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

Submission date
07/01/2015

Recruitment status
No longer recruiting

Registration date
23/02/2015

Overall study status
Completed

Last Edited
07/03/2023

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet (in Swedish).

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/12/2013

Completion date
01/08/2021

Eligibility

Key inclusion criteria
1. Eligible for gastric bypass surgery: body-mass index >35 kg/m2, 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

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
240

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

Sponsor details
Karolinska institutet
Stockholm
Sweden
171 77

Sponsor type
University/education

Website
http://ki.se

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 epidimeology and social medicine

Results and Publications

Publication and dissemination plan
The study will be a part of a 4 year PhD student project with at least two publications.

Intention to publish date
01/01/2019

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?
Protocol article	protocol	09/05/2018		Yes	No
Results article		04/11/2021	05/11/2021	Yes	No
Results article		05/02/2019	07/03/2023	Yes	No