Stepped care for chronic fatigue syndrome compared to care as usual: a randomized noninferiority trial

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

Samenvatting

ID

NL-OMON22165

Bron
NTR

Verkorte titel
Stepped care for CFS

Aandoening

Chronic fatigue syndrome (CFS)

Ondersteuning

Primaire sponsor: Radboud University Medical Centre, Nijmegen, The Netherlands
Overige ondersteuning: Radboud University Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatigue severity assessed with the CIS sub scale 'fatigue severity’.

Toelichting onderzoek

Achtergrond van het onderzoek

Cognitive behaviour therapy (CBT) for Chronic fatigue syndrome (CFS) is an effective but intensive treatment. Wider implementation of CBT is hampered by a limited treatment capacity. To increase treatment capacity, less intensive interventions have been developed like web-based CBT. In this randomized noninferiority trial it will be tested if stepped care for CFS is noninferior to care as usual with respect to its effect on fatigue severity. Stepped care will be formed by 1) web-based CBT with protocol driven feedback followed by individual face to face CBT if patients are still severely fatigued and/or disabled after the web-based CBT or 2) web-based CBT with feedback on demand followed by additional individual face to face cognitive CBT if patients are still severely fatigued and/or disabled after the web-based CBT intervention. Care as usual consists of individual face to face CBT. Both forms of stepped care will be compared to care as usual.

Doel van het onderzoek

In this noninferiority trial it will be tested if stepped care for chronic fatigue syndrome (CFS) is noninferior to care as usual with respect to its effect on fatigue severity. Stepped care will be formed by: 1) web-based cognitive behaviour therapy (CBT) with protocol driven feedback followed by individual face to face cognitive CBT if patients are still severely fatigued and/or disabled after web-based therapy or 2) web-based CBT with feedback on demand followed by individual face to face CBT if patients are still severely fatigued and/or disabled after web-based therapy. Care as usual consists of individual face to face CBT. Both forms of stepped care will be compared to care as usual.

This noninferiority trial is a follow-up study of a randomized controlled trial testing the efficacy of the two formats of web-based CBT by comparing each of the interventions with a waiting list condition. In this study fatigue severity is also the primary outcome measure. This study is registered in the Dutch trial register (NTR) with number NTR4013.

Onderzoeksopzet

Baseline assessment prior to randomization (T0), second assessment, 6 months after randomization (T1), third assessment, 6 months after start of face to face CBT (T2).

The proportion of patients with clinical significant improvement in fatigue severity and the total therapist time needed to deliver the interventions will be determined at T1 for patients who stop after the web-based intervention or waiting list and at T2 for patients who follow (additional) face to face CBT.
All other secondary outcome measures and the primary outcome measure will be assessed at

T0 and T1 for patients who stop after the web-based intervention or waiting list and at T0, T1 and T2 for patients who follow (additional) face to face CBT.

23-aug-2016: For patients in the care as usual condition, it was decided that when the waiting period is less than 3 months, the T1 assessment will be dropped.

Onderzoeksproduct en/of interventie

This noninferiority trial is a follow-up study of a trial with number NTR4013 in the Dutch trial register (NTR). In this study the efficacy of two formats of web-based CBT is determined. Eligible patients who have given written informed consent are randomized to one of three arms after baseline assessment (T0):

1. Web-based CBT with protocol driven feedback;

2. Web-based CBT with feedback on demand;

3. Waiting list.

Six months after randomization all patients will be assessed again (T1). If patients at T1 are still severely fatigued (CIS>=35) and/or disabled (SIP>=700) they will be offered individual face to face CBT. A therapist can decide to offer CBT even when a patient is no longer severely fatigued and/or disabled if the goals of treatment are not attained and the therapist thinks that additional treatment is needed to reach these goals. This decision can only be made after consultation of a supervisor (experienced therapist). The reasons for continuation will be recorded and reported. Six months after the start of additional CBT (stepped care) or regular CBT (care as usual) patients will be assessed again (T2). When a patient does not want treatment after the web-based intervention or waiting list, there will be only two assessments: at baseline (T0) and after the web-based therapy or waiting period (T1).

When 240 patients are randomized the target number of participants is reached for the trial testing the efficacy of the two formats of web-based CBT. In order to reach the target number of 362 participants for the noninferiority trial an additional 122 patients has to be included. The remaining 122 patients will also be randomized to one of three arms. However, the waiting period for the patients in the care as usual condition will no longer be fixed on six months but will depend on available treatment capacity. The waiting period will not be longer than 6 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients must meet the following inclusion criteria:

- >= 18 years;

- Able to speak, read and write Dutch;

- Meet the US Centers for Disease Control and Prevention criteria for chronic fatigue syndrome (revised 2003);

- Score >= 35 on the Checklist Individual Strength (CIS), subscale fatigue severity;

- Have a total score of >= 700 on the Sickness Impact Profile 8 (SIP8);

- Give written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be (temporarily) excluded if they are engaged in a legal procedure concerning disability-related financial benefits.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2013
Aantal proefpersonen:	363
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-09-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39926
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4640
NTR-old	NTR4809
CCMO	NL42543.091.12
OMON	NL-OMON39926

Resultaten