

Matched treatment of obesity in overweight patients. A randomised controlled trial. (pilot is non-randomised treatment-control study. This ABR application pertains to the pilot study)

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

Summary

ID

NL-OMON31706

Source

ToetsingOnline

Brief title

Matched treatment of obesity

Condition

- Other condition
- Eating disorders and disturbances

Synonym

obesity and eating disorders

Health condition

overgewicht

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)

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

Intervention

Keyword: DEBQ, matched treatment, Obesity

Outcome measures

Primary outcome

DEBQ: emotional, external and restraint eating

- EDI-2: eating related and non-related psychological traits
- UCL-90: coping
- SCL-90: psychological symptoms
- TAS: Toronto alexithymia scale
- EDI-II-NL Screeningslijst
- EDES
- BIS (impulsivity)
- BMI

With the exception of body weight at T2 al scales will show amelioration in comparison with control-

At T3 also weight loss in treatment group.

Secondary outcome

not applicable

Study description

Background summary

Dieting, treatment of choice for counteracting weight gain and obesity, has become controversial. At its best it is ineffective. At its worst it is damaging to health, as it may contribute to binge eating problems. Obesity is a major risk factor in the development of hypertension, cardiovascular disease and type 2 diabetes. At present 8% of the adult North American population is suffering from type 2 diabetes and the majority of these patients are obese. Since obesity is increasing world-wide, type 2 diabetes is becoming the pandemic disease of 21st century . Reduction of body weight either by diet or bariatric surgery has substantial positive effects on glycemic control and the development of diabetes. In practice however, consults with a dietician lead only in very few cases to long term loss of body weight. On the basis of a review of studies of long-term outcomes of calorie-restricting diets it was recently concluded that dieting does not lead to lasting weight loss. A similar finding was recently obtained with Dutch patients with newly diagnosed Type-2 diabetes. In spite of their high motivation for weight loss as this would positively affect their diabetes mellitus and their anti-diabetic medication, about half of them weighted even more at the 4-year follow up than they did at diagnosis .

Study objective

The present project aims at giving obese patients new opportunities to loose body weight by enabling care providers to match treatments to patients by using an evidence based matching procedure with the Dutch Eating Behaviour Questionnaire (DEBQ). The DEBQ assesses the degree of emotional eating (eating in response to negative emotions), external eating (eating in response to external food cues such as sight and smell of food) and restrained eating (eating less than desired to maintain or lose weight). A distinction can be made between patients with low and patients with high tendency toward emotional eating with/without external eating. It is possible to determine the patients with potentially good responses to weight loss diets, the potentially successful dieters (low emotional and external eaters) and to determine those for which diets for reason of low interoceptive awareness and hypofunctionality of dopamine related reward circuits are contra-indicated, the unsuccessful dieters (high emotional and external eaters). Treatment target for the potentially successful dieters is weight loss by means of diet and the

treatment target for unsuccessful dieters is improvement of interoceptive awareness and enhancement of emotion regulation abilities as well as decrease of overeating and binge eating problems by means of Dialectical Behaviour Therapy (DBT) and regulation of eating behaviour by means of (cognitive)behaviour therapy.

The ultimate aim of this project is to investigate the effects of these different treatments of obesity in overweight and obese patients on weight reduction and emotion regulation on long term using a randomised control design taking account of DEBQ-scores with pre-test, and post tests (6(T1) and 12 (T2) months and 4-years (T4)). The immediate aim is a pilot study on a treatment and control group (treatment as usual) in the outpatient clinic for eating disorders of the GGZ Oostbrabant with pretest and posttests (T1, T2, T3).

Study design

In a pilot study a treatment group will be compared with a control group (treatment as usual) in an eating disorder clinic (day treatment setting) with a pre-test en posttests((T1 (pre-test); T2 (6 months); T3 (12 months)).

Intervention

An emotion regulation therapy for people with eating binges vs treatment as usual.

Study burden and risks

The completion of questionnaires at three moments takes one hour a time. The intervention consists of 20 groupsessions (two hours pers session) and a maximum of six sessions (45 minutes) with a trained dietician for the control group.

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) ≥ 30 and BMI < 40

Exclusion criteria

remaining BMI

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-04-2008
Enrollment: 50
Type: Actual

Ethics review

Approved WMO
Date: 01-04-2008
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

No registrations found.

In other registers

Register	ID
CCMO	NL20739.097.07