

# TREating FAtigue in Multiple Sclerosis: Cognitive behavioural therapy

<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> 24/01/2019	<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

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 disabling fatigue in multiple sclerosis occurs frequently. How should it be treated?

**Acronym**

TREFAMS-C

**Study objectives**

What is the effect of Cognitive Behavioural Therapy (CBT) on participation and fatigue in patients with Multiple Sclerosis (MS)? Can this effect be explained by altered cognitions about fatigue?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Medical Ethics Committee of the VU University Medical Center, 5 April 2011 ref: 2010/289

**Study design**

Multicenter two armed randomized 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. Cognitive Behavioural Therapy (CBT) with two arms
2. CBT will focus on the fatigue maintaining behaviour and cognitions of the patient
3. CBT consists of 12 individual therapist-supervised 45-minute therapy sessions in a period of 4 months, and an individualized schedule to gradually expand participation
4. The time interval between therapy session will be gradually increased as therapy progresses
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
6. Patients receive this information package personally in the first week

7. In week 6 and 16, 45-minute appointments with the MS nurse will be scheduled in order to ask questions about the information package
8. This control treatment covers two important aspects that we want to control for:
  - 8.1. Good information about MS related fatigue, and
  - 8.2. Attention of a professional who has experience in MS in order to reassure the patient that his concerns or questions will be taken seriously
9. 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)

**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)

**Overall study start date**

15/09/2011

**Completion date**

01/04/2014

**Eligibility****Key inclusion criteria**

Ambulatory MS patients fulfilling the following enrollment 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

**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)

**Sponsor details**

Dept Rehabilitation Medicine

PO Box 7057

Amsterdam

Netherlands

1007 MB

**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****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="#">Protocol article</a>	protocol	12/08/2013		Yes	No
<a href="#">Results article</a>	results	01/11/2016		Yes	No
<a href="#">Other publications</a>	In	01/11/2016	24/01/2019	Yes	No
<a href="#">Results article</a>	results	19/03/2015	24/01/2019	Yes	No
<a href="#">Results article</a>	results	13/02/2018	24/01/2019	Yes	No
<a href="#">Results article</a>	results of the effectiveness of cognitive behavioural therapy for the treatment of fatigue in patients with multiple sclerosis.	01/11/2016	24/01/2019	Yes	No

<a href="#">Results article</a>	results of the effectiveness of cognitive behavioural therapy to improve MS-related fatigue and participation.	01/10/2017	24/01/2019	Yes	No
<a href="#">Results article</a>	results of the role of appraisal and coping style in relation with societal participation in fatigued patients with multiple sclerosis.	01/10/2016	24/01/2019	Yes	No
<a href="#">Results article</a>	results of which psychological factors mediate change in fatigue during and after cognitive behavioural therapy.	01/03/2018	24/01/2019	Yes	No