Effect van GRAIL training in incomplete dwarslaesie

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	Ruggenmerg- en zenuwwortelaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22779

Bron
NTR

Verkorte titel
Effect of GRAIL training in incomplete spinal cord injury

Aandoening

- Ruggenmerg- en zenuwwortelaandoeningen

Aandoening

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

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: NWO-TTW wearable robotics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Incomplete dwarslaesie (American Spinal Injury Association Impairment Scale (AIS) C of D)

Minimaal 6 maanden na het begin van het letsel om een stabiele neurologische toestand te waarborgen

- In staat om minimaal 10 meter te lopen met of zonder loophulpmiddel

- Loop snelheid bij inclusie tussen 0.3 en 1.0 m/s (gemeten met de 10MWT)

- Een revalidatiedoel gericht op het verbeteren van (functionele) loopcapaciteit

- Leeftijd ≥18 jaar

- Bereidheid en vermogen om andere interventies of behandelingen gericht op het verbeteren van functionele balanscapaciteit of participatie gedurende de studieperiode te annuleren/uitstellen

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Andere neurologische of beperking aan de onderste extremiteiten naast de dwarslaesie

- Loop- of balansproblemen voorafgaand aan de dwarslaesie

- Verwachte levensgebeurtenissen tijdens de onderzoeksperiode die invloed hebben op het activiteitsniveau van de deelnemer (zoals pensionering, ouderschap, een nieuwe baan of een operatie)

- Binnen de eerste 6 maanden na een eerder GRAIL-traject

- Geplande botuline toxine (Botox) injecties tijdens de interventieperiode

- Onvoldoende begrip van of beheersing van de Nederlandse taal om trainings- en meetinstructies te begrijpen

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-10-2019
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	13-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7964
Ander register	METC regio Arnhem-Nijmegen : METC nr. 2019-5255

Resultaten