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TREating FAtigue in Multiple Sclerosis: Energy conservation management

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
11/03/2015	Nervous System Diseases	

Plain English summary of protocol
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
Disabling fatigue in multiple sclerosis occurs frequently: how should it be treated? A randomized clinical trial

Acronym
TREFAMS-E

Study objectives
What is the effect of Energy Conservation Management (ECM) advices on fatigue and participation in patients with Multiple Sclerosis? Can this effect be attributed to the use of ergonomic advices given or adhering to altered time-schedules?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Medical Ethics Committee of the VU University Medical Center (2010/289), 05/04/2011
2. The Board of the Erasmus Medical Center Rotterdam, 27/06/2011

Study design
Randomized clinical 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

Health condition(s) or problem(s) studied
Multiple Sclerosis

Interventions
1. Energy Conservation Management consists of 12 individual therapist-supervised 45-minute sessions, in which energy-management and ergonomic advices are given, in a period of 4 months; in the first 8 weeks one occupational therapist-supervised session will be given per week, in the subsequent 8 weeks one therapist-supervised session will be given every other week. In addition, individualized home-assignments are given.
2. 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. In week 6 and 16, 45-minute appointments with the MS nurse will be scheduled in order to ask questions about the information package. This control treatment covers two important aspects that we want to control for:
2.1. Good information about MS related fatigue, and
2.2. Attention of a professional who has experience in MS in order to reassure the patient that his concerns or questions will be taken seriously. The MS nurses will receive instructions on how to provide the information without additional therapeutic interventions or specific personal advises

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)
The 6 time points are: week-1, week 0, week 8, week 16, week 26 and week 52

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
5. Modified Fatigue Impact Scale (MFIS)
The 6 time points are: week -1, week 0, week 8, week 16, week 26 and week 52

Overall study start date
15/09/2011

Completion date
01/04/2014

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
90

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
VU University Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Center (Netherlands)

Sponsor details
Dept Rehabilitation Medicine,
PO Box 7057
Amsterdam
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1007 MB

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) (ZonMw 60-61300-98-024)

Funder Name
Fonds NutsOhra (Netherlands)

Alternative Name(s)
NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/01/2015		Yes	No