

Trial Description

Title

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

Trial Acronym

ANTOP (Anorexia Nervosa Treatment of OutPatients)

URL of the trial

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

Brief Summary in Lay Language

Anorexia nervosa is a serious eating disorder leading to high morbidity and mortality as a result of both malnutrition and suicide. The seriousness of the disorder requires extensive knowledge of effective treatment options. However, evidence for treatment efficacy in this area is remarkably weak. The aim of the so-called ANTOP study is to examine the efficacy of two manualised outpatient treatments for patients with anorexia nervosa - focal psychodynamic and cognitive behavioral therapy - as compared to treatment as usual, reflecting the general German psychotherapy guidelines.

Brief Summary in Scientific Language

Showing the highest mortality rate of all psychiatric disorders, anorexia nervosa (AN) has not lost its relatively poor prognosis in the 21st century. Because of the scarcity of randomized intervention studies with sufficient power and adequate evaluation of outcome no definite conclusion as to the impact of treatment on the long-term course of the illness can be made. This study represents the first multisite outpatient intervention trial on adults with AN. Its purpose is to examine the efficacy of two manualized psychotherapeutic outpatient treatments for patients with AN, based on either focal psychodynamic (FPT) or cognitive-behavioral therapy (CBT), in comparison to treatment as usual (TAU).

Organizational Data

- DRKS-ID: **DRKS00000079**
- Date of Registration in DRKS: **2009/03/13**
- Date of Registration in Partner Registry or other Primary Registry: **2007/05/01**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **440/2006** , **Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

- Primary Registry-ID: **ISRCTN72809357 (Current Controlled Trials)**
- Sponsor-ID: **01GV0624 (BMBF)**

Health condition or Problem studied

- ICD10: **F50.0 - Anorexia nervosa**
- ICD10: **F50.1 - Atypical anorexia nervosa**

Interventions/Observational Groups

- Arm 1: **Focal psychodynamic psychotherapy, 40 individual outpatient session over 10 months**
- Arm 2: **Cognitive-behavioural therapy, 40 individual outpatient sessions over 10 months**
- Arm 3: **Treatment as usual**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

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

Secondary Outcome

1. Morgan-Russell criteria

2. **General psychopathology**
3. **Eating disorder psychopathology**
4. **Depression**
5. **Quality of life**
6. **Process measure: therapeutic alliance**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/05/14**
- Target Sample Size: **237**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional 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 amenorrhea 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**

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 psychotherapy trials**

Addresses

■ Primary Sponsor

**Medizinische Fakultät der Eberhard-Karls-Universität Tübingen
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ Contact for Scientific Queries

**Abteilung für Psychosomatische Medizin und Psychotherapie
Innere Medizin VI
Universitätsklinikum Tübingen
Ms. Dr. rer. nat. Gaby Groß
Osianderstr. 5
72076 Tübingen
Germany**

Telephone: **+49 7071/29-86719**

Fax: **+49 7071/29-4541**

E-mail: **[gaby.gross at med.uni-tuebingen.de](mailto:gaby.gross@med.uni-tuebingen.de)**

URL: **www.psychosomatik-tuebingen.de**

■ Contact for Public Queries

**Abteilung für Psychosomatische Medizin und Psychotherapie
Innere Medizin VI
Universitätsklinikum Tübingen
Ms. Dr. rer. nat. Gaby Groß
Osianderstr. 5
72076 Tübingen
Germany**

Telephone: **+49 7071/29-86719**

Fax: **+49 7071/29-4541**

E-mail: **[gaby.gross at med.uni-tuebingen.de](mailto:gaby.gross@med.uni-tuebingen.de)**

URL: **www.psychosomatik-tuebingen.de**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**BMBF: Bundesministerium für Bildung und Forschung
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: <http://www.bmbf.de/index.php>

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Paper **Gross G, Teufel M, Giel K, de Zwaan M, Zipfel S. Manual zur kognitiven Verhaltenstherapie bei Anorexia nervosa. Unpublished Manuscript (version of 24th April 2007).**
- Paper **Schauenburg H, Friederich HC, Wild B, Zipfel S, Herzog W. Fokale Psychodynamische Psychotherapie (FPT) der Anorexia nervosa - ein Behandlungsmanual. Psychotherapeut (in press).**
- Paper **Wild B, Friederich HC, Gross G, Teufel M, Herzog W, Giel K, de Zwaan M, Schauenburg H, Schade-Brittinger C, Schaefer H, Zipfel S. The ANTOP study: focal psychodynamic psychotherapy, cognitive-behavioral therapy, and treatment as usual in outpatients with anorexia nervosa - a randomized controlled trial. Submitted to Trials (in revision).**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.