The effect of vibrotactile feedback on exoskeleton use in people with complete spinal cord injury

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The aim of the study is to investigate the effect of vibrotactile feedback on exoskeleton use in people with complete spinal cord injury.

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

Summary

ID

NL-OMON51408

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 measure is the walking distance covered.

Secondary outcome

The secondary outcome measures are:

- Crutch loading

- Center of mass movement smoothness

- User experience

Study description

Background summary

People with complete spinal cord injury (SCI) lack motor function below the lesion level and are, thus, wheelchair-dependent. In recent years, wearable exoskeletons have emerged as potential mobility devices for this population. Although exoskeletons generate the basic motions for ambulation, postural stability must be maintained by the user. People with complete SCI miss essential somatosensory perception, which affects their ability to maintain postural stability. Hence, walking in an exoskeleton is demanding, and crutches are necessary.

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 people missing essential sensory information, such sensory substitution may also be effectively incorporated in people with complete SCI using an exoskeleton.

Study objective

The aim of the study is to investigate the effect of vibrotactile feedback on

exoskeleton use in people with complete spinal cord injury.

Study design

The proposed study is an experimental study.

Study burden and risks

The study protocol includes six two-hour sessions spread over three weeks. Sessions 1 to 5 are training sessions, and session 6 is an evaluation session. The training sessions are similar to the sessions of the clinical exoskeleton training program of the Sint Maartenskliniek. The study provides opportunities for people with complete SCI to use an exoskeleton without reimbursing it themselves. The exoskeleton we use in the study is the ABLE Exoskeleton. Previous research has shown that the ABLE Exoskeleton is safe and feasible for gait training. Reported medium-level risks of the ABLE Exoskeleton could potentially lead to falls or skin injuries. However, these risks are well-known for the use of all exoskeletons, and we took mitigation measures to address the potential risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

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

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):	06-03-2023
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	ABLE Exoskeleton
Registration:	No

Ethics review

Approved WMO Date:	14-12-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL82999.091.22