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Treating bulimia nervosa in female adolescents with either cognitive-behavioral therapy (CBT) or psychodynamic therapy (PDT)

Submission date
27/01/2017

Recruitment status
No longer recruiting

Registration date
03/02/2017

Overall study status
Completed

Last Edited
27/03/2017

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
Bulimia nervosa is an eating disorder, where a person overeats (binges) and then tries to remove the food quickly by vomiting or using laxatives (purges). Bulimia is considered a mental health condition and is linked to low self-esteem, obsession with weight and food, depression and self-harm. Bulimia can affect anyone but it is more common in women and especially in teenage girls. The common way of treating bulimia nervosa is through cognitive behavioral therapy (CBT) a type of talking therapy which works on changing thoughts and behavior. However other treatments such as psychodynamic therapy (PDT), a type of talking therapy focusing on the emotional state, feelings and perceptions, could help treat the bulimia just as well or even better. However, there are no studies showing how well these treatments work with teenagers and young adults. The aim of this study is to compare these two treatments to see how well they help teenage girls reduce eating disorder symptoms and improve their mental health.

Who can participate?
Females aged 14-20 years old who are diagnosed with bulimia nervosa.

What does the study involve?
Participants are randomly allocated to one of two groups to receive 60 sessions of treatment over 12 months. Those in the first group receive CBT. This involves five phases that explore reasons for the disorder, educate about mental health, promote healthy behaviors and relationships, discuss fears about weight, eating and body shape, trains on social skills, problem solving and preventing relapsing. Those in the second group receive PDT. This involves three phases that helps participants understand the disorder affects their mind and emotional state, increasing awareness of emotional and social meanings of the symptoms, and helps apply strategies learned in the program to difficult situations. Participants are followed up 6 and 12 months after the intervention to assess their symptoms and overall mental health.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in eating disorder symptoms. There are no direct risks of participating.

Where is the study run from?
Department of Psychiatry University Hospital of Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
May 2006 to July 2013

Who is funding the study?
Association of psychoanalytic child- and adolescent-psychotherapists (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled multi-center study for treating bulimia nervosa in female adolescents with cognitive-behavioral therapy (CBT) versus psychodynamic therapy (PDT)

Study objectives
Manualized cognitive-behavioral therapy (CBT) and manualized psychodynamic therapy (PDT) are both effective in reducing symptoms of bulimia nervosa. In comparison, CBT would result in higher remission rates at the end of therapy than PDT does.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Medical Faculty of the University of Heidelberg, 25/10/2006, ref: 283 /2006
2. Ethics Committee of the University of Medicine Göttingen, 19/09/2006, ref: 19/9/06

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files (in German)

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

Interventions
Participants are randomly assigned to receive one of two treatments using block randomization, which was conducted by a research assistant who was not involved in the diagnostic procedures or outcome evaluation.

Manualized cognitive-behavioral therapy (CBT) group: This group receives 60 sessions of CBT over 12 months. This therapy is mainly based on Fairburn's manual for treating eating disorders and its extensions for perfectionism, low self-esteem and interpersonal problems but was modified to adhere to the treatment volume of this study. It is the established treatment for adolescents with this condition. It includes five phases:
Phase 1: Focuses on exploring problematic behavior, educating patients about the disorder and the rationale for treatment. This motivates participants by building a reliable working relationship.
Phase 2: Focuses on correcting disordered eating behavior and reducing purging behavior through eating protocols and education about body mass index (BMI) and the physiological processes associated with eating.
Phase 3: The patient and therapist assess and work on dysfunctional cognition and fears concerning eating, weight and body shape.
Phase 4: In addition to the focus and strategies introduced in phases 1-3, this phase focuses on training in social skills, affect regulation and problem solving, as needed, to address the problems underlying and associated with the eating disorder.

Phase 5: Primarily addresses relapse prevention. Patients' autonomy and self-efficacy in regulating eating behavior are stressed, problematic situations are anticipated, and patients choose skills they found helpful during therapy to prepare for these critical situations.
In phases 1-4, one or two sessions per phase are held with significant others, and is an option in phase 5.

Manualized psychodynamic therapy (PDT) group: This group receives 60 sessions of PDT over 12 months. This program is developed specifically for adolescents and young adults with bulimia nervosa. It includes three phases:
Phase 1: Therapists build good working relationships with patients, frames the disorder in psychodynamic terms and helps patients understand bulimic symptoms as a displacement from psychological self to body self. Consensus regarding the conflicts and deficits that the participants intend to overcome to improve their bulimic behavior must be established. Bulimic symptoms are contextualized and targeted according to the participants' conflicts and ego-structural deficits. The involvement of significant others in treatment is discussed with the patient and adapted to the patient's needs.
Phase 2: The patient and therapist work on foci that are part of the overall therapeutic aim, as defined in the initial phase. In PDT, the topics typically highlighted include typical patterns of interpersonal relationships, transference, conflict, defense and structural problems, and these issues are worked through while explicitly addressing bulimic symptoms. In this phase, special attention is paid to implementing alternative behaviors and associated problems and improving self-monitoring and introspection, shame and guilt, perfectionism, and symptoms serving as defense and coping mechanisms. Patients are encouraged to develop an increased awareness of the emotional and social meaning of symptoms, the functionality of symptoms, and the symbolic nature of their actions.
Phase 3: Consolidates the essential aspects of therapy, and patients should be able to identify and thus anticipate difficult situations and apply the strategies learned in therapy. Another important feature of this final phase is valuing the progress that has been attained and accepting disappointments.

Participant's eating disorder symptoms and mental health are assessed at baseline, 15th session, 30th session, 45th session, and end of therapy. Participants are followed-up at 6 and 12 months post-treatment to evaluate their mental health and eating disorder symptoms.

Intervention Type
Behavioural

Primary outcome measure
Severity of the eating disorder is assessed by the German version of EDE 27 at baseline, session 15, 30, 45 and 60 (end of therapy) and 6 and 12 months post-treatment.

Secondary outcome measures
1. Self-evaluated psychopathologies of the eating disorder is measured using the EDE Questionnaire (EDE-Q) at baseline, session 15, 30, 45 and 60 (end of therapy) and 6 and 12 months post-treatment
2. Overall severity of mental symptoms is assessed using the Symptom Check List (SCL-90-R) at baseline, session 15, 30, 45 and 60 (end of therapy) and 6 and 12 months post-treatment

Overall study start date
01/05/2006

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Females between the age of 14 and 20 years old
2. Diagnosis of bulimia nervosa according to the critieria in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV)
3. Diagnosis of partial bulimia nevosa which includes participants who binged and purged less than two times per week in three months

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
A minimum of 70 participants with 35 participants for CBT and PDT respectively

Key exclusion criteria
1. Diagnosis of anorexia nervosa
2. Other severe physical or mental conditions such as current psychosis, alcohol or drug abuse or addiction, suicidal, and attention deficit hyperactivity disorder (ADHD)
3. An IQ<80
4. Current psychotherapeutic or psychotropic treatment

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital of Heidelberg
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69115

Study participating centre
Institute for Analytic Child and Adolescent Psychotherapy Heidelberg
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Study participating centre
Georg-August-University Goettingen
Clinic of Psychosomatic Medicine and Psychotherapy
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Study participating centre
University of Heidelberg
Center of Psychological Psychotherapy, Institute for Psychology
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Study participating centre
University of Goettingen
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Sponsor information

Organisation

VAKJP / Association of psychoanalytic child- and adolescent-psychotherapists in Germany

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Sponsor type
Other

ROR
https://ror.org/02r08m051

Funder(s)

Funder type
Government

Funder Name
Vereinigung Analytischer Kinder- und Jugendlichen-Psychotherapeuten

Alternative Name(s)
VaKJP

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication of outcome data is JAACAP in March 2017. Further publications such as manuals are planned by December 2017.

Intention to publish date
01/03/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		31/01/2017	03/02/2017	No	Yes
Participant information sheet		31/01/2017	03/02/2017	No	Yes
Results article	results	01/04/2017		Yes	No