# **Bariatric Surgery and Education**

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>			
25/01/2013		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
18/02/2013	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
22/01/2019	Nutritional Metabolic Endocrine				

### 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  $\geq 40 \text{kg/m}^2$  respectively BMI  $\geq 35 \text{ kg/m}^2$  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  $\geq$  40kg/m<sup>2</sup> respectively BMI  $\geq$  35 kg/m<sup>2</sup> 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

Dr Beate Wild

#### Contact details

Department of General Internal Medicine and Psychosomatics University Hospital Heidelberg Im Neuenheimer Feld 410 Heidelberg Germany 69120 +49 6221 56 8663 beate.wild@med.uni-heidelberg.de

## Additional identifiers

#### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

- 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)

## Key secondary outcome(s))

- 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

### Completion date

31/01/2013

# **Eligibility**

## Key inclusion criteria

- 1. Severe obesity (BMI  $\geq$  40 or BMI  $\geq$ 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

### Lower age limit

18 years

#### Sex

All

#### 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)

#### **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**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes