

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

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

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.medizin.uni-tuebingen.de/psychosomatik/>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

**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 measure**

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.

### **Secondary outcome measures**

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])

### **Overall study start date**

01/10/2006

### **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/m<sup>2</sup>
5. Signed consent form

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

237

**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)

## Sponsor details

Deutsches Zentrum für Luft- und Raumfahrt (DLR) e.V.

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## Sponsor type

Government

## ROR

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

## Funder(s)

### Funder type

Government

### Funder Name

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

## 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?
<a href="#">Protocol article</a>	protocol	23/04/2009		Yes	No
<a href="#">Results article</a>	results	11/01/2014		Yes	No