Treatment of bulimia nervosa and eating disorders not otherwise specified: Cognitive Behaviour Therapy versus Cognitive Therapy

Published: 25-03-2009
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The goal of this study is to learn whether:The above described CBT according to protocol is more effective than CT according to protocol without behavioral interventions (binge cue exposure with respons prevention and body exposure including...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eating disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON44125

Source
ToetsingOnline

Brief title
Treatment of eating disorders

Condition

- Eating disorders and disturbances

Synonym
bulimia nervosa, eating disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive Behaviour Therapy, Cognitive Therapy, Eating disorders

Outcome measures

Primary outcome

- Specific eating psychopathology using the interview Eating Disorder Examination

- Body dissatisfaction and Body Checking (ASI-R short, EDI Body Image subscale, Body Checking Scale)

- Eating Behaviour (DEBQ and Power of Food Scale (PFS)).

- Self-esteem (RSE)

- Mood (depression, positive and negative affect) (Beck Depression's Inventory-II and PANAS; Positive and Negative Affect Schedule)

- Body Mass Index (BMI)

Secondary outcome

process variables each session:

- Positive and Negative Affect (PANAS)

- Urge to eat (VAS)

- Belief in idiosyncratic irrational cognitions (VAS)

- Anxiety to lose control about eating (VAS)

- Body loathing (VAS)

- general well-being (VAS)

process variables VM & NM:

- Personality Disorder (interview SCID-II)

- Impulsivity (inhibition capacity) (Stop Signal Task - computer)

secundary (VM, NM, FU's):

- Dichotomous Thinking (DTS)

- General Psychopathology (BSI)

- Treatment credibility (3 items)

- Treatment integrity

Study description

Background summary

Cognitive Behaviour Therapy (CBT: a therapy with components from cognitive therapy (CT) as well as behaviour therapy components (BT)) currently is the treatment of choice for bulimia nervosa (BN) and eating disorders not otherwise specified (EDNOS). CBT is the treatment of choice because it is, until now, the most effective therapy for eating disorders, in particular BN and EDNOS. There is, however, room for improvement; this (international form of) CBT ends up in a considerable improvement in about 2/3 of the patients, but in the long run 1/3 of the CBT treated patients still fulfills the criteria of an eating disorder, although often a more mild eating disorder. Based on our experimental studies we developed a new CBT taking maintenance models for binge eating and body dissatisfaction that are empirically supported as a starting point. The C of CBT is the cognitive therapy that is succesfully provided for years in the adults care unit (VZK) of the RIAGG Maastricht. The B includes exposure in two forms: 1) exposure to binge eating cues with response prevention (no binge, no eating), and 2) body exposure with attention retraining. The new CBT is a combination of cognitive interventions with exposure interventions. Based on our experience and earlier research data as well, we expect the gradual exposure to binge cues leading to a prompt reduction of binge frequency, soon after the start of treatment. We further expect the body exposure + attentional retraining leading to a sharp decline in body dissatisfaction. The research question is whether this new CBT is more effective than pure CT without behavioral interventions.

Study objective

The goal of this study is to learn whether:
The above described CBT according to protocol is more effective than CT according to protocol without behavioral interventions (binge cue exposure with respons prevention and body exposure including attention reallocation training).

Study design

This study is a randomised clinical trial (open trial).

Intervention

The intervention consists of 16 sessions cognitive treatment (CT) or 16 sessions cognitive behavioral treatment (CBT). Each session lasts 60 minutes. In the CT and CBT homework will be assigned (completing 'thought' diaries and doing behavioral experiments). The homework will cost about 15 - 30 minutes a day, 5 days a week.

Study burden and risks

Participants do not run any risk. Participation takes time (completion of questionnaires, participation in interviews and performing a computer task). The research participation takes about 13 to 14 hours over 1,5 years. According to the researchers this is acceptable considering the research question and anticipated answers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosis Bulimia Nervosa (BN) or Eating Disorder Not Otherwise Specified (EDNOS - bulimic subtype) according to DSM-IV (APA, 1994)
2. BMI between 18 en 30
3. sex: female
4. age: between 18 and 40 years

Exclusion criteria

1. A primary Axis-1 diagnosis other than eating disorders (eating disorder should be the primary diagnosis)
2. BMI < 18, BMI > 30
3. Anorexia Nervosa
4. Simultaneous other treatment for psychopathology
5. IQ less than 80
6. Not able to speak and/ or write Dutch
7. Acute danger of suicide
8. Alcohol- and/or drug use that requires a first treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2010
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-02-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2016
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27127
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL17291.068.07
OMON	NL-OMON27127