

The influence of leg position on muscle activity during electrostimulation

Submission date 20/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/08/2023	Condition category Circulatory System	<input type="checkbox"/> 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 formation 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 be 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?

Dr James Gavin

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Contact information

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Scientific

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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

Primary study design

Observational

Study design

Observational; Pilot; Single-centre

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

55 Years

Sex

All

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

United Kingdom

England

Study participating centre

Bournemouth University

Faculty of Health and Social Sciences

Bournemouth House

17-19 Christchurch Road

Bournemouth

United Kingdom

BH1 3LH

Sponsor information

Organisation

Bournemouth University

ROR

<https://ror.org/05wwcw481>

Funder(s)

Funder type

University/education

Funder Name

Bournemouth University

Alternative Name(s)

Bournemouth Municipal College, Bournemouth College of Technology, Dorset Institute of Higher Education, Bournemouth Polytechnic, BU, DIHE

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

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?
Results article		21/08/2018	18/08/2023	Yes	No
Basic results		28/09/2016	28/09/2016	No	No

