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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21294

Source
Nationaal Trial Register

Brief title
N/A

Health condition

MDR

Sponsors and support

Primary sponsor: UWV the Amsterdam & Stichting Embas te Driebergen
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

Introduction:
A significant part of disabled clients (‘claimants’) receiving long term disability benefits from income protection insurance organizations suffer from a disabling fatigue and have other CFS like symptoms. For most clients receiving benefits, the disability situation appears to be a perpetuating or spiralling down process limiting the recovery from the fatigue. Until now CBT is the only evidence based treatment for CFS. But it is also known that CFS patients with disease related benefits are not a good indication for CBT. Work resumption is seldom an explicitly named goal in CBT for CFS or is not easily reached. So mono disciplinary CBT alone seems to be insufficient to change fatigue and the disability in these patients. So for CFS patients receiving benefits from income protection insurers (IPI), CBT has to be extended to a multidisciplinary approach, like field management. Also the goals of the treatment have to be explicitly extended to vocational goals. Such a field management approach is available in the Netherlands: the Multidisciplinary Disability Resolution (MDR) Program. But the effects of this program have never been investigated in a randomised controlled trial. Because of the long treatment duration of this field management approach, this RCT is a good basis to study the processes of change in these patients.
Research questions:
Therefore the following research questions will be answered: 1.What is the efficacy of the MDR programme to achieve an off-claim situation i.e. a full recovery and no mental and/or physical limitations preventing to earn the pre-disability income.2.What are the process variables of the resolution process that are predicting the outcome of the MDR programme?Methods:
130 patients with an income protection insurance will be randomised in two conditions, MDR program and usual care. MDR last about 18 months. Measurements will take place at baseline, at 6, 12, 18 and 24 months. The primary outcome measures are: a) off-claim or not at the post test 18 months and at follow up, b) number of hours as a paid job during 12 days of self observation and c) self report of a paid job or not and number of hours in this job. Some of the process variables of interest are cognitions, anxiety, coping and physical activity.The effects of the treatment will be analysed by a general linear model for repeated measurements will be used to analyse the effects of the interventions on the primary

variables. To study the process of change, analyses of variance and regression analyses will be used.
Relevance:
The relevance of this study is that it will possibly make available an effective treatment program for chronic fatigued patients with a long term disability and long term claims. It will also result in knowledge about the process of change and predictors of the effects of the treatment program.

Study objective

It is hypothesized 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 te pre-disability income. Furthermore an explorative study into the process variables that are predictive of a successful treatment will be conducted.

Intervention

Patients in the intervention group will recieve 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 recieve care as usual.

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Eligibility criteria

Inclusion criteria

Patients are included with:
1. Extreme fatigue;
2. With considerable impairment in daily functioning;
3. Disease (objective finding) - illness (subjective complaints) discrepancy present;
4. Not older than 45 years;
5. Recieving disability benefits for a period longer than 3 years.

Exclusion criteria

Patients with:
1. A disease present that can explain the fatigue;
2. A history of psychosis or schizophrenia;
3. Primary drugs or alcohol abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2006
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-03-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL562
NTR-old	NTR618
Other	: 2005/227
ISRCTN	ISRCTN31632033

Study results

Summary results
N/A