Walking-induced motor fatigability in Multiple Sclerosis: a pilot study on underlying mechanisms and the feasibility of sequential resistance and walking-specific endurance training

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a) To study the relationship between ankle push off and walking-induced motor fatigability and the potential confounders of this relationship in persons with progressive MS and healthy controls. b) To assess the feasibility of a targeted, sequential...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON44052

Source
ToetsingOnline

Brief title
Walking-induced motor fatigability in MS / MS-walk-I

Condition

- Demyelinating disorders

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: Exercise Training, Walking, Walking-induced motor fatigability Multiple Sclerosis

Outcome measures

Primary outcome

Walking-induced motor fatigability, with the central determinant: ankle push

off power.

Secondary outcome

Spatiotemporal gait characteristics, energy cost of walking, feasibility

outcomes of the pilot intervention and measurement procedures.

Study description

Background summary

In Multiple Sclerosis (MS) the ability to walk long distances is not only influenced by disease severity, but is also progressively affected during a single continuous bout of exercise. This motor fatigability is poorly understood and not targeted in rehabilitation interventions. Understanding the underlying mechanisms and exploring new treatments of motor fatigue is highly relevant, because it may lead to more effective treatments to improve quality of life and promotion of a healthy life style. In addition, we will assess the feasibility and preliminary effect of a targeted sequential training program in which resistance training of the lower leg muscles serves as a preconditioning phase for high intensity endurance training on a treadmill. It is hypothesized that by using this sequential step-wise exercise approach, persons with more severe walking-induced motor fatigability will be prepared and able to exercise at a higher intensity level.

Study objective

a) To study the relationship between ankle push off and walking-induced motor

fatigability and the potential confounders of this relationship in persons with progressive MS and healthy controls.
b) To assess the feasibility of a targeted, sequential resistance plus walking-specific endurance training regime on walking-induced motor fatigability in persons with MS.

Study design

pre-post intervention pilot-study in patients with MS, plus a healthy-control assessment (reference group).

Intervention

Patients with MS will receive a sequential exercise program for 4 months, 3x per week, in which the first 8 weeks consist of progressive resistance training (2-3 sets, 8-12 reps, 60-70% 1RM), followed by 8 weeks of progressive walking endurance training (High Intensity Interval Training, 3-6 cycles, 90%HRmax vs. comfortable walking speed).

Study burden and risks

Gait impairments can already be seen in the early stage of MS and cause difficulties in ambulation for a large number of patients with MS (pwMS). Ambulation has been shown to be an important factor in the ability to engage in social participation and health-related quality of life. Moreover, reduced ambulation may greatly affect the ability to maintain physical fitness and healthy activity levels, and might even further exaggerate deconditioning, disease progression and specific symptom experience like fatigue and cognitive function. The multi-dimensional assessment of walking-induced fatigability and the underlying mechanisms that may explain some of the gait characteristics may benefit future treatment of patients with MS. As part of this pilot study, a targeted sequential exercise training regime is used to assess the feasibility and preliminary effects on walking-induced motor fatigability in MS. The use of healthy controls as reference allows for a better understanding of walking-induced motor fatigability that can be attributed to MS.

Healthy participants will not benefit from participation. They will, however, contribute to future treatment of walking problems in patients with MS. In both healthy as well as person with MS, the risks and burden of the experiments may be related to walking on the GRAIL (dual-belt instrumented treadmill), to cardiopulmonary exercise testing, central and peripheral muscle fatigue testing, or in the case of the pwMS, the sequential exercise training. Patients with MS may benefit from the sequential training program on a function, activity, and participation level. All measurements and exercise therapy are non-invasive, and have been shown safe. The risk classification for this study

is *negligible*.

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

Inclusion criteria
- Definite MS
- Age >= 18
- Complain of early occurring fatigue or reduced walking speed during prolonged walking.
- Able to walk continuously for 12 minutes without walking aids

Exclusion criteria

Exclusion criteria
- Other medical conditions that affect gait (e.g. amputation).
- Serious comorbidities precluding high-intensity exercise training
- Already participating in a high intensity (>=2 per week), guided exercise protocol.
- Pregnancy, given birth previous 6 months, or active pregnancy wish < 6 months
- Use of (dal)fampridine (i.e. fampyra®).
- Use of heart rate regulating medication (i.e. Beta-blockers)
- MS exacerbation <= 3 months

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	13-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	19-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL53873.029.15