

The effectiveness of self-instructions in the treatment of patients with chronic fatigue syndrome (CFS): a randomised controlled study

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/03/2014	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof G. Bleijenberg

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

Additional identifiers

Protocol serial number
CMO 2005/233; NTR570

Study information

Scientific Title

Study objectives

There are two research questions:

1. Do self-instructions lead to a significant decrease of fatigue and functional impairments of CFS patients compared to a waiting list condition?
2. For which patients are self-instructions a suitable treatment method?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committees

Primary study design

Interventional

Study design

Randomised single-blind controlled parallel group 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 two conditions. In the self-instruction condition patients receive a self-instruction book and email a therapist once every two weeks about their improvements.

In the waiting list condition patients receive no treatment after the baseline assessment. After a period of 6 to 12 months patients get a second assessment. Both patients in the self-instruction and in the waiting list condition are then offered (regular) individual cognitive behavioural therapy (CBT) for CFS. As there is a waiting period of 6-12 months for individual CBT because of lack of treatment capacity participation in the self-instruction study will not lead to a longer waiting period for treatment as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Fatigue (measured with the CIS-Fatigue severity)
2. Disabilities (measured with the SIP total score and SF-36 subscale 'physical functioning')
3. The CIS-f, SIP and SF-36 are used in two assessments, a baseline and a post-treatment (or post waiting list) assessment

4. Determine the effect of the treatment - the difference in CIS-f, SIP and SF-36 scores between baseline and post-treatment for the treatment condition is compared with the difference scores of the waiting list condition

Key secondary outcome(s)

Psychological distress measured with the SCL-90 (symptom checklist 90)

Completion date

01/09/2007

Eligibility

Key inclusion criteria

1. Greater than 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 CIS-fatigue severity score of greater than or equal to 35)
5. Severely disabled (weighted total score on the Sickness Impact Profile of greater than or equal to 700)
6. Being motivated for treatment of CFS
7. 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 herefore mentioned inclusion criteria
2. Patient is currently engaged in a legal procedure concerning disability-related financial benefits

Date of first enrolment

01/02/2006

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre St. Radboud

Nijmegen

Netherlands

6500 HB

Sponsor information

Organisation

University Medical Centre St. Radboud (The Netherlands)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre St. Radboud (Netherlands)

Results and Publications

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	01/10/2008		Yes	No
Results article	results	01/09/2013		Yes	No