

Screening and support for depression in people with diabetes: a randomised controlled study

Submission date 19/08/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 26/09/2008	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 05/04/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
Diabetes v.14

Study information

Scientific Title

Study objectives

The self-rating scores for depression will be more improved in the intervention arm than in the treatment as usual (control) arm.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Glasgow and Clyde Primary Care, Community and Mental Health Ethics Committee. Date of approval: 12/08/2008 (REC No: 08/S0701/65)

Study design

Single-centre, randomised controlled trial

Primary study design

Intentional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes and depression

Interventions

Trial status amended to 'stopped' as of 05/04/2013 due to notification of lack of staff/resources.

Control arm: Treatment as usual

Intervention arm: Treatment as usual plus computerised cognitive behavioural therapy (CCBT). The CCBT is a self-help intervention supported by mental health practitioners.

Added as of 24/10/2008: The supported self-help intervention will comprise 4 support sessions over 6 weeks, and 6 sessions using an online CCBT package. It is approximated that this will take the participants 8 weeks to complete.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Change in depression as measured by BDI-II, assessed at baseline, Month 4, 5 and 12.

Key secondary outcome(s)

1. Anxiety state and other depression measures will be carried out using the Hospital Anxiety and Depression Scale (HADS) and PHQ-9 at baseline, Month 4, 5 and 12
2. Social functioning will be measured using the Work and Social Adjustment Scale (WASAS) at baseline, Month 4, 5 and 12
3. Mental health literacy will be measured using a revised questionnaire from previous studies at baseline, Month 4, 5 and 12
4. Acceptability of the trial interventions will be measured using two satisfaction items asking

overall satisfaction with the treatment option at Month 4 and 12 (this is in line with other similar studies)

5. Health care usage/costs will be costed using the Client Service Receipt Inventory (modified) and euroqol EQ-5D at baseline, Month 4, 5 and 12

6. Diabetes status: Hb1Ac will be sought using routine clinical data from clinical notes

In addition, a qualitative interview will be carried out in a subset of participants from both arms at 5 months, to collect data for the following aspects of the self-help CCBT:

1. Personal experience of low mood
2. Interaction with support worker
3. First and subsequent experiences of CCBT
4. Outcome of CCBT

Completion date

31/07/2010

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

Participants will be recruited from a diabetic clinic, therefore all participants will be diabetic.

Inclusion criteria:

1. Both males and females, aged 18 and above
2. Currently experiencing depression as defined by a score of 10 or greater on the Patient Health Questionnaire 9 (PHQ-9)
3. Able and to use the computerised cognitive behavioural therapy (CCBT) package (have access to computer and broadband internet and an active e-mail address)
4. Willing to use the CCBT self-help package

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Not fluent in the English language (unable to read/write or communicate)
2. Alcohol intake above 31 and 22 units for men and women, respectively (1.5 times the current

recommended maximum drinking levels)

3. Drug dependency defined as using street drugs everyday

4. Those who are actively suicidal, as defined by a score of 2 or more on the Beck Depression Inventory II (BDI-II) suicide item

5. Those who have received access to supported self-help in the last 6 months

6. Involved in other clinical research studies

7. Past or current history of psychosis or bipolar disorder

Date of first enrolment

01/08/2008

Date of final enrolment

31/07/2010

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

University of Glasgow

Glasgow

United Kingdom

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Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Government

Funder Name

Glasgow Institute for Psychosocial Interventions (GIPSI), NHS Greater Glasgow and Clyde (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration