

TREating FATigue in Multiple Sclerosis: Aerobic training

Submission date 13/07/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 19/07/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/01/2023	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ZonMw 60-61300-98-024; CCMO NL33451.029.10

Study information

Scientific Title
A randomized clinical trial looking at disabling fatigue in multiple sclerosis occurs frequently. How should it be treated? A randomized clinical trial

Acronym

TREFAMS-A

Study objectives

What is the effect of regular Aerobic Training (AT) on fatigue and participation in patients with Multiple Sclerosis on fatigue and participation in patients with Multiple Sclerosis? Can this effect be attributed to an increase in fitness parameters?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethics Committee of the VU University Medical Center, 5 April 2011 Ref: 2010/289

Study design

Randomized two armed trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple Sclerosis

Interventions

1. Aerobic Training consists of 12 individual therapist-supervised 45-minute physical exercise sessions with an intensity of at least 60%VO₂max in a period of 4 months
2. In the first 8 weeks one physiotherapist-supervised session will be given per week, in the subsequent 8 weeks one therapist-supervised session will be given every other week
3. The sessions include a warming-up and cooling down
4. In addition, patients will perform two aerobic training sessions per week at home of the same duration and at the same intensity as measured by heart rate
5. Control treatment for each RCT of the TREFAMS-ACE research programme consists of currently available standardized written patient information and will be provided in a standardized manner by an MS nurse. Patients receive this information package personally in the first week
6. In week 6 and 16, 45-minute appointments with the MS nurse will be scheduled in order to ask questions about the information package
7. This control treatment covers two important aspects that we want to control for
 - 7.1. Good information about MS related fatigue, and
 - 7.2. Attention of a professional who has experience in MS in order to reassure the patient that his concerns or questions will be taken seriously
 - 7.3. The MS nurses will receive instructions on how to provide the information without additional therapeutic interventions or specific personal advises
8. It is a two-arm trial

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Fatigue: checklist individual strength (CIS) subscale fatigue
2. Participation: impact on participation and autonomy (IPA)

Key secondary outcome(s)

1. Medical outcome study short form 36 (SF36)
2. Rehabilitation activities profile (RAP)
3. Fatigue severity scale (FSS)
4. Checklist individual strength (CIS) subscales motivation, concentration, activity modified fatigue impact scale (MFIS)

Completion date

01/04/2014

Eligibility

Key inclusion criteria

1. Diagnosis of MS according to the criteria of McDonald
2. Able to walk with no more than one unilateral walking aid i.e. able to walk with no more than one unilateral walking aid
3. Suffering from fatigue, defined as a score higher than 35 on the subscale fatigue of the Checklist Individual Strength (CIS)
4. Age between 18-70 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Key exclusion criteria

1. Patients using in the last three months prior to inclusion Amantadine, Modafinil, Ritalin or Pemoline for their fatigue
2. Major depression

Date of first enrolment

15/09/2011

Date of final enrolment

01/04/2014

Locations

Countries of recruitment

Netherlands

Study participating centre

Dept Rehabilitation Medicine

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Center (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organization for Health Research and Development Rehabilitation Research Program II, Fonds NutsOhra (ZonMw 60-61300-98-024)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No
Results article	results	19/03/2015		Yes	No
Results article	results	11/09/2015	24/01/2019	Yes	No
Results article	results	01/10/2017	24/01/2019	Yes	No
Results article	results	01/11/2016	24/01/2019	Yes	No
Results article	results	01/07/2014	24/01/2019	Yes	No
Results article	results	01/08/2014	24/01/2019	Yes	No
Results article	results	01/02/2016	24/01/2019	Yes	No
Results article	results	19/03/2015	24/01/2019	Yes	No
Results article	Secondary analysis	28/12/2022	10/01/2023	Yes	No
Protocol article	protocol	12/08/2013		Yes	No