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Chronic fatigue syndrome (CFS): cognitive behavioural therapy or rehabilitation?

Submission date	Recruitment status	[ ] Prospectively registered
02/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/06/2017	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

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

Acronym
FatiGo

Study objectives
This study aims to evaluate the effects of both treatment approaches in outpatient rehabilitation on fatigue severity and quality of life for patients with chronic fatigue syndrome (CFS). Our hypothesis is that the multidisciplinary treatment will result in a significantly greater decrease in fatigue severity and a higher level of quality of life compared to patients treated with cognitive behavioural therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Board of Rotterdam and surroundings (Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o.), 18/11/2008, ref: 2008/22 (NL19992.101.08, ABRv4)

Study design
Multicentre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.rcbreda.nl (Dutch only)

Health condition(s) or problem(s) studied
Chronic fatigue syndrome (CFS)

Interventions
After the intake, patients will be randomly divided into two groups: cognitive behavioural therapy (CBT) and multidisciplinary rehabilitation therapy (MRT):

1. Cognitive behavioural therapy (CBT):
CBT is based on process variables of a CFS model. This model shows that high physical attributions will decrease physical activity and increase fatigue and functional impairment. A low level of sense of control over symptoms and focusing on physical sensations have a direct causal effect on fatigue. In CFS precipitating and perpetuating factors are important. The perpetuating factors become the focus of the intervention in CBT. An important subject in the therapy is the balance between activity and rest and the patients' responsibility to see to it. Negative beliefs regarding the symptoms of fatigue, self-expectations or self-esteem are identified and patients are encouraged to challenge them the conventional way. Specific lifestyle changes are encouraged if deemed appropriate. At the end of the therapy relapse prevention is addressed. Patients who are assigned to this group will attend 16 individual therapy sessions of one hour duration, spread out over 6 months with a psychologist or behavioural therapist.

2. Multidisciplinary rehabilitation therapy (MRT):
MRT includes CBT, GET, Pacing and Body awareness therapy (investigational treatment):
2.1. CBT: as above
2.2. Graded exposure therapy (GET): a structured and supervised activity management that aims at a gradual but progressive increase in aerobic activities. It is completed by graded activity and graded exposure in which a gradual and progressive increase of physical and mental activities is trained. The activities include activities of daily living, occupational and social or leisure activities.
2.3. Pacing: helps the patient divide energy over the day/week. Eventually they are encouraged to carry out a gradual increase in physical and mental activity.
2.4. Body awareness therapy: teaches the patient to be aware of healthy physical sensations and to link them in the mind (body mentalisation). Patients will be taught to react adequately to disturbances in the balance between the daily workload and the capacity to deal with it. The balance between activity and rest is also linked to the patients inner control and healthy physical sensations.

MRT includes the following:
1. Two weeks: observation (2 sessions of 1 hour psychology, 2 sessions of 1 hour with a social worker, 2 sessions of 1/2 hour occupational therapy, 2 sessions of 1/2 hour physiotherapy)
2. Two weeks: no therapy
3. Ten weeks therapy (5 sessions of 1 hour psychology, 4 sessions of 1 hour with a social worker, 26 sessions of 1/2 hour physiotherapy and 20 sessions of 1/2 hour occupational therapy)
4. Six weeks no therapy
5. One session of 1 hour with a social worker (after 6 weeks of no therapy)
6. Two sessions of both 1/2- 1 hour of therapy with the therapists choice by the participants.
During MRT therapy, a participant sees the physician in rehabilitation three times (20 minutes per visit).

The total duration of both treatments is 6 months. The duration of follow up for both treatments is also 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Fatigue severity measured using the Checklist Individual Strength at baseline, 6 months and 12 months after start of therapy

Secondary outcome measures
1. Quality of life measured using the 36-item Short-Form Health Survey (SF-36)
2. Psychological wellbeing measured using Symptom Check List-90
3. Sense of control in relation to CFS complaints measured using Self-Efficacy Scale
4. Somatic attributions measured using Causal Attribution List
5. Mindfulness measured using Mindfulness Attention Awareness Scale
6. Functional activities (the most important) which a patient wants to improve during treatment measured using Patient Specific Complaints and Goals questionnaire
7. Impact of disease on both physical and emotional functioning measured using Sickness Impact Profile
8. Physical activity measured using the Body Media Sensewear activity monitor
9. Self-rated improvement measure using five questions on 5 and 10-point Likert-scale
10. Life satisfaction measured using Life Satisfaction Questionnaire
11. Utility measured using EuroQol 6-D
12. Treatment expectancy and credibility measured using Devilly and Borkovec questionnaire

All outcomes are measured at baseline, 6 and 12 months after start of therapy. Treatment costs and additional expenses (work related costs, health care and non-health care costs) are measured using Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness which will be measured every month (from baseline until 12 months after start of therapy).

Overall study start date
27/11/2008

Completion date
01/07/2011

Eligibility

Key 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. 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:
1. Is of new onset, that is to say it has not been lifelong
2. Is not the result of ongoing exertion
3. Is not substantially alleviated by rest
4. 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:
5. Self-reported impairment in memory or concentration
6. Sore throat
7. Tender cervical lymph nodes
8. Muscle pain

9. Multi-joint pains
10. Headache
11. Unrefreshing sleep
12. Post-exertional malaise lasting 24 hours or longer

Other additional inclusion criteria for this study are:
13. Patients are willing to participate in a treatment which is set up to change behaviour
14. Aged between 18 years and 60 years, either sex
15. Able to speak, understand and write the Dutch language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Any medical condition that may explain the presence of chronic fatigue
2. A psychotic, major or bipolar depressive disorder (but not an uncomplicated depression)
3. Dementia
4. Anorexia or bulimia nervosa
5. Alcohol and/or drug abuse
6. Severe obesity (body mass index [BMI] greater than or equal to 45)
7. Pregnancy
8. Not able to speak, understand or write the Dutch language
9. Patients who had cognitive behavioural therapy (CBT) and multidisciplinary rehabilitation therapy (MRT) in the past involving CFS

Date of first enrolment
27/11/2008

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Netherlands

Study participating centre

Rehabilitation Centre Breda
Breda
Netherlands
4817 JW

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
Laan van Nieuw Oost Indië 334
Den Haag
Netherlands
2593 CE

Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Rehabilitation Centre Breda (Netherlands)

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
The Rehabilitation Fund (Revalidatiefonds) (Netherlands) (ref: 2007176/SW)

Funder Name
The Nuts-Ohra Foundation (Stichting Nuts Ohra [SNO]) (Netherlands) (ref: 0801-06)

Funder Name
Myalgic encephalomyelitis/chronic fatigue syndrome Foundation Netherlands (ME/CVS Stichting Nederland) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/05/2012		Yes	No
Other publications	economic evaluation	02/06/2017		Yes	No