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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20843

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: VU Medisch Centrum/GGZinGeest
Overige ondersteuning: Stichting MS Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

GGZinGeest / VU Medical Center
Academic Anxiety Outpatient Clinic
A. J. Ernststraat 1187

R.E. Boeschoten
Amsterdam 1081 HL
The Netherlands
+31 (0)20 7884659

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	166
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-02-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2644
NTR-old	NTR2772
Ander register	Stichting MS Research : 09-678
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A