Novel, user-friendly, home-based electrostimulation-induced muscle activation in people with a spinal cord injury*

Published: 01-08-2017
Last updated: 15-04-2024

Regular electrical stimulation induced muscle activation increases muscle mass and volume and augments muscle, subcutaneous and skin blood flow in individuals with a spinal cord injury. Moreover, electrical stimulation applied to the ischial...

Ethical review	Approved WMO
Status	Pending
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON45626

Source
ToetsingOnline

Brief title
Electrical muscle stimulation and pressure ulcers

Condition

- Spinal cord and nerve root disorders

Synonym
paraplegia, spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Buckinghamshire Healthcare NHS Trust

Intervention

Keyword: electrical stimulation, pressure sores, spinal cord injury

Outcome measures

Primary outcome

The primary outcome measure will be the feasibility of using the shorts garment

during the 3 months. More specifically:

* Compliance (% of days worn, average time worn per day)

* Recruitment rate (ratio of patients recruited and total number of patients

invited)

* Willingness of participants to be randomised into a randomised controlled

trial

* Time spent for instrumentation

* Ability to wear the ES garment under normal clothing without

discomfort/difficulties

* Able to continue with day to day activities without impairment

* Able to put the garment on themselves

* Willingness to continue to use the garment

Secondary outcome

-Muscle mass. Leg circumference measurement.

-Perfusion on gluteal/thigh areas.

Skin blood flow/vascular function (laser-Doppler flowmetry)

Small areas (5 cm2) of the skin will be heated using small increments (1 deg C) every 5 min up to 44 deg C. The participant will lie sideways or on their front on a large purpose built bed during these tests.

Muscle blood flow and Tissue oxygenation (reflection spectroscopy and laser-Doppler flowmetry)

Small non-invasive probes will be placed on the gluteal/thigh skin areas. Oxygenation and perfusion data will be obtained using an Oxygen To See device (O2C, LEA Medizintechnik GmbH, Giessen, Germany).

Assessments will be made in the participant*s wheelchair during various maneuvers (randomised order, 5-min seated rest before each condition): bending forward, leaning sideward (to the right side to release the probe), and push up (2-min maximum).

-Pressure distribution.

Ischial tuberosities interface pressure and pressure gradients will be assessed continuously (1Hz) using a force-sensitive mapping system (Force sensitive array, mFlex) placed between the wheelchair and buttocks. A thin 42 x 42cm soft flex mat containing 256 pressure sensors (1.82cm2 per sensor) will be used.

-Clinical effects

-Skin quality/pressure ulcer incidence. A clinician will score the quality of

the skin, including possible incidence/severity of any pressure ulcers.

-Quality of life. The self-completed Dermatology Life Quality Index will be

used; a scoring list for individuals with (risk of) skin problems.

Study description

Background summary

Pressure ulcers are the most prevalent secondary complication in individuals with a spinal cord injury. 80% of people with a spinal cord injury suffer from a pressure ulcer, and 91% of those are at risk of developing a recurrent pressure ulcer. Pressure ulcers lead to radical consequences such as decreased mobility and independence, delayed rehabilitation, rehospitalisation, and exclusion from social activities. Furthermore, pressure ulcers have a tremendous impact on the individual*s physical ability to participate in daily life activities. Therefore, pressure ulcers place an enormous physical/emotional/financial burden on the individual, their caregivers and society. This highlights the need for interventions to prevent pressure ulcers.

Entrapment of soft tissue between bony prominences and an external surface (such as a wheelchair) represents the primary cause of pressure ulcers. Consequently, this leads to mechanical deformation, increased peak sitting pressures and prolonged periods of relative hypoxia (reduced oxygen supply to the tissue). The marked leg muscle loss in individuals with spinal cord injury contributes importantly to the increase in mechanical deformation and increased sitting pressures, whilst the impaired blood flow after a spinal cord injury contributes to a local tissue oxygen deficiency. Consequently, these changes in muscle size, sitting pressure and blood flow importantly contribute to the increased risk for developing pressure ulcers in individuals with a spinal cord injury.

Study objective

Regular electrical stimulation induced muscle activation increases muscle mass and volume and augments muscle, subcutaneous and skin blood flow in individuals with a spinal cord injury. Moreover, electrical stimulation applied to the ischial tuberosity area (sitting bone) improves sitting pressure distribution. Long term electrical stimulation of the gluteal muscles improves blood flow and even increases gluteal muscle thickness. Although electrical stimulation is potent in improving these key components in pressure ulcer development, current electrical stimulation methods are limited by their laboratory based nature, the need for trained personnel and expensive machinery; this importantly limits

the practicality of electrical stimulation. Therefore the proposed research project is significant in that it involves the use of a home-based electrical stimulation garment (shorts) with built in electrodes that overcomes these limitations and can be used at home and in the community.

The aim of this study is to explore whether 3 months, daily use of electrical stimulation in a home-based setting in individuals with SCI improves sitting pressure distribution, muscle mass, skin circulation and dermatology quality of life.

Study design

Twenty individuals with a spinal cord injury will receive an electrical stimulation garment for 3 months.
Stimulation causes effective, comfortable levels of electrical stimulation with visible muscle contractions, without significant limb movement (checked/adjusted weekly if necessary). Participants will undergo daily electrical stimulation..

Intervention

The ES garment (Axiobionics, Ann Arbor, MI, USA) will be custom-developed lycra shorts which house wires and surface electrodes. Two built-in surface electrodes are placed over the upper part of the gluteal muscles above the sitting area and 1 over halfway of the hamstring muscles, on both sides. The surface electrodes (with conductive gel) are connected to elastic conductors, guided through the side of the shorts to the front, ensuring the participant does not sit on the wires. An eight-channel electrical stimulator connected to the shorts will be used. Stimulation will be delivered biphasically at 50Hz to induce a (visible) tetanic contraction. This amplitude will be applied with a duty cycle of 1 s stimulation and 4 s rest for 3min with 16 min between each block of stimulation. The average current amplitude using this stimulation protocol has been 94±12.5mA, ranging from 70 to 115mA in our previous studies. The current amplitude will be adjusted for each subject by increasing the current amplitude in steps of 5mA to a point that doesn*t cause discomfort or excessive muscle contractions that may disturb normal sitting. Weekly telephone/skype questionnaires will also provide the opportunity to adjust the intervention/stimulation.

The stimulation protocol will be delivered for 8 hours each day (during waking hours). In the initial 2 weeks we will use an incremental 'dosage' protocol whereby in the first week participants will undergo 4 hours of stimulation and then 6 hours of stimulation in the 2nd week with 8 hours of stimulation starting in week 3.

Study burden and risks

The paralyzed gluteal and hamstring muscles of the participants will be activated. This will cause no pain and will not be uncomfortable. A small risk of skin irritation under the electrodes exists, but this irritation will disappear quickly after removal of the electrode.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 9
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 9
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 18-75 years
* ASIA Impairment Scale A-B with intact reflex arcs (i.e. spastic paralysis)
* Lesion level * Time since injury >6 months
* No current pressure ulcers/damage to skin covering the ischial tuberosities and/or lower limbs
* Able to tolerate stimulation (i.e. no autonomic dysreflexia induced)

Exclusion criteria

* An intolerance to or contraindication for electrical stimulation
* A history of severe autonomic dysreflexia or severe cognitive or communicative disorders
* A flaccid paralysis or areflexia

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2017
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-08-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58476.048.16