

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	☐ Prospectively registered ☒ Protocol
Registration date 28/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/01/2012	Condition category Mental and Behavioural Disorders	☐ 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

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

Primary study design

Interventional

Study design

Randomised, controlled, parallel group trial

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 access 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

Netherlands

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