rates and to provide baseline data for a sample size calculation, an internal pilot study was conducted with the first 10 participants from each of the three groups (30 participants in total). Based on multiple publications, an improvement of '2' points in the COPM performance score for an individual participant was considered a 'minimally clinically important difference (MCID)', and therefore set as the threshold required for a participant to be considered a 'responder'. From the internal pilot study, the responder rate was calculated for the EMS Type 1 group (Sham), and based on this, an absolute risk difference was defined for determining what the responder rate in the two test interventions EMS Types 2 & 3 (Standard & Vigorous) needed to be to demonstrate a treatment benefit. The difference in responder rates was then used to calculate the total sample size required for the study. The 30 participants from the internal pilot will be included in the final analysis, as they followed the same protocol as the remaining participants will follow. No hypothesis test for stopping for futility or efficacy was conducted at the end of the internal pilot, and so inflation of Type I or Type II errors is considered negligible.

Based on the proportion of responders obtained from the internal pilot, an absolute difference of 30% in the proportion of participants that meet the COPM performance responder definition (improvement by '2' points) between EMS Type 1 (Sham) and EMS Type 2 (Standard) or EMS Type 3 (Vigorous) interventions was considered necessary to demonstrate a clinically meaningful difference for either test device. To control the Type I error, a single primary endpoint was chosen, namely EMS Type 1 (Sham) versus EMS Type 2 (Standard). The comparison between EMS Type 1 (Sham) and EMS Type 3 (Vigorous) interventions was taken as the secondary endpoint. A sequential testing procedure is being employed such that the secondary end point can only be formally assessed if the primary endpoint achieves statistical significance ($p < 0.05$). Basing the calculation on this design it was determined that 39 participants will be needed in each of the three intervention groups to show an absolute difference of 30% in the proportion of responders between EMS Type 1 intervention and EMS Types 2 & 3 interventions at 80% power and two-sided 5% significance. The statistical test to compare the groups is a Pearson Chi-square test at the two-sided significance level ($p < 0.05$).

Previous intervention:
Participants will be randomised to three groups, each receiving a different type of foot electrical muscle stimulation, EMS (Group 1: EMS Type 1 in a low sensory mode; Group 2: EMS Type 2 in a standard motor mode; Group 3: EMS Type 3 in a high motor mode). The randomisation will be performed with concealed envelopes, which will be prepared a priori using a computer-generated randomisation chart (IBM SPSS Statistics, Version 23) and blinded from the participants. Each group will self-administer the treatment at home for 30 minutes twice daily (total one hour per day) for eight weeks. A baseline assessment will be carried out at WEEK ZERO for all participants prior to the start of the 8-week intervention. A post treatment assessment will be carried out at week 8 at the end of the 8-week intervention period for all participants. All participants will again return for a 4-week post intervention follow-up assessment at week 12.

EMS will be delivered using Revitive™ machines (Actegy Health Limited). They will be administered in sitting position with the participants placing the soles of their feet on the rubberised foot plates. The machine is timed to run for 30 minutes continuously. The user can

increase or decrease the intensity of treatment with a remote control. During the study all participants will continue with their normal life, activities, medications and diet with no restrictions attached.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Revitive™ machines (Actegy Health Limited)

Primary outcome measure
Self-perception of performance in everyday living measured using the Canadian Occupational Performance Measure (COPM) at baseline, 8-weeks, 12-weeks.

Secondary outcome measures
Current secondary outcome measures as of 07/03/2022:
1. Symptoms of heaviness, tiredness, aching and cramps in legs and feet in the preceding 2 weeks measured using a 0 - 10 numerical rating scale (NRS) at baseline, 8 weeks and 12 weeks
2. Pain measured using a 0 - 10 numerical pain rating scale (NPRS) at baseline, 8 weeks and 12 weeks
3. Deep leg blood flow measured at the ankle using Doppler ultrasound before and during EMS use

Previous secondary outcome measures from 06/04/2021 to 07/03/2022:
1. Symptoms of heaviness, tiredness, aching and cramps in legs and feet in the preceding 2 weeks measured using a 0 - 10 numerical rating scale (NRS) recorded in a symptom diary weekly from the end of week 1 to the end of week 7
2. Pain measured using a 0-10 visual analog scale (VAS) at baseline, 8 weeks and 12 weeks

Original secondary outcome measures:
1. Symptoms of heaviness, tiredness, aching and cramps in legs and feet in the preceding two weeks measured using a 0 - 10 NRS recorded in a symptom diary weekly from the end of week 1 to the end of week 7
2. Pain measured using 0 -10 VAS at baseline, 8-weeks, 12-weeks
3. Limb volume (for people with ankle and foot swelling) measured using a Perometer at baseline, 8-weeks, 12-weeks

Overall study start date
01/10/2018

Completion date
31/10/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/04/2021:
Community-dwelling adults aged over 65 years affected by one or more of the following symptoms:
1. Heaviness in the leg.
2. Cramps in the leg, mainly during the night or at rest.
3. Aching in the leg.
4. Tiredness in the leg.

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Previous inclusion criteria:
Community-dwelling adults over the age of 65 affected by one or more of the following symptoms:
1. Swelling, mainly in the lower leg, ankle or foot.
2. Heaviness in the leg.
3. Cramps in the leg, mainly during the night or at rest.
4. Aching in the leg.
5. Tiredness in the leg.

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
117

Total final enrolment
129

Key exclusion criteria
1. Significant co-morbidities such as diabetic neuropathy.
2. Significant injury to the leg(s) in the last 6 months.
3. Active cancer.
4. Electronic implants in the body.
5. People who have recently used/currently using foot EMS.
6. Non-ambulant people.
7. Inability to consent or communicate in English.

Date of first enrolment
01/07/2019

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Hertfordshire
Physiotherapy Research Lab LF311
College Lane
Hatfield
United Kingdom
AL10 9AB

Sponsor information

Organisation
Actegy Health Limited.

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Sponsor type
Industry

Website
https://www.revitive.com

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
Results to be published in a peer-reviewed international journal.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The availability of full data publicly is subject to commercial embargo.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/06/2019	01/07/2019	No	Yes
Protocol article		14/10/2022	17/10/2022	Yes	No
Statistical Analysis Plan	version 1.0	23/09/2022	18/05/2023	No	No
Results article		14/08/2024	15/08/2024	Yes	No