THE EFFICACY OF COGNITIVE BEHAVIOURAL INTERNET THERAPY FOR ADULT PATIENTS WITH CHRONIC FATIGUE SYNDROME: A RANDOMISED CONTROLLED TRIAL.

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The main research question of this study is: 1. Does CBITlead to a reduction of fatigue severity in adult patients with CFS compared to a waiting list condition? Secondary research questions for phase one of the study: 2. Does CBIT lead to a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39926

Source
ToetsingOnline

Brief title
CBIT for CFS.

Condition

- Other condition

Synonym
chronic fatigue/ ME

Health condition

chronisch vermoeidheidssyndroom

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic fatigue syndrome, cognitive behavioural therapy, internet intervention, internet therapy

Outcome measures

Primary outcome

The primary outcome measure is fatigue severity. Fatigue severity will be

measured with the subscale *fatigue severity* of the Checklist Individual

Strength (CIS)[8, 9].

Secondary outcome

Secondary outcome measures are:

• level of disabilities ((Sickness Impact Profile total score and Short Form 36

Health Survey (=RAND-36 in Dutch) subscale physical functioning))

• level of psychological distress (total score on Symptom CheckList-90)

• proportion of patients with clinical significant improvement on fatigue

severity. Clinical significant improvement is defined as a reliable change

index > 1.96 (Jacobson & Truax, 1991) between baseline and T1, and a score of <

35 on the CIS Fatigue Severity subscale at T1

• Quality Adjusted Life Years (Euro Qol Group-5D)[10].

Phase 2 of the study:

(Secondary) outcome measures in phase two of this study are:

• fatigue severity (CIS-fatigue)

• level of disabilities (SIP-total)

• proportion of patients with clinical significant improvement on fatigue

severity. Clinical significant improvement is defined as a reliable change

index > 1.96 (Jacobson & Truax, 1991) between baseline and T1/ T2, and a score

of < 35 on the CIS Fatigue Severity subscale at T2

• quality adjusted life years (EQ-5D)

• number of sessions per patient (login data internet)

• therapist time per patient (login data internet)

Study description

Background summary

Chronic fatigue syndrome (CFS) is characterized by severe fatigue that lasts longer than 6 months and leads to functional impairments. It is not the result of an organic disease or ongoing exertion and is not alleviated by rest [1]. Besides severe fatigue and substantial functional impairments, most patients report additional symptoms. According to the CFS criteria of the U.S. Centers for Disease Control [1] a patient must report four out of eight additional symptoms: unrefreshing sleep, postexertional malaise, headache, muscle pain, multi-joint pain, sore throat, tender lymph nodes, and concentration and memory impairment. Only in the Netherlands there are at least 30.000-40.000 CFS patients according to Dutch Health Council. The natural course of CFS without treatment is unfavourable; only 5% of the patients recover spontaneously [2].

Cognitive behavioural therapy (CBT) for CFS is an effective [3, 4] but intensive treatment. CBT for CFS is directed at changing fatigue-related cognitions and behaviours that perpetuate the fatigue and disabilities. A substantial subgroup of patients fully recover during treatment [3]. It requires an average of 14 face to face sessions to change the fatigue perpetuating factors [5]. Wider implementation of this effective therapy is hampered by the fact that the treatment is time consuming for both patient and therapist. Moreover, licensed cognitive behaviour therapists need additional

training and supervision to learn to treat CFS. The aforementioned leads to a limited treatment capacity is limited and makes that many CFS patients do not get the treatment they need.

Therefore, less intensive interventions are needed to reach more patients with a limited number of qualified therapists. There is evidence that not all patients need an intensive treatment. A previous study of our own research group showed in a randomized controlled trial (RCT) for a subgroup of patients with CFS a less intensive treatment sufficed to significantly reduce fatigue and disabilities [6]. We developed a minimal intervention based on CBT that consisted of a booklet with self-instructions and two-weekly email contact with a trained therapist.

Although the minimal intervention significantly reduced fatigue it was only effective in a limited number of patients (about 25%). Recent research in adolescents CFS patients has shown that treatment delivered by the internet can be highly effective and comparable in effectiveness to face to face therapy. In the present study we want to test the efficacy of an internet based intervention for adult CFS patients. It is developed on the basis of the self-help booklet and consist of structured exercises with feedback provided by the therapist. It is unclear how much feedback from the therapist is needed to for patients to profit from an internet based intervention. To test this we developed two versions of the CBIT: one in which the patients will receive frequent feedback according to a predefined schedule (protocol driven feedback) and one version in which patients only receive support on demand (support on demand).

In the first phase of this study we will investigate the efficacy of CBIT for adult CFS patients with different levels of support offered by therapists. Both conditions will be compared to a waiting list control group and with each other with respect to its effect on fatigue severity (primary outcome measure).

We expect that not all patients will profit from the CBIT and therefore we added a second phase to the study. In this second phase patients who have not sufficiently benefited from the CBIT (i.e. are still severely fatigue and/or disabled at post-intervention assessment) will be offered regular face to face cognitive behaviour therapy. This stepped care (CBITfollowed by regular CBT if the patient is still fatigued) will be compared to care as usual (CBT after a waiting period) in a randomised non-inferiority trial.

Study objective

The main research question of this study is:
1. Does CBITlead to a reduction of fatigue severity in adult patients with CFS compared to a waiting list condition?

Secondary research questions for phase one of the study:

2. Does CBIT lead to a reduction of disabilities, psychological distress and/or a progress of clinical significant improvement of fatigue and/or quality adjusted life years in adult patients with CFS compared to a waiting list condition?

3. Is CBIT with protocol driven feedback more effective than CBITwith support on demand concerning its effect on fatigue severity?

Secondary research questions of phase two of the study:
4. Is stepped care consisting of CBIT with protocol driven feedback or with support on demand followed by regular face to face therapy (for those patients who are still fatigued and/ or disabled after cognitive behavioural internet therapy) non-inferior to care as usual i.e. CBT following the waiting list with respect to its effect on fatigue severity?

5. Is stepped care consisting of CBIT followed by regular face to face therapy (for those patients who are still fatigued and/ or disabled after cognitive behavioural internet therapy) as effective as care as usual i.e. CBT following the waiting list with respect to its effect on level of disabilities and clinical significant improvement of fatigue?

6. Is stepped care consisting of CBIT followed by regular face to face therapy (for those patients who are still fatigued and/ or disabled after cognitive behavioural internet therapy) as efficient (i.e. required number of sessions and therapist time per patient and for quality adjusted life years) as care as usual i.e. CBT following the waiting list?

Study design

The first part of this study consists of an open randomised controlled intervention study comparing the efficacy of CBIT (protocol driven feedback or support on demand) with a waiting list condition. Patients are only blind for the type of CBIT they are allocated to (protocol driven feedback versus support on demand). We hypothesized patients will behave differently if they would know that the level of feedback is manipulated.

The second part of this study will consist of a randomised controlled non-inferiority trial testing if CBIT followed by face to face CBT (for those patients who still are fatigued and/or disabled following CBIT) is non-inferior to care as usual (waiting list followed by face to face cognitive behaviour therapy).

Intervention

Patients allocated to the CBIT learn how to change fatigue perpetuating cognitions and behaviour. The treatment is based on the protocol for individual

face to face cognitive behavioural therapy. The cognitive behavioural model for CFS assumes there is a trigger for fatigue which does not account for the fatigue to perpetuate. According to the model the fatigue is perpetuated by behaviours and cognitions. By changing these, the fatigue and disabilities will decrease. There are 2 intervention conditions in the first phase of the study:

CBIT with protocol driven feedback.
During 6 months in which patients receive information and make assignments patients will receive weekly feedback from their therapist. This feedback consists validation of their progress and suggestions/ advice. Feedback will be given (at least) within 5 workdays counted from the date of the patient*s reaction. During the treatment of 6 months the feedback become less frequent (once to two-weekly) following the same frequency of contact as face to face therapy.

CBIT with support on demand.
Patients in the support on demand condition will follow the same internet therapy. Patients can ask for support or feedback by sending an email to the therapist. Then, feedback will (also) be given within 5 workdays after the email/ message send by the patient. Feedback will be given in the same way as in the protocol driven feedback condition.

If patients do not profit enough from the CBIT, regular face to face CBT-treatment will be offered with a maximum duration of 6 months and 12-14 session. CBT is offered when patients are still severely fatigued (CIS-fatigue > 35) and/or disabled (SIP total >700) following the CBIT or waiting list.

Study burden and risks

Previous research has shown there are no detrimental effects of CBT for CFS [11] and guided self instructions. There were no adverse events reported in the study testing a CBIT in adolescent CFS patients[7]. There are also no specific risk factors associated with the CBIT for CFS and the burden for patients is limited. Patients who participate in the waiting list condition will receive an extra asked assessment compared to patients who not participate in this study. Patients in the waiting list condition will not wait longer than usual before they start with individual CBT for CFS. Because many patients are referred to the Expert Centre Chronic Fatigue for treatment the waiting period for starting treatment is 6 months. The waiting period is due to a limited treatment capacity. The benefit of participating in this study when a patient is allocated to the CBIT starting directly with (internet) therapy instead of waiting half a year before CBT starts.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* >= 18 years
* Able to speak, read and write Dutch language
* Meet the 1994 US Center for Disease Control and Prevention criteria for chronic fatigue syndrome
* Score >= 35 on the Checklist Individual Strength (CIS), fatigue severity sub-scale
* Have a total score of >= 700 on the Sickness Impact Profile r_08 (SIPr08)
* Give written informed consent

Exclusion criteria

Patients who are engaged in a legal procedure concerning disability-related financial benefits cannot start treatment.
This is a temporary exclusion criteria. If the legal procedure is finished patients can enter the study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2013
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-09-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 22165
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42543.091.12
OMON	NL-OMON22165
OMON	NL-OMON25622