The influence of psychological factors on the outcome of Gastric Bypass operation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Appetite and general nutritional disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35151

Source
ToetsingOnline

Brief title
Optimizing GB outcomes

Condition

- Appetite and general nutritional disorders

Synonym
obesity, overweight, psychological factors

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: via de SKWOSZ (stichting klinisch wetenschappelijk onderzoek slotervaartziekenhuis

Intervention

Keyword: Gastric Bypass, Obesity, Outcome, Psychological

Outcome measures

Primary outcome

Main study endpoint is insight in the determinants of the variation in weight reduction and quality of life in the two years after a gastric bypass operation.

Secondary outcome

Secondary parameters are number of complications, compliance and the prevalence of psychopathology.

Study description

Background summary

Gastric bypass surgery has been shown to be an effective treatment against morbid obesity. Research shows that after a gastric bypass operation overweight decreases while health and quality of life increases significantly. Although the majority of the patients clearly profit from the operation there is also a small but considerable portion of the patients who show less improvements post-operatively. Insight in the determinants of post-operative outcomes is important as it may help optimize care and improve the outcomes of a gastric bypass operation even further.
Although surgical and metabolic factors may play a role in post-operative outcomes, psychological factors may also help to explain individual differences in weight loss and quality of life post-operatively. A gastric bypass operation enforces behavioral changes in patients which may be experienced as a serious life-event and requires psychological resilience. Although most patients will be able to adapt to the changes imposed by the operation, other patients may be less able to change their diet and exercise behavior and show less improvements in weight loss and quality of life over time. This is supported by research showing that patients with two or more psychiatric disorders profit less from a gastric bypass operation as they report less weight-loss, poorer quality of life post-operatively and worse compliance. These studies are however limited as they (1) do not follow patients over time and (2) are not able to explain

the differences in post-operative outcomes sufficiently.

Study objective

The purpose of the proposed research is to investigate which patients may report less weight loss and worse quality of life in the first two years after a gastric bypass operation. Moreover, the proposed study will offer information why and when these less than optimal outcomes may evolve. The main hypothesis states that in addition to medical factors (co-morbidity, initial weight) psychological factors such as life-time and current psychopathology and personality characteristics (independent variables) will be associated with weight loss and quality of life (dependent variables) in the first two years after a Gastric Bypass operation. The second hypothesis states that the association between psychological factors and gastric bypass outcomes will be mediated by medical complications, compliance to diet and exercise recommendations, coping, social support and stressors.

Study design

In this 3 year prospective study we will include 100 patients receiving a gastric bypass operation in Slotervaart Hospital. These patients will be followed over a 24 month period using an internet based data collection and monitoring system. To be able to investigate when and why suboptimal gastric bypass outcomes may evolve patients will be requested (by SMS, email) to complete digitalized questionnaires at 1 month, 3 months, 6 months, 12 months, 18 months and 24 months after the operation. Moreover, patients will be screened pre-operatively. A pre-surgical assessment is standard in the appraisal process and consists of a questionnaire and semi-structured interview investigating among other things, weight (BMI), preoperative diet and exercise habits, co-morbidity, sociodempgraphics, lifetime and current psychopathology. For the proposed study a few questionnaires will be added assessing personality characteristics and quality of life preoperatively. Postoperatively, weight and quality of life as well as medical complications, compliance to dietary and exercise recommendations, coping, social support and current stressors will be assessed six times in a two year period. This data collection schedule will be long and intensive enough to detect and explain variations in gastric bypass outcomes.

Study burden and risks

The aim of a gastric bypass operation is to improve health and quality of life in patients suffering from morbid obesity by reducing their weight. To optimize the outcome of a gastric bypass operation a perceptive that takes psychological factors into account may be vital. However, the gravity of the obesity and the health improvements imposed by the surgery usually do not allow much attention for psychological factors pre-operatively which may leave psychological

risk-factors undetected and untreated. This may in turn result in poorer weight loss, worse quality of life, more healthcare utilization, reduced compliance and increased costs. Therefore is important to have notion, at an early stage, which patients may experience less optimal outcomes after a gastric bypass operation and why. In order to be able to answer these questions patients will be asked to complete questionnaire six times in a two year period with a total time burden of approximately 3 hours. Moreover, patients will be assessed pre-operatively using a semi-structured interview (45 minutes) and questionnaires (60 minutes). The total time burden pre-operatively will be approximately 1hour and 45 minutes which of which 1hour and 15 minutes is part of normal preoperative assessment.
Moreover, in the present study instead of paper-and-pencil measurements, the use of an internet based data collection and monitoring system (*Zorgportaal*) is proposed. Given the longitudinal design and of the study the multiple assessment points a computerized system that allows patients to complete questionnaires at home will be less demanding for patients as well as the researcher team and may minimize drop-out. .
In the future such a system may also help to optimize clinical practice. First, a longitudinal internet based monitoring and data collection system meets the wishes of bariatric surgery guidelines to offer systematic long-term follow-up. Secondly, it may to help organize postoperative care more effectively and efficiently by identifying those in need of additional (medical/ dietetic/psychological) care at an early stage. That is, patients reporting scores on the post-operative assessments that warrant clinical attention may be invited by appointed members of the Multidisciplinary team (surgeon, dietician, psychologist, internist) for additional diagnostics and, when needed, treatment. This early detection may alleviate the outcome of Gastric bypass surgery, especially for those patients with a more extensive psychiatric history.

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 > 40 or BMI > 35 with comorbidity
Age between 18-60 years
Sufficient command of the Dutch language (speaking and reading)

Exclusion criteria

mentally handicapped
acute psychotic symptoms

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	14-02-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	23-11-2011
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL38363.048.11