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The Gothenburg anorexia nervosa treatment study

Submission date
25/06/2015

Recruitment status
No longer recruiting

Registration date
21/07/2015

Overall study status
Completed

Last Edited
13/11/2019

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 the most serious eating disorder, is relatively rare and mostly affects young women. Despite anorexia nervosa being well-known few research studies has been conducted. We compare two types of psychotherapy, individual and family therapy for young adults between 17-24 years of age. Our aim is to study which treatment is most effective for whom.

Who can participate?
Women aged 17-25 with anorexia nervosa.

What does the study involve?
All patients underwent a medical examination and the treatment lasted for 18 months at an outpatient unit in Gothenburg, Sweden. Participants were randomly allocated to either individual or family therapy. In individual therapy the patient meets one psychotherapist for 60 minutes once a week during 60 sessions. In family therapy the patient and parents meet two psychotherapists for 90 minutes once a week for 40 sessions. All therapists follow a treatment manual. All patients and parents were interviewed with questionnaires before the start of treatment and after 18 and 36 months.

What are the possible benefits and risks of participating?
One benefit of participating is that we follow the patients' progress during three years and offer research-based psychotherapy with experienced psychotherapists at a specialist eating disorder unit. In case no progress is achieved or a medical risk emerges, we can always consider day or inpatient care at our unit.

Where is the study run from?
Queen Silvia Children's Hospital (Sweden).

When is the study starting and how long is it expected to run for?
From January 2006 to September 2015.

Who is funding the study?
Vardal Foundation (Sweden).

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The Gothenburg anorexia nervosa treatment study - a randomized control trial comparing individual cognitive behavioral therapy (I-CBT) and family therapy (FT) for young adults with anorexia nervosa

Study objectives
Family Therapy (FT) for young adults with anorexia nervosa will be superior to Individual Cognitive Behavioral Therapy (I-CBT) in producing greater weight-gain and greater improvement in eating-disorders related psychopathology in adults with anorexia nervosa (AN).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of Gothenburg, Sweden, 06/04/2005, ref: 123-05

Study design
Single-centre randomized control trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Individual Cognitive Behavioral Therapy (I-CBT) aims to target specific factors related to the eating disorder psychopathology that are involved in the development and maintenance of the disorder. The treatment is manual based and tailored for each patient regarding attitudes and behaviors associated with weight, shape and eating control and general psychopathology such as perfectionism, low self- esteem and interpersonal problems. The treatment consists of a maximum of 60 one-hour sessions divided into three phases over 18 months. Phase 1 focuses on alliance, motivation and treatment formulation and includes two 60-minute sessions per week for four weeks. One family session is included for the purpose of educating about eating disorders and its consequences and how the family can support the patient. Phase 2 lasts for a year with one session per week targeting the psychopathology of the eating disorder in order to change the dysfunctional thoughts and behaviors related to eating, body image and weight.

Family Therapy (FT) for young adults focuses on restoring a normal body weight and establishing functional family relations. The treatment is based on the Maudsley model with the basic stance that the patient is part of its family of origin and that the parents' participation in treatment is very important for a successful outcome. The FT is a manual-based treatment with a maximum of 40 90-minute sessions divided into three phases: a weekly session for the first ten weeks focuses on parents and how they can help their child to eat, which transfers to the second phase that sums up the achievements and establishes the further treatment in two sessions. Phase three includes 23 sessions, one every second to third week, where the aim is to give the patient more responsibility for their own weight restoration and development. The last phase starts when a normal body weight is achieved and the focus is on relationships and establishing a functional family.

Intervention Type
Behavioural

Primary outcome(s)
1. Body Mass Index (BMI)
2. The Rating of Anorexia and Bulimia Interview-revised version (RAB-R) is a Swedish semi-structured interview for clinical and research purposes for a wide range of eating disorder symptoms and related psychopathology through which the patient receives a DSM-IV diagnosis.

All patients/parents were recruited consecutively and measured at baseline (after 2 weeks for treatment credibiltiy, Weaver), at 18 months and at 36 months after treatment start (baseline).

Key secondary outcome(s))
1. Eating Disorder Inventory-3 (EDI-3)
2. Beck's depression Inventory (BDI)
3. Family Relation Scale (FARS)
4. Inventory of Interpersonal Problems (IIP)
5. Eating Disorder Expectations and Experiences (EDPEX)
6. Body Shape Questionnaire (BSQ)
7. Treatment Credibility
8. Visual Analoge Scale regarding Parental burden (VAS)
9. Rosenberg Self- Esteem Scale (RSE)
10. Treatment Satisfaction Scale (TSS)
11. Background questionnaire

All patients/parents were recruited consecutively and measured at baseline (after 2 weeks for treatment credibiltiy, Weaver), at 18 months and at 36 months after treatment start (baseline).

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Confirmed AN diagnosis
2. Accepting both treatment models
3. Age 17-25
4. Woman
5. Written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment

Key exclusion criteria
1. If inpatient treatment is required
2. Serious personality disturbances
3. Serious suicidal risk
4. Drug dependence
5. Chaotic social situation
6. Present psychotherapeutic/psychopharmacological treatment

Date of first enrolment
01/01/2006

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Anorexia and Bulimia Unit, Child and Adolescent Psychiatry Centre
Queen Silvia Children's Hospital
Gothenburg
Sweden
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Sponsor information

Organisation
Anorexia and Bulimia Unit, Child and Adolescent Psychiatry Centre

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Research organisation

Funder Name

Vardal Foundation (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	13/11/2019	Yes	No