Neural plasticity and recovery after early and intensive upper extremity motor training in people with cervical spinal cord injury.

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This project aims to investigate peripheral and central neuroplasticity following an early (

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

Summary

ID

NL-OMON53224

Source
ToetsingOnline

Brief title
REPAIR-SCI

Condition

- Spinal cord and nerve root disorders

Synonym
Spinal Cord Injury, tetraplegia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Hasselt
Source(s) of monetary or material Support: FWO (Vlaanderen)

Intervention

Keyword: cervical spinal cord injury, motor training, plasticity, recovery

Outcome measures

Primary outcome

Central plasticity via: Single pulse TMS (cortical mapping and rest motor threshold) 8 weken after randomisation

Secondary outcome

Klinische maten: Upper Extremity Motor Score, Spinal Cord Independence Measure (SCIM-zelfzorg); Van Lieshout Test (VLT); Grades redefined assessment of strength sensibility and Prehension (GRASSP); Hand-Held Dynamometrie; accelerometrie (sessie densiteit: actievetherapietijd/sessie lengte); ervaring moeilijkheid en ervaring intensiteit.

Centrale plasticiteit: Paired pulse TMS: (SICI; LICI; SICF); perifere plasticiteit: NET (Nerve excitability testing) en MScanFit MUNE (Compound muscle action potential (CMAP).

Study description

Background summary

Paralysis or paralysis is the most common effect of spinal cord injury (SCI) on individuals. Paralysis affects the ability to walk, perform self-care, live independently and participate in work and leisure activities. In individuals with cervical spinal cord injury, arm and hand function is very important. Motor training of the upper extremities can improve the functioning of. The most promising and easily implemented intervention that could promote neurological recovery and make a lasting difference in the lives of people with spinal cord injury is early and intensive motor training aimed at recovery below the injury level. This intervention takes advantage of the early plasticity of the nervous system. By maximizing muscle activation in the first

few days after injury, we can target the nervous system's unique capacity for neural plasticity where changes can occur in central and peripheral motor systems.

Study objective

This project aims to investigate peripheral and central neuroplasticity following an early (<13 weeks after injury) and intensive (8 weeks of 6 hours of additional therapy) upper extremity motor training program (EIUMT) aimed at recovery below the lesion level. This project has 4 objectives: to investigate 1) central neural plasticity(identify changes in cortical neuroplasticity and corticospinal excitability; 2) peripheral neural plasticity (identify change in axonal excitability and number of motor units); 3) clinical motor recovery of the upper limbs and 4) relationships between dose dimensions of motor intervention and clinical and neurophysiological outcome measures after EIUMT. Advanced neurophysiological measurements and clinical measurements will be taken before and after EIUMT, after 4 weeks, 8 weeks and at 6-month follow-up.

Study design

a multicenter pragmatic randomised controled study in 2 countries

Intervention

The intervention group receives 6 hours of motor training each week. This involves active and targeted motor training of all affected muscles below the injury level in the context of functional activities.
The control group receives only standard rehabilitation and care.

Study burden and risks

Benefits such as improved strength, balance and improvements in functional movements may be noted. In addition, researchers will better understand how to improve outcomes after spinal cord injury. There are minimal risks associated with participating in this research project. Patients in this study may experience discomfort due to receiving intensive therapy (i.e., 6h/week of additional therapy on top of standard rehabilitation). However, the RCT from Sydney University has been running for one year and few adverse events have been reported. Therefore, we can assume that the risks of the intervention are limited. Regarding measurements, the participant may experience some discomfort, but no risk. With transcranial magnetic stimulation measurements, it is possible that the participant may experience discomfort in the form of tapping on the head. At high stimulation intensities there may be some incidental stimulation of the muscles in the face, this may be experienced as a jaw twitch or eye blink. Also, the magnetic pulse in the coil makes a loud clicking sound, which gets louder at high intensities. Earplugs are available

for participants who wish to minimize any discomfort from the noise. Participants will be screened for risk factors including presence of epilepsy or pregnancy to participate in the transcranial magnetic stimulation measurements. The complete protocol (treatment and measurements) will be monitored by the rehabilitation physician and the treatment team. The benefits namely the increased strength and better outcome for the intervention group and the knowledge of the underlying mechanisms at the origin of neurological recovery and plasticity, which are of interest to the whole paraplegic population and caregivers, outweigh the expected disadvantages. Therefore, asking patients to participate is justified.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria: Traumatic or non-traumatic C-SCI in the preceding 13 weeks; age over 16 years; have an incomplete SCI or an AIS A SCI with zones of partial motor paralysis (as defined
by the International Standards for the Neurological Classification of SCI (ISNCI) and medically stable.

Exclusion criteria

Exclusion criteria: SCI with ASIA Impairment Scale (AIS) A without zones of partial preservation (decided based on former studies [58]) and expertise of the team; SCI with any significant medical condition that could prevent the person from participating. In order to ensure TMS measurement can be performed, patients will only be included in this WP if they have a positive response to motor evoked potential measurement (MEP+) [59] and will be excluded in the presence of contraindications for TMS application such as epilepsy, metal implants in the brain, defibrillator, pacemaker and pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2024
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	14-08-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	15-08-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
Other	is in progress
CCMO	NL84212.015.23