e-TREFAMS-CBT: Blended CBT for MS-related fatigue

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To investigate the non-inferiority of blended CBT compared to evidence-based face-to-face CBT delivered according to the TREFAMS-CBT treatment protocol in severely fatigued patients with MS. It is hypothesized that blended CBT for severe MS-related...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23922

Bron
Nationaal Trial Register

Verkorte titel
e-TREFAMS-CBT: Blended CBT for MS-related fatigue

Aandoening

Multiple Sclerosis related fatigue
MS-gerelateerde vermoeidheid
Cognitive Behavioural Therapy
Blended cognitive Behavioural Therapy

Ondersteuning

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Overige ondersteuning: Dutch MS Research Foundation (16-937 MS)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In both subsequent trials, fatigue as measured by the CIS20r fatigue severity subscale will be the primary outcome. A cut-off score of 35 or higher is an indication for severe fatigue.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.

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: An 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 end of the treatment patients will be randomized again (R2) to either booster sessions or no additional intervention until follow-up.
Study population: 166 ambulatory adult patients (EDSS ¡Ü 6) with severe MS-related fatigue (CIS20r fatigue ¡Ý 35) are required.

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

Doel van het onderzoek

To investigate the non-inferiority of blended CBT compared to evidence-based face-to-face CBT delivered according to the TREFAMS-CBT treatment protocol in severely fatigued patients with MS. It is hypothesized that blended CBT for severe MS-related fatigue (consisting of 2 face-to-face contacts at the outpatient clinic, 3 patient-therapist contacts via a secured video connection, and web-based therapy sessions and assignments) will lead to similar (non-inferior) clinical improvements as the proven effective face-to-face TREFAMS-CBT treatment directly post-treatment, within the non-inferiority margin of 5.3 points on the CIS20r fatigue scale. H0 in this non-inferiority RCT is that the blended CBT treatment is less effective and inferior to face-to-face CBT. 2. To study the effectiveness of CBT booster sessions aimed to improve long-term outcome with respect to fatigue at 1-year follow-up. We hypothesize that two additional booster contacts (video-consultation) with the same therapist, combined with email contact between the end of initial treatment and 1-year follow-up, and access to a web-based portal with information and assignments on fatigue relapse prevention will lead to sustained treatment effects (i.e. between-group difference of 6.7 points on CIS20r fatigue) compared to the interventions (either face-to-face or blended CBT) without booster sessions.

Onderzoeksopzet

The set of determinants, and primary and secondary outcomes will be measured at baseline, at 20 weeks at the end of post-treatment (non-inferiority hypothesis), at 9 months (39 weeks) and 12 months (52 weeks, long-term superiority hypothesis). Most of measurements are self-reported questionnaires that can be completed online from home.

Onderzoeksproduct en/of interventie

TREATMENTS

1.1 Face-to-face CBT (TREFAMS-CBT protocol)

In the face-to-face-CBT study arm, patients receive twelve individual, face-to-face, 45-min therapy sessions distributed over a 5-month period according to the protocol tested in a previous RCT (van den Akker et al., 2017). CBT will be provided by certified health care psychologists or cognitive behavioural therapists who will be trained to deliver (blended) CBT for MS-related fatigue.

CBT for MS-related fatigue is directed at the fatigue maintaining behaviours and beliefs of the patient. The general aim of the CBT is to lessen the fatigue by changing fatigue maintaining cognitions and behaviours and improve daily functioning). As the individual differences in the maintaining factors are large, first the relevant fatigue maintaining factors for the individual patient are assessed using specific screening instruments. For each maintaining factor at stake a specific treatment module is available. The patient is treated with the CBT modules that are aimed at the specific factors that maintain the fatigue of the individual patient. Therapists will get information about the assessment results that are necessary to determine which CBT treatment modules are indicated for the individual patient.

The CBT consists of 10 possible treatment modules:

1. Treatment goals.

2. Sleep and rest.

3. Uncertainty about the (consequences of the) illness and appraisal of MS as threatening.

4. Fatigue-related cognitions.

5. Focusing on fatigue.

6. Physical activity regulation.

7. Regulation of social activity.

8. Regulation of mental activity.

9. Social support.

10. Unhelpful thoughts about pain.

1.2 Blended CBT

Blended CBT consists of 5 patient-therapist contacts, either face-to-face, or via video-consultation, and information and assignments in 7 web-based therapy modules delivered via an internet portal (Minddistrict) and supported by email contact with a therapist providing feedback on the progress made by the patient.

Treatment will start with one face-to-face session, and a maximum of three therapist sessions via a secured video connection. After 4-5 months, blended CBT will be completed with a face-to-face contact.

The blended CBT will also be patient-tailored based on the same 10 treatment modules as described earlier. The information and assignments provided in the internet portal are developed by experts on CBT for MS-related fatigue.

1.3 Booster sessions

At the end of the initial therapy, patients are randomized again (R2) and allocated to either receiving booster sessions, or no booster sessions. Two patient-therapist booster consults with the same psychologist will be scheduled at 2 and 4 months following end of initial treatment. Booster sessions will be delivered via the internet via a secured video connection and combined with email contact and web-based CBT assignments on prevention of fatigue relapses.

1.4 Therapists

Blended CBT, TREFAMS-CBT and the booster sessions will be provided by psychologists who will be trained in delivering the interventions with a four day training (3 days face-to-face and 1 day of training for the e-health intervention). During the treatment period of the study, they will receive bi-weekly patient-specific supervision from an experienced cognitive behavioural therapist.

1.5 Use of co-intervention

Participants are asked not to follow or use any other therapies or pharmaceuticals aimed at treating fatigue during study participation. All interventions not aimed at treating fatigue are allowed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

a) definitive diagnosis of MS; b) severely fatigued (CIS20r fatigue ¡Ý 35); c) ambulatory patients (EDSS ¡Ü 6); d) no evident signs of an exacerbation, or a corticosteroid treatment in the past 3 months; e) no current infections; f:) no anaemia; g) a normal thyroid function.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

a) depression (assessed with BDI-II-PC ≥ 4 and M.I.N.I) ; b) primary sleep disorders; c) severe comorbidity (CIRS item scores ¡Ý 3); d) current pregnancy or having given birth in the past 3 months; e) pharmacological treatment for fatigue that was started in the past 3 months (e.g.

Amantadine, Modafinil, Ritalin, Pemoline); f) non-pharmacological therapies for fatigue that took place in the past 3 months. Patients who already received CBT in the TREFAMS study will be excluded as well.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	166
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55707
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6782
NTR-old	NTR6966
CCMO	NL62622.029.17
OMON	NL-OMON55707

Resultaten