ISRCTN81212636 https://doi.org/10.1186/ISRCTN81212636

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

Submission date
10/05/2006

Recruitment status
No longer recruiting

Registration date
26/05/2006

Overall study status
Completed

Last Edited
22/08/2013

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ulrich Stangier

Contact details
Humboldt-Str. 11
Jena
Germany
D-07743

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Time to first relapse

Key secondary outcome(s)
Depression (Hamilton Rating Scale for Depression)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

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)

ROR
https://ror.org/05qpz1x62

Funder(s)

Funder type
Research organisation

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

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	01/06/2013		Yes	No