The effectiveness of cognitive behavioural therapy in groups for patients with Chronic Fatigue Syndrome (CFS): a randomised controlled study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24062

Source
NTR

Brief title
N/A

Health condition

Chronic Fatigue Syndrome

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: Radboud University Nijmegen Medical Centre

Intervention

Outcome measures

Primary outcome

1. Fatigue severity (measured with the CIS subscale fatigue severity).
2. Disabilities (measured with the SIP total score and the SF-36 subscal 'physical functioning')
The CIS-f, SIP and SF-36 are used in two assessments, a baseline and a post-treatment (or post-waiting list) assessment. The change score between post-treatment and baseline of each of the treatment conditions is compared with the difference score between post-waiting list and baseline assessment of the waiting list condition.

Secondary outcome

Psychological distress measured with the Symptom Checklist 90 (SCL_90).

Study description

Background summary

Chronic Fatigue Syndrome (CFS) is characterised by severe fatigue, lasting longer than six months and leading to functional impairment. It is not the result of an organic disease or ongoing exertion and not alleviated by rest. The aetiology of CFS is unknown, but cognitions and behaviour can perpetuate CFS. Several controlled trials have shown that individual Cognitive Behaviour Therapy (CBT) aimed at these perpetuating factors leads to a reduction of fatigue and disabilities. In the Netherlands there a between 30.000 and 40.000 CFS patients while at the same time the availability of individual CBT for CFS is limited due to a limited treatment capacity. It is important to develop treatment programmes that require less treatment capacity. Group treatment is an example of such a treatment program. An earlier study showed that CBT for CFS in a group was not effective (Bazelmans et al, 2005). On the basis of this study a new protocol for group CBT for CFS was developed in the Expert Centre Chronic Fatigue of the Radboud University Nijmegen Medical Centre. The two objectives of the current study are 1) to evaluate the efficacy of a cognitive behavioural treatment in groups for CFS 2) to find out for which CFS patients group treatment is specifically suitable. This is a randomised controlled trial in which two types of group treatment (treatm in a small group of 4 patients and a treatment in a larger group of 8 patients) are compared with a waiting list condition. Patients are included if they meet the 1994 US Center for Disease Control criteria for CFS, are severely fatigued and disabled, are willing to follow group treatment and gave their written informed consent. Consecutive patients are randomly assigned to the two treatment conditions or a waiting list condition. All patients are assessed again after treatment or the waiting period. The main outcome measures are fatigue severity (CIS) and functional impairment (SF-36 and SIP).

Study objective

There are two research questions:
1. Does cognitive behavioural therapy (CBT) in groups lead to a significant decrease of fatigue and functional impairment of CFS patients compared to a waiting list condition?

2. For which patient is group therapy a suitable treatment method?

Intervention

After a basline assessment patients are randomly assigned to one of three conditions. The are two treatment conditions: small group (4 patients and 1 therapist) and large group (8 patients and two therapists). Both group treatments consist of 16 sessions of two hours in a period of about six months. There is a second assessment after the treatment. The third condition is a waiting list condition. After the waiting period of a least 6 months patients get a second assessment.

Contacts

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Eligibility criteria

Inclusion criteria

1. > 18 years old;
2. Being able to speak and read Dutch;
3. Meeting the 1994 research criteria for CFS as formulated by the US Center for Diasease Control;
4. Severely fatigued (having a CIS-fatigue severity score of >=35);
5. Severely disabled (weigthed totalscore on the Sickness Impact Profile of >=700);
6. Motivated for treatment of CFS with CBT;
7. Having functioned good in groups before (self-report) and willing to follow a group treatment for CFS;

8. Given written informed consent for participation in the study.

Exclusion criteria

1. Patient does no meet the herefore mentioned inclusion criteria;
2. Patients is currently engaged in a legal procedure concerning disability-related financial benefits.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	204
Type:	Actual

Ethics review

Positive opinion

Date:	21-07-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL727
NTR-old	NTR737
Other	: CMO 2006/030
ISRCTN	ISRCTN15823716

Study results

Summary results
N/A