Cognitive behaviour therapy versus problem solving therapy with depressive symptomatology

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Main question:* Are the minimal interventions effective in reducing depressive symptoms comparing to a waitinglist-controlgroup?Subquestions:* Do the interventions differ in effectiveness?* Are the effects specific for the interventions?* Are there...

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON30124

Source
ToetsingOnline

Brief title
Depression under control

Condition

- Psychiatric disorders

Synonym
depressive symptoms, sadness

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cognitive behaviour therapy, depression, problem solving therapy, self-help

Outcome measures

Primary outcome

Depressive symptom level will be measured with the Center for Epidemiological Studies Depression scale (CES-D).

Secondary outcome

Secundairy outcomes:

Quality of life is measured by the Euroqol

Anxiety symptoms are measured by the anxiety subschale of the Hospital Anxiety and Depression Scale (HADS)

Dysfunctional cognitions are measured by the Dysfunctional Attitude Scale (DAS)

Worrying is measured by the Penn State Worry Questionnaire (PSWQ)

Problem solving skills are measured by the Social Problem Solving Skills-Revised (SPSI-R)

Mastery is measured by the Mastery Scale

Absence at work and use of healthcare are measured by the TIC-P

Study description

Background summary

Depression is highly prevalent: More than 15% of the adult population under 65 had major depression in their history according to DSM-III-R criteria. Minimal interventions are effective in the treatment for depression. The purpose of this study is to investigate the efficacy of two minimal interventions with adults reporting elevated depressive symptoms. The two interventions are cognitive-behavioural therapy (Color your life) and self-examination therapy (Alles onder controle).

Study objective

Main question:

* Are the minimal interventions effective in reducing depressive symptoms comparing to a waitinglist-controlgroup?

Subquestions:

* Do the interventions differ in effectiveness?
* Are the effects specific for the interventions?
* Are there subgroups who respond different to the interventions?

Study design

People will be recruited through advertisements in local newspapers and websites. Inclusion criterion is a score of 16 or higher on the Center for Epidemiological Studies Depression scale (CES-D). Participants are assigned on a random basis to two treatment conditions and a delayed-treatment condition. Both interventions are delivered through computer administration. During the interventions respondents receive support by email. Respondents in the delayed-treatment condition receive the interventions three months later. Data are collected at baseline and at 5 weeks, 8 weeks, 12 weeks and 9 months after baseline. Data are collected by email.

Intervention

The cognitive-behavioural intervention is called Color your life (Kleur je leven). This intervention consists of 8 lessons (1 lesson a week). Four weeks later, the 9th lesson takes place. The intervention focuses on increasing

pleasurable activities, increasing social skills and decreasing dysfunctional cognitions.

Self Examination Therapy is based on problem solving therapy. We used the Dutch version, called 'Alles onder controle'. This intervention takes 5 weeks. During this intervention participants determine what matters to them, think less negatively about things that do not matter to them, invest their energy in things that are important to them (by using problem-solving strategies) and accept situations they cannot change.

Both interventions are computer-based.

Study burden and risks

Burden: participants receive a questionnaire five times. Filling in takes at most 60 minutes each time.

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

score of 16 or higher on the Center for Epidemiological Studies Depression scale (CES-D)

Exclusion criteria

none

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

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	NL13573.029.06