The effect of a gastric bypass operation on family members

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Primary objective:To observe the effect of gastric bypass surgery on household members and partners who live together with the patient on body mass index (measured as weight/height²) in the first year following bariatric surgery compared to family...

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

Summary

ID

NL-OMON37446

Source
ToetsingOnline

Brief title
Halo effect GB

Condition

- Appetite and general nutritional disorders

Synonym
Obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: via de SKWOSZ

Intervention

Keyword: Eating behavior, Family members, Gastric bypass, Weight changes

Outcome measures

Primary outcome

Main study endpoint is insight in the determinants of the variation in weight change (both weight loss and weight gain) of household members 12 months after a gastric bypass operation compared to household members of obese patients visiting the obesity outpatient clinic.

Secondary outcome

Secondary parameters are examining the prevalence of obesity in household members of patients who underwent gastric bypass surgery and differences in eating behaviour after surgery compared to household members of obese patients visiting the obesity outpatient clinic.

Study description

Background summary

Bariatric surgery is the most reliable and effective treatment for the morbidly obese population. The benefits of a gastric bypass operation include weight loss, resolution of comorbidities, and improvements in overall mortality and specifically mortality related to diabetes, heart disease and cancer.
Since the biggest risk factor for becoming an obese child is having an obese parent and a persons risk of becoming obese is influenced by associating with obese individuals, it would be interesting to investigate in which way gastric bypass surgery affects family members. If one member of the family makes necessary drastic lifestyle changes following surgery, it is possible that other family members will adopt similar healthy habits.
There are multiple possible effects that the gastric bypass may have on family members of the patient. These effects may be divided in two broad categories: 1) the so-called *garbage can* effect, the family member of the patient may actually have an increase in dietary intake and 2) the *mimicking* effect,

which could actually cause a decrease in the non-operated family member*s weight. It is unknown which of these two effects, if any, will prevail in patients* family. To our knowledge, only two studies have examined the effects of bariatric surgery on family members of patients who underwent a gastric bypass surgery. These studies are however limited as they have a small sample size.

Study objective

Primary objective:
To observe the effect of gastric bypass surgery on household members and partners who live together with the patient on body mass index (measured as weight/height²) in the first year following bariatric surgery compared to family members of obese patients visiting the obesity outpatient clinic.

Secondary objective:
To observe the effect of gastric bypass on household members and partners who live together with the patient in the first year following bariatric surgery compared to family members of morbidly obese patients visiting the obesity outpatient clinic on:
- Changes in eating behavior
- Prevalence of obesity in the family
- Change in BMI of the gastric bypass patient with the BMI of the family members one year after surgery and change in BMI of the obese patient from the obesity clinic with the BMI of the family members one year after baseline measurements
- Correlation of family size with change in BMI

Study design

In this one year prospective longitudinal control study we will include 100 families of patients receiving a gastric bypass operation in Slotervaart Hospital and 50 families of obese patients visiting the obesity outpatient clinic. The duration of the study will be approximately one year or until a sufficient amount of participants has been reached. To be able to investigate if gastric bypass surgery has any influence on family members body mass index and eating behaviour, we also include a control group, 50 families of obese patients visiting the obesity outpatient clinic. Furthermore, family members of patients receiving a gastric bypass operation will be requested to complete eating behavior questionnaires pre-operative at 3 months, 6 months and 12 months after the operation. Family members of patients visiting the obesity outpatient clinic will be requested to complete the questionnaires at baseline, 6 months and 12 months after operation.
For the proposed study family members of patients receiving a gastric bypass operation will be asked to fulfill questionnaires assessing sociodemographic

characteristics (including family size), length and weight and eating behavior preoperatively. Postoperatively, weight and height will be measured in the patient and the family members 3 times in a one year period. The postoperatively assessments will be executed at home, where a digital questionnaire will be filled out and weight and height will be measured, with telephonic assistance of the researcher (see appendix 1a).
Family members of patients visiting the obesity outpatient clinic will be asked to fulfill questionnaires assessing sociodemographic characteristics (including family size), length and weight and eating behavior after patient and family members signed for informed consent. The patient and the family members will be asked to measure their weight and height two times in a one year period. The assessments will be executed at home, where a digital questionnaire will be filled out, with telephonic assistance of the researcher (see appendix 1b).
This data collection schedule will be long and intensive enough to detect and explain the influence of gastric bypass on family members. Weight reduction will be measured trough body mass index (measured as weight/height^2) for adults and with the standardized Z-BMI score for children.

Study burden and risks

nvt

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age between 12 - 60 years
- Sufficient command of the Dutch language (speaking and reading)
- Family members have to live together in a domicile

Exclusion criteria

- Endocrinologic disorders (e.g. Cushing Syndrome, hyperthyroidism)
- Current or history of treatment with medications that may cause significant weight gain, within 3 months prior to screening
- Current participation in an organised weight reduction program (or within the last 3 months)
- Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2012
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	18-01-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	12-11-2012
Application type:	Amendment
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	NL39073.048.11