

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	<input type="checkbox"/> Prospectively registered
Registration date 23/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/09/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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-efficacy 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-Efficiency-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

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)

Sponsor details

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Sponsor type

Research organisation

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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