Toward a More Effective Treatment of Obesity: A RCT on Emotional Eating Reduction by Dialectical Behaviour Therapy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36670

Source
ToetsingOnline

Brief title
Treatment of Obesity by Dialectical Behaviour Therapy

Condition

- Other condition
- Eating disorders and disturbances

Synonym
Obesity, overweight / eating disorders

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Binge Eating Disorder, Dialectical Behaviour Therapy, Emotional eating, Obesity

Outcome measures

Primary outcome

At all six moments the following measures will be used:

- BMI, measured individually by the PhD-student

- EuroQol (The Euroqol Group, 1990), to assess the quality of life

- Dutch Eating Behavior Questionnaire (DEBQ, Van Strien, 2005): emotional,

external and restraint eating

- EDI-2-screeningslist (Van Strien, 2002): screens on eating disorders

Secondary outcome

- Eating Disorder Inventory-2 (EDI-2, Garner, 1991; Dutch translation, van

Strien, 2002): eating related and non-related

psychological traits, like interoceptive awareness and impulsivity

- Symptom Checklist-90 (SCL-90, Derogatis, 1977): psychological symptoms, like

anxiety and depression

- Utrechtse Coping List (UCL, Schreurs & Willinge, 1988): measures different

types of coping

- Toronto Alexithymia Scale (TAS, Bagby et al., 1994): difficulty identifying

feelings, difficulty describing feelings and externally

orientated thinking

- Barratt Impulsiveness Scale-30 (BIS-30, Patton, Stanford & Barratt, 1995):

attentional and motor impulsivity, as well as

non-planning

Study description

Background summary

Over half of the Dutch adult population has a Body Mass Index of 25 kg/m2 or higher (overweight or obesity) and in 14% obesity occurs (CBO, 2008). Present interventions, aimed at changes in life style, fail to result in long-lasting weight loss (Mann et al., 2007). The same holds true for behavioural treatments (Wilson, 1994), though they are associated with less short-term relapse (Werrij et al., 2009). There are important reasons to assume that weight reduction treatment can be substantially improved by paying systematic attention to emotional eating as a core characteristic of (a high proportion of) obesity. Emotional eating is eating in response to negative emotional states and as much as 40% of the obese show significant degrees of emotional eating (Van Strien, in press). The efficacy of the adapted version of DBT for eating disorders was shown in two case reports, one uncontrolled trial and two RCT*s. These last two studies however used waiting list conditions as control conditions (Chen, et al., 2008), no comparison was made with CBT. There has thus not been any direct comparison between DBT and CBT. The effectiveness of this DBT (in a Dutch translation) for reduction of body weight and emotional eating in the Netherlands was recently shown in a case-control study at GGZ Oost-Brabant (Roosen, 2008). Of course, as is well-known, the limitation of such a study is the risk on selection bias and confounding. These limitations of the scarce studies available together with the promising nature of DBT for treatment improvement of obesity led us to propose the present study.

We will examine whether the delivery of Dialectical Behaviour Therapy to obese patient with high levels of emotional eating compared to that of the treatment as usual, Cognitive Behavioural Therapy, is preferable in terms of effectiveness.

DBT is expected to result in larger decreases in BMI, emotional eating and binge eating and in larger increases in quality of life compared to CBT.

Moreover we expect that these changes will persist.
Finally, secondary beneficial psychological effects are expected, specifically reduction of levels of anxiety, depression and impulsivity and improvement of skills regarding coping with emotions.

Study objective

This study assesses the effectiveness of DBT in comparison to the effectiveness of the treatment as usual, the (standard) cognitive behavioural therapy, by using a randomised controlled design situated in the eating disorder and obesity unit of Amarum.

Based on this objective several sub-questions are relevant, such as:
1a) What are the (extra) effects (measured in BMI, and quality of life) of DBT compared to CBT?
1b) What are the (extra) effects of DBT compared to CBT in the long run?

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Finally, secondary beneficial psychological effects are expected, specifically reduction of levels of anxiety, depression and impulsivity and improvement of skills regarding coping with emotions.

Study design

Participants will be allocated at random to either of the two treatment conditions:
- Emotion regulation skills training based on the Stanford Dialectical Behaviour Therapy protocol for binge eating disorder (DBT), without a diet advice or stimulation of physical exercise. This is a systematic skills training, aimed at improving identification of feelings, mindfulness, tolerance of distress, and skills to regulation of emotions. The treatment consists of 20 sessions 2 hour group therapy and is given by two expert therapists.
- The Cognitive Behavioural Therapy (CBT) is based on the cognitive model of eating disorders. The program focuses on normalizing eating behavior, (i.e. realizing a regular eating pattern and stopping bingeing), raising body awareness, and optimizing physical movement by psycho-education, self-monitoring, self-control, cognitive restructuring as well as psychomotor therapy. It does not aim at improvement of emotion regulation skills. The treatment consists of 20 days of group therapy, and is given by a cognitive-behavioural therapist, a sociotherapist and a psychomotor therapist.

Treatments will be given by different therapists. The therapists will be self selected at Amarum (under supervision of Mirjam Lammers). Maries Roosen of the GGZ Oost-Brabant will train the therapist for the DBT. She has extensive experience with the very detailed DBT protocol and has been the principal therapists of the case-control (calorie restricted diet by dietician) for treatment of obese people with high degrees of emotional eating (Roosen, 2008).

Data-collection and random assignment to DBT or CBT takes place at Amarum by Mirjam Lammers. Data-entry and analysis of the data takes place at Radboud University Nijmegen.

Measurements take place before treatment (T1), after treatment (T2) and at four follow-up measurements (T3 at * year, T4 at 1 year, T5 at 2 years and T6 at 4 years after treatment).

Intervention

One group receives 20 sessions of grouptherapy (2 hours/week, DBT).
The other group receives 20 sessions of grouptherapy (1 day/week, CBT).

Study burden and risks

Not applicable.

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

BMI (Body mass Index; weight/height * height) between 30 and 40;
High scores on the subscale 'emotional eating' on the Dutch Eating Behavior Questionnaire (DEBQ).

Exclusion criteria

Previous CBT treatment for overweight or eating disorders, substance abuse, psychoses, suicidality, severe personality disorder and physically caused obesity, concurrent treatment for overweight or eating disorders by medical specialist or dietician and BMI (Body mass Index; weight/height * height) above 40.

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:	Recruitment stopped
Start date (anticipated):	19-01-2012
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2011
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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: 25741
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL33332.097.10