

TREating FATigue in Multiple Sclerosis: Energy conservation management

Submission date 13/07/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 19/07/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/03/2015	Condition category Nervous System Diseases	☐ 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
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

Study type(s)

Treatment

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(s)

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

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
5. Modified Fatigue Impact Scale (MFIS)

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

Completion date

01/04/2014

Eligibility

Key inclusion criteria

Ambulatory multiple sclerosis (MS) patients fulfilling 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

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

VU University Medical Center

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Center (Netherlands)

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

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?
Results article	results	01/01/2015		Yes	No
Protocol article	protocol	12/08/2013		Yes	No