

What is the added value of psychological treatment prior to gastric bypass surgery?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22132

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Morbid Obesity
Morbide Obesitas
Bariatric surgery
Bariatrische chirurgie
Cognitive behavioral therapy
Cognitieve gedragstherapie

Sponsors and support

Primary sponsor: Stimuleringsfonds Wetenschappelijk Onderzoek PsyQ

Source(s) of monetary or material Support: Stimuleringsfonds Wetenschappelijk Onderzoek PsyQ

Intervention

Outcome measures

Primary outcome

- Weight: The calibrated weighing scale of the department bariatric surgery Maasstad Ziekenhuis or Sint Franciscus Gasthuis is used. Definitions stated in the guidelines for morbid obesity are used for the operationalisation of the outcome measure weight. The ideal weight will be calculated per patient, based on length and the below calculation from the guideline. Subsequently, the excess weight can be determined by subtraction of the ideal weight from the actual weight.

Ideal weight = female: 5ft=119 lb + 3 lb for every extra inch male: 5.3 ft= 135 lb + 3 lb for every extra inch.

1cm= 0.0328 ft, 1 cm= 0.394 inch, 1 kg= 2.205 lb, 1 ft= 12 inch.

The weight loss will be expressed in terms of % Excess Weight Loss: $\text{Excess Weight} = \text{actual weight} - \text{ideal weight}$ % Excess weight loss = $\frac{\text{weight loss after surgery}}{\text{excess weight}} \times 100$.

In the guidelines, the success of the operation is expressed conform the criteria in terms of percentage of overweight loss: : > 75% excellent 50-75% good 25-50% fair < 25% treatment failure.

- Eating behavior: DEBQ, Dutch Eating Behavior Questionnaire. This questionnaire has been developed by T. van Strien, University of Nijmegen, and assesses eating behavior. Four subscales are distinguished, including eating in response to clearly labeled emotions, eating in response to diffuse emotions, external eating, and restraint eating. Three types of eating behavior are distinguished: emotional eating (divided into clearly labeled emotions and diffuse emotions), restraint eating and external eating. The items can be answered on a 5-point scale ranging from 1 'never' to 5 'very often.' The scores are classified in 7 categories ranging from 'very high' to 'very low'.

Secondary outcome

- Eating disorder: EDE-Q, Eating Disorder Examination Questionnaire is self report questionnaire developed by prof. C.G. Fairburn from Oxford and in is translated into Dutch by H. Nauta, university of Amsterdam. The EDE-Q has four subscales; restraint, eating concern, weight concern, and shape concern.

- Depression: QIDS-SR, , Quick inventory of depressive symptomatology-Self rating is a self report questionnaire for depression based on the DSM-IV criteria and measures the severity of depressive symptoms based on the total score. Five level of severity categories can be distinguished, ranging from 'no depression' to 'very severe'.

- Quality of life: WHOQOL-bref, World Health Organisation Quality of Life is a questionnaire developed by the WHO to assess quality of life. Four subscales are distinguished; physical health, psychological health, social relations, and environment. The total score reflects the overall level of quality of life.
- Psychological distress: BSI, Brief Symptom Inventory is the brief form of the SCL-90-R that assesses psychological symptoms. The following subscales are distinguished; somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. The total score represents the level of psychological distress,
- Demographic variables, weight course: At the first moment of measurement, a number of social demographic questions are asked concerning weight course, the number of diet attempts, and somatic complaints.
- Somatic comorbidity: Prior to the randomization, the somatic comorbidity is assessed by the surgeon/nurse practitioner. Subsequently the research assistant ticks the applicable boxes of the checklist containing the most frequently occurring somatic health problems, including diabetes, high blood pressure, sleep apnea, high cholesterol, heart- and cardiovascular diseases, joint diseases, and thyroid abnormalities, and gout. This is done on each of the following moments of measurement.

Study description

Background summary

This study aims to examine the added value of cognitive behavioral therapy prior to bariatric surgery. 128 patients that are on the waiting list for bariatric surgery are randomly assigned to the control or treatment condition. Patients in the treatment condition receive 10 sessions of cognitive behavioral therapy focused on lifestyle change including healthy eating and physical activity. Before and after treatment, as well as 1, 3, and 5 year following surgery, the weight, eating behavior, eating disorders, depression, overall psychological and somatic health are assessed. It is expected that the preoperative psychological treatment supports the compliance after the operation and that this leads to better weight loss maintenance.

Study objective

1. Patients that received cognitive behavioral therapy prior to bariatric surgery show better weight loss maintenance at the post treatment measurement and follow-up measurements after one, three, and five years after the operation, than patients that did not receive this psychological treatment.

2. Patients that were offered cognitive behavioral therapy prior to bariatric surgery show healthier eating behaviors, have less frequently an eating disorder or mood disorder, have better psychological and physical health, and experience a higher quality of life, than patients who did not receive this psychological treatment.

Study design

The study includes 5 moments of measurement. For the control condition, measurements are performed at the following moments: at the start of participation, after 8 weeks (in order to synchronize the moments of measurement of the two conditions), and at follow up measurements 1 year, 3 year, and 5 year after the surgery.

Intervention

- Control condition: Patients that do not receive psychological treatment, but follow the conventional preperation procedure in Maasstad Ziekenhuis or Sint Franciscus Gasthuis consisting of an information meeting by the surgeon or nurse practitioner and an information meeting by the dietitian. Patients also receive a detailed patient information booklet.

- The treatment condition consists of a treatment protocol based on cognitive behavioral therapy of 10 individual sessions of 45 minutes, of which the first 4 sessions take place within two weeks and the remaining 8 sessions on a weekly basis. Treatment takes place at PsyQ Rijnmond and is conducted by a (GZ; healthcare) psychologist or cognitive behavioral therapeutic worker. De intervention pertains to awareness of psychological factors underlying eating behaviors, the development and internalization of new eating and activity behavior and coping with emotions, as well as to cognitive restructuring. Homework assignments are part of the intervention, for example keeping an eating- and physical activity diary and registering thoughts and feelings. The time investment of the treatment is 7,5 hours of treatment sessions (excluding travel time) and 5 hours of homework (see attachment treatment protocol cognitive behavioral therapy).

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria: - Patients with a BMI ≥ 40 kg/m² or with a BMI ≥ 35 kg/m² and (somatic) comorbidity that meet the postulated criteria for bariatric surgery and are indicated for gastric bypass.

- Patients are on the waiting list of the hospital (Maasstad Ziekenhuis, Sint Franciscus Gasthuis) for gastric bypass.

- Age from 21 to 65 years

- Psychological comorbidity and medication use form no contraindication for study participation with the exception of the circumstances stated at the exclusion criteria.

Exclusion criteria

Exclusion criteria:

- Patients that are currently being treated by a dietitian, psychiatrist, psychologist.

- Patients with severe psychopathology (psychotic disorders, such as schizophrenia, bipolar disorder, suicidality or severe emotional instability)

- Patients with an addiction to alcohol or soft or hard drugs, or patients that abuse substances.

- Patients receiving psychotropic drugs that are used for a period of less than 3 months.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2012
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion	
Date:	03-09-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37711
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3960
NTR-old	NTR4140
CCMO	NL40203.101.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register

OMON

ID

NL-OMON37711

Study results

Summary results

N/A