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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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
15/09/2011

Overall study end date
01/04/2014

Eligibility

Participant 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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
90

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

Recruitment start date
15/09/2011

Recruitment end date
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)

Sponsor details
Department Rehabilitation Medicine
PO Box 7057
Amsterdam
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Sponsor type
University/education

Website
http://www.vumc.com/patientcare/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	12/08/2013		Yes	No
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