The effectiveness of Self-instructions in the treatment of patients with Chronic Fatigue Syndrome (CFS): a randomised controlled study.

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There a two research questions: 1. Do Self-instructions lead to a significant decrease of fatigue and functional impairments of CFS patiente compared to a waiting list condition? 2. For which patients are Self-instructions a suitable treatment...

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

Samenvatting

ID

NL-OMON24671

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 (measured with the CIS-Fatigue severity);
2. Disabilities (measured with the SIP total score and SF-36 subscale 'physical functioning');
3. The CIS-f, SIP and SF-36 are used in two asessements, a baseline and a post-treatment (or post waiting list) assessment;.
4. Determine the effect of the treatment the difference in CIS-f, SIP and SF-36 scores between baseline and post-treatment for the treatment condition is compared with the difference scores of the waitinglist 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 Cognitive Behaviour Therapy (CBT) aimed at these perpetuating factors leads to a reduction of fatigue and disabilities. In the Netherlands there are 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.
Furthermore, there is possibly a subgroup of CFS patient for whom a less intensive CBT treatment suffices. Because of this, the Expert Centre Chronic Fatigue of the Radboud University Nijmegen Medical Centre developed a Self-Instruction (SI) program based on the current protocol of individual CBT for CFS.

The two objectives of this study are

1) to evaluate the efficacy of the SI program for CFS and

2) to find out for which CFS patients specifically the SI is a suitable form of treatment.

This is a randomised controlled trial in which the SI condition is 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 and gave their written informed consent. Consecutive patients are randomly assigned to SI or a waiting list condition. All patients are assessed again after 6-12 months. The main outcome measures are fatigue severity (CIS) and functional impairment (SF-36 and SIP).

Doel van het onderzoek

There a two research questions:

1. Do Self-instructions lead to a significant decrease of fatigue and functional impairments of CFS patiente compared to a waiting list condition?

2. For which patients are Self-instructions a suitable treatment method?

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

After a baseline assessement patients are randomly assigned to one of two conditions. In the Self-instruction condition patients receive a self-instruction book and email a therapist once every two weeks about their improvements. In the waiting list condition patients receive no treatment after the baseline assessment. After a period of 6 to 12 months patients get a second assessment. Both patients in the self-instruction and in the waiting list condition are then offered (regular) individual cognitive behavioural therapy (CBT) for CFS. As there is a waiting period of 6-12 months for individual CBT because of lack of treatment capacity participation in the self-instruction study will not lead to a longer waiting period for treatment as usual.

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 Disease 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. Being motivated for treatment of CFS;

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patient does not meet the herefore mentioned inclusion criteria;

2. Patient is currently engaged in a legal procedure concerning disability-related financial benefits.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2006
Aantal proefpersonen:	171
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-01-2006
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	NL526
NTR-old	NTR570
Ander register	CMO : 2005/233
ISRCTN	ISRCTN27293439

Resultaten

Samenvatting resultaten
N/A