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

Gepubliceerd: 05-02-2009 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON28402

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Chronic Fatigue
Chronic Fatigue Syndrome (CFS)

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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?

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-02-2009
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	NL1581
NTR-old	NTR1660
Ander register	CMO : 2008/206
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A