

Cognitive behavioural therapy in elderly type 2 diabetes patients with minor depression or mild major depression

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Registration date 11/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/07/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
Version 1.0

Study information

Scientific Title

Cognitive behavioural therapy in elderly type 2 diabetes patients with minor depression or mild major depression: a randomised controlled trial

Acronym

MIND-DIA

Study objectives

The aim of the planned trial is to evaluate the efficacy of a diabetes-specific cognitive behavioural therapy (CBT) vs an intensified treatment as usual (TAU) vs a guided self-help intervention (SH) in elderly patients (65-85 years of age) with diabetes mellitus type 2 and minor depression or mild major depression.

Primary hypothesis:

i. CBT is significantly and clinically more effective than TAU in terms of improvement of Health-Related Quality of Life (HRQoL) at one year follow-up

Secondary hypotheses:

i. CBT offers a specific advantage and is significantly more effective than SH which is shown by a significantly higher increase in HRQoL compared to SH-groups at one year follow-up

ii. CBT is significantly more effective than TAU in terms of reduction of depression symptoms and prevention of moderate/severe major depression, improvement of glycaemic control (HbA1c), prevention of mortality and cost effectiveness, at one year follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Medical Ethics Committee (Ethikkommission bei der Landesärztekammer Hessen), approved on 09/04/2009 (Ref: FF 15/2009)

Study design

Open (observer-blinded) parallel-group randomised controlled multi-centre 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes, minor or mild major depression

Interventions

This is a three-arm trial, randomisation on individual basis (i.e. not cluster randomisation).

Cognitive Behavioral Therapy is based on a manualised programme (12 weekly sessions) designed for older adults with type 2 diabetes, including cognitive and behavioural strategies to overcome depression and to diminish diabetes-related distress, reduce perceived barriers to various aspects of self-management, and enhance coping skills. Central elements are: psychoeducation, support, problem solving, pleasant activities, activity scheduling by using pedometers, thought control techniques, cognitive restructuring, Socratic dialogue, social skills and interpersonal contact training, crisis intervention, emergency planning.

The guided self-help intervention 'Successful aging with Diabetes' (SH) with a focus on living and ageing with diabetes will be delivered by trained moderators (elderly care nurses, nurses or others). Moderators should pay attention, be empathetic and give support to all patients. The guided self-help intervention will provide an intact community and a sense of belonging, thus controlling for unspecific group effects due to the participation in a social network of people sharing the same problems which may reduce social or emotional isolation. The moderators should promote reciprocal caring and the sharing of relevant information regarding diabetes and ageing. The primary value of this group condition will be the mutual aid offered by members to one another. Therefore no formal therapeutic aspects will be involved and moderators should restrict their function to guide the group and give support. The Cognitive Behavioural Therapy intervention is based on a manualised programme, whereas only recommendations are given to the moderators for SH groups. Primarily patients decide about the topics or group activities. Thematically the intervention modules will be comparable to programmes of German self-help groups, comprising spontaneous conversation or several group activities.

The participants of the TAU group and their treating physician will receive diagnostic feedback regarding the minor or mild depression symptoms and cognitive function. Furthermore a feedback on the therapeutic options will be given to the physicians if minor or mild depression symptoms are diagnosed. For minor depression or depressive symptoms on a subclinical level the following treatment options including their combination are generally possible:

1. 'watchful waiting' (to await the spontaneous remission of the disorder)
2. Psychotherapy and/or physical activity
3. Currently, there is no scientific evidence for medical treatment with antidepressants in elderly diabetes patients with minor depression, but a treatment attempt with a well-tolerated antidepressant (e.g., sertraline, citalopram) could be an optional medical intervention

The review of current clinical trials for treating minor depression is undetermined. Currently no medical guidelines exist for treating minor depression or depressive symptoms on a subclinical level. Hence, in this TAU group the respective treating physician has to decide if a patient will get antidepressant medication, psychotherapeutic interventions or treatment as usual awaiting the course of depressive symptoms.

Total duration of interventions: 15 months (one session per week for 12 weeks, then 1 session per month for 12 months)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Mental Component Summary z-transformed score of the SF-36® Health Survey (generic HRQoL) assessed at the one year follow-up.

Secondary outcome measures

The following will be assessed at one year follow-up:

1. HRQoL (Physical Component Summary z-transformed score of the SF-36® Health Survey)
2. Reduction of depressive symptoms (Quick Inventory of Depressive Symptoms Clinician Rated [QIDS-C-16])
3. Prevention of moderate/severe major depression (Depression module, Structured Clinical Interview for DSM-IV [SCID])
4. Improvement of glycaemic control (HbA1c)
5. Mortality (yearly follow-up evaluations with mortality as an additional endpoint are planned depending on subsequent funding)
6. Cost effectiveness (direct treatment costs: medication, hospitalisation and other costs over a period of one year)

Overall study start date

01/04/2009

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

1. Diabetes mellitus type 2 diagnosed at least 6 months before entering the trial
2. Both males and females, 65 to 85 years of age
3. Minor depression (adapted from the Diagnostic and statistical manual of mental disorders [4th edition, text revision] [DSM-IV-TR] research criteria: we require 3-4 symptoms rather than 2-4 symptoms and a past history of major depression is not an exclusion criteria), or mild major depression (according to DSM-IV-TR criteria 5 to 6 depressive symptoms)
4. Living near the coordination institution where treatment will take place
5. Signed written informed consent

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

315

Key exclusion criteria

1. Serious violent, homicidal, or suicidal ideation; particularly clinically significant suicide risk or history of attempted suicide within the past 2 years
2. History of schizophrenia, psychotic symptoms or bipolar disorder
3. Organic brain syndrome, dementia or substantial cognitive impairment
4. Alcohol or substance abuse or dependence in the past 12 months (other than nicotine abuse /dependence)
5. Insufficient ability to understand German
6. Regular participation in a self-help-group (minimum 4 sessions in the last 12 months)
7. Psychotherapy (in the past 3 months)
8. Bereavement and grief reaction (loss <3 months)
9. Planned hospital admission next 3 months
10. Medical contraindication for physical activity
11. History of severe acute or chronic medical disorder (other than diabetes) which would probably impair trial commitment or lead to biased trial results (based on the critical appraisal of the investigator)
12. Patients who have taken antidepressants or mood stabilizing medication regularly over the 30 days prior to screening, patients who have taken fluoxetine regularly over the 60 days prior to screening, or patients on depot neuroleptic medication over the 5 inter-injection intervals prior to screening
13. History of severe acute or chronic medical disorder (other than diabetes) in the opinion of the investigator - preventing trial commitment or confounding interpretation of trial results
14. Blood chemistries alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) value(s) greater than or equal to three times the upper limit of normal prior to randomisation; estimated glomerular filtration rate (GFR) lower than 30; blood chemistries thyroid-stimulating hormone (TSH) values lower than 0.5 mU/l or greater than 5 mU adapted to reference ranges of the laboratory
15. Legal incompetence or legal guardianship
16. Participation in competing trials

Date of first enrolment

01/04/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Germany

Study participating centre

LWL-Klinik Dortmund

Wiesbaden

Germany

65183

Sponsor information

Organisation

Ruhr University of Bochum (Germany)

Sponsor details

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Sponsor type

University/education

Website

<http://www.ruhr-uni-bochum.de/psy-som-do/>

ROR

<https://ror.org/04tsk2644>

Funder(s)

Funder type

Government

Funder Name

Federal Ministry of Education and Research (BMBF) (Germany)

Alternative Name(s)

Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

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?
Results article	results	01/07/2009		Yes	No