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

No registrations found.

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

## **Summary**

### ID

NL-OMON26174

**Source** Nationaal Trial Register

**Brief title** Vibrotactile feedback in exoskeletons

#### **Health condition**

People with a complete spinal cord injury (AISA A or B)

### **Sponsors and support**

Primary sponsor: Sint Maartenskliniek Source(s) of monetary or material Support: NWO-TTW Wearable Robotics

### Intervention

### **Outcome measures**

#### **Primary outcome**

Concerning standing performance

- The maximal weight transfer onto a single limb during a standing lateral weight-shifting exercise

- Mean velocity of the centre of pressure during quiet stance

Concerning gait performance

- Walked distance during approximately 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

- Patients experience (derived from the QUEST-score part I (Quebec User Evaluation of Satisfaction with Assistive Technology), the SUS-score (System Usability Scale) and a VAS-score (Visual Analogue Scale))

# **Study description**

#### **Background summary**

Rationale: 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.

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: The proposed study is an experimental pilot study.

Study population: Ten complete SCI patients (American Spinal Injury Association Impairment Scale (ASIA) A or B), who previously participated in the exoskeleton training program of the Sint Maartenskliniek and are able to walk individually, are included.

Main study parameters/endpoints: 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.

### **Study objective**

Based on promising results of studies on sensory substitution, it is hypothesised that vibrotactile feedback provided to a complete SCI patient improves the performance with an exoskeleton.

### Study design

Two sessions of one and a half hour.

#### Intervention

In this experimental pilot study complete SCI patients, who previously participated in the exoskeleton training program of the Sint Maartenskliniek, are included. In the first session, subjects will start with a training session of one hour to become familiar with the vibrotactile feedback system during standing and walking in an exoskeleton. Subsequently, an experimental session of half an hour will follow in which the subjects will perform stance exercises while vibrotactile feedback is alternately present or absent. Within a week, subjects complete another experimental session of one and a half hour in which they will perform gait exercises while sensory feedback of different modalities is alternately present or absent.

# Contacts

#### Public

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# **Eligibility criteria**

## **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:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	10
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: Undecided

**Plan description** N/A

# **Ethics review**

Positive opinion Date: Application type:

10-12-2020

First submission

# **Study registrations**

### Followed up by the following (possibly more current) registration

ID: 49102 Bron: ToetsingOnline Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL9107
ССМО	NL74476.091.20
OMON	NL-OMON49102

# **Study results**

### Summary results

N/A