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Diabetes And Depression Study

Submission date	Recruitment status	[X] Prospectively registered
04/01/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/04/2015	Nutritional, Metabolic, Endocrine	

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
2005-004525-26

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01KG0505

Study information

Scientific Title
Diabetes And Depression Study

Acronym
DAD

Study objectives
Study hypotheses: As of 11/11/2010 this record has been updated based on an amendment from 12/11/2008; all updates can be found in the relevant section with the above update date. At this time the target number of participants was decreased from 304 - 230.

Current hypothesis as of 11/11/2010 due to the amendment of 12/11/2008:
A diabetes-specific cognitive behavioural therapy (CBT) leads to a clinically important improvement of glycaemic control when compared with sertraline. This is then measured by a one-year follow-up in patients who initially responded to short-term therapy (CBT or sertraline) with regards to improvement in depression.

Initial information at time of registration:
A diabetes-specific cognitive behavioural therapy (CBT) leads to a greater proportion of patients achieving clinically important improvement of glycaemic control when compared with sertraline. This is then measured by a one-year follow-up in patients who initially responded to short-term therapy (CBT or sertraline) with regards to improvement in depression.

On 12/11/2008 the target number of participants was changed from 304 to 230.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local Medical Ethics Committee (Ethik-Kommission der Landesärztekammer Hessen) on the 21st February 2006 (EudraCT: 2005-004525-26). Last amendment approved on 12/11/2008.

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type 1 or type 2 diabetes mellitus

Interventions
Please note that as of 08/05/2008 the anticipated end date of this trial was extended. The previous anticipated end date of this trial was 31/01/2009.

1. Ten sessions (20 hours) of diabetes-specific CBT in an outpatient setting within a 12-week time period. This treatment will comprise of manualised semi-structured standard CBT for depression. In addition, it will include diabetes-specific aspects. Cognitive and behavioural techniques (cognitive restructuring, stress management, cueing) are used in this intervention to help patients diminish diabetes-related distress, reduce perceived barriers to various aspects of self-management, and enhance coping skills. The aim is to improve self-care behaviour and consequently improve glycaemic control.

2. Anti-depressive medication, with the selective serotonin reuptake inhibitor (SSRI) sertraline. Sertraline will be started at 50 mg per day in the morning. If no clinical response is achieved within 2-4 weeks, the dose may be raised to 100 mg per day in the morning. Further dose escalation is possible up to 200 mg per day at the clinician's discretion with changes not more rapidly than 50 mg per week.

After 12 weeks of open-label therapy, only the treatment-responders, showing 50% improvement of depression, in both groups will be included in the one-year long-term phase of the study.

In the long-term phase, diabetological treatment as usual will be given to both groups. CBT-responders will receive no further treatment, while patients responding to Selective Serotonin Reuptake Inhibitor (SSRI) will be given a sustained sertraline regimen as a relapse prevention.

Intervention Type
Mixed

Primary outcome measure
Current information as of 11/11/2010 due to the amendment of 12/11/2008:
Change of glycaemic control (difference in HbA1c value from baseline to the end of the long term phase).

Initial information at time of registration:
Improvement of glycaemic control (minimum 1% decrease in glycosylated haemoglobin A1c test [HbA1c value]) from baseline.

Secondary outcome measures
Current information as of 11/11/2010 due to the amendment of 12/11/2008:
1. "Improvement of glycaemic control" defined as a decrease of at least 1% in HbA1c value from baseline to the end of the long-term phase
2. Remission of depression, not fulfilling the DSM-IV-TR criteria for depression according to the Structured Clinical Interview Diagnosis (SCID) and depression score Hamilton Rating Scale (HAMD) Interview less than or equal to 7
3. Improvement of depression, i.e. a reduction of the HAMD-score from baseline to the end of

study by at least 50%
4. Change from baseline to end of study in generic HRQoL as assessed per SF-36
5. Change from baseline to end of study regarding problems in daily living with diabetes as assessed per PAID

Initial information at time of registration:
1. Remission of depression: no longer fulfilling the DSM-IV-TR criteria for depression according to the Structured Clinical Interview Diagnosis (SCID), and depression score on the Hamilton Depression Rating Scale (HAMD) Interview less than or equal to 7
2. Improvement of depression (greater than or equal to 50% reduction on the HAMD-baseline score)
3. Improved generic Health-Related Quality of Life (HRQoL), per SF-3
4. Decreased problems in daily living with diabetes, per Problem Areas In Diabetes scale (PAID)

Overall study start date
01/03/2006

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/05/2008:
1. Type 1 or type 2 diabetes mellitus diagnosed at least 12 months beforehand
2. Insulin treatment for at least the past six months
3. 21 to 69 years of age
4. Poor glycaemic control (HbA1c level greater than 7.5% measured twice within the preceding nine months)
5. Current major depression - Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV-TR) criteria

Previous inclusion criteria:
1. Type 1 or type 2 diabetes mellitus diagnosed at least 12 months beforehand
2. Insulin treatment for at least the past six months
3. 21 to 65 years of age
4. Poor glycaemic control (HbA1c level >8% measured twice within the preceding nine months)
5. Current major depression - Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV-TR) criteria

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
230

Key exclusion criteria
1. Clinically significant suicide risk or history of attempted suicide
2. History of schizophrenia or psychotic symptoms
3. Bipolar disorder
4. Organic brain syndrome or dementia
5. Alcohol or substance abuse or dependence in the past 6 months

Date of first enrolment
01/03/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor information

Organisation
Ruhr University of Bochum (Germany)

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Sponsor type
University/education

ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany) (ref: 01KG0505)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/08/2013		Yes	No
Results article	results	01/05/2015		Yes	No