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Diabetes Anxiety and Depression Study: A randomised controlled trial of group sessions of cognitive behavioural therapy (CBT) for people with diabetes

Submission date
10/07/2009

Recruitment status
No longer recruiting

Registration date
27/08/2009

Overall study status
Completed

Last Edited
28/02/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N/A

Study information

Scientific Title
A randomised controlled trial of group sessions of cognitive behavioural therapy for people with anxiety and depression following a new diagnosis of diabetes

Acronym
DADS (Diabetes Anxiety and Depression Study)

Study objectives
Group sessions of cognitive behavioural therapy (CBT) can improve diabetic control in patients newly diagnosed with diabetes who also have anxiety and depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Argyll and Clyde NHS Health Board Local Research Ethics Committee (LREC), 13/09/2002, ref: LREC 48/02

Study design
Randomised controlled intervention trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes type 1 and 2, anxiety and/or depression

Interventions
Diabetic patients whose Hospital Anxiety and Depression Scale (HADS) score indicated anxiety and depression (greater than or equal to 11 on either HADS-A or HADS-D or a total of both scores together (HADS-T) of greater than or equal to 18), were randomised by a computerised randomisation system to either cognitive behavioural therapy (CBT) delivered in group sessions over a six week period or to a control of standard care. Patients whose HADS score did not indicate anxiety or depression continued as an observation group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The difference in glycaemic control 12 months from baseline as measured by HbA1c.

Key secondary outcome(s))

1. The change in depression and anxiety as measured by HADS 12 months from baseline
2. The change in quality of life as measured by the 36-item short form health survey version 2 (SF-36V2), 12 months from baseline

Completion date
05/02/2007

Eligibility

Key inclusion criteria
1. New diagnosis of diabetes (less than 12 months)
2.18 years of age and above, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with a poor understanding of English
2. Patients whose mental health requires immediate referral to a psychiatrist
3. Patients too physically impaired to attend group sessions

Date of first enrolment
15/09/2002

Date of final enrolment
05/02/2007

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

Diabetes Centre
Greenock
United Kingdom
PA16 0XN

Sponsor information

Organisation
University of Glasgow (UK)

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Research organisation

Funder Name
Novo Nordisk Research Foundation (UK) - university tuition fees

Funder Name
Inverclyde Royal Hospital (UK) - Endowment Fund (diabetes)

Funder Name
University of Glasgow (UK) - statistical support

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?
	Participant information sheet				

Participant information sheet	11/11/2025	11/11/2025	No	Yes