Blended versus face-to-face Cognitive Behavioural Therapy in treating severe fatigue in patients with MS - an observer-blinded randomized clinical trial testing non-inferiority at post-treatment and long-term effectiveness.

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1. To investigate the non-inferiority of blended CBT compared to proven effective face-to-face CBT according to the TREFAMS-CBT treatment protocol in severely fatigued patients with MS, using a non-inferiority margin of 5.3 points on the Checklist...

Ethical review	Approved WMO
Status	Completed
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON55707

Source
ToetsingOnline

Brief title
e-Trefams CBT: blended CBT for MS-related fatigue

Condition

- Demyelinating disorders

Synonym
fatigue in patients with Multipele Sclerosis, MS-related fatigue

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: cognitive behavioral therapy, e-health, fatigue, Multiple sclerosis

Outcome measures

Primary outcome

Fatigue severity measured by the CIS20r subscale fatigue severity will be the primary outcome in the non-inferiority trial (at week 20) and in the additional booster trial (at 12 months).

Secondary outcome

- Fatigue as measured with the PROMIS fatigue-short form 8a, and the FSS.

- CIS20r subscales reduction in motivation due to fatigue, reduction in physical activity due to fatigue, and concentration problems

- limitations in daily functioning as measured with the SIP, WSAS and SF-36.

other determinants:

- Socio-demographic and disease-related characteristics

- Symptom Checklist (SCL-90)

- Epworth Sleepiness Scale (ESS)

- Pittburg Sleep Quality Index (PSQI)

- The Multiple Sclerosis Self-Management Scale

- Visual Probe Task (VPT)

- Interpretative bias task

- Sleeplog

Patient-therapist variabels:

- Treatment preference at baseline (online vs f2f)

- Treatment Outcome Expectations Questionnaire (TOEQ)

- Working Alliance Inventory (WAI-SR)

- Satisfaction with treatment

- System Usability Scale (SUS)

- Patient therapy adherence

Patient-tailoring (blended) CBT modules

- Impact of Event Scale (IES)

- Illness Cognition Questionnaire (ICQ)

- Cognitive-Behavioural Responses on Symptoms (CBRSQ)

- Beck Depression Inventory (BDI-II-PC)

- Fear of Disease Progression-SF (FoPQ-SF)

- Self-Efficacy Scale (SES-28)

- Jacobsen Fatigue Catastrophizing Scale

- Illness Management Questionnaire (IMQ)

- Social Support List (SSl & SSL D)

- Pain Catastrophizing Scale (PCS).

Study description

Background summary

The recent results of the TREFAMS-ACE research programme with 3 randomized clinical trials showed that severe MS-related fatigue can be significantly reduced with individual face-to-face CBT. TREFAMS is an acronym for TReating FAtigue in Multiple Sclerosis, while ACE refers to the rehabilitation treatment methods under study, i.e. Aerobic training, Cognitive behavioural therapy, and Energy conservation management. The TREFAMS-CBT treatment protocol consists of 12 face-to-face therapy sessions in 4-5 months. However, there are important barriers for patients to follow such an intervention, like having to travel to a treatment centre. Especially for severely fatigued patients this is burdensome. Blended CBT, i.e. a combination of face-to-face sessions and web-based CBT, has the potential to address these drawbacks. TREFAMS-CBT was effective in reducing fatigue directly post-treatment. However, the positive effects gradually wore off after treatment cessation. Therefore, booster sessions will be added to the blended and face-to-face treatment protocol to maintain post-treatment effects over the long-term.

Study objective

1. To investigate the non-inferiority of blended CBT compared to proven effective face-to-face CBT according to the TREFAMS-CBT treatment protocol in severely fatigued patients with MS, using a non-inferiority margin of 5.3 points on the Checklist of Individual Strength (CIS20r) fatigue subscale.
2. To study the effectiveness of CBT booster sessions to improve long-term outcome with respect to fatigue severity at 1-year follow-up.

Study design

A observer-blinded non-inferiority multicentre randomized clinical trial. At baseline patients will be randomized (R1) to face-to-face CBT or blended CBT. At the ed of the intitial treatment patients will be randomized again (R2) to either booster sessions or no additional intervention until follow-up. Total follow-up is 1 year.

Intervention

Patients will receive 12 face-to-face CBT sessions, according to the TREFAMS-CBT protocol or blended CBT, based on the same protocol, but supported with web-based assignments and only 2 face-to-face and 3 video consultations. The CBT will be applied by trained and supervised psychologists.

Study burden and risks

Patients will be informed about a total study participation time of one year. Patients in both groups receive a treatment for their fatigue, which are both expected to be effective. Their benefit will be a decrease in severe fatigue. There are no risks to their health. The burden of participating in this scientific study is that participants will have to complete additional questionnaires and a computer task, before and after treatment and at 9 and 12 months follow-up after randomization. Most of these measurements can be completed online.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Definitive diagnosis of MS
- Being severely fatigued (CIS20r fatigue >= 35).
- Aged between 18 and 70 years

- Ambulatory patients (EDSS <= 6)
- No evident signs of exacerbation or a corticosteroid treatment in the past 3 months

Exclusion criteria

- Depression (BDI-II-PC >= 4 + depression assessed by M.I.N.I.)
- primary sleep disorder
- severe co-morbidity (CIRS item scores >= 3)
- current pregnancy or having given birth in the past three months
- Started with pharmacological treatment for fatigue in the past three months (other pharmacological treatment, p.e. for MS, is allowed)
- Started with non-pharmacological therapies for fatigue in the past three months
- previous treatment with Trefams-CBT

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-04-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23922
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62622.029.17

Study results

Date completed: 31-12-2022

Results posted: 17-09-2024

Actual enrolment: 157

First publication
17-09-2024