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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

Registration date
01/05/2007

Overall study status
Completed

Last Edited
25/10/2013

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Not provided at time of registration

Study website
http://www.medizin.uni-tuebingen.de/psychosomatik/

Contact information

Type(s)
Scientific

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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 hypothesis
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

Condition
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 willl 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

Overall study end date
31/12/2009

Eligibility

Participant 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^2
5. Signed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
237

Participant 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

Recruitment start date
01/10/2006

Recruitment end date
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?
Protocol article	protocol	23/04/2009		Yes	No
Results article	results	11/01/2014		Yes	No