The effectiveness of Self-instructions in the treatment of 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-OMON24671

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 (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.

Secondary outcome

Psychological distress measured with the SCL-90 (symptom checklist 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 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).

Study objective

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?

Study design

N/A

Intervention

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.

Contacts

Public
University Medical Center St. Radboud, Expert Center Chronic Fatigue,
P.O. Box 9011
G. Bleijenberg
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3610030
Scientific
University Medical Center St. Radboud, Expert Center Chronic Fatigue,
P.O. Box 9011
G. Bleijenberg
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3610030

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 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.

Exclusion criteria

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

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2006
Enrollment:	171
Type:	Actual

Ethics review

Positive opinion

Date:	20-01-2006
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	NL526
NTR-old	NTR570
Other	CMO : 2005/233
ISRCTN	ISRCTN27293439

Study results

Summary results

N/A