

On-line: Web-based Cognitive Behavioural Therapy (CBT) for Diabetic Adults with Minor to Moderately Severe Depression. A Randomised Controlled Trial.

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This study aims to test the effectiveness and appreciation of a web-based cognitive behavioural therapy (CBT) program for adult diabetic persons with minor to moderately severe depression in a randomized controlled trial.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30593

Source

ToetsingOnline

Brief title

ODDS: Online Depression in Diabetes Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Psychiatric disorders

Synonym

depression, diabetes, diabetes mellitus, mood disorder

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Diabetesfonds Nederland

Intervention

Keyword: depression, diabetes mellitus type 1 and type 2, Internet therapy

Outcome measures

Primary outcome

Primary outcomes are depressive symptoms and diabetes-related distress.

Secondary outcome

Secondary outcomes are satisfaction with the program, perceived health status, self-care, glycaemic control, days in bed/absence from work, and mental health care consumption.

Study description

Background summary

Depression is common among people with diabetes, negatively affecting quality of life, treatment adherence and diabetes outcomes. For diabetes patients access to mental health services is limited and Internet counseling is a potentially effective way to provide psychosocial care to large groups of patients at low costs.

Study objective

This study aims to test the effectiveness and appreciation of a web-based cognitive behavioural therapy (CBT) program for adult diabetic persons with minor to moderately severe depression in a randomized controlled trial.

Study design

We propose a RCT in 180 patients (90/90), with measurements at baseline, 3 and 6 months after completion of the program.

The experimental condition (on-line CBT) is compared to care-as-usual,

supplemented with a patient information booklet on depression.

Intervention

A moderated web-based 12-weeks program based on the successful program Coping with Depression (*In de put, uit de put*), that will be tailored to the needs of persons living with diabetes. The program is offered on an individual basis, with a weekly moderated group chat (forum).

Study burden and risks

No risks are associated with participation and the burden is minimal. Participants are asked to fill out a questionnaire via the Internet at three moments in time and one short interview will take place over the telephone. There are no risks or burden associated with participating in the Internetprogramme.

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

Inclusion criteria: 18 * 75 years of age, type 1 or type 2 diabetes (diagnosed by physician), minor to moderate depression (CES-D>16), and easy access to the Internet.

Exclusion criteria

Exclusion criteria: loss of significant other < previous 6 months, history of suicide attempts, insufficient Dutch language skills, visually too impaired to read, major depressive disorder, currently taking anti-depressant medication, co-morbid organic psychiatric disorder, and alcohol or drug addiction.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date: 06-06-2007

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
ISRCTN	ISRCTN24874457
CCMO	NL14981.029.07