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Combined Cognitive-Behavioral and Pharmacological Continuation and Maintenance Treatment of Recurrent Depression

Submission date	Recruitment status	[X] Prospectively registered
10/05/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/08/2013	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG STA512/5-1

Study information

Scientific Title

Acronym
CBCMT

Study objectives
To compare the long-term outcome of a cognitive-behavioral continuation or maintenance therapy versus manualized active psychoeducation

Parallel group design with two treatment groups. After a two month run-in period, patients will be randomized to either treatment group. Therapists will be unblinded with regards to allocations of treatment groups. Blinded independent raters will assess outcome criteria after the eight-month treatment phase and then every three months up to one-year follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Local Ethics Committee of the University Clinic of Jena, Germany

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent depression

Interventions
Cognitive-behavioral continuation or maintenance therapy versus manualized active psychoeducation

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to first relapse

Secondary outcome measures
Depression (Hamilton Rating Scale for Depression)

Overall study start date
01/06/2006

Completion date
31/05/2009

Eligibility

Key inclusion criteria
1. Diagnosis of recurrent depressive disorder (>3 major depressive episodes [MDE]), currently in remission (ICD-10 F33.4)
2. Complete remission over 8 weeks after acute treatment of MDE
3. At least one index depressive episode within 12 months prior to the treatment
4. Hamilton Rating Scale for Depression (HRSD-17) score of 9 or less over 8 weeks prior to treatment
5. Age 18-70 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
168

Key exclusion criteria
1. Organic mental disorder
2. Psychological or behavioral disorders caused by psychotropic substances
3. Schizophrenia, schizoaffective disorder
4. Bipolar depression
5. Adjustment disorders
6. Borderline personality disorder
7. Mental retardation
8. Acute suicidality

9. Severe co-morbid medical condition
10. More than five individual sessions of regular cognitive-behavioral treatment within one year before randomization

Date of first enrolment
01/06/2006

Date of final enrolment
31/05/2009

Locations

Countries of recruitment
Germany

Study participating centre
Humboldt-Str. 11
Jena
Germany
D-07743

Sponsor information

Organisation
University of Jena (Germany)

Sponsor details
Fürstengraben 1
Jena
Germany
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Sponsor type
University/education

Website
http://www.uni-jena.de/

ROR
https://ror.org/05qpz1x62

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinsschaft) (DFG)

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	01/06/2013		Yes	No