

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20703

Source

Nationaal Trial Register

Brief title

ODDS (Online Depression in Diabetes Study)

Health condition

Minor to moderately severe depression; Diabetes Mellitus Type 1 or Type 2

Sponsors and support

Primary sponsor: VU University Medical Center

Source(s) of monetary or material Support: Dutch Diabetes Research Foundation

Intervention

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. In this study we aim to deliver a moderated web-based 12-weeks program to adults with minor to moderately severe depression, and test its efficacy and appreciation. The program is 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). We propose a RCT in 180 patients (90/90), with measurements at baseline, 3 and 6 months after completion of the program. Primary outcomes are depressive symptoms and diabetes-related distress. 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. Questionnaires are administered via the internet. Patients in the control condition receive care-as-usual, supplemented with minimal depression education. We hypothesize that the on-line intervention will prove to be significantly more effective in improving mood and reducing diabetes-related distress in diabetes patients with minor to moderately severe depression compared to the control condition, both at 3 and 6 month follow-up.

Study objective

The on-line intervention will prove to be significantly more effective in improving mood and reducing diabetes-related distress in diabetes patients with minor to moderately severe depression compared to the control condition (CAU, supplemented with information on depression) both at 3 and 6 month follow-up.

Intervention

A moderated web-based 12-weeks program to adults with minor to moderately severe depression. The program is 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.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

1. 18 – 75 years of age;
2. Type 1 or type 2 diabetes (diagnosed by physician);
3. Minor to moderate depression (CES-D>16);
4. Easy acces to the Internet.

Exclusion criteria

1. Loss of significant other < previous 6 months;
2. History of suicide attempts;
3. Insufficient Dutch language skills;
4. Visually too impaired to read;
5. Major depressive disorder;
6. Currently taking anti-depressant medication;
7. Co-morbid organic psychiatric disorder;

8. Alcohol or drug addiction.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	16-10-2006
Application type:	First submission

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

NTR-new

NTR-old

Other

ISRCTN

ID

NL782

NTR793

MEC : 2007/047

ISRCTN24874457

Study results

Summary results

N/A