

Cognitive behaviour therapy versus psychoanalytic psychotherapy for bulimia nervosa

Submission date 02/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/05/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/07/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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 percentage 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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 psychotherapeutic 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

Denmark

DK-1353

Sponsor information**Organisation**

Danish Council for Independent Research (Denmark)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration