

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	☒ Prospectively registered
Registration date 12/10/2006	Overall study status Completed	☐ Protocol
Last Edited 12/10/2006	Condition category Nervous System Diseases	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Fatigue Syndrome (CFS)

Interventions

After a baseline 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR
<https://ror.org/05wg1m734>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center St. Radboud (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration