

Focal psychodynamic psychotherapy, cognitive-behavioural therapy and treatment as usual in outpatients with anorexia nervosa

Submission date 23/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/05/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2013	Condition category Mental and Behavioural Disorders	<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

Protocol serial number
01GV0624

Study information

Scientific Title

Acronym

ANTOP (Anorexia Nervosa Treatment of OutPatients)

Study objectives

Compared to treatment as usual, both specific manualised psychotherapeutic outpatient interventions show a significantly better outcome in gain in body mass index (BMI) at the end of treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board of the Faculty of Medicine, University Hospital Tuebingen, approved on 21/02/2007 (ref: 440/2006)

Study design

Multicentre prospective randomised superiority trial with 3 parallel arms

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anorexia nervosa

Interventions

Participants will be randomised into one of the three arms:

1. Focal psychodynamic psychotherapy: 40 outpatient individual therapy sessions over 10 months according to a manual
2. Cognitive-behavioural therapy: 40 outpatient individual therapy sessions over 10 months according to a manual
3. Treatment as usual (control intervention): Patients are provided with a list of local psychotherapists

They will be assessed at the study centre after 4 and 10 months and at 13-month follow-up. GP consultation once a month.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current information as of 04/02/2009:

Body mass index (BMI) at the end of the treatment (10 months after randomisation; T2). In the statistical analysis, the BMI at T2 will be adjusted for the baseline BMI at T0.

Initial information at time of registration:

Individual changes in BMI between beginning and end of treatment, assessed at 4 and 10 months and at 13-month follow-up.

Key secondary outcome(s)

1. Morgan-Russell criteria
2. General psychopathology
3. Eating disorders psychopathology
4. Depression (Structured Clinical Interview for DSM-IV [SCID-I], Structured Inventory for Anorexic and Bulimic Syndromes [SIAB-EX], PHQ-D [The "Patient Health Questionnaire"])
5. Quality of life (the 36-item Short Form health survey [SF-36])

Added as of 04/02/2009:

6. Process measure: therapeutic alliance (Helping Alliance Questionnaire [HAQ])

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Anorexia nervosa (AN) and subsyndromal AN (lacking 1 diagnostic criterion according to Diagnostic and Statistical Manual of Mental Disorders [DSM] IV such as amenorrhoea or body image disturbance)
2. Female
3. Aged 18 years or older
4. Body mass index (BMI) between 15.0 and 18.5 kg/m²
5. Signed consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Current substance abuse
2. Current neuroleptic medication
3. Current suicidal ideation
4. Psychotic disorder
5. Bipolar disorder
6. Serious unstable medical problems
7. Primary somatic illness
8. Pregnancy or lactation
9. Ongoing psychotherapy
10. Participation in other trials

Date of first enrolment

01/10/2006

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Germany

Study participating centre

University Hospital Tuebingen

Tuebingen

Germany

72076

Sponsor information

Organisation

German Federal Ministry of Education and Research (BMBF) (Germany)

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (BMBF) (Germany)

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	11/01/2014		Yes	No
Protocol article	protocol	23/04/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes