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The effectiveness of cognitive behavioural therapy in groups for patients with Chronic Fatigue Syndrome (CFS): a randomised controlled study

Submission date
12/10/2006

Recruitment status
No longer recruiting

Registration date
12/10/2006

Overall study status
Completed

Last Edited
12/10/2006

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
CMO 2006/030

Study information

Scientific Title

Study objectives
There are two research questions:
1. Does Cognitive Behavioural Therapy (CBT) in groups lead to a significant decrease of fatigue and functional impairment of Chronic Fatigue Syndrome (CFS) patients compared to a waiting list condition?
2. For which patient is group therapy a suitable treatment method?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Fatigue Syndrome (CFS)

Interventions
After a basline assessment patients are randomly assigned to one of three conditions. There are two treatment conditions: small group (four patients and one therapist) and large group (eight patients and two therapists). Both group treatments consist of 16 sessions of two hours in a period of about six months. There is a second assessment after the treatment. The third condition is a waiting list condition. After the waiting period of at least six months, patients get a second assessment.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. Fatigue severity (measured with the CIS subscale fatigue severity).
2. Disabilities (measured with the Sickness Impact Profile (SIP) total score and the Short form health survey (SF-36) subscale 'physical functioning'). The CIS-f, SIP and SF-36 are used in two assessments, a baseline and a post-treatment (or post-waiting list) assessment. The change score between post-treatment and baseline of each of the treatment conditions is compared with the difference score between post-waiting list and baseline assessment of the waiting list condition.

Secondary outcome measures
Psychological distress measured with the Symptom Checklist 90 (SCL 90).

Overall study start date
01/01/2008

Completion date
01/12/2008

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Being able to speak and read Dutch
3. Meeting the 1994 research criteria for CFS as formulated by the US Center for Disease Control
4. Severely fatigued (having a Checklist Individual Strength (CIS)-fatigue severity score of more than or equal to 35)
5. Severely disabled (weighted total score on the Sickness Impact Profile of more than or equal to 700)
6. Motivated for treatment of CFS with CBT
7. Having functioned good in groups before (self-report) and willing to follow a group treatment for CFS
8. Given written informed consent for participation in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
204

Key exclusion criteria
1. Patient does not meet the previously mentioned inclusion criteria
2. Patient is currently engaged in a legal procedure concerning disability-related financial benefits

Date of first enrolment
01/01/2008

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center St. Radboud
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
University Medical Center St. Radboud (The Netherlands)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center St. Radboud (The 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