ISRCTN58583714 https://doi.org/10.1186/ISRCTN58583714

TREating FAtigue in Multiple Sclerosis: Cognitive behavioural therapy

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
24/01/2019	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
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 fulfulling 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
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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?
Protocol article	protocol	12/08/2013		Yes	No
Results article	results	01/11/2016		Yes	No
Other publications	In	01/11/2016	24/01/2019	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