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

Submission date	Recruitment status	[X] Prospectively registered
12/10/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/10/2006	Completed	Results
Last Edited	Condition category	Individual participant data
12/10/2006	Nervous System Diseases	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Professor G Bleijenberg

### Contact details

University Medical Center St. Radboud Expert Center Chronic Fatigue P.O. Box 9011 Nijmegen Netherlands 6500 HB +31 (0)24 3610030 g.bleijenberg@nkcv.umcn.nl

# 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)

# Sponsor details

P.O. Box 9101 Nijmegen Netherlands 6500 HB +31 (0)24 3611111 info@ozi.umcn.nl

## 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