# Effect of GRAIL training in incomplete spinal cord injury

Published: 13-08-2019
Last updated: 11-06-2023

Both interventions (GRAIL training & endurance and strength training (control intervention)) will result in an increase in gait speed, functional walking ability and social participation. However, the GRAIL training will result in larger…

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | Spinal cord and nerve root disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22779

**Source**
Nationaal Trial Register

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

### Condition

- Spinal cord and nerve root disorders

**Health condition**

People with a chronic (>6 months) incomplete spinal cord injury (AIS C or D)

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Maartenskliniek
**Source(s) of monetary or material Support:** NWO-TTW wearable robotics

## Intervention

**Keyword:** Exercise therapy

## Outcome measures

### Primary outcome

The primary outcome parameter is walking speed measured with the 2MWT during overground walking. This outcome will be assessed five times.

### Secondary outcome

Secondary study parameters are: - Functional walking ability measured with the spinal cord injury – functional ambulation profile (SCI-FAP) - Participation measured with the Utrecht scale for evaluation of rehabilitation-participation (USER-P). - Two rehabilitation goals, one on the activity level and one on participation level of the ICF, assessed with the Goal Attainment Scaling (GAS) - Walking speed measured with the 2 minute walking test (2MWT) during self-paced treadmill walking on the GRAIL. - Balance confidence measured with the activities-specific balance confidence (ABC) scale - Patients' experience on the different interventions will be captured with a customized questionnaire. These outcome measures will be assessed three times.

# Study description

### Background summary

Rationale: 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. 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. Study population: 40 people with iSCI (American Spinal Injury Association Impairment Scale (AIS) C or D)), who are interested in participating in the study will be included. They will be recruited from the patient files of the Sint Maartenskliniek and the Radboudumc (Rehabilitation department) in Nijmegen and UMC (Groningen). The main inclusion criteria are: age ≥18 years, at least 6 months post injury onset, able to walk at least 10m with a walking speed between 0.3 and 1.0 m/s. Exclusion criteria: other neurological or lower limb impairments in addition to the iSCI, walking or balance problems prior to the iSCI and within the first 6 months after a previous GRAIL trajectory. 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. Main study parameters/endpoints: The primary outcome measure is walking speed. Secondary outcome measures are functional walking ability, participation, achievement of rehabilitation goals, balance confidence and patients' experience. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The study will be performed with chronic iSCI subjects. 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.

**Study objective**

Both interventions (GRAIL training & endurance and strength training (control intervention))

will result in an increase in gait speed, functional walking ability and social participation. However, the GRAIL training will result in larger increases in gait speed, functional walking ability and participation than the endurance and strength training (control intervention).

### Study design

Assessments will be performed at five time points: baseline and after 6, 12, 18 and 24 weeks.

### 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.

## Contacts

**Public**
Sint Maartenskliniek & Radboudumc
Eline Zwijgers

+31243659499
**Scientific**
Sint Maartenskliniek & Radboudumc
Eline Zwijgers

+31243659499

## Eligibility criteria

**Age**
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
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: - Spinal cord injury (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

A potential subject who meets any of the following criteria will be excluded from participation in this study: - 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 phase: | N/A |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-10-2019 |
| Enrollment: | 40 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 13-08-2019 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL7964 |
| Other | METC regio Arnhem-Nijmegen : METC nr. 2019-5255 |

## Study results