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Bariatric Surgery and Education

Submission date
25/01/2013

Recruitment status
No longer recruiting

Registration date
18/02/2013

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The use of bariatric surgery (also called weight loss surgery) for severely obese patients (Body Mass Index BMI ≥ 40kg/m² respectively BMI ≥ 35 kg/ m² with comorbidities) has proven to be an effective treatment method in recent years. However, longitudinal studies indicate weight regain after the initial successful weight-loss period. For successful weight loss, patients need a high compliance and adherence to nutritional and lifestyle changes. Because of the many psychosocial and lifestyle challenges after surgery, there may be a need for professional support. Until now, no study has investigated the impact of a postoperative psycho-educational program on weight course, quality of life, or self-efficacy. The aim of this study is to prove how well a psycho-educative intervention works in patients after weight loss surgery.

Who can participate?
Severely obese patients (BMI ≥ 40kg/m² respectively BMI ≥ 35 kg/m² with co-morbidities) who are going for weight loss surgery.

What does the study involve?
120 patients undergoing weight loss surgery are randomly allocated in an intervention or control group after the operation. Patients in the control group receive conventional post-surgical visits. Patients in the intervention group receive a one year psycho-educative group program in addition to conventional care. This program includes face-to-face and video-conferencing sessions. Sessions are conducted by an interdisciplinary team and include all the topics that are considered to be important for severely obese patients.

What are the possible benefits and risks of participating?
The benefits of participating in this trial are as follows: all participants will be monitored closely by a professional interdisciplinary team throughout the course of the study. In addition, comprehensive psychosomatic diagnostics procedure will be carried out. Participants who are allocated to the intervention group may participate in a psycho-educative group program conducted by an interdisciplinary expert team.
Participation does not involve imminent risks of physical injury or harm.

Where is the study run from?
- Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg, Germany (Dr. sc. hum. Beate Wild, Dipl. Psych. Katharina Hünnemeyer, Dr.med Bernhard Hain,

Prof. Dr. med. Wolfgang Herzog)
- Department of Psychosomatic Medicine and Psychotherapy, University Hospital Tuebingen, Germany (Dr. med. Martin Teufel, Prof. Dr. med. Stephan Zipfel)
- Department of General, Visceral, and Transplant Surgery, University Hospital Tuebingen, Germany (Prof. Dr. med. Alfred Königsrainer)
- Department of General, Visceral, and Transplant Surgery, University Hospital Heidelberg, Germany (PD Dr. med. Beat Müller)
- Hospital Sachsenhausen,Frankfurt, Germany (Prof. Dr. med. Rudolf Weiner)

When is the study starting and how long is it expected to run for?
The study started in October 2009 and was expected to last approximately 40 months.

Who is funding the study?
German Ministry of Research and Education (BMBF)

Who is the main contact?
Dr Beate Wild, Beate.Wild@med.uni-heidelberg.de
Dr Martin Teufel, Martin.Teufel@med.uni-tuebingen.de

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
German Ministry of Research and Education (BMBF) 01G10853

Study information

Scientific Title
Investigation of the efficacy of a psycho-educative program following bariatric surgery a randomized controlled trial

Acronym
BaSE

Study objectives
The aim of the study is to assess the effect of a postoperative psycho-educative program on weight loss, quality of life, and self-efficacy of bariatric patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the University of Tuebingen; Gartenstraße 47, D- 72074Tübingen; approved on March 24th , 2009; Ref.-Nr. 86/2009B02
2. Ethics Committee of the University of Heidelberg, Glockengießerei 11/1; D-69115 Heidelberg, approved on May 28th, 2009; Ref.-Nr. S-181/2009

Study design
Randomized controlled two-armed multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe obesity, bariatric surgery

Interventions
Ratio of intervention to control-group of 1:1

Patients who undergo bariatric surgery are randomly assigned to an intervention or control group. Patients of the intervention group receive in addition to regular post-surgical visits a psycho-educative program over a period of 12 months. The psycho-educative group-program consists of 14 face-to-face and webcam-sessions which are conducted by an interdisciplinary

team. The program includes all topics proposed to be important for severely obese patients. Awareness and self-monitoring of ones behavior is essential and will be commented and trained in each session.

Patients of the control group receive the conventional post- surgical visits.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Weight loss in kilograms at one year after surgery
2. Quality of life at one year after surgery (measured by the SF-36)
3. Self-efficacy at one year after surgery (measured by the GSE, General Self Efficacy Scale)

Secondary outcome measures
1. Depressive symptoms at one year after surgery (measured by the PHQ)
2. Eating behavior according to the EDE-Q at one year after surgery
3. Composite endpoint consisting of defined criteria regarding weight loss, eating behavior, and depression

Overall study start date
01/10/2009

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Severe obesity (BMI ≥ 40 or BMI ≥35 with comorbidity) and an indication for bariatric surgery
2. Male or female adult patients aged ≥18 years
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Severe mental health problems or active psychotic disorder
2. Insufficient knowledge of the German language
3. Not being able to give informed consent due to neurological or other illness
4. No internet access
5. Age >65 years

Date of first enrolment
01/10/2009

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
Germany

Study participating centre
Department of General Internal Medicine and Psychosomatics
Heidelberg
Germany
69120

Sponsor information

Organisation
German Ministry of Research and Education (BMBF) (Germany)

Sponsor details
Deutsches Zentrum für Luft- und Raumfahrt e.V.
Projektträger im DLR
- Gesundheitsforschung
Heinrich-Konen-Str. 1
Bonn
Germany
53227

Sponsor type
Government

Website
http://www.gesundheitsforschung-bmbf.de

ROR

https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
German Ministry of Research and Education (BMBF) (Germany) ref: 01G10853

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015	22/01/2019	Yes	No
Results article	results	01/09/2017	22/01/2019	Yes	No