

# TREating FATigue in Multiple Sclerosis: Energy conservation management

<b>Submission date</b> 13/07/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/03/2015	<b>Condition category</b> 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**  
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 advices

### **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?
<a href="#">Results article</a>	results	01/01/2015		Yes	No
<a href="#">Protocol article</a>	protocol	12/08/2013		Yes	No