

# Can group therapy improve well-being and mental health of overweight women after gastric bypass surgery?

<b>Submission date</b> 07/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/03/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Gastric bypass surgery can help individuals who are overweight and cannot lose weight through non-surgical ways. The surgery reduces weight and increases patients' quality of life, but some patients start to gain weight after some years or do not lose as much weight as expected. The reasons are usually poor health, shame and feelings of loss of control. The aim of this study is to reduce these problems and improve the effects of gastric bypass in women.

### Who can participate?

Women who are overweight, can speak Swedish and are planning to have a gastric bypass surgery at any of our four hospitals (Ersta, Uppsala, Örebro or Danderyds) from January 2015 to November 2015

### What does the study involve?

Participants are randomly allocated to receive four 1-hour sessions of group therapy about 2 months after surgery or usual care after surgery. The group sessions comprise discussions with a small task to be done at home. All participants are given an accelerometer (an instrument to measure movement) and questionnaires about eating habits, social life, happiness of life and self-esteem every 6 months until 2 years after surgery.

### What are the possible benefits and risks of participating?

No known risks

### Where is the study run from?

Hospitals Ersta Sjukhus, Danderyds sjukhus, Universitetssjukhuset Örebro and Akademiska sjukhuset (Sweden)

### When is the study starting and how long is it expected to run for?

December 2013 to January 2018

Who is funding the study?  
Karolinska Institutet (Sweden)

Who is the main contact?  
Fanny Sellberg

## Contact information

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Scientific

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## Additional identifiers

### Study information

**Scientific Title**  
Can a dissonance-based intervention improve quality of life, social adjustment, eating behaviour and physical activity in women after gastric bypass surgery? A randomised controlled study

**Acronym**  
WELG (study of well-being after gastric bypass)

**Study objectives**

1. Quality of life and social adjustment will be higher at follow-up in the intervention group than before surgery and higher than in the control group.
2. Fewer symptoms of disordered eating behaviours and higher body satisfaction will be noted

at follow-up in the intervention group than before surgery and fewer than in the control group.  
3. Physical activity and weight loss will be higher at follow-up in the intervention group than in the control group.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Stockholm Ethics Review Board, 10/12/2013, Dnr: 2013/1847-31/2

### **Study design**

Randomised controlled study

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Prevention of unwanted mental and physical outcomes after gastric bypass surgery

### **Interventions**

50% of the recruited patients will be randomly allocated to the intervention group after surgery and 50% to the control group (usual post-operative follow-up). The first intervention session will start about 2 months after surgery. The group sessions will consist of 1 hour discussions, role plays and other activities and will be led by a researcher. We will use a dissonance-based group setting with four 1 hour sessions (one session per week) in the intervention group, covering eating behaviour, physical activity and social and intimate relations. Other versions of this intervention have been successfully used in other settings with the same structure, for example, for the prevention of eating disorders in non-obese individuals. The theory is that the participants will discuss difficult situations that might occur after surgery and propose approaches and solutions in a group setting. It is suggested that individuals will then tend to use these approaches themselves if they face difficulties in the future.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Quality of life, measured with a validated questionnaire (SF-36)
2. Eating behaviour, measured with the Three-Factor Eating Questionnaire and the Disordered Eating after Bariatric Surgery
3. Body esteem, measured with the Body Esteem Scale
4. Social adjustment, measured with the Social Adjustment Scale
5. Physical activity, measured with an accelerometer at before surgery and at 6 months, 1 year and 2 years after surgery; the accelerometers will be posted to the participants and returned in the post

All questionnaires (except SF-36) will be completed at home and emailed to the research group before surgery and at 6 months, 12 months, 18 months and 24 months after surgery. SF-36 will be measured at the same timepoints with a national register as a part of the usual care.

## **Key secondary outcome(s)**

1. Weight
2. Height
3. Waist circumference

The secondary outcomes will be measured before surgery and at 6 months, 12 months, 18 months and 24 months after surgery by the nurses at the hospital where the surgery is done.

## **Completion date**

01/08/2021

## **Eligibility**

### **Key inclusion criteria**

1. Eligible for gastric bypass surgery: body-mass index  $>35$  kg/m<sup>2</sup>, usually between 18–65 (with some exceptions)
2. Aged over 18 years old
3. Able to speak and read Swedish
4. Women

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **Total final enrolment**

259

### **Key exclusion criteria**

Current diagnosis of depression

### **Date of first enrolment**

15/01/2015

### **Date of final enrolment**

01/11/2015

## **Locations**

## **Countries of recruitment**

Sweden

### **Study participating centre**

#### **Ersta Sjukhus**

Fjällgatan 44

Stockholm

Sweden

116 91

### **Study participating centre**

#### **Danderyds sjukhus**

Mörbygårdsvägen, Danderyd

Stockholm

Sweden

182 88

### **Study participating centre**

#### **Universitetssjukhuset Örebro**

Södra Grev Rosengatan

Örebro

Sweden

703 62

### **Study participating centre**

#### **Akademiska sjukhuset**

Akademiska sjukhuset

Uppsala

Sweden

751 85

## **Sponsor information**

### **Organisation**

Karolinska Institute

### **ROR**

<https://ror.org/056d84691>

# Funder(s)

## Funder type

Government

## Funder Name

Karolinska Institutet

## Alternative Name(s)

Karolinska Institute, KI

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

Sweden

## Funder Name

Centre for epidemiology and social medicine

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at registration

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		04/11/2021	05/11/2021	Yes	No
<a href="#">Results article</a>		05/02/2019	07/03/2023	Yes	No
<a href="#">Protocol article</a>	protocol	09/05/2018		Yes	No