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Process and outcome of day clinic and inpatient psychotherapy in severe bulimia nervosa: a randomised-controlled trial

Submission date
30/05/2005

Recruitment status
No longer recruiting

Registration date
23/08/2005

Overall study status
Completed

Last Edited
29/09/2009

Condition category
Mental and Behavioural Disorders

[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ZE 520/4-1

Study information

Scientific Title

Study objectives
1. 3 month follow-up:
1.1. Inpatients will suffer from more relapses after discharge (bulimic symptoms)
1.2. Inpatients will show less feelings of specific self-efficiacy compared with day clinic patients between discharge and 3-month-follow-up
1.3. Day clinic patients will show some improvement in social adjustment whereas after inpatient treatment there will be no change

2. 12 month follow up:
2.1. Both groups will show comparable results in general and specific pathology
2.2. Day clinic patients will show more improvements in social adjustment
2.3. Day clinic patients will be more satisfied with treatment in retrospect

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Severe bulimia nervosa

Interventions

3 month of day clinic or inpatient treatment (multimodal treatment) with the same treatment elements in similar quantity in both conditions (individual and group therapy, work with eating diaries, rounds, art therapy, body therapy etc.). The treatment concept is psychodynamic, integrating cognitive-behavioral and family-oriented elements.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Eating- Disorder-Inventory (EDI-II) (scale 2: bulimia)
2. Symptom-Check-List (SCL-90-R)
3. Global Severity Index (GSI)
4. Self-Efficiacy-Questionnaire; Social Adjustment Scale (SAS) (total score)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Bulimia nervosa: International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD 10) / Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV)
2. Age >17
3. Indication for day clinic/inpatient treatment
3.1. failure of outpatient psychotherapy
3.2. chronicity
3.3. severe symptom expression
3.4. severe comorbidity

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

60

Key exclusion criteria
1. Severe, acute somatic complications
2. Psychosis
3. Severe addiction (detoxification is needed)
4. Acute suicidality
5. Clinic can not be reached within a reasonable time (>60 minutes travel time)

Date of first enrolment
01/01/2003

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Germany

Study participating centre
Dept. of Psychosomatic Medicine and Psychotherapy
Freiburg
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Sponsor information

Organisation
German Research Foundation (Deutsche Forschungsgemeinschaft) (DFG) (Germany)

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Sponsor type
Research organisation

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http://www.dfg.de/

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft) (DFG) (Germany) - (ref: ZE 520 /4-1_

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	01/08/2009		Yes	No