

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

<b>Submission date</b> 10/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/02/2018	<b>Condition category</b> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

## 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 measure**

The difference in glycaemic control 12 months from baseline as measured by HbA1c.

**Secondary outcome measures**

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

**Overall study start date**

15/09/2002

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

608: 103 to treatment arm, 104 to control arm, 401 to observation group

**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**

Scotland

United Kingdom

**Study participating centre**

**Diabetes Centre**

Greenock

United Kingdom

PA16 0XN

## **Sponsor information**

**Organisation**

University of Glasgow (UK)

**Sponsor details**

University Avenue

Glasgow

Scotland

United Kingdom

G12 8QQ

**Sponsor type**

University/education

**Website**

<http://www.gla.ac.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**

**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