Daily electrical stimulation to prevent recurring pressure ulcers in persons with a spinal cord injury compared to usual care

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21504

Source
NTR

Brief title
SCI PREVOLT

Health condition

Spinal Cord Injury, Pressure Ulcers

Sponsors and support

Primary sponsor: VU, Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: ZonMw Efficiency Studies Program, Grant no: 853001111

Intervention

Outcome measures

Primary outcome

The primary outcome is the incidence of PUs, assessed by a blinded person assessing the presence or absence of a PU on a photo made by the participant or his/her caregiver. The incidence of a PU will be evaluated every 2 weeks.

Secondary outcome

The secondary outcomes include: interface pressure distribution, local circulation of the profunda femoris artery, muscle thickness of the hamstrings and gluteal muscles and questionnaires about different dimensions of life; participation, quality of life, etc. The secondary outcomes will be measured at baseline and 3, 6, 9 and 12 months after randomization.

Study description

Background summary

Pressure ulcers (PUs) are among the most common secondary complications in individuals with chronic spinal cord injury (SCI). PUs can result from sitting for extended periods, disuse atrophy, increased sitting pressure, and reduced circulation. Compared with usual care, activation of paralyzed muscles using electrical stimulation has been shown to markedly increase paralyzed muscle mass, improve circulation of skin and muscle, and improve sitting pressure distribution. Electrical stimulation might therefore be a useful method to reduce PU incidence. The aim of this study is to determine the (cost-)effectiveness of daily electrical stimulation compared to usual care to prevent recurring PUs in individuals with a chronic SCI.

A multicenter randomized controlled trial (SCI PREVOLT) will be conducted with an economic and process evaluation alongside. 100 participants with a chronic SCI and a minimal incidence of 1 PU in the last 5 years will be recruited from rehabilitation centers across the Netherlands. Participants will be stratified by center and age and randomized to the intervention or control group. The intervention group will use electrical stimulation at least 1 hour/day during at least 4 times a week for one year next to usual care. The control group will receive only usual care. The primary outcome is the incidence of PUs, assessed by a blinded person assessing the presence or absence of a PU on a photo made by the participant or his/her caregiver. The secondary outcomes include: interface pressure distribution, local circulation of the profunda femoris artery, muscle thickness of the hamstrings and gluteal muscles and questionnaires about different dimensions of life; participation, quality of life, etc. The incidence of a PU will be evaluated every 2 weeks. The secondary outcomes will be measured at baseline and 3, 6, 9 and 12 months after randomization. Recruitment is expected to start in May 2021.

Study objective

Primary Objective:
1.To investigate whether daily electrical stimulation of gluteal and hamstring muscles

combined with usual care is more effective in reducing recurrences of PUs than only usual care in individuals with chronic SCI, who often have PUs and/or at high risk of recurring PUs.

Secondary Objective(s):
2. To investigate whether daily electrical stimulation of gluteal and hamstring muscles combined with usual care is more effective than only usual care in improving:
a. factors related to PU risk: interface- pressure distribution, local circulation, and muscle size.
b. mobility, participation, and quality of life in individuals with chronic SCI who often have PUs and/or at high risk of recurring PU's
in individuals with chronic SCI, who often have PU's and/or at high risk of recurring PU's.
3.To determine the cost-effectiveness of this method compared with usual care alone.
4.To investigate facilitators and barriers within the RE-AIM model for the implementation and sustainability of daily electrical stimulation of gluteal and hamstring muscles combined with usual care.
5.To evaluate the usability and user friendliness of this electrical stimulation system.

Study design

The incidence of a PU will be evaluated every 2 weeks. The secondary outcomes will be measured at baseline and 3, 6, 9 and 12 months after randomization.

Intervention

The intervention group will use electrical stimulation at least 1 hour/day during at least 4 times a week for one year next to usual care.

Contacts

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Eligibility criteria

Inclusion criteria

To be eligible to participate in this study, an individual must meet all of the following criteria:
- Individuals (male/female) with either a complete (AIS A) or incomplete (AIS B, C and D) chronic SCI*
- Age 18 years and older
- Intact gluteal and hamstring muscles.**
- Individuals with a time since injury < 5 years and a minimal incidence of 1 PU or more, or Individuals with a time since injury ≥ 5 years and a minimal incidence of 1 PU or more within the last 5 years.***
- Able to lie in a prone position for at least 10 minutes (safely for the neck, comfortable, not compromising breathing and taking possible contractures into account)
*In this study, a chronic SCI is defined as follow: 'Every individual with an SCI who has been discharged from a rehabilitation center.'
** Potential participants who underwent flap surgery or some other form of plastic surgery can still be included if the stimulation can induce a good muscle contraction.
***Only individuals with a PU in (Category 2-4) in the sacral or ischial tuberosity's region will be included, according to the European pressure Ulcer Advisory Panel.(22).

Exclusion criteria

Exclusion criteria are:
- Current PUs in the gluteal or sacral area
- Flaccid paralysis (areflexia)
- A history of severe autonomic dysreflexia
- Insufficient mastery of the Dutch language (speaking and reading)
- Severe cognitive or communicative disorders
- Intolerance to or contra-indication for ES (cancer, pregnant, metal implants in stimulation area)
- Recent or current participation in an ES-induced exercise program or study (up to 6 months prior to this study)
- Severe psychiatric illness or disorders (to the discretion of the treating rehabilitation physician)

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The research group intends to make the coded and de-identified syntaxes and data files accessible for further research and verification. However, access to the data set will be limited and access can only be allowed under certain conditions, because it will be hard to fully anonymize the dataset. The data of this study can only be reused for research in the same line as this study (similar goals, aims and purposes). Next to that, access to the data will only be granted when there is approval of the original research team and assurance that the receiving party will sufficiently protect the data. Extra safety precautions will be made when the data will leave the EU. The researchers intend to share coded and de-identified syntaxes and data-files.

Ethics review

Positive opinion

Date:	26-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54487
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9469
CCMO	NL74020.029.20
OMON	NL-OMON54487

Study results