

Online Depression in Diabetes Study: Web-based cognitive behavioural therapy for diabetic adults with depression

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2012	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR793

Study information

Scientific Title

On-line: web-based cognitive behavioural therapy for diabetic adults with co-morbid depression: a randomised controlled trial

Acronym

ODDS

Study objectives

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 (care as usual [CAU], supplemented with information on depression) both at three and six month follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 06/02/2009: Ethical Review Committee of the VU University Medical Centre gave approval on the 6th June 2007

Study design

Randomised, controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Minor to moderate depression

Interventions

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.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Primary outcomes are depressive symptoms and diabetes-related distress.

Secondary outcome measures

1. Satisfaction with the program
2. Perceived health status
3. Self-care
4. Glycaemic control
5. Days in bed/absence from work
6. Mental health care consumption

Overall study start date

01/10/2006

Completion date

01/10/2010

Eligibility**Key inclusion criteria**

1. 18 to 75 years of age, either sex
2. Type one or type two diabetes (diagnosed by physician)
3. Minor to moderate depression (Center for Epidemiological Studies Depression Scale [CES-D] more than 16)
4. Easy acces to the Internet

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Key exclusion criteria

1. Loss of significant other within the previous six 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

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2010

Locations**Countries of recruitment**

Netherlands

Study participating centre

VU University Medical Centre

Amsterdam

Netherlands

1081 BT

Sponsor information**Organisation**

Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Diabetes Research Foundation (Netherlands)

Alternative Name(s)

Dutch Diabetes Research Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	study protocol	19/02/2008		Yes	No
Results article	results	05/01/2012		Yes	No