Exercise in Progressive Multiple Sclerosis

Published: 06-01-2020
Last updated: 15-05-2024

We hypothesize that both progressive resistance training and high intensity interval training positively affect the primary outcome measure (i.e. no change in percentage brain volume change). In addition, we expect positive effects on the secondary...

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29122

Source
NTR

Brief title
Exercise PRO-MS

Health condition

Multiple Sclerosis

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: Dutch MS Research Foundation, project number: MS 18-358f

Intervention

Outcome measures

Primary outcome

Percentage brain volume change, a measure of brain atrophy to determine neurodegeneration

Secondary outcome

Neurodegeneration: - White matter microstructural integrity - lesion load - regional atrophy - functional connectivity - Brain derived neurotrophic factors - Serum neurofilament light - Immune cell profiles Disability: - Expanded disability status scale - Cardiorespiratory fitness (VO2peak) - Muscle strength (1-RM) - Cognition (Brief Cognitive Assessment for Multiple Sclerosis) - 25 foot timed walked test - Energy cost of walking - Balance (Berg Balance Scale) - Depression (Hospital Anxiety and Depression Scale) - Disease impact (Multiple Sclerosis Impact Scale) - Fatigue (Checklist Individual Strength) - Health related quality of life (SF-36) - Walking ability (Multiple Sclerosis Walking Scale) - Exercise self-efficacy (Exercise Self-Efficacy Scale) - Stress resilience (Connor Davison Resilience Scale) Cardiovascular risk profile - Anthropometrics (height, weight, % body fat) - Blood pressure - Cardiovascular risk profile in blood (lipid-profiles, CRP, Glucose (HbA1c))

Study description

Background summary

Currently there are no disease modifying treatment options for people with progressive multiple sclerosis. Neurodegeneration rather than inflammation, seems to play a key role in the progressive phase of MS. Evidence from animal models, healthy aging individuals and people with multiple sclerosis suggests that exercise (e.g. resistance training and endurance training) might be a possible therapy affecting neurodegeneration. The primary aim of this trail is to assess whether two types of exercise programs can slow down neurodegeneration in progressive multiple sclerosis. In addition, we want to examine the effects of these interventions on disability and on the cardiovascular risk profile. In this extended baseline randomized clinical trial, participants are their own control group.

Study objective

We hypothesize that both progressive resistance training and high intensity interval training positively affect the primary outcome measure (i.e. no change in percentage brain volume change). In addition, we expect positive effects on the secondary outcomes measures for disability and the cardiovascular risk profile. Also, we will exploratory evaluate the effect sizes for the different interventions for future research.

Study design

baseline (week 1), extended baseline (week 16), post-intervention (week 33),16-week follow-up (week 48)

Intervention

Progressive Resistance Training and High Intensity Interval training

Contacts

Public
Amsterdam UMC, location VUmc
Arianne Gravesteijn

020-44 44925
Scientific
Amsterdam UMC, location VUmc
Arianne Gravesteijn

020-44 44925

Eligibility criteria

Inclusion criteria

PMS diagnosis defined as: ‘definite diagnosis of MS according to the 2017 McDonald Criteria with gradual progression of neurological impairments according to the Lublin criteria 2013.’ EDSS Scale 3.5 – 6 Able to participate in the exercise programs, i.e. no contra-indications for training according to the guidelines of the American college of Sports Medicine. o No history of heart problems o No symptoms that might indicate heart problems o No other major health issues Age between 18 and 60 years old Able to understand therapists instructions Fulfilling the safety criteria for magnetic resonance (MR) assessment o No metal inside the body o Not claustrophobic o No pregnancy

Exclusion criteria

Diagnosed with PPMS Relapse within 3 months of baseline visit Severe comorbidity (Cumulative Illness Rating Scale (CIRS) ≥ 3 on 1 or more organ systems). Initiation of Fampridine within 6 months of baseline visit. Depression, Hospital Anxiety and Depression Scale (HADS) score, depression subscale ≥11 (i.e. indicative of clinical anxiety disorder or clinical depression) Other neurological- and/or musculoskeletal disorders Already participating in a (guided) high intensity exercise training Participating in another intervention study Pregnancy, given birth previous 6 months, or active pregnancy wish.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55151
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8265
CCMO	NL71762.029.19
OMON	NL-OMON55151

Study results