

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/09/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr H. Vissers

Contact details

University Medical Center St Radboud
Expert Center Chronic Fatigue, 4628
P.O. Box 9101
Nijmegen
Netherlands
6500 HB
+31 (0)24 3610046
H.Vissers@nkcvc.umcn.nl

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

Netherlands

6500 HB

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