The effect of self-instructions in the treatment of patients with Chronic Fatigue Syndrome type Idiopathic Chronic Fatigue (CFS-ICF) : a randomised controlled study.

No registrations found.

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

Summary

ID

NL-OMON28402

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Chronic Fatigue
Chronic Fatigue Syndrome (CFS)

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

Primary outcome variables are fatigue severity and functional disabilities. Fatigue severity will be measured with subscale ‘fatigue severity’ of the Checklist Individual Strength (CIS). This indicates the experienced fatigue over the past 2-week period and consists of 8 items that have to be answered to a 7-point scale. The score can be range between 8 to 56. 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. The eight subscales are added to provide one weighted score of disability (SIP total score).

Secondary outcome

The secondary outcome variables are physical and social disabilities and the level of psychological distress. Physical and social disabilities are measured with the ‘physical functioning’ and ‘social functioning’ subscale of the Medical Outcomes Survey Short Form-36 (SF-36). The scores can range from 0 (maximum limitations) to 100 (no limitations). Psychological distress will be measured with the symptom Checklist 90 (SCL-90). The SCL-90 consists of 90 items scored on a 5-point Likert scale. The total score ranges from 90 to 450. A high total score reflects high psychological distress.

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 from 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.
The two objectives of this study are 1) to evaluate the efficacy of the minimal intervention for CFS-ICF patients and 2) to find out for which CFS-ICF patients the minimal intervention is a suitable form of treatment. This is a randomised controlled trial in which the minimal intervention condition is compared with a waiting list condition. Patients are included if they are severely fatigued and disabled and gave their written informed consent. Consecutive patients are randomly assigned to the minimal intervention or the waiting list condition. The main outcome measures are fatigue severity (CIS) and functional impairments (SIP).

Study objective

There a two research questions:

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

Study design

1. T1: after a baseline assessment patients are randomly assigned to the intervention- or waiting list condition;

2. T2: after 6 months, second assessment will take place in both conditions;

3. T3: after 12 months (6 months after T2), post treatment for the patients in the waiting list condition will take place.

Intervention

After a baseline assessment (T1) patients are randomly assigned to the intervention- or waiting list condition. The patients in the intervention condition start immediately with the minimal intervention. This intervention consists of a self help booklet with exercises, supported by email contact with a therapist. The patient is asked to send an email about the progression and the problems with the program every two weeks. At the end of the treatment, after 6 months, second assessment will take place in both conditions (T2). At this point changes in both condition will be compared to analyse the effect of the treatment. Subsequently, treatment will be offered to the patients in the waiting list condition. After six months, post treatment for the patients in the waiting list will take place (T3).

Contacts

Public

Radboud University Nijmegen Medical Centre
4628 Expert Centre Chronic Fatigue
P.O. box 9101
M. Tummers
Nijmegen 6500 HB
The Netherlands
+31 (0) 243610048
Scientific
Radboud University Nijmegen Medical Centre
4628 Expert Centre Chronic Fatigue
P.O. box 9101
M. Tummers
Nijmegen 6500 HB
The Netherlands
+31 (0) 243610048

Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Able to speak, read and write Dutch language;

3. CIS fatigue score of 35 or higher;

4. Sickness Impact Profile between 450 and 700 and/or 3 or less CDC symptoms.

Exclusion criteria

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

2. Patient is currently engaged in a legal procedure concerning disability-related 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):	01-03-2009
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	05-02-2009
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	NL1581
NTR-old	NTR1660
Other	CMO : 2008/206
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A