Appendix 2

TIDieR TREFAMS-Cognitive Behavioural Therapy
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Cognitive Behavioural Therapy

Why CBT for MS-related fatigue

Research has indicated that non-pharmacological interventions (both exercise and psychological/educational interventions) appear to have a greater impact on fatigue than commonly prescribed pharmacological treatments. To provide an entry point for the treatment of MS-related fatigue, van Kessel et al. (2006) developed a cognitive-behavioural model to explain the persistence of MS-related fatigue. This theoretical model encompasses both disease-related factors and psychological factors identified in literature. According to this model, disease-related factors trigger fatigue in MS, and cognitive, emotional, and behavioural factors determine the extent to which this fatigue influences daily life. The goal of Cognitive Behavioural Therapy (CBT) for MS-related fatigue is to influence dysfunctional cognitions, behaviours and emotions that perpetuate fatigue.

What

Qualified psychologists were trained in accordance with the TREFAMS-CBT treatment manual (in Dutch: Hans Knoop & Gijs Bleijenberg. Cognitieve gedragstherapie voor chronische vermoeidheid bij MS patiënten – Behandelprotocol. Nijmeegs kenniscentrum chronische vermoeidheid, mei 2011).
Who provided the therapy

All CBT therapists were state-certified healthcare psychologists who completed a 3-day course on how to provide CBT in accordance with the TREFAMS-CBT protocol. Furthermore, the CBT therapists were supervised every second week by a supervising CBT psychologist.

How, when and how much

The patients received 12 sessions of individual face-to-face therapy over a 4-month period (8 sessions in the first 2 months, 4 sessions in the last 2 months). Each session lasted 45 minutes.

Where

Sessions took place in the outpatient clinics of the VU University Medical Center, Amsterdam, and the Expert Centre for Chronic Fatigue of the Radboud University Medical Center, Nijmegen, the Netherlands.

Tailoring

The TREFAMS-CBT trial aimed to decrease fatigue by changing a patient’s fatigue-related dysfunctional cognitions and behaviour, and thus to eventually improve societal participation. The CBT protocol consists of 10 modules (Table A.1). The intervention was patient-tailored: the specific modules indicated for a particular patient were determined using questionnaires with predefined cut-off scores and information from the intake session with the psychologist. The subsequent CBT treatment was individualized based on the indicated modules and thus aimed to treat the cognitive-behavioural factors that were thought to maintain or worsen fatigue in an individual patient. After an intake session in which information was given about the cognitive-behavioural model of MS-related fatigue and CBT, patients began by formulating their treatment goals. The following sessions addressed the fatigue-maintaining cognitions and behaviours and were aimed at realizing the set treatment goals. The final therapy sessions focused on integrating the obtained skills into daily life, and on how patients with MS should handle relapses of fatigue.
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Modifications

In cases where participants did not require all 12 sessions with the psychologist due to completion of the intervention in fewer sessions, therapy was ended earlier in joint consultation between the participant and the psychologist.

How well

We used the following measures of adherence:
1) the number of sessions a participant completed
2) the indicated modules that were used during the CBT treatment

Control intervention

Background

The MS-nurse consultations covered two important aspects to control for: (1) reliable information on MS-related fatigue; and (2) attention from an experienced MS professional in order to reassure the patient that his/her concerns or questions will be taken seriously.
**What**

All MS-nurses involved in one of the TREFAMS-ACE trials participated in a 1-day training course. In this course the MS-nurses shared their approach to taking a fatigue-related nursing history, they were instructed as to how to provide relevant information on MS-related fatigue without giving concrete therapeutic advice, and they were informed of the restrictions concerning the referral of patients to other healthcare professionals within the hospital (MS team members). These newly-learned skills were practised using role-playing.

**Equipment**

A study-specific (Dutch) brochure was developed with the aim to provide standardized information about MS-related fatigue. Any referral to first or second line health care professionals was removed.

**Who**

Experienced and trained MS-nurses.

**How, when and how much**

The low-intensity treatment consisting of three, face-to-face, consultations of 45 minutes over a 4-month period.

- Session 1 (baseline): Acquaintance, MS-related fatigue history, and providing standardized brochure.
- Session 2 (1.5 months): Evaluating brochure and goal-setting.
- Session 3 (4 months): Goal and treatment evaluation.

**Where**

MS-specialized outpatient clinic.
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**Modifications**

In some cases the face-to-face sessions were replaced with phone sessions if needed.

**Adherence**

The number of sessions completed as well as the amount of allied healthcare during the study period was recorded.