The effect of GRAIL training on functional walking capacity and social participation in patients with incomplete spinal cord injury.

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

Summary

ID

NL-OMON48297

Source
ToetsingOnline

Brief title
Effect of GRAIL training in incomplete spinal cord injury.

Condition

- Spinal cord and nerve root disorders

Synonym
incomplete spinal cord injury, partial paralysis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: NWO-TTW Wearable Robotics

Intervention

Keyword: Gait adaptability, Spinal cord injury, Virtual reality, Walking capacity

Outcome measures

Primary outcome

1. Walking speed measured with the 2 minutes walking test (2MWT).

Secondary outcome

2. Functional walking ability measured with the spinal cord injury - functional ambulation profile (SCI-FAP)

3. Participation measured with the Utrecht scale for evaluation of rehabilitation-participation (USER-P).

4. Two rehabilitation goals, one on the activity level and one on participation level of the ICF, assessed with the Goal Attainment Scaling (GAS)

5. Walking speed measured with the 2 minute walking test (2MWT) during self-paced treadmill walking on the GRAIL.

6. Balance confidence measured with the activities-specific balance confidence (ABC) scale

7. Patients* experience on the different interventions will be captured with a customized questionnaire.

Study description

Background summary

Approximately 60% of the patients with a spinal cord injury (SCI) suffer an incomplete lesion (Nijendijk et al., 2014). In the chronic phase of an

incomplete SCI (iSCI) many patients experience problems such as a reduced functional ambulation (Hedel van, 2009) which can negatively influence social participation (Lund et al., 2005). Frequently, an important goal of rehabilitation is to improve functional ambulation. Various interventions and training approaches aiming to improve walking performance in iSCI patients have been introduced and all approaches show some improvement without supremacy of one intervention over others (Morawietz & Moffat, 2013). A promising training approach in rehabilitation is GRAIL (Gait Real-time Analysis Interactive Lab) training. The GRAIL is a training device where people train on a treadmill in a virtual environment. During GRAIL training the focus is on adjustment of the gait pattern, which is referred to as *gait adaptability training*. Results from our own (pilot) study show that a short period of GRAIL training led to an improved walking and balance capacity during treadmill walking in ambulatory iSCI patients. After 6 weeks of GRAIL training iSCI patients increased their walking speed, stride length, and gait stability in anterior-posterior direction while walking on a self-paced treadmill (van Dijsseldonk et al., 2018). This effect was remained at 6 months follow-up. However, it is unknown whether the effect of GRAIL training also extends to functional walking and to social participation in ambulatory iSCI patients. Moreover, we do not know the effect size of GRAIL training compared to other gait interventions.

Study objective

The main objective of this study was to evaluate the effect of 6 weeks of GRAIL training on functional walking capacity compared to endurance and strength training (control intervention) in ambulatory patients with chronic iSCI. In addition the effect of GRAIL training on social participation will be assessed.

Study design

The proposed study is a randomized controlled trial with parallel groups design.

Intervention

The GRAIL intervention consist of twelve one-hour training sessions spread over a six-week period. During the GRAIL intervention the focus is on training gait adaptability on a treadmill using a virtual reality training device.
The control intervention also consist of twelve one-hour training sessions spread over a six-week period. During the control intervention the focus is on training endurance and lower body strength. As a contrast to the GRAIL intervention, participants will not train their gait adaptability during the control intervention.

Study burden and risks

The study will be performed with chronic iSCI subjects. Participants will receive either the control intervention or the GRAIL intervention twice a week for one hour each time. After a 6-weeks rest period, participants will cross-over to the other intervention. Therefore, each participants will receive both interventions. The frequency and duration of the interventions are part of the rehabilitation process and are based on actual care pathways that match the inclusion criteria of the study population. This category of patients is generally well tolerable to training. The GRAIL is a safe training device, which will not expose participants at risk. The trainings frequency (of both interventions) does not exceed the normal frequency during rehabilitation. Most of the measurements for the study are already part of the rehabilitation trajectory and are used for the clinical evaluation of the intervention. The clinical evaluation consists of four measurements. For the study we add extra tests to these (clinical) measurements and we ask participants to participate in one extra (fifth) measurement. The additional tests for the study consist of questionnaires and functional tests. The functional tests (2MWT and SCI-FAP) reflect tasks in daily life and do not involve extra risks. Participants are allowed to take rest in between the tests. The total extra time/burden for the study is 2 hours and 45 minutes (of which 1 hour and 10 minutes for questionnaires (USER-P, rehabilitation goals, patients* experience and ABC) and 1 hour and 35 minutes for functional tests (2MWT and SCI-FAP)).
The training and the measurements will be accompanied by experienced physiotherapists who will take care of the patient. Any additional (physical) therapy aimed at improving the walking or balance capacity will be temporarily stopped during the study duration in consultation with the patient.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria
- SCI classification (American Spinal Injury Association Impairment Scale (AIS) C or D))
- At least 6 months post injury-onset to ensure a stable neurological condition
- Able to walk at least 10m with or without a walking aid and/or braces
- Walking speed at inclusion between 0 3 and 1 0 m/s (measured with the 10MWT)
- A rehabilitation goal on improving (functional) walking capacity
- Age >18 years
- Willingness and ability to cancel/postpone other interventions or treatments aimed at improving functional balance capacity or participation during the study duration

Exclusion criteria

The main exclusion criteria are
- Other neurological or lower limb impairments in addition to the iSCI
- Walking or balance problems prior to the iSCI
- Expected life events during the study period that influence the activity level of the patient (such as retirement, parenthood, a new job or an operation)
- Within the first 6 months after a previous GRAIL trajectory
- Scheduled Botulinum Toxin (Botox) injections during the intervention period.
- Insufficient understanding or mastery of the Dutch language to understand training and measurement instructions

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2019
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	NL69379.091.19