Behandeling van patiënten met chronisch vermoeidheidssyndroom met gedoseerde oefentherapie en/of cognitieve gedragstherapie.

Gepubliceerd: 14-12-2011 Laatst bijgewerkt: 13-12-2022

The hypothesis is that a combination of graded exercise training and cognitive behavioural therapy is more effective than each of these therapies alone.

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

Samenvatting

ID

NL-OMON20281

Bron
NTR

Verkorte titel
CFS-ReAct

Aandoening

Chronic fatigue syndrome
Chronisch vermoeidheidssyndroom

Ondersteuning

Primaire sponsor: Isala klinieken
Overige ondersteuning: Isala klinieken, afdeling sportgeneeskunde

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

CIS-20 questionnaire (fatigue severity) at 6 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Both cognitive behaviour therapy and graded exercise therapy are proven effective therapies that can improve outcome, however both therapies are only moderately effective. The hypothesis is that a combination of graded exercise training and cognitive behavioural therapy is more effective than each of these therapies alone.

Study design:

Prospective intervention study.

Study population:

Patients with chronic fatigue syndrome, 18-65 yr old. An internal physician will refer patients eligable for this study to the investigator. All patients will be recruted in the Netherlands.

Intervention:

Group one receives graded exercise training by a sports physician, group two receives cognitive behavioural therapy by a clinical physchologist and group three receives both cognitive behaviour therapy and graded exercise therapy by both a sports physician and a clinical psychologist.

Main study parameters/endpoints:

The main study parameter will be fatigue, the main symptom in chronic fatigue syndrome, measured by a validated questionnaire (CIS-20) at 6 months treatment. Secondary endpoints will be fatigue at 3 months treatment, psychiatric symptoms, functional impairment, physical

condition, work participation and medical consumption at 3 and 6 months treatment.

Doel van het onderzoek

The hypothesis is that a combination of graded exercise training and cognitive behavioural therapy is more effective than each of these therapies alone.

Onderzoeksopzet

Baseline, 3 and 6 months.

Onderzoeksproduct en/of interventie

Graded exercise therapy:

The duration is gradually increased to 3 times 30 minutes in 6 months. The treatment starts with an intake interview followed by 3 individual sessions of 1 hours in 6 months.

Cognitive behaviour therapy:

The treatment starts with an intake interview followed by 14 individual sessions of 2 hours in 6 months and 2 follow-up sessions.

Combined Graded exercise therapy and Cognitive behaviour therapy:

The treatment starts with an intake interview followed by 10 to 12 individual sessions of 2 hours and 2 follow-up sessions with the psychologist and 3 sessions with the sports physician of 1 hour in 6 months.

Contactpersonen

Publiek

Afdeling sportgeneeskunde
Isala klinieken Zwolle
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Wetenschappelijk

Afdeling sportgeneeskunde
Isala klinieken Zwolle
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Meet CDC-94 CFS criteria;

2. Age: 18-65 yr;

3. CIS-20 score > 35 on subscale fatigue.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not able to understand, speak, read or write Dutch sufficiently;

2. Severe mental disorder or severe physical co-morbidity, impeding physical exercise;

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

4. Previously treated with GET or CBT for CFS.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-12-2011
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-12-2011
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	NL3066
NTR-old	NTR3214
CCMO	NL32433.075.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A