

Feasibility and effectiveness of web-based cognitive behavioral therapy for multiple sclerosis patients with comorbid depression: a pilot study.

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The goal of this research project is to evaluate feasibility and outcome of a cognitive behavioural therapy self-help intervention offered through the Internet in multiple sclerosis (MS) patients with a comorbid depressive disorder.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON32466

Source

ToetsingOnline

Brief title

Web-based therapy for MS patients with depression

Condition

- Central nervous system infections and inflammations
- Mood disorders and disturbances NEC

Synonym

depressive disorder, Multiple sclerosis (MS)

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Stichting tot Steun VCVGZ en eventueel Stichting MS Research (aanvraag voor subsidie loopt nog)

Intervention

Keyword: depression, Internet, MS, problem solving treatment

Outcome measures

Primary outcome

Effect measurements will be taken at 0 weeks (first measurement) and upon conclusion of the treatment at five weeks (last measurement). The primary outcome measure is the BDI, which will be used to measure the reduction in the severity of the depression.

We will register the willingness of the MS-patients to participate in the web-based treatment. In addition, we will analyse the specific composition of the group of patients who are willing to participate. During the intervention we will keep track of work-progress, work-pace and activity of the patients. These data will be summarized to analyze the compliance of patients with the intervention. After the intervention (5 weeks) patient satisfaction with the care received will be assessed by means of the Client Satisfaction Questionnaire (CSQ-8) (De Brey 1983). We will also ask the participating subjects to complete a brief survey in which they are asked to share their experiences, opinions and any suggestions for enhancing the intervention.

Secondary outcome

A number of secondary outcome measures will also be employed, including the

EuroQol, which measures the degree of impairment and the quality of life (Dolan 1999) and the Medical Outcome Study Short Form 26 (SF-36), which measures health status (Freeman et al. 2000). Symptoms of anxiety will be assessed using the Hospital Anxiety and Depression scales (HADS).

Study description

Background summary

There is a high incidence of comorbid depressive disorders among people with MS. Despite high prevalence figures, cases of depression fail to be diagnosed in more than half of all MS patients, and adequate treatment tends to be lacking. Effectiveness studies have shown that MS patients are receptive to treatment for their depressive episodes. It has been demonstrated that self-help cognitive behavioural therapy * the *problem-solving treatment* * using the Internet as a medium is an effective intervention for reducing depressive complaints. In this study, the self-help intervention will be offered through the Internet (Dutch website: allesondercontrole.psy.vu.nl). This accessible self-help intervention has never previously been investigated for treatment of MS patients with comorbid depressive symptoms.

Study objective

The goal of this research project is to evaluate feasibility and outcome of a cognitive behavioural therapy self-help intervention offered through the Internet in multiple sclerosis (MS) patients with a comorbid depressive disorder.

Study design

The feasibility and effectiveness of a low-intensity Internet-based self-help treatment for MS patients will be evaluated in a non-randomized study.

Intervention

In view of the findings described above, the obvious next step is to use the Internet as a medium in providing an accessible treatment that has proven effective in patients with depressive disorders. We aim for such treatment to link up with an existing intervention that is currently being offered as part of various depression trials. The intervention at issue is called Allesondercontrole (*everything-under-control*; website:

allesondercontrole.psy.vu.nl). This intervention takes up little time and is based on what is known as *problem-solving treatment*, comprising a cognitive behavioural therapy self-help intervention. The existing Allesondercontrole intervention has a duration of five weeks. During this period, participants are asked to identify the things that are most important to them in their lives; their answers are then used to create an inventory of problems currently affecting them in their lives. These problems are subsequently placed into one of three different categories: unimportant problems (problems that are unrelated to the things that are important in life); important and resolvable problems (these problems are resolved using the six-step problem-solving method) and important but irresolvable problems (for example, a lost loved-one; these problems are addressed by means of a specially designed plan for learning to cope with the loss). Dutch and international studies alike have found the intervention to be effective in the treatment of depression. A recent meta-analysis has shown that Internet-based self-help interventions are just as effective in treating depressive disorders as are face-to-face treatments.

Study burden and risks

The burden of participation will be 2 hours of extra work, next to the intervention. These 2 hours consist of:

- screening questionnaire (5-10 minutes)
- interview by telephone (45 minutes)
- pre-test: several questionnaires (30 minutes)
- post-test: several questionnaires (35 minuten)

Participation in this study is without any risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients (minimum age 18) from the MS centre of the VU medical centre can take part if they: 1) are diagnosed with MS 3 months before the screening and 2) are able to manage the Dutch language. Inclusion criteria for the intervention are: 1) a minimum score of 16 on the Beck Depression Inventory (BDI) and the intention and capability to invest 5 weeks of their time to follow a selfhelp intervention through the internet.

Exclusion criteria

No access to Internet or no email-address, no experience with Internet, unable to read, current use of antidepressants or other treatment of depression, current suicidal ideation.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO	
Date:	31-12-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL25173.029.08