Mindfulness-Based Cognitive Therapy (MBCT) and Cognitive Behavioral Therapy (CBT) for depression in patients with diabetes: a randomized controlled trial

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Primary Objective: To assess immediate and long-term effects of Mindfulness-based Cognitive Therapy (MBCT) and Cognitive Behavioral Therapy (CBT) in reducing depressive symptoms in patients with diabetes. Regarding immediate effects, we expect that...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON36275

Source
ToetsingOnline

Brief title
MBCT and CBT for depression in patients with diabetes

Condition

- Diabetic complications

Synonym
depressed mood, depression, Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: Cognitive behavioral therapy, Depression, Diabetes, Mindfulness

Outcome measures

Primary outcome

Depressive symptoms severity.

Secondary outcome

Well-being, generalized anxiety, diabetes related distress

Study description

Background summary

Depression is a common comorbidity of diabetes, negatively affecting physical performance, glycemic control, and adherence to medication, dietary, and exercise recommendations. Modalities of psychotherapy can reduce depressive symptoms in diabetes patients. Both mindfulness-based cognitive therapy (MBCT) and cognitive behavioral therapy (CBT) are effective in medical settings in attenuating adverse emotional and psychological components associated with chronic disease. However, research about mindfulness is in its infancy and proper designed randomized controlled trials are rare. Furthermore, more reasearch is needed to assess the long-term effects of MBCT.

Study objective

Primary Objective:
To assess immediate and long-term effects of Mindfulness-based Cognitive Therapy (MBCT) and Cognitive Behavioral Therapy (CBT) in reducing depressive symptoms in patients with diabetes. Regarding immediate effects, we expect that both MBCT and CBT are more effective than a wait-list control condition in reducing depressive symptoms in diabetes patients.
Secondary Objectives:
- To examine factors that moderate treatment effects of MBCT and CBT
- To examine factors that mediate treatment effects of MBCT and CBT
- To examine the role of treatment integrity and therapeutic relationship in treatment effects and mediators of MBCT and CBT

Study design

A randomized wait-list control design.

Intervention

Both treatment conditions comprise eight individual sessions led by a psychologist and focusing on emotional, cognitive and behavioral aspects of coping with depressive symptoms. Patients will also be asked to further practice the skills they learn at home and in their daily lives.

Study burden and risks

The burden for patients consists of completing questionnaires on six occasions (total time-costs: approximately 3 hours), eight 45-minute psychological treatment sessions, and a telephone interview post treatment (20 minutes). The patients will also be asked to engage in homework exercises during the course of treatment (time-costs: about 30 minutes per day).
The therapy sessions will be recorded on video only if patients provide written informed consent. The same is true for using any data from medical files of the patients and using sampled blood to assess biochemical measures. For this, a maximum of 3 ml extra blood will be sampled during routine blood sampling.

All patients receive psychological treatments in which techniques are used that have proven to be effective for treating depression. To our knowledge, there are no negative effects of these treatments. Risks of this study are considered to be null, as patients are primarily asked to invest time and effort.

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

Diabetes mellitus Type 1 or 2 for at least three months (prior to inclusion)
Written informed consent
Age >= 18 and <= 70
Depressive symptoms (BDI-II score >= 14, indicating at least mild symptoms of depression)

Exclusion criteria

Not being able to read and write Dutch
Severe (psychiatric) co-morbidity
Acute suicidal ideations
Pregnancy
Currently receiving alternative psychological treatment for depression

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2011
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-09-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL31736.042.10