# Online Depression in Diabetes Study: Webbased cognitive behavioural therapy for diabetic adults with depression

Submission date Recruitment status [ ] Prospectively registered 28/12/2006 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 28/12/2006 Completed [X] Results [ ] Individual participant data Last Edited Condition category Mental and Behavioural Disorders 24/01/2012

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

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# Additional identifiers

Protocol serial number 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

# Study type(s)

Treatment

# 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(s)

Primary outcomes are depressive symptoms and diabetes-related distress.

# Key secondary outcome(s))

- 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

# 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

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

### Sex

All

## 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

# Study participating centre VU University Medical Centre Amsterdam

Netherlands 1081 BT

# Sponsor information

# Organisation

Vrije University Medical Centre (VUMC) (Netherlands)

### **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**

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?
Results article	results	05/01/2012	Yes	No
Protocol article	study protocol	19/02/2008	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes