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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26174

Bron
Nationaal Trial Register

Verkorte titel
Vibrotactile feedback in exoskeletons

Aandoening

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

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: NWO-TTW Wearable Robotics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Two sessions of one and a half hour.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	10-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49102
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A