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The influence of leg position on muscle activity during electrostimulation

Submission date
20/07/2015

Recruitment status
No longer recruiting

Registration date
28/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Neuromuscular electrical stimulation is a non-invasive, clinical method that has the potential to alleviate symptoms associated with immobilisation and disuse. Stimulation devices initiate involuntary, muscle contraction that result in a muscle-pump action. A clinical application of this is for patients undergoing orthopaedic surgery. These individuals are prone to develop deep-vein thrombosis (DVT), due to reduced blood circulation arising from muscle inactivity in bed-rest and hospitalisation. Clot formulation may arise due to blood vessel wall injury and blood pooling. Immobilisation after operations can contribute to blood pooling in the legs, due to a reduced muscle-pump action. This in turn increases DVT risk. What is not clearly understood is whether the patient's leg position influences the muscular activity (and therefore the muscle-pump action) when receiving electrical stimulation. Existing counter-measures to promote leg circulation, such as compression stockings and automated devices, are restricted by bulk and discomfort. As a consequence, their effectiveness is limited due to poor compliance. However, electrostimulation devices, such as the Geko™, which send gentle electrical impulses to the leg muscles appear to improve leg circulation and reduce swelling. The Geko™ device is self-adhesive, wrist watch-shaped and attaches above the knee crease. Interestingly the Geko™ device appears to improve blood circulation according to leg position. We believe that if blood circulation is improved when Geko™ is applied at different leg positions, muscle activity may also vary. Whether the potential improvements in muscle activity then influences a person's balance remains to be seen. This is the aim of this initial observational study.

Who can participate?
Healthy adults aged 55 and above.

What does the study involve?
Participants are required to attend the Bournemouth University Exercise Physiology Laboratory on one occasion lasting around 2 hours to undergo leg Geko™ electrostimulation. Prior to the visit, the Chief Investigator will explain the study to each participant via telephone or in person, and by email. A patient information sheet (PIS) and a pre-test medical questionnaire will also be emailed or mailed to the individual to consider study participation. The visit will begin with participants providing verbal and written informed consent, and then completing a Physical Activity Scale for the Elderly (PASE) Questionnaire. The participant's Pre-test Health

Questionnaire will be reviewed and approved prior to data collection.
Eligible participants will then have anthropometric measurements taken (height, weight, leg girth); this will be followed by electromyography (EMG) placement to record leg muscle activity. Participants will then perform standing balance tests whilst muscle activity is recorded. Next, the Geko™ device will positioned on the non-dominant leg and we will determine the individual's stimulation intensity in accordance to maximal participant tolerance. The Geko™ device will then be activated for 60 minutes with the participant seated. The knee joint will be positioned at 0°, 45° and 90° in a random order, each for 20 minutes. Muscle activity and self-reported discomfort will be measured throughout. Following Geko™ electrostimulation, anthropometry and balance tests will be repeated.

What are the possible benefits and risks of participating?
The Geko™ device is known to increase blood flow in healthy adults. We expect it to do the same for muscle activity in healthy, older adults, and alter according to leg position. There may also be a positive effect on swelling and standing balance, although we do not know yet if this is true. We will provide participants with transport to the Laboratory and refreshments during the visit. We do not expect any risk. The device is available commercially and has passed the national testing process and has been CE awarded. The use of the Geko™ device within this study has been acknowledged by the manufacturer. Once activated, the device sends small impulses through the skin to cause the foot and calf to twitch. This may be an unfamiliar sensation, but it should not cause pain or discomfort. Some older participants may have a skin reaction to the adhesive gel of the Geko™ device and EMG sensors. Participants will be compensated for their time and effort by provision of a £10 Amazon voucher.

Where is the study run from?
Bournemouth University - Exercise Physiology Laboratory (Faculty of Health and Social Sciences), UK

When is the study starting and how long is it expected to run for?
June 2015 to October 2015

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of Neuromuscular Electrical Stimulation of the common peroneal nerve on muscle activity, balance and proprioception of healthy, older adults: the influence of leg position

Acronym
NMES (Neuromuscular Electrical Stimulation)

Study objectives
We are studying the influence of leg position on a small electrostimulation device (on the common peroneal nerve), designed to promote limb blood circulation. Using the device in patients, we have observed that the electrostimulated, involuntary muscle contraction differs according to knee angle. We postulate that greater knee flexion angle may enhance the muscle

activity during electrostimulation, in comparison to knee extension. Therefore, we are testing this in an observational pilot study in healthy older adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee - Bournemouth University, 22/06/2015, ref: 8029

Study design
Observational; Pilot; Single-centre

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Deep vein thrombosis

Interventions
Geko device: small, neuromuscular electrostimulation device (over common peroneal nerve)

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
1. Lower limb muscle activity (peroneus longus, tibialis anterior, and medial and lateral gastrocnemius) - 2. Static balance and proprioception
3. Oedema

All at baseline, during, and immediately after 60 minutes of electrostimulation.

Secondary outcome measures
1. Participant perceived discomfort (visual analogue scale and visual rating score)
2. Habitual physical activity (Physical Activity Scale for the Elderly (PASE) questionnaire)

All measured on a single occasion to establish measures in healthy older individuals.

Overall study start date
29/06/2015

Completion date
29/09/2015

Eligibility

Key inclusion criteria
1. Aged 55 years and above
2. Good general health
3. Able to understand the Participant Information Sheet (PIS) and willing to sign the written Informed Consent form
4. Able and willing to follow the protocol requirements

Participant type(s)
Healthy volunteer

Age group
Senior

Lower age limit
55 Years

Sex
Both

Target number of participants
Planned Sample Size: 20

Total final enrolment
15

Key exclusion criteria
1. Has a neuromuscular, haematological and/or cardiovascular disorder
2. Has a pacemaker
3. Chronic obesity (body mass index (BMI) >40kg/m2)
4. Pregnancy
5. Recently undergone surgery and/or suffered illness
6. History or signs of previous superficial or deep vein thrombosis (DVT)/pulmonary embolism
7. Varicosities, ulceration or erosion around the area of the leg where the study device would be fitted
8. Not able to fit the Geko electrostimulation device

Date of first enrolment
01/06/2015

Date of final enrolment
07/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bournemouth University
Faculty of Health and Social Sciences
Bournemouth House
17-19 Christchurch Road
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Sponsor information

Organisation
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Sponsor type
University/education

Website
https://www1.bournemouth.ac.uk/

ROR

https://ror.org/05wwcw481

Funder(s)

Funder type
University/education

Funder Name
Bournemouth University

Alternative Name(s)
BU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of this study will be submitted for publication to an appropriate scientific conference and then peer-reviewed journal (e.g., Physical Therapy [impact factor, 3.2], Clinical Rehabilitation [impact factor, 2.1]) according to best practice.

The authors on the publication shall be the Chief Investigator, plus others deemed to have significantly contributed to the generation of the data and/or inputted to the study design and documentation.

Intention to publish date
30/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		28/09/2016	28/09/2016	No	No

Results article	21/08/2018	18/08/2023	Yes	No