Is a multidisciplinary rehabilitation treatment more effective than monodisciplinary cognitive behavioural therapy for patients with chronic fatigue syndrome? A multicentre randomised controlled trial

Published: 26-11-2008
Last updated: 11-05-2024

To assess the difference in treatment effect (change between start and 6, 12, 54 and 78 months follow-up of fatigue severity and quality of life in patients with chronic fatigue syndrome) between individual multidisciplinary rehabilitation treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39182

Source
ToetsingOnline

Brief title
FatiGo (Fatigue-Go-trial)

Condition

- Other condition

Synonym
Chronic fatigue syndrome (CFS), Myalgic encephalomyelitis (ME)

Health condition

somatoforme stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Revant, Revalidatiecentrum Breda
Source(s) of monetary or material Support: ZonMw,Revalidatiefonds;Fonds Nutsohra;patientenorganisatie (CVS/ME-stichting Nederland)

Intervention

Keyword: chronic fatigue syndrome, cognitive behavioral treatment, randomised controlled trial, rehabilitation

Outcome measures

Primary outcome

Primary study parameters: fatigue severity (on the Checklist Individual

Strength), quality of life (measured by the Short-Form 36)

Secondary outcome

Secondary outcome parameters are:

Psychological wellbeing (Symptom Check List-90), depression and anxiety

(Hospital Anxiety and Depression Scale), sense of control in relation to CFS

complaints (Self-Efficacy Scale), somatic attributions (Causal Attribution

List), (the most important) functional activities which a patient wants to

improve during treatment (Patient Specific Complaints and Goals questionnaire),

impact of disease on both physical and emotional functioning (Sickness Impact

Profile), physical activity (measured by the Body Media Sensewear activity

monitor), self-rated improvement (five questions on 5 and 10-point

Likert-scale), life satisfaction (Life Satisfaction Questionnaire), utility

(EuroQol 6-D), mindfulness attention and awarenes (Mindfulness attention and

awareness scale) and treatment expectancy and credibility (Devilly and Borkovec questionnaire). Treatment costs and additional expenses (work related costs, health care and non-health care costs) will also be recorded (Trimbos/iMTA questionnair for Costs associated with Psychiatric Illness).

Study description

Background summary

In the Netherlands approximately 30.000-40.000 patients suffer from Chronic Fatigue Syndrome (CFS) (Health Counsil of The Netherlands, 2005). Systematic reviews show that Cognitive Behavioural Therapy (CBT) and Graded Exercise Therapy (GET) are the only interventions found to be beneficial. Interpretation of the results for clinical practice is however limited because of the considerable number of drop-outs and a significant number of non-responders in the included RCTs.
Positive effects of multidisciplinary interventions for patients with CFS have been seen in 4 non-controlled studies. Viner et al. (2004) evaluated the effects of a multidisciplinary rehabilitation treatment for young patients with chronic fatigue. Results showed positive effects on wellness, school attendance and severity of CFS. A study by Post et al. (2006) with adolescents with chronic pain and fatigue also showed strong positive effects on fatigue severity, school/work attendance and general health after multidisciplinary rehabilitation treatment. In the study by Torenbeek et al. (2006), in clinical CFS patients, positive effects were found on fatigue severity, experienced impairments and physical functioning. The results of a pilot study at Rehabilitation Centre Breda, in which 36 patients participated, were promising (Vos-Vromans, 2005). There was a significant improvement of fatigue severity and activities of daily living 6 months after the start of treatment, which persisted for 12 months after the start of treatment.
The difference in effectiveness between individual multidisciplinary rehabilitation treatment and individual cognitive behavioural therapy for treatment of CFS is as yet unknown. This study aims to evaluate the effects of both treatment approaches in outpatient rehabilitation on fatigue severity and quality of life in patients with CFS after treatment, 6 months after the end of treatment and 4 and 6 years after the end of treatment.

Study objective

To assess the difference in treatment effect (change between start and 6, 12, 54 and 78 months follow-up of fatigue severity and quality of life in patients

with chronic fatigue syndrome) between individual multidisciplinary rehabilitation treatment and individual cognitive behavioural therapy.

Study design

Patients with CFS referred to Rehabilitation Centre Breda, Rehabilitation Centre Amsterdam and Rehabilitation Centre Blixembosch will be asked to participate in this study. After inclusion (and signing the informed consent form), patients will be randomly assigned to one of the two treatment groups (cognitive behavioural therapy or multidisciplinary rehabilitation therapy). Patients will be measured before the treatment starts, and at 6, 12, 54 and 78 months there will be a follow-up assessment. Outcomes of treatment will be measured using valid and reliable assessment scales. The results of the different therapy conditions on the different assessments will be compared using an *intention to treat* approach. The longitudinal effect of MRT versus CBT on the primary and secondary outcomes will be assessed using linear mixed models.

Clarification:
Both treatments take 6 months to complete. The first assessment is directly after treatment. The second assessment is 6 months after the end of treatment. For the FatiGo II study (long term follow up study) the assesments are at 4 and 6 years after the end of treatment.

Intervention

After the inclusion (and signing informed consent form), patients will be randomly divided into two groups: Cognitive Behavioural Therapy and Multidisciplinary rehabilitation therapy. The multidisciplinary therapy includes Cognitive behavioural therapy, Graded exercise therapy, Pacing and Body awareness therapy. Patients will attend a 13 week program and one follow up meeting 3 months later. Patients have weekly contact with a physiotherapist, occupational therapist , psychologist or behavioural therapist (once every two weeks) and a social worker (once every two weeks). Patients who are assigned to cognitive behavioural thearpy will attend 16 individual therapy sessions, spread out over 6 months with a psychologist or behavioural therapist.

Study burden and risks

The risks associated with participation can be considered negligible and the burden is minimal. Two existing therapies that have been in practice for several years will be investigated. Measurements (three times during the study) are limited to filling out questionnaires (2 hours) and carrying an activity monitor for one week. Everyt month, during one year, a patient is asked to fill out a short questionnaire (5 minutes).

During FatiGo II study the patients are asked to fill in questionnaires at home which takes 30 minutes to complete.

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

Patients are included if they fulfil the CDC-94 criteria for CFS and score more or equal to 40 on the Checklist Individual Strength (CIS)-fatigue questionnaire (Prins et al. 2001).
CDC-94 criteria for CFS are as follows:
At least 6 months of persistent or recurring fatigue for which no physical explanation has been found and which:
- is of new onset, that is to say it has not been lifelong
- is not the result of ongoing exertion
- is not substantially alleviated by rest

- severely limits functioning
In combination with four or more of the following symptoms, persistent or regularly recurring over a period of 6 months and which must not have predated the fatigue:
- self-reported impairment in memory or concentration
- sore throat
- tender cervical lymph nodes
- muscle pain
- multi joint pains
- headache
- unrefreshing sleep
- post-exertional malaise lasting 24 hours or longer
- dementia
- anorexia or bulimia nervosa
- alcohol and/or drug abuse
- severe obesity;Other additional inclusion criteria for this study are:
- patients are willing to participate in a treatment which is set up to change behaviour
- age between 18 years and 60 years
- able to speak, understand and write the Dutch language

Exclusion criteria

Exclusion criteria
- any medical condition that may explain the presence of chronic fatigue
- a psychotic, major or bipolar depressive disorder (but not an uncomplicated depression)
- dementia
- anorexia or bulimia nervosa
- alcohol abuse or the use of drugs
- severe obesity
- pregnancy
- not able to speak, understand or read the Dutch language
- patients who had CGT or rehabilitation therapy in the past involving CFS.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	122
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2008
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	21-03-2013
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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
ISRCTN	ISRCTN77567702
CCMO	NL19992.101.08