ISRCTN69520623 https://doi.org/10.1186/ISRCTN69520623

TREating FAtigue in Multiple Sclerosis: Aerobic training

Submission date	Recruitment status	[X] Prospectively registered
13/07/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2023	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Heleen Beckerman

Contact details
Dept Rehabilitation Medicine
VU University Medical Center
PO BOX 7057
Amsterdam
Netherlands
1007 MB

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

Primary study design
Interventional

Study design
Randomized two armed trial

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