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Efficacy of psychoeducation in the treatment of unipolar depression

Submission date 20/04/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/04/2009	**Overall study status** Completed	
Last Edited 30/04/2009	**Condition category** 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
N/A

Study information

Scientific Title
Efficacy of psychoeducation in the treatment of unipolar depression: a multicentric randomised controlled trial

Study objectives
Psychoeducation combined with treatment as usual leads to a greater reduction in depressive symptoms as measured by the Beck Depression Inventory (BDI) and Hamilton Depression Scale (HAM-D), and greater increase of subjective perception of the quality of life as measured by the Manchester Quality of Life Scale (MANSA) in subjects diagnosed with unipolar depression, than treatment as usual alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Clinical Centre of Sarajevo Ethics Committee approved on the 21st March 2008

Study design
Interventional opened multicentric randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Only available to recruiting centres

Health condition(s) or problem(s) studied
Unipolar depression in adults

Interventions
The subjects in the experimental group will receive an 8-week course on psychoeducation based on Lewinsohn's Coping With Depression Course combined with treatment as usual (TAU). The subjects in the control group will receive TAU only.

Assessments will be made with the use of standardised psychometric instruments:
1. International Neuropsychiatric Interview (MINI 5.00)
2. Mini Mental State Exam (MMSE)
3. Beck Depression Inventory (BDI)
4. Hamilton Depression Scale (HAM-D)
5. Manchester Quality of Life Scale (MANSA)
6. Socio-demographic questionnaire (specially designed for this study)

Assessments will be performed before the intervention, after the intervention and in 6 and 12 months follow-up. The study will adhere with the methodology of a randomised controlled trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To assess possible changes in the total score on Beck Depression Inventory scale (BDI), and Hamilton Depression Scale (HAM-D), between the subjects who received psychoeducation and treatment as usual and the subjects who received only treatment as usual, after a 12 week course of psychoeducation, and in 9 months follow-up.

Secondary outcome measures
1. To assess possible changes in the total score on Manchester Quality of Life Scale (MANSA) between the subjects who received psychoeducation and treatment as usual and the subjects who received only treatment as usual, after a 12 week course of psychoeducation and in 9 months follow-up
2. To assess possible differences in types of mental health services received between the two groups in 9 months follow-up

Overall study start date
01/05/2009

Completion date
01/05/2010

Eligibility

Key inclusion criteria
1. Adult subjects aged 18 to 65 years, either sex
2. Diagnosis of unipolar depression (F 32.0-2, F 33.0-2)
3. Not due to a medical condition (Diagnostic and Statistical Manual of Mental Disorders, 4th Edition [DSM IV] Axis V = 0)
4. No other Axis I co-morbid psychiatric disorder
5. Duration of symptoms not less than 3 months
6. Able to read and write (8 years formal education)
7. Subjects who sign the informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Refused to sign informed consent
2. Illiterate
3. Deaf or hearing impaired
4. Serious speech impairment or mutisim
5. Duration of symptoms less than three months
6. Symptoms of psychotic depression
7. History of a manic or hypo-manic episode
8. Cognitive impairment (mini Mental State Examination [MMSE] greater than or equal to 25)
9. Co-morbid anxiety disorder
10. Organic affective disorder
11. Depression caused by an underlying medical condition
12. Co-morbid personality disorder
13. Alcohol and preliminary alcohol screening (PAS) abuse and dependence
14. Subjects who are currently involved in other research
15. Pregnancy
16. Epilepsy
17. Subjects whose present condition requires psychiatric hospitalisation
18. Suicidality

Date of first enrolment
01/05/2009

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Bosnia and Herzegovina

Study participating centre
Bolnicka 25
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Sponsor information

Organisation
Clinical Centre University of Sarajevo (Bosnia and Herzegovina)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/019bz1656

Funder(s)

Funder type
Government

Funder Name
European Union (EU) (Belgium) - Sixth Framework Programme (FP6): EVIDENCE (Strengthening Research Capacities and Evaluation of Mental Health Services in Bosnia and Herzegovina) (grant ref: INCO-CT-2007-043654 FP6)

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