Depression in MS: The effectiveness of web-based self-help treatment.

No registrations found.

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

Summary

ID

NL-OMON20843

Source
NTR

Health condition

English:
Depression
Multiple sclerosis (MS)
Problem Solving Therapy (PST)
Internet-based treatment
Beck Depression Inventory

Nederlands:
Depressie
Multiple Scleroses (MS)
Problem Solving Therapie
Internet therapie
Beck Depression Inventory

Sponsors and support

Primary sponsor: VU Medisch Centrum/GGZinGeest
Source(s) of monetary or material Support: Stichting MS Research

Intervention

Outcome measures

Primary outcome

The primary outcome measure of this study is depressive symptoms. The Beck Depression Inventory (BDI) is a self-report instrument for assessing the existence and severity of depressive symptoms and is the most commonly used measure of depression severity in patients with MS. The Beck Depression Inventory Second Edition (BDI-II) is the most recent version of the BDI. Each of the 21 items match a symptom of depression according to the DSM-IV (DSM-IV, 1994). The total score is calculated by adding all the items and lies in between 0 and 63. The sum of the scores indicates the severity of the depression. Scores of 0 to 13 represent minimal depressive symptoms, scores from 14 to 19 indicate mild depression, scores from 20 to 28 moderate depression and scores of 29 to 63 indicate severe depression. The BDI has shown to be reliable, valid and responsive, and has been widely used in research on MS patients.

Secondary outcome

Secondary outcomes include other measures of depression, problem solving skills, quality of life, disability level, well-being, social support, suicide ideation, fatigue, anxiety, mastery and satisfaction.

Measurements:

1. Depression: Beck Depression Inventory and Inventory (BDI) of Depressive Symptomatology (IDS);

2. Anxiety: Beck Anxiety Inventory (BAI), Hospital Anxiety and Depression Scale (HADS);

3. Quality of life: The EuroQol consists of the EQ-5D and EQ-VAS;

4. Well-being is further measured with the WHO-5 wellbeing index (WHO-5);

5. Impact of MS and disability level is measured by the Multiple Sclerosis Impact Scale (MSIS-29). Disability level is also measured by the Expanded Disability Status Scale (EDSS), assessed by telephone;

6. Fatigue: The Fatigue Severity Scale (FSS) is a 9-item scale, used to assess the severity of fatigue;

7. Cognition: The Multiple Sclerosis neuropsychological questionnaire (MSNQ) is a self-report screening measure of neuropsychological functioning in MS;

8. Problem solving skills: The Social Problem Solving Inventory - Revised (SPSI-R) contains 52

items and determines individual problem-solving skills. The scales ‘avoidance style’ (AS) (7 items), ’negative problem orientation (NPO, 10 items) and positive problem orientation’ (PPO, 5 items) will be used;

9. Mastery: The 5-item Pearlin and Schooler Mastery Scale.
Social support: The Social Support Inventory contains questions on details about social support from the four most intimate persons;

10. Satisfaction: The Client Satisfaction Questionnaire (CSQ-8) measures patient satisfaction with the intervention;

11. Interview (pre-test only): Patients who score above the cut-off score of 16 on the BDI are invited for a structured clinical interview for presence of depression and anxiety disorders and suicidal ideation (World Health Organiszation (WHO) version 2.1). The CIDI establishes diagnoses according to the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV). The CIDI interview is conducted by telephone, as well as the Percieved Need of Care Questionnaire (PNCQ). The PNCQ assesses the patients' perceptions of their needs for mental health care and the meeting of those needs;

12. Sociodemographic data (pre-test only): Age, gender, social status, employment, partner status, nationality;

13. Medical – somatic data (pre-test only): Diagnosis, time since first symptoms, time since diagnosis, number of exacerbations, utilization of health care resources (medication and other treatment modules).

Study description

Background summary

Depressive symptoms are higly prevalent among persons with multiple sclerosis (MS). However, depression is often not recognized in MS, patients do not seek treatment for depression and adequate treatment tends to be lacking. Depression is related to poorer quality of life, disrupts social support and has been associated with fatigue, a decrease in working hours and cognitive impairment in MS-patients. Recently web-based self-help treatment has been demonstrated as an effective intervention for reducing depressive symptoms in patients with a depressive disorder. We expect it to be a promising approach to the treatment of co-morbid depression in MS patients, because it is easy accessible and can overcome disease-related barriers to participate in face-to-face counseling. A pilot study has shown promising results (MS Research project: 08-651 MS) in treating depressive symptoms in MS patients with a web-based CBT intervention. It encourages us to proceed with the intervention and to examine the effectiveness of this web-based self-help course for the treatment of depressive symptoms in MS in a randomized clinical trial. To the best of our knowledge, this will be the first randomized controlled study to evaluate effectiveness of a

web-based CBT self-help treatment for depressive symptoms in MS. We expect that the online intervention will be more effective for the treatment of depressive symptomatology in MS patients than care as usual. Moreover, we expect positive effects from the online intervention on anxiety, fatigue, disability level and quality of life because of the suggested association of depression with these parameters.

Study objective

The aims of this study are twofold:

1. Examine the effectiveness of the web-based CBT self-help intervention for MS-patients with depressive symptoms;

2. Compare characteristics of symptoms of depression and anxiety, quality of life and perceived need of care in MS patients with comorbid depression versus a cohort of patients with current depression.

Research Questions:

1. Is the web-based self-help intervention (cognitive behavior therapy based on the principles of problem solving therapy) more effective in reducing depressive symptoms in MS patients than care as usual?

2. What are the effects of the web-based intervention at issue on quality of life, disability level, fatigue, cognitive functioning, mastery and anxiety?

3. Which predictors of a faborable outcome of the web-based intervention on depressive symptoms can be identified?

By comparing the RCT data with a large-scale available depression cohort:

4. Is there a difference in presentation of depressive symptoms in people with MS, compared to persons with a current depressive disorder (and no MS) and chronically ill with a comorbid depressive disorder?

Study design

MS patients with a score of 16 or higher on the Beck Depression Inventory (BDI) online screening will be randomized to the intervention group or care as usual control group. Patients in the intervention group and the control group are evaluated before, after the 5 week self-help course, at 4 months follow-up and at 10 months follow-up (only the intervention group to investigate the effects at longer term).

Intervention

Problem Solving Therapy:

The online cognitive-behavioural self-help treatment examined in this study is based on what is known as ‘problem-solving therapy’ (PST). PST, comprising a cognitive behavioural self-help method, is based on the assumption that psychological symptoms of depression are often caused by problem-solving deficits and practical problems people face in their daily lives. The treatment helps people to solve these problems in a structured way by providing them a specific problem-solving procedure. The original PST-based intervention for depression is described by van Straten et. al (J Med Internet Res, 2008). With a number of modifications we adjusted this intervention for people with MS and co-morbid depression, conserving the intent of the PST-based intervention. Modifications concerned additional information about MS and its psychosocial consequences and text and examples applying to MS patients. The intervention is called ‘minderzorgen’: (website: www.minderzorgen.nl)
The web-based intervention exists of five modules with text, exercises, and figures. The patients access the intervention from their personal computers via the Internet. The recommended time for completion of the course is five weeks, one session per week. Patients are asked to work on their assignments for at least 2 hours per week. In that period, respondents describe what they think is important in their lives, make a list of their problems and concerns, and divide these into three categories: unimportant problems (problems which are not related to what is important in their life), important and solvable (these are solved during and after the intervention through a six-step procedure of problem-solving), and important but unsolvable (such as loosing someone through death; for each of these problems the respondent makes a plan how to cope with this). The six-step problem-solving method is the most important step of the intervention and is offered in the second week and practised throughout the intervention. Patients have to (1) write a clear definition of the problem, (2) generate multiple solutions to the problem, (3) select the best solution, (4) work out a systematic plan for this solution, (5) carry out the solution, and (6) evaluate as to whether the solution has resolved the problem.

Support consists of communication through brief, weekly e-mails sent through the website, and will be provided by supervised and trained clinical psychology Master students. The e-mail correspondence is intended to facilitate the patient’s effective use of the self-help method, and is explicitly not intended to build up a patient – therapist relationship.

Care as usual consists of the care provided by the health care centre visited by the patient. We will not intervene in the given care, and the patient is free to accept any intervention (medication, psychological treatment) given in the time period of the study. The received mental health care will be registered. We will provide the care as usual control group the intervention on voluntary basis after the study has been finalized.

Contacts

Public
GGZinGeest / VU Medical Center
Academic Anxiety Outpatient Clinic
A. J. Ernststraat 1187
R.E. Boeschoten
Amsterdam 1081 HL
The Netherlands
+31 (0)20 7884659
Scientific
GGZinGeest / VU Medical Center
Academic Anxiety Outpatient Clinic
A. J. Ernststraat 1187
R.E. Boeschoten
Amsterdam 1081 HL
The Netherlands
+31 (0)20 7884659

Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Score 16 or higher on the Beck Depression Inventory (BDI);

3. Report a diagnosis of definite MS confirmed by a neurologist more than 3 months ago.

Potential patients will be excluded if they are currently following psychotherapy, do not have excess to the Internet, have insufficient command of the Dutch language or report suicidal ideation. The latter group of patients will be contacted by telephone and referred to their general practitioner.

Exclusion criteria

1. No access to Internet or no email-address;

2. No experience with Internet;

3. No sufficient command of Dutch;

4. Unable to read;

5. Current use of antidepressants or other treatment of depression;

6. Current suicidal ideation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2011
Enrollment:	166
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-02-2011
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	NL2644
NTR-old	NTR2772
Other	Stichting MS Research : 09-678
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A