The effect of vibrotactile feedback for complete spinal cord injury patients on exoskeleton performance

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The aim of this study is to investigate the effect of discrete vibrotactile feedback of mediolateral weight shift and step initiation for complete SCI patients on the use of an exoskeleton.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49102

Source
ToetsingOnline

Brief title
Vibrotactile feedback in exoskeletons

Condition

- Spinal cord and nerve root disorders

Synonym
Complete spinal cord injury, paralysis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO-TTW Wearable Robotics

Intervention

Keyword: Exoskeletons, Sensory substitution, Spinal cord injury, Vibrotactile feedback

Outcome measures

Primary outcome

The primary outcome measures are the maximal weight transfer onto a single limb during a standing lateral weight-shifting exercise, the mean velocity of the centre of pressure during quiet stance and the walked distance during one minute of straight walking.

Secondary outcome

The amount of weight exerted onto the crutches during quit stance, maximal weight shift and at heel strike during gait. Furthermore, the patients experience will be evaluated with the QUEST-score part I, the SUS-score and a VAS-score.

Study description

Background summary

Complete Spinal Cord Injury (SCI) patients lack motor function below the level of lesion and are wheelchair dependent. Exoskeletons give complete SCI patients the ability to walk individually. Although exoskeletons generate the basic motions for ambulation, postural stability has to be maintained by the user. However, the ability of complete SCI patients to maintain postural stability is affected. This is because complete SCI patients miss essential somatosensory information from below their level of lesion. Hence, walking in an exoskeleton is demanding and crutches are necessary to maintain balance. When sensory information of a specific system is lost, the lack of sensory information can be substituted by providing feedback to another sensory system. As sensory feedback has shown to improve postural control in patients missing essential sensory information, such sensory substitution may also be effectively incorporated in complete SCI patients using an exoskeleton.

Study objective

The aim of this study is to investigate the effect of discrete vibrotactile feedback of mediolateral weight shift and step initiation for complete SCI patients on the use of an exoskeleton.

Study design

Experimental pilot study.

Study burden and risks

During the study, subject visit the clinic twice. During these visits of one and a half hour, subjects have the opportunity to train and use an exoskeleton again without reimbursing it themselves. Furthermore, subjects fill in three questionnaires about their experiences. This will take approximately 10 minutes. There are no disadvantages to the research since the risks are similar to the clinical training sessions provided during the exoskeleton training program of the Sint Maartenskliniek. Besides, mitigation measuers have been taken to address potential risks of the vibrotactile feedback system.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- SCI classification ASIA A or B
- Level of SCI between T1 and L1
- Age >= 18
- Having experience with the ReWalk exoskeleton and able to walk without a physiotherapist

Exclusion criteria

- Somatosensory problems prior to the complete SCI
- Visual or auditory problems that are not resolved with glasses or a hearing device
- Insufficient mastery of the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Prototype of vibrotactile feedback system
Registration:	No

Ethics review

Approved WMO Date:	07-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26174
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74476.091.20
OMON	NL-OMON26174