The effect of self-instructions in the treatment of patients with Chronic Fatigue Syndrome type Indiopathic Chronic Fatigue: a randomised controlled study

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The objective of this study is to investigate wether a minimal intervention is an effective treatment for patients with chronic fatigue syndrome type idiopathic chronic fatigue.Objectives:- What is the effect of a minimal intervention for CFS-ICF…

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

Summary

ID

NL-OMON32795

Source
ToetsingOnline

Brief title
Self-intructions for CFS-ICF

Condition

- Other condition

Synonym
chronic fatigue, chronic fatigue syndrome type idiopathic chronic fatigue

Health condition

chronisch vermoeidheidssyndroom type idiopathische chronische vermoeidheid

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: Idiopathic Chronic Fatigue, Randomised controlled trial, Self-instruction, Treatment

Outcome measures

Primary outcome

Primary outcome variables are fatigue severity and level of disabilities.

Fatigue severity will be measured with subscale *fatigue severity* of the

Checklist Individual Strength (CIS). The Sickness Impact profile will be used

to measure functional disability in ambulation, home management, mobility,

alertness behavior, sleep/rest, work, limitations, social interactions,

recreation and pastimes. Physical and social disabilities are measured with the

physical functioning and *social functioning* subscale of the Medical

Outcomes Survey Short Form-36 (SF-36).

Secondary outcome

The secondary outcome variable is the level op psychological distress measured

with the symptom Checklist 90 (SCL-90).

Study description

Background summary

Minimal interventions are developed to improve the efficiency of psychological

therapy provision, presuming that less severe patients suffice with a less intensive treatment. The Nijmegen Expert Centre for Chronic Fatigue demonstrated in a randomised controlled study that a minimal intervention for patients with chronic fatigue syndrome (CFS), consisting of guided self-instructions based on cognitive behavioral therapy (CBT), lead to a significant reduction of fatigue and disabilities compared to a waiting list condition. To examine the hypothesis whether minimal interventions are also suitable for patients with less severe symptoms of chronic fatigue, this study will determine the effect of guided self instructions for patients with CFS type idiopathic chronic fatigue (CFS-ICF). Patients with CFS-ICF experience just as patients with CFS: severe fatigue lasting longer than six months and leading to impairments. However, the impairments and disabilities are insufficient to justify the diagnosis CFS they fulfill the criteria for CFS-ICF and suffer fromm there symptoms. Just for this group of patients such a minimal intervention could be a suitable treatment. In an earlier study the intervention was successful for 27% of the patients. We expect that with CFS-ICF patients we reach a much higher percentage of successful treatments. Testing the effectiveness of a minimal intervention with CFS-ICF patients contributes to the development of efficient care for chronic fatigue. This study joins up to the randomised clinical trial that determines the effect of a minimal intervention for CFS patients in primary care, carried out by social psychiatric nurses.

Study objective

The objective of this study is to investigate wether a minimal intervention is an effective treatment for patients with chronic fatigue syndrome type idiopathic chronic fatigue.

Objectives:
- What is the effect of a minimal intervention for CFS-ICF patients with regard to level of fatigue en disabilities compared to a waiting list condition?
- What are the characteristics of CFS-ICF patients who do improve by a minimal intervention?

Study design

Referred patients are randomised after informed consent in one of the two conditions:
1) Minimal intervention with email support by a therapist
2) Waiting list control group. The patient will wait 6 months before starting with the minimal intervention

Intervention

The self-instructions are derived from the protocol for CBT that is developed on the basis of a model of perpetuating factors of CFS. It*s aim is to change fatigue related cognitions and to improve gradual the physical activity of the patient. The minimal interventions consist of a self help booklet with exercises, supported by email contact with the therapist. In this self help booklet, patients can follow the instructions week by week. The patient is asked to send an email about the progression and the problems with the program every two weeks. The self help booklet is the improved version of the booklet that as has been tested in a previous study. The duration of the minimal intervention is 6 months.

Study burden and risks

There are no specific risk factors. Extend of the burden for patients is limited. Patients that have to wait 6 months for the intervention have to fill in the assesment once more. Because of the many patients refferd to the Expert Centre Chronic Fatigue fro treatment it takes usually around 6 months before patients can start with a treatment. So there is almost no difference between patients that have to wait 6 months and patients that receive treamtent following the usual procedure.

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

*18 years or older
* Able to speak, read and write Dutch language
* CIS fatigue score of 35 or higher
* Sickness Impact Profile between 450 and 700 and/or 3 or less CDC symptoms

Exclusion criteria

See inclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	110
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL24487.091.08