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Cognitive behaviour therapy versus psychoanalytic psychotherapy for bulimia nervosa

Submission date	Recruitment status	[ ] Prospectively registered
02/12/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/05/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/07/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims?
The purpose of the study is to compare two different psychological treatments for the eating disorder Bulimia Nervosa. The aim is to find out which of the two treatments are most helpful to persons with Bulimia Nervosa. In Denmark, eating disorders have traditionally been treated with psychotherapy. More recently, another treatment method known as cognitive behavior therapy has become increasingly used in the treatment of eating disorders. Cognitive behavior therapy is a focused, symptom-oriented treatment method lasting 20 weeks with sessions twice a week for the first three weeks and bi-weekly for the last three weeks. Several studies have demonstrated that cognitive behavior therapy has a beneficial impact on Bulimia Nervosa. Psychotherapy, which comprises weekly sessions over two years, is oriented toward more fundamental aspects of the personality and focuses less directly on the bulimic symptoms. This is considered a promising treatment, however, it has not been researched thoroughly with regard to Bulimia Nervosa. Thus, it is not possible to tell in advance, which of the two methods are the most efficient.

Who can participate?
All in all, 70 persons will participate. To participate you must be diagnosed with Bulimia Nervosa. Furthermore, participants must be available for the whole two-year treatment period. Although it is possible to participate in the study while in psychopharmacological treatment, the study does not apply for persons with serious psychiatric disorders such as for instance severe depression.

What does the study involve?
In addition to participation in the psychotherapeutic treatment, the study involves a number of assessment interviews before beginning treatment as well as 6 and 24 months after beginning treatment. Additionally, participants will be asked to fill out a number of questionnaires every six months for the first three and a half years after beginning treatment and again five years after beginning treatment.

What are the possible benefits and risks of participating?
The benefits of the study are a reduction or end to bulimic symptoms. There are no known negative side effects related to the treatments.

Where is the study run from?
All assessment interviews will be undertaken at the University Clinic, Department of Psychology, University of Copenhagen. Some of the psychotherapeutic treatments will take place at the University Clinic whereas others will take place with psychologists and psychiatrists in private practice in central Copenhagen.

When is the study starting and how long is it expected to run for?
The study begins in November 2004 and will continue to recruit participants until May 2008. Accordingly, we expect the final data of the study to be collected in May 2013.

Who is funding the study?
Danish Research Council for the Humanities and the Egmont Foundation

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

9901684/25-01-0011 (Danish Council for Independent Research, 41470 (Egmont Foundation), 07018005 (Ivan Nielsen Foundation)

Study information

Scientific Title
Cognitive behaviour therapy versus psychoanalytic psychotherapy for bulimia nervosa: a randomised, observer blinded clinical trial

Study objectives
1. After 20 weeks of therapy in an intent-to-treat analysis the percentage of both recovered and remitted patients will be the same after cognitive behavior therapy (CBT) as after psychoanalytic psychotherapy (PPT).
2. At the end of each treatment (20 weeks after the start of CBT / 2 years after the start of PPT) the percentage of both recovered and remitted patients will be the same after CBT as after PPT.
3. Two years after the start of the treatment in an intent-to-treat analysis the per-centage of both recovered and remitted patients will be the same after CBT as after PPT
4. At follow-up 2½, 3½, and 5 years after the start of the treatment in an intent-to-treat analysis the percentage of both recovered and remitted patients will be the same after CBT as after PPT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, Capital Region of Denmark, 21/03/2004

Study design
Single-centre randomised parallel-group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Bulimia Nervosa (DSM-IV-TR)

Interventions

1. Psychoanalytic psychotherapy, weekly sessions for two years (approximately 90 sessions)
2. Cognitive behavior therapy, 21 sessions over approximately 20 weeks

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Recovery from bulimia nervosa, defined as no binge eating or purging during the previous 28 days assessed with the Eating Disorder Examination (Fairburn & Cooper, 1993)
2. Remission of the bulimic symptoms, defined as binge eating and purging less than twice per week over the last 28 days (i.e. below the DSM-IV frequency threshold) assessed with the Eating Disorder Examination (Fairburn & Cooper, 1993)

Secondary outcome measures
Symptom measures
1. Symptom Checklist-92 (SCL-92) (Derogatis, 1983; Derogatis & Lazarus, 1994)
2. Beck Depression Inventory (BDI) (Beck et al., 1961)
3. State-Trait Anxiety Inventory (STAI) (Spielberger, 1983)
4. Target complaints (TC) (Battle et al., 1966; Mintz & Kiesler, 1982)

Personality measures
1. Defense Style Questionnaire-40 (DSQ-40) (Bond et al., 1983)
2. Inventory of Interpersonal Problems (IIP) (Horowitz et al., 1988)
3. Inventory of Personality Organization (IPO) (Lenzenweger et al., 2001)
4. Adult Attachment Interview (AAI) (George et al., 1985; Main & Goldwyn, 1998)
5. Reflective-Functioning Scales (Fonagy et al., 1998)

Overall study start date
08/11/2004

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Age > 17 years
2. Patient fulfilling the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for bulimia nervosa
3. The patient has signed written informed consent before randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Concurrent ICD-10 diagnosis within the categories F00-31 (organic disorders, substance-related disorders, disorders of the schizophrenic spectrum, manic and bipolar disturbances), F32.1, 32.2, 32.3, 33.1, 33.2 and 33.3 (moderate and severe depression)
2. Concurrent ICD-10 diagnosis within the categories F40-49 (anxiety disorders, dissociative disorders, somatoform disorders), if the disorder is judged to be a major obstacle to the psychotherapeutic treatment of bulimia
3. Alcohol dependency or abuse of psychoactive substances
4. Concurrent somatic illness which will be a major obstacle to the psychothera-peutic treatment
5. Pregnancy or plans interfering with the treatment such as longer travels
6. Inability to speak and/or understand Danish

Date of first enrolment
08/11/2004

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
Denmark

Study participating centre
University of Copenhagen
Copenhagen K
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DK-1353

Sponsor information

Organisation
Danish Council for Independent Research (Denmark)

Sponsor details
Humanities
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Sponsor type
Government

Website
http://en.fi.dk/councils-commissions/the-danish-council-for-independent-research/scientific-research-councils/humanities

ROR
https://ror.org/02sptwz63

Funder(s)

Funder type
Government

Funder Name
Danish Council for Independent Research, Humanities (Denmark) ref: 9901684/25-01-0011

Funder Name
Egmont Foundation (Denmark) ref: 41470

Funder Name
Ivan Nielsen Foundation (Denmark) ref: 07018005

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