

TREating FATigue in Multiple Sclerosis: Cognitive behavioural therapy

Submission date 13/07/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 19/07/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/01/2019	Condition category 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
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

Study type(s)

Treatment

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(s)

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

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)

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

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**Dept Rehabilitation Medicine**

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Center (Netherlands)

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

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	01/11/2016		Yes	No
Results article	results	19/03/2015	24/01/2019	Yes	No
Results article	results	13/02/2018	24/01/2019	Yes	No
Results article	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
Results article	results of the effectiveness of cognitive behavioural therapy to improve MS-related fatigue and participation.	01/10/2017	24/01/2019	Yes	No
Results article	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
Results article	results of which psychological factors mediate change in fatigue during and after cognitive behavioural therapy.	01/03/2018	24/01/2019	Yes	No
Protocol article	protocol	12/08/2013		Yes	No
Other publications	In	01/11/2016	24/01/2019	Yes	No