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Treatment of childhood and adolescent anorexia nervosa: day treatment versus inpatient treatment

Submission date
31/07/2006

Recruitment status
No longer recruiting

Registration date
18/01/2007

Overall study status
Completed

Last Edited
17/03/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anorexia nervosa is a serious mental health condition where a person keeps their body weight as low as possible. There are very few studies exploring the effectiveness of treatment setting in adolescent anorexia nervosa. The aim of this study is to compare inpatient treatment with day patient treatment after short inpatient medical stabilization.

Who can participate?
Adolescent girls aged between 11 and 18 at first admission to hospital treatment for anorexia nervosa

What does the study involve?
All participants are first admitted to inpatient treatment for the first three weeks of the study. After completing this three-week stabilization period, participants are randomly allocated to either continued inpatient treatment or day patient treatment. Both day treatment and inpatient treatment include medical management as required, physiotherapy, occupational therapy, nutritional counseling, nutritional therapy (e.g. eating according to a plan, model eating, eating in a restaurant, guided family meals), weight management with a behavioural program to support weekly weight gain up to a target weight, group therapy for eating disorders, individual psychotherapy (Cognitive-Behavioural Therapy [CBT]), and family-based therapy. To assure safety, all participants are assessed twice a week by physicians who are experienced in the complications associated with adolescent AN.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Universitätsklinikum Aachen (Germany)

When is the study starting and how long is it expected to run for?
October 2006 to October 2012

Who is funding the study?
Federal Ministry of Education and Research (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Treatment of childhood and adolescent Anorexia Nervosa: Day treatment versus Inpatient treatment

Acronym
ANDI

Study objectives
The effect of 12 weeks of day patient treatment is not different (non-inferior) from inpatient treatment of the same length in terms of weight gain after one year concerning adolescents with non-chronic Anorexia Nervosa (AN).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Ethik-Kommission at the Medical Faculty of the Rheinisch-Westfälischen Technischen Hochschule Aachen [RWTH Aachen]), 24/01/2007, ref: 127/06

Study design
Multicentre prospective randomised non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Day treatment and inpatient treatment includes:
1. Medical management as required
2. Physiotherapy
3. Occupational therapy
4. Nutritional counselling
5. Nutritional therapy (e.g. eating according to a plan, model eating, eating in a restaurant, guided family meals)
6. Weight management with flexible operant conditional behavioural program to support a weekly weight gain of 500-1000 gr/week up to the achievement of target weight (15 to 20th Body Mass Index [BMI] percentile)
7. Group therapy for eating disorders
8. Individual psychotherapy psychotherapy (Cognitive-Behavioural Therapy [CBT])
9. Family-based therapy

Outpatient treatment includes:
1. Re-admission contract
2. One to two weekly individual psychotherapy including weight management and nutritional counselling (anorexia nervosa oriented CBT according to the evaluated manual-based outpatient program from Pike et al. 2003 adapted to adolescents)
3. Four-weekly family-based interventions (one hour/session) until week 52 (one-year follow-up)

Added 23/07/2010:
As of the above update date, a new follow-up was added to this record; patients will now also be followed-up in week 130 (1.5 years after the primary outcome).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 05/02/2013:
Difference between BMI at admission, after one year and after two and a half years. Discontinuation of day treatment will be penalised appropriately. All treatment studies of AN have investigated weight gain during treatment and weight gain and weight maintenance after achievement of a target weight as major goals in the treatment of AN (e.g. British, American and German guidelines). BMI can be easily and objectively assessed even by general practitioners in case of relocations.

Previous primary outcome measures until 05/02/2013:
Difference between BMI after one year and at admission. Discontinuation of day treatment will be penalised appropriately. All treatment studies of AN have investigated weight gain during treatment and weight gain and weight maintenance after achievement of a target weight as major goals in the treatment of AN (e.g. British, American and German guidelines). BMI can be easily and objectively assessed even by general practitioners in case of relocations.

Secondary outcome measures
Current secondary outcome measures as of 05/02/2013:
The clinical claim in favour of day treatment will only be supported in the case of the rejection of the null hypothesis based on the primary outcome measure. However, due to limited follow-up time, even in this case additional outcome variables will be analysed to support the clinical claim.

The descriptive outcome measures comprise:
1. Difference between BMI after one year and at admission
2. Morgan-Russell criteria
3. BMI percentile
4. Improvement of eating disorder psychopathology (self report: Eating Disorder Inventory - 2 [EDI-2], structured interview: SIAB)
5. Depressive symptoms (patients: Depressionsinventar für Kinder und Jugendliche [Depression Inventory for Children and Adolescents] [DIKJ], parents: Beck Depression Inventory [BDI])
6. Obsessive-compulsive symptoms (Childrens Yale-Brown Obsessive Compulsive Scale [CY-BOCS])
7. General psychopathology (Symptoms CheckList [SCL-90-R56])
8. Burden of parents (Brief Symptom Inventory [BSI])

At one-year follow-up additionally:
1. The number of relapses (hospitalisations)
2. Quality of life
3. Days of hospital treatment upon achievement of target weight

At two and half-year follow-up:
1. The number of relapses (hospitalisations)

2. Quality of life
3. Days of hospital treatment upon achievement of target weight
4. Treatment satisfaction

All psychometric outcome measures will be derived from validated and internationally used questionnaires and interviews.

Previous secondary outcome measures until 05/02/2013:
The clinical claim in favour of day treatment will only be supported in the case of the rejection of the null hypothesis based on the primary outcome measure. However, due to limited follow-up time, even in this case additional outcome variables will be analysed to support the clinical claim.

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At one-year follow-up additionally:
1. The number of relapses (hospitalisations)
2. Quality of life
3. Days of hospital treatment upon achievement of target weight

All psychometric outcome measures will be derived from validated and internationally used questionnaires and interviews.

Overall study start date
01/10/2006

Completion date
31/10/2012

Eligibility

Key inclusion criteria
Amendments as of 23/07/2010:
As of the above date, point one below was updated as follows:
1. Female patients between 11 and 18 years

Initial information at time of registration:
1. Female patients between 12 and 18 years
2. At first admission to hospital treatment for AN according to Diagnostic and Statistical Manual of mental disorders - fourth edition (DSM-IV) criteria as assessed by the Structured Interview for Anorexic and Bulimic disorders (SIAB) (Fichter et al. 1998)

3. Reasonable distance from residence to hospital: less than 60 minutes by bus/train
4. Written informed consent of the patient and - if necessary - of her legal guardian
5. All patients have passed a somatical stabilisation of three weeks in an inpatient setting prior to randomisation

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Female

Target number of participants
176 recruited in six hospitals

Key exclusion criteria
1. Any psychotic or personality disorder
2. Current alcohol or other substance abuse disorder
3. Self-injury behaviours as assessed by a structured diagnostic interview (Kiddie-Schedule for Affective Disorders and Schizophrenia [SADS], Delmo et al. 2001)
4. Insufficient ability to understand German (patients and parents)
5. Intelligence Quotient (IQ) less than 85

Date of first enrolment
01/10/2006

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Aachen
Aachen
Germany
52074

Sponsor information

Organisation
German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

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Sponsor type
Government

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ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
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?
Results article	results	15/11/2013		Yes	No
Results article	results	05/04/2014		Yes	No