A better view of your Self: strengthening your self-image in order to counter anxiety and depression. A randomized trial of the effectiveness of a guided self-help intervention.

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To study the effectiveness of a low-threshold guided self-help intervention targeted at improving one's self image in people with anxiety and/or depressive symptoms and low self esteem. We expect to find both a significant improvement of self-...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34412

Source
ToetsingOnline

Brief title
A better view of your Self.

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
melancholy, nervousness, sadness (depression), stress (anxiety)

Health condition

angststoornissen en -symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anxiety, depression, self concept, self-help

Outcome measures

Primary outcome

The intervention's primary focus is enhancing self-esteem. The primary outcome measure used in this study is the Rosenberg self-esteem scale (Rosenberg, 1965). This scale includes 10 statements (such as 'generally speaking, I am content with myself'). The respondent then checks a score on a 4-point scale which indicates the extent to which the respondent identifies with the statement. Total scores vary from 0 to 30, higher scores indicate higher self esteem. In a sample of the Dutch population, a mean score of 20.9 was reported with a standard deviation of 4.4. Both international and Dutch studies report high reliability, validity and internal homogeneity (Cronbach alpha .86; Franck et al., 2008).

Secondary outcome

The study's secondary focus is establishing whether the intervention is succesful in reducing anxiety and/or depressive symptoms.
Anxiety symptoms are measured with the Anxiety subscale of the Hospital Anxiety and Depression Scale (the HADS-A). This is a validated 7-item self-report measure of anxiety, with a 4-point scale. Total scores vary from 0 to 21, with

higher scores indicating more anxiety symptoms(Spinhoven et al., 1997).
Depressive symptoms are measured with the Center for Epidemiological Studies Depression Scale (CES-D). This is a validated 20-item self report questionnaire, with a 4-point scale. Total scores vary from 0 to 60, with higher scores indicating more depressive symptoms (Radloff, 1977).
In order to establish whether the respondent uses other health care resources and to establish the presence of work related problems as a consequence of the psychological symptoms, the Tic-P will be administered. This questionnaire is developed by the Institute of Medical Technology Assessment (iMTA) of the Erasmus university and the Trimbos-institute and has been used in a variety of different studies (van Dam et al., 1998; Hakkaart-van Roijen, 2002; Penninx et al., 2008).
Quality of life is increasingly regarded as an important secondary outcome measure. In order to establish quality of life, the SF-36 will be administered. This is a 36-item self-report questionnaire involving a variety of subscales that portray health-related quality of life (Ware and Sherbourne, 1992).

Study description

Background summary

Within the last decade, the concept of self has received more and more attention within cognitive psychological theory and cognitive therapy. Research indicates that a negative self-image may form a vulnerability and sustaining factor in the development and course of a variety of mental health problems, such as anxiety and depression (Glashouwer & de Jong, 2010; Risch et al., 2010; Talbot, Harris & French, 2009; Mann e.a., 2004). This calls for specific (preventive) interventions targeted at changing one's self image, and at trials including changes in self image as a measure of effect, besides

measures of anxiety and depression. Such interventions, such as the 'white book', which entails keeping a diary of concrete and positive feedback about one's own personality and achievements, are now a regular feature of treatment and secondary prevention programs for anxiety and depression. However, the (surplus) effect of these types of interventions for the treatment and prevention of anxiety and depression has hardly been studied.
Even when adequately treated, anxiety and depression carry a high risk of recurrence (Spijker et al., 2002). In order to combat the onset and recurrence of anxiety and depression, attention has shifted from a sole focus on treatment of full-blown disorders to both indicated prevention (prevention of full blown disorders for people with subclinical anxiety and depressive symptoms) as well as secondary prevention (prevention of recurrence of anxiety and dperession in patients who have been succesfully treated in the past (Cuijpers, 2003).
Indicated prevention interventions often involve short term low intensity treatments that are administered through self help books, the Internet or a group program. Self-help interventions have proven very effective, especially when some form of guidance is offered (Cuijpers, Donker, van Straten, Li, & Andersson, 2010).
Recently, a self-help book based on cognitive behavioural techniques targeted at improving one's self image has been published (de Neef, 2010). In the current study, the effectiveness of the use of this self-help book is s tudied and compared to a wait list control group of people with low self esteem and subclinical anxiety and/or depressive symptoms. Guidanceprovided to all participants receiving the self-help book entails feedback and aswers to questions regarding the assignments described in the book.

Study objective

To study the effectiveness of a low-threshold guided self-help intervention targeted at improving one's self image in people with anxiety and/or depressive symptoms and low self esteem. We expect to find both a significant improvement of self-esteem (primary outcome measure) and a significant diminshment of anxiety and depression.

Study design

The study involves a randomized open-label effectiveness trial, with an experimental condition and a wait-list control group.

Intervention

Respondents in the experimental condition are offered the self-help book. The intervention or course entails 6 different techniques, based on elements from cognitive behavioural therapy. Duration of the intervention may vary from 6 to 10 weeks, depending on the pace of the individual respondent. Guidance by specially trained students and research assistants is mainly focused on

motivating the respondent to work through the entire book, whilst providing feedback and information in case of any misunderstanding of the assignments described in the book. Respondents in the control condition are placed on a wait-list. Throughout the waiting period they do not receive the self-help book, but are free to seek help through the common channels. After the follow-up period of 6 months, they are offered the self-help book, with the same guidance provided by the university.

Study burden and risks

The respondent is requested to fill out a series of questionnaires at three different occasions. Each series of questionnaires will take approximately 30 minutes. Time investment in taking the self-help course will vary, depending on inidivual pace and motivation. The respondent suffers from mental health symptoms that are perceived as distressing and/or limiting. Any intervention targeted at alleviating these symptoms will inevitably entail some degree of effort and time. However, the intervention included in the present study is relatively short, very accessible and less strenuous than a specialized treatment at a mental helath care institute. Also, the respondent is free to seek alternative or extra treatment and is explicitly informed about this right.

Contacts

Public
Vrije Universiteit

van der Boechorststraat 1
1081 BT Amsterdam
Nederland
Scientific
Vrije Universiteit

van der Boechorststraat 1
1081 BT Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The presence of clinically relevant anxiety and/or depressive symptoms as established by a score of 7 or higher on the HADS-A and/or a score of 16 or higher on the CES-D.
2. The participant is suffering from low self-esteem as established by administration of the Rosenberg self-esteem scale (Rosenberg, 1965).
3. The participant is troubled and/or limited by the aforementioned symptoms.

Exclusion criteria

Insufficient understanding of the Dutch language

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO Date:	13-12-2010
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

ID: 21642
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33798.029.10
OMON	NL-OMON21642