

# 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/height<sup>2</sup>) in the first year following bariatric surgery compared to family...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Appetite and general nutritional disorders
<b>Study type</b>	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 person's 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/height<sup>2</sup>) 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 through body mass index (measured as  $\text{weight/height}^2$ ) for adults and with the standardized Z-BMI score for children.

## **Study burden and risks**

nvt

## **Contacts**

### **Public**

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### **Scientific**

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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