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

Submission date	Recruitment status	[_] Prospectively registered
26/03/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/07/2009	Mental and Behavioural Disorders	

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
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 im-provement 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

Study type(s)
Treatment

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).

Cogntive 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 depres-sion 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 feed-back 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 antidepressents 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(s)
Mental Component Summary z-transformed score of the SF-36® Health Survey (generic HRQoL) assessed at the one year follow-up.

Key secondary outcome(s))
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 SymptomsClinician 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)

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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 ap-praisal 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 chemis-tries thyroid-stimulating hormone (TSH) values lower than 0.5 mU/l or greater than 5 mUl 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)

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

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