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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

Registration date
14/02/2006

Overall study status
Completed

Last Edited
27/03/2014

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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 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

Study design
Randomised single-blind controlled parallel group 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 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 measure
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

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

Overall study start date
01/02/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
196

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)

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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 Centre St. Radboud (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	01/10/2008		Yes	No
Results article	results	01/09/2013		Yes	No