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

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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...

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

Samenvatting

ID

NL-OMON24062

Bron
NTR

Verkorte titel
N/A

Aandoening

Chronic Fatigue Syndrome

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: Radboud University Nijmegen Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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?

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	204
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A