

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	<input type="checkbox"/> Prospectively registered
Registration date 27/08/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/02/2018	Condition category Nutritional, Metabolic, Endocrine	<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
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