Innovative training method in patients with Multiple Sclerosis and Spinal Cord Injury, a pilot study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46786

Source
ToetsingOnline

Brief title
Innovative training method in MS and SCI, a pilot study.

Condition

- Other condition
- Demyelinating disorders

Synonym
Multiple Sclerosis (MS), Spinal Cord Injury (SCI)

Health condition

incomplete dwarslaesies

Research involving
Human

Sponsors and support

Primary sponsor: Libra Revalidatie & Audiologie
Source(s) of monetary or material Support: Onderzoeksgelden Libra Revalidatie & Audiologe; en CZ-fonds

Intervention

Keyword: Multiple Sclerosis (MS), Spinal Cord Injury (SCI), Training

Outcome measures

Primary outcome

Main study parameters: Primary parameters are:

- aerobic capacity (progressive cardiopulmonary exercise test)

- physical performance (Stair Climb Test, Progressive Isoinertial Lifting

Evaluation, Sit To Stand test, Timed-up-and-Go test, 6 minute walk test maximal

distance).

Secondary outcome

Secondary parameters are:

- maximal muscle strength (1RM handgrip, 1RM legpress),

- walking efficiency (6 minute walk test at comfortable speed),

- fatigue (Fatigue Severity Scale (FSS),

- quality of life (Short Form (36) Health Survey (SF-36), and Multiple

Sclerosis Impact Scale (MSIS-29)),

- feasibility of the program (questionnaire developed for this study).

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Study description

Background summary

In neurorehabilitation, Multiple Sclerosis (MS) and Spinal Cord Injury (SCI) are highly prevalent conditions. It has been shown that these patients often have a reduced fitness level and experience severe fatigue, which interferes with many aspects of daily life functioning. However, the effects achieved with training programs in people with MS and SCI are generally heterogeneous, not large, do not lead to reduction of fatigue, or are not extensively studied. Libra Rehabilitation & Audiology developed an innovative whole-body training program, aimed at improving fitness using mainly functional exercises, three types of strength training with free weights, cardio training and functional skills training. We expect this training program to lead to improvements in fitness in people with MS or incomplete SCI, resulting in improvements in fatigue and quality of life.

Study objective

The main objective of this pilot study is to explore the changes in physical fitness in patients with MS or SCI who participate in this training program. Secondary, we will explore the changes in walking efficiency, fatigue, quality of life, and the feasibility of the program.

Study design

This study is an observational cohort pilot study. Patients will participate in this innovative training program. One week before (pre-treatment), one week after (post-treatment) and eight weeks after (follow-up) the training program participants will be tested.

The training program (intervention) consists of: three weeks of observation period, 12 weeks training period, following a follow-up period of 8 weeks. The training period consists of three days per week cardio training, strength training, functional skills training, and once a week physiotherapy. Finally, a total of three consults at the Sportloket will be conducted, to maintain physical activity after the training program.

Study burden and risks

Participants will follow the innovative training program as usual care, because this is since two years the regular rehabilitation protocol at Libra Rehabilitation & Audiology, location Blixembosch. The training program consists of the 12 week training program as described above. Extra burden will be the three assessments, consisting of 1) progressive cardiopulmonary exercise test including respiratory exchange analysis, 2) 6 minute walking test (comfortable speed) including respiratory exchange analysis, 3) physical performance tests, 4) maximal muscle strength tests (handgrip and leg press), 5) questionnaires:

Fatigue Severity Scale (FSS), Short Form Survey 36 (SF-36) and a questionnaire developed to test feasibility (maintaining physically active, possible negative effects (e.g. injuries, overtraining), time schedule, intensity, and experiences during the training) for both MS and SCI. In addition, we will use the Multiple Sclerosis Impact Scale (MSIS-29) in participants with MS. Assessments have a duration of two and a half hours per patient, resulting in a total of seven and a half hour for three assessment periods. Assessments periods will be conducted over three days and in consideration of sufficient rest periods. The research group has experience in previous projects with similar assessments (Learn to Move (cerebrale parese): MEC-2009-079; Subarachnoidale Bloeding: MEC-2008-288; Neuro-oncologie: MEC 2015-577). Furthermore, Libra Rehabilitation & Audiology has extensive experience with this innovative training program and physical fitness tests. A strict protocol is applied to ensure safety of testing.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Multiple Sclerosis (MS)
-EDSS * 6.5 (needs mainly support on two sides or support tools to walk 20 meters (EDSS <= 6.5), or performs better physically);
-Age * 18 years;;Spinal Cord Injury (SCI)
-WISCI-II score * 1 (ambulates in parallel bars, with braces and physical assistance of two persons, less than 10 meters (WISCI-II <= 1), or performs better physically);
-Age * 18 years;

Exclusion criteria

- Contra-indications to perform a progressive cardiopulmonary exercise test (CPET) (Lausanne protocol);
- Abnormalities detected during the CPET which contra-indicate high intensity physical activities;
- Pregnancy;
- Unable to complete the full intervention based on time investment;
- Essential changes in medication during the intervention period (e.g. disease-modifying drugs in MS);
- Use of beta-blockers;
- MS Relapse during the intervention period;
- Malignant tumor as cause of SCI;
- Any premorbid (before diagnosis of MS/SCI) progressive neuromuscular or brain disease.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	04-04-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	30-03-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-08-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL64522.078.18