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The efficacy and predicting variables of a multidisciplinary disability resolution (MDR) program for Chronic Fatigue Syndrome (CFS) patients receiving long term disability benefits from income protection insurers

Submission date
04/04/2006

Recruitment status
No longer recruiting

Registration date
04/04/2006

Overall study status
Completed

Last Edited
01/09/2009

Condition category
Nervous System Diseases

[ ] 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
NTR618; 2005/227

Study information

Scientific Title

Study objectives
It is hypothesised that long term disabled persons who participate in the MDR program will return to work and have less mental and/or physical limitations to prevent the pre-disability income. Furthermore, an explorative study into the process variables that are predictive of a successful treatment will be conducted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Patients in the intervention group will receive a highly individualised treatment by experts on different fields of expertise (i.e. medical, psychological, physical, legal). A major part of this treatment is based on the principles of cognitive behavioral therapy. The MDR program usually last between 12-18 months, depending on the nature of difficulties.
The patients in the control group will receive care as usual.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Off-claim and number of hours in a paid job.

Secondary outcome measures
1. Fatigue severity
2. Functional impairment
3. Physical limitations
4. Psychological well-being
5. Pain

Overall study start date
01/04/2006

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Extreme fatigue
2. Considerable impairment in daily functioning
3. Disease (objective finding) - illness (subjective complaints) discrepancy present
4. Not older than 45 years
5. Receiving disability benefits for a period longer than 3 years

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
130

Key exclusion criteria
1. A disease present that can explain the fatigue
2. A history of psychosis or schizophrenia
3. Primary drugs or alcohol abuse

Date of first enrolment
01/04/2006

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Netherlands

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

Sponsor information

Organisation
University Medical Centre St Radboud, Expert Centre Chronic Fatigue (Netherlands)

Sponsor details
P.O. Box 9101
Nijmegen
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Research organisation

Funder Name
Workers Insurance Authority (Uitvoeringsinstituut Werknemers Verzekeringen [UWV]) (Netherlands)

Funder Name
Embas Foundation (Stichting Embas) (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