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

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2008	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2008	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/04/2013	Mental and Behavioural Disorders	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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

Secondary outcome measures
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 euroquol 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

Overall study start date
01/08/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
184

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
Scotland

United Kingdom

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
Research and Development Directorate
Dalian House
350 St Vincent Street
Glasgow
United Kingdom
G3 8YZ

Sponsor type
Government

Website
http://www.nhsgg.org.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

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