

# (Cost-)Effectiveness of a guided-self help internet-based intervention for employees with depressive symptoms: a randomized trial

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This randomized controlled trial examines whether a guided-self-help intervention is effective in treating depressive symptoms by employees. Cost effectiveness is also examined.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37988

### Source

ToetsingOnline

### Brief title

Self-help for employees with depressive symptoms

### Condition

- Mood disorders and disturbances NEC

### Synonym

depression, feeling down

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** depressive symptoms, occupational stress, psychotherapy, self-help

## Outcome measures

### Primary outcome

Primary outcome of this study are the depressive symptoms, as measured with a self-report questionnaire of depressive symptoms.

### Secondary outcome

Secondary outcome measures are: absenteeism, anxiety symptoms, burnout symptoms, quality of life, locus of control and coping.

## Study description

### Background summary

Unipolar depressive disorders are highly prevalent, have high incidence, and have considerable impact on quality of life in patients and their relatives. Moreover, depressive disorders are linked with increased mortality rates, high levels of service use and huge economic costs.

Prevention of depression is in the interests of businesses because they pay about 75% of the total economic costs of depression. These costs exist of absenteeism from work and loss of work productivity (presenteeism).

Research has shown that depressive symptoms can be treated effectively with psychological interventions. There is also growing evidence that these interventions can be applied through guided self-help interventions. In this research we will examine whether a guided self-help intervention is effective in treating depressive symptoms by employees. This intervention also focuses on work aspects such as stress.

### Study objective

This randomized controlled trial examines whether a guided-self-help intervention is effective in treating depressive symptoms by employees. Cost effectiveness is also examined.

### Study design

This is a randomized controlled trial of an internet based guided self-help intervention for employees with depressive symptoms. 50% of the participants will be randomized to the guided self-help intervention (experimental group). The other 50% of the participants will be randomized to the control group. In this control group is no actual form of health intervention offered but participants are free to seek help for there symptoms (control group, care as usual).

## **Intervention**

This intervention is based on an interconnection of different modules witch have been shown to be effective in treating depressive symptoms and work-related problems, namely the Problem Solving Treatment, Mind over Mood and Prevention Guide. The course exists of 6 weekly lessons (with an option to extend to 9 lessons). The participantss need to do \*homework\*. They are supported by a coach (social worker or bachelor psychologist).

## **Study burden and risks**

Not applicable

## **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

18 years or older and depressive symptoms

### Exclusion criteria

change in antidepressant medication, legal labor dispute

## 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:	Recruitment stopped
Start date (anticipated):	10-10-2011
Enrollment:	200
Type:	Actual

## Ethics review

Approved WMO

Date: 18-04-2011

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	12-03-2012
Application type:	Amendment
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	NL34653.029.11