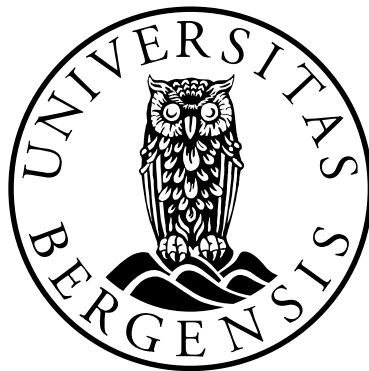


Psychiatric disorders, quality of life and effect of preoperative counselling in patients who undergo bariatric surgery

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Dissertation for the degree philosophiae doctor (PhD)
at the University of Bergen

2012

Dissertation date: February 24th 2012

Scientific environment

This research and writing of this thesis was conducted during the years 2007 to 2011 at the Section of Mental Health Research, Department of Psychiatry, Haugesund Hospital, Fonna Health Trust, Haugesund, Norway in collaboration with the Section of Psychiatry, Institute of Clinical Medicine, University of Bergen, Norway and the Department of Health Promotion and Development, University of Bergen, Norway. The research work on this thesis was supervised by Tone Tangen, Hege R. Eriksen, and Eva Biringer.

Acknowledgements

Many people have contributed with their knowledge and support during the work on this thesis and I am grateful to all of them. First and foremost, I would like to thank all the participants in this study for cooperation and participation; each of you made this study possible.

A special thanks to my main supervisor, Tone Tangen for your help, encouragement, and guidance throughout this thesis. Also warm thanks to my co-supervisors Hege R. Eriksen for your willingness to help, to teach, and to share your knowledge and to Eva Biringer who provided me with constructive methodological counselling and important contributions on all the papers - her enthusiasm and skillfulness in everything she pursues have encouraged and inspired me.

I also wish to express my appreciation to all my co-authors for their contribution to this work (in alphabetical order): Jofrid Bjørkvik, Oddbjørn Hove, Jan Rosenvinge, and Bjarte Stubhaug. Bjarte Stubhaug deserves a special thanks because, in addition to his contribution on all the papers, he also contributed to the process of designing the study. I am grateful for your generosity, wisdom, and friendship; knowing you is a privilege.

The clinical work included in the thesis was carried out at Haugesund Hospital. I am grateful for the help and cooperation from many of the people at the Department of Psychiatry and the Department of Surgery. A special thanks to Solveig Arne and Hege Feet who were co-workers in the trial and Per Espen Hovde-Hansen who facilitated data collection.

I am appreciative for the help and support in statistical analyses throughout the thesis, which was provided by Jörg Aßmus at Centre for Clinical Research, Haukeland University Hospital. Further, I am grateful to John Roger Andersen at Faculty of Health Studies, Sogn og Fjordane University College for helping with analyses regarding quality of life. I would also like to acknowledge Nancy Bjerkeset for her help with language.

I am thankful to my colleagues at Section of Mental Health Research, Division of Psychiatry: Arvid Rongve, Oddbjørn Hove, Anne Lise Kvalevaag, Eva Biringer, Kirsten Bråtveit, and Signe Marie Parlati. You are all important to me, both socially and professionally, and have helped me through this process. A special thanks to Signe Marie Parlati for the essential help with data collection and management of the database. Further, I would like to acknowledge the financial support from Fonna Health Trust and Western Regional Health Authority.

Last, but certainly not least, I would like to thank my family and friends who supported me during the years I worked on this thesis. I would like to express my gratitude to my parents who preached the importance of education. You have always encouraged me to do my best in everything I pursue. I am deeply grateful to my husband Kalle for his love and friendship and his constant belief in my ability to cope and to my children, Sigval, Cecilie, and Svein Reidar, for showing me what is most important in life – many big hugs to you.

Abbreviations

ACT	Acceptance and Commitment Therapy
BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory
BED	Binge Eating Disorder
BMI	Body Mass Index
BSI	Borderline Syndrome Index
CBT	Cognitive Behavioural Therapy
CIDI	Composite International Diagnostic Interview
DSQoL	Disease-Specific health-related Quality of Life
DSM-IV	Diagnostic and Statistical Manual, 4 th edition
EDE-Q	Eating Disorder Examination Questionnaire
EDE	Eating Disorder Examination
EDO	Eating Disorder in Obesity
EE	Emotional Eating
FTO gene locus	Fat mass and obesity-associated gene locus
HRQoL	Health Related Quality of life
ICD-10	International Classification of Diseases 10 th edition
ISS	Cook's Internalized Shame Scale
IWQoL	Impact of Weight on Quality of Life
LOC	Loss of Control
MINI	The M.I.N.I. International Neuropsychiatric Interview
PMT	Protection Motivation Theory

RYGBP	Roux-en-Y gastric bypass
SCID-II	Structured Clinical Interview for DSM-IV Axis II Personality Disorders
SCL	Symptom checklist
SF-36	Short Form Health Survey 36
SPSS	Statistical Package for the Social Sciences

Abstract

Background: Bariatric surgery is increasingly recommended as the treatment of choice for patients with severe obesity (BMI >40 kg/m² or BMI >35 kg/m² and a serious comorbid somatic condition). Surgical success, which includes the patients' ability to achieve sustained weight loss and subjective well-being, is dependent on psychological and behavioural factors. Psychiatric assessment and support prior to and after surgery are assumed to be beneficial for all patients undergoing surgery. Factors related to participation in such comprehensive treatment programmes, the necessary design elements of such comprehensive treatment programmes, and the relationship between participation in adjuvant treatment and weight loss and adherence to treatment guidelines are largely unknown. Further, little is known about the association between postoperative psychiatric comorbidity and weight loss and quality of life outcome.

Objectives: The objectives in this thesis were to assess prevalence rates of comorbid psychiatric disorders prior to and one year after bariatric surgery and to compare prevalence rates of preoperative comorbid psychiatric disorders between patients willing to participate in counselling groups and patients unwilling to participate in such groups. The effects of preoperative psychological counselling on weight loss and adherence to guidelines for eating habits and physical exercise one year after surgery were examined. Finally, the association between psychiatric disorders and quality of life at follow-up one year after surgery were assessed.

Methods: A total of 169 patients with obesity were screened for participation in the study. They were all referred from general practitioners (GPs) for gastrobariatric surgery at the Department of Surgery at Haugesund Hospital, Norway. Of these, 150 patients had psychiatric assessment and 144 were invited to participate in preoperative and postoperative counselling groups. Patients were interviewed using Mini International Neuropsychiatric Interview (M.I.N.I.) and Structured Clinical Interview (SCID-II) at assessment prior to and one year after surgery. The participants

completed self-report questionnaires on depression (BDI), anxiety (BAI), shame (ISS), and quality of life (SF-36) at preoperative assessment, three months after surgery, and one year after surgery. They also accounted for compliance with guidelines of eating habits and exercise at follow-up three months and one year after surgery.

Results: The overall prevalence of current psychiatric disorders was 49% among patients on a waiting list for bariatric surgery. Sixteen patients (18%) fulfilled the diagnostic criteria for a psychiatric disorder at one year follow-up. Significant predictors for postoperative psychiatric disorder were preoperative psychiatric disorder and preoperative level of shame.

Patients who were unwilling to participate in counselling groups had significantly higher prevalence of preoperative Social Phobia and Avoidant Personality Disorder than patients who agreed to participate. At follow-up one year after surgery, there were no differences regarding treatment adherence (eating habits and physical exercise) and weight loss in patients who participated in preoperative counselling groups compared to patients who did not participate in such groups.

In the entire study sample, significant improvement in HRQoL was found in seven of the eight SF36 subscales from preoperative assessment to follow-up one year after surgery. However, in patients with postoperative psychiatric disorders, only a trend toward improvement could be detected in several of the subscales measuring HRQoL, and they still had impaired HRQoL one year after surgery compared to the population norm.

Conclusion: Psychiatric disorders are prevalent among candidates for bariatric surgery. The presence of Social Phobia and Avoidant Personality Disorder influence the willingness to participate in preoperative counselling groups. At one year follow-up after surgery, we found no differences regarding weight loss, eating habits, or physical activity between patients who participated in preoperative counselling and patients that did not participate in such counselling.

Prevalence of psychiatric disorders was significantly lower one year after bariatric surgery compared to prevalence rates at preoperative assessment. Level of shame at preoperative assessment was associated with maintenance of psychiatric problems. Compared to the population norm, patients with preoperative, but without postoperative comorbid psychiatric disorders, had impaired HRQoL on only two of the subscales measuring HRQoL one year after surgery. However, HRQoL in patients with postoperative psychiatric disorders did not reach the level of the general population, and compared to the population norm, they had impaired quality of life in all subscales measuring HRQoL one year after surgery.

List of publications

The thesis is based on the following papers, which will be referred to by their Roman numerals:

- I. Lier HO, Biringer E, Stubhaug B, Eriksen HR, Tangen T (2011). Psychiatric disorders and participation in pre- and postoperative counselling groups in bariatric surgery patients. *Obes. Surg* 2011, 21:730-7.
- II. Lier HO, Biringer E, Stubhaug B, Tangen T. Prevalence of psychiatric disorders before and one year after bariatric surgery. *Submitted*.
- III. Lier HO, Biringer E, Hove O, Stubhaug B, Tangen T (2011). Quality of life among patients with severe obesity: associations with mental health- A 1 year follow-up study of bariatric surgery patients. *Health Qual Life Outcomes* 9,79
- IV. Lier HO, Biringer E, Stubhaug B, Tangen T. The impact of preoperative counseling on postoperative treatment adherence in bariatric surgery patients: A randomized controlled trial. *Accepted for publication in Patient Education and Counseling*.

Other publications:

Lier, HO, Biringer E, Bjørkvik J, Rosenvinge JH, Stubhaug B, Tangen T:
Shame and obesity: Associations with mental health and engagement in health promoting activities three months after bariatric surgery. *Submitted*.

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1. General introduction

This thesis is based on baseline data from 141 patients referred to bariatric surgery at Haugesund Hospital. The bariatric procedure at Haugesund Hospital is laparoscopic Roux-en-Y gastric bypass (RYGBP). The patients were all offered a preoperative counselling programme aimed at improving patient behaviour (eating habits and exercise) associated with long term weight loss success. The study was performed with a randomized controlled design: patients who gave their consent to participate in the counselling programme were randomised to either the preoperative counselling programme or treatment as usual. Information was gathered before gastric bypass (T0), three months after gastric bypass (T1), and one year after gastric bypass (T2).

The main focus of the present study has been on determining psychological factors that may enhance or impede the patient's surgical outcome for patients undergoing bariatric surgery, namely, quality of life, engagement in health promoting behaviour, and weight loss. Further, we have evaluated the effect of a preoperative counselling programme on postoperative engagement in health promoting behaviour.

The prevalence of obesity is increasing, and globally it is estimated that more than 700 million adults will be obese by 2015 (1). In 2008, 1.5 billion adults were overweight and 500 million adults were obese (1). Overweight is defined as having a BMI ≥ 25 kg/m², and obesity as having a BMI ≥ 30 kg/m². Overweight and obesity were once considered problems of only high income countries, however, overweight and obesity are now on the rise in low and middle income countries, particularly in urban areas (1). The introduction of the Western life style, with its excessive energy intake and low energy expenditure, to these countries may account for this epidemic. However, genetic factors have also been found to play an important role in explaining predisposition to obesity. Several obesity genes have been identified (2). Variation in fat mass and obesity-associated gene locus (FTO) is found to be associated with

energy intake and satiety responsiveness (3, 4). However, physical activity and diet modify this association between FTO genotype and obesity (5).

The problem of obesity is described in Hippocratic writings as causing disease and shortening life expectancy (6). And, modern research has documented that overweight and obesity are major causes of both somatic (7) and psychiatric comorbidities (8). In a review that included prospective cohort studies of the general population, people with overweight and obesity were found to have increased risk of various types of cancer, (including breast cancer, endometrial cancer, ovarian cancer, colorectal cancer, oesophageal cancer, kidney cancer, pancreatic cancer, and prostate cancer), hypertension, diabetes type II, stroke, coronary artery disease, congestive heart failure, asthma, chronic back pain, osteoarthritis, pulmonary embolism, and gallbladder disease compared to people with normal weight (7). Further, obesity is associated with an approximately 25% increase in odds for mood and anxiety disorders (8). It is also well documented that obese people face discrimination both in their professional and social lives (9). Several studies have documented that patients with obesity are stereotyped by the general public as being lazy, weak-willed, unsuccessful, unintelligent, and lacking self-discipline (10-12). These stereotypes give way to stigmatisation and discrimination in multiple domains of living, including education and work (10, 11). In one study, patients who have successfully maintained weight loss after surgery were asked to make a hypothetical choice between severe obesity and a number of other serious disabilities; only 10% preferred morbid obesity to blindness, and no patient chose morbid obesity over deafness, dyslexia, and serious heart disease (13).

Health care costs related to overweight and obesity are substantial (14), and maintenance of a healthier weight could be an important aspect of disease burden prevention, both the individual disease burden and the burden for society.

Treatment for obesity, according to the Hippocratic view (aiming at restoring the balance of liquids) includes diet, drugs, and exercise (6). Today, these treatment

ingredients are reflected in weight loss treatments. There is particular emphasis on importance of appropriate life style to maintain a healthy weight.

Although there has been great focus on various ways to prevent obesity, the prevalence rate is increasing, which necessitates the development and implementation of effective treatment strategies.

1.1 Obesity, definition and prevalence

Definition

Obesity is defined as a BMI of greater than 30 kg/m². Severe or morbid obesity is defined as having a BMI greater than 40 kg/m² or having BMI greater than 35 kg/m² and a serious comorbid (weight-related) somatic disorder.

Prevalence

The latest data from the World Health Organization reported 1.5 billion overweight adults and 500 million obese adults worldwide, corresponding to 5% of the world's population (1). Prevalence of obesity is nearly the same in men and women, except in the elderly where the prevalence rate is higher for women (15). In Norway, the prevalence of obesity has almost doubled during the last two decades; about 15% of the forty year old Norwegian population has BMI of 30 or more (15), and prevalence rates are increasing for both adults and children (15, 16). The increasing prevalence rate for children is alarming because 50% to 70% of overweight adolescents will suffer from obesity into adulthood (17) and overweight and obesity are associated with increased risk for a number of chronic diseases.

1.2 Obesity and comorbid psychiatric disorders

It has not yet been established whether or to what degree the prevalence of psychiatric disorders is elevated in obese persons compared to non-obese persons. It has been questioned whether the association between obesity and psychiatric disorders is biased by the known association between impaired somatic health status and increased prevalence rates of mental disorders (18). However, in studies that assess the relationship between obesity and psychiatric disorders in large representative samples using structured clinical interviews, the predominant finding is elevated rates of mood and anxiety disorders in persons with obesity compared to the general population (8, 19, 20). The relationship between BMI and mental disorders varies with age and gender (21). In women, higher BMI is associated with increased risk for mental disorders, and the association is diminished in older women. In men, there is a u-shaped relationship between BMI and mental disorders (21). In a study published in 2006, obesity was found to be associated with 25% increase in odds ratios for mood and anxiety disorders (8). A recent meta-analysis found that obese persons were 1.18 times more likely to be depressed compared to non-obese persons (obesity threshold BMI >30) (22). Further, Petry et al. reported an association between obesity and psychiatric disorders (23). However, the comparison group in this study consisted of somatically healthier persons.

Patients presenting for treatment for obesity also report more psychopathology and more binge eating than patients with obesity not seeking treatment and normal-weight controls (24). In the study by Fitzgibbon et al., psychopathology was measured by Borderline Syndrome Index (BSI), Symptom Distress Checklist (SCL-90), and Binge scale (24). There were significant differences between the three groups on all these measurements (patients presenting for obesity treatment, patients with obesity not seeking treatment, and normal-weight controls). Further, one study examined differences between two groups of patients with obesity, one group seeking medical intervention (including bariatric surgery) and one group seeking dietary counselling (25). They found that the group seeking medical intervention reported significantly

more general and specific psychopathology measured by SCL-R-90 than the group seeking dietary counselling.

About 70% to 80% of the patients presenting for bariatric surgery are women. Women have higher prevalence rates of psychiatric disorders in the general population (26). It is therefore to be expected that the prevalence of psychiatric disorders is higher in samples presenting for bariatric surgery than in samples not seeking such treatment. The prevalence rates of comorbid psychiatric disorders are also increased in women with obesity compared to non-obese women (20). Such an increased prevalence of psychiatric comorbidity has not been detected in men with obesity (20). This can explain why the prevalence of psychiatric conditions is higher in samples presenting for bariatric surgery than in samples not seeking such treatment. Several studies have found associations between severity of obesity and prevalence of psychiatric disorders, especially mood disorders (27, 28) and Binge Eating Disorder (BED) (29). In patients seeking bariatric surgery, psychiatric disorders were associated with higher BMI (30).

Comorbid psychiatric disorders in patients undergoing bariatric surgery

Studies that had evaluated prevalence rates of psychiatric disorders by structured diagnostic interviews in patients undergoing bariatric surgery were identified by searching MEDLINE, EMBASE, and PsycINFO (1.1.2000 to 31.12.2010) using the following search words: “bariatric surgery” OR “weight loss surgery” OR “obesity surgery” OR “weight reduction surgery” OR “gastric bypass” OR “gastric band” OR “gastric sleeve” OR “biliopancreatic diversion” OR “duodenal switch” AND “obesity” AND “mental disorders” OR “mental disease” OR “psychiatric comorbidity”. The same search terms were applied to the Medline, Embase and PsycINFO search engines to retrieve all potentially relevant English articles from 1.1.2000 until 31.12.2010. The articles obtained from the literature search were then evaluated according to the criteria described in Figure 1.

Prevalence rates from the seven studies that used a structured interview in assessing psychiatric disorders are reported in Table 1 (one study by de Zwaan et al. published in 2011 and Paper I in this thesis are included in the overview).

Axis I and II disorders

There is evidence for elevated prevalence rates for Axis I Disorders, especially mood and anxiety disorders in bariatric surgery samples (30). In the studies by Mauri et al. (31), Kalarchian et al. (30) and Muhlans et al. (32), prevalence rates of psychiatric disorders in bariatric surgery populations were compared to prevalence rates of the general population. In these study samples, the prevalence of psychiatric disorders was higher than in the general population. Only in one study, by Rosenberger et al., was prevalence of comorbid psychiatric disorders in patients seeking bariatric surgery found to be similar to the prevalence in the general population (33) (Table 1).

There is also evidence for elevated rates of personality disorders in patients waiting for bariatric surgery, with Avoidant Personality Disorder being the most prevalent personality disorder. Kalarchian et al. found that in patients waiting for bariatric surgery, 29% (95% CI = 23.76 to 34.24) had at least one personality disorder and 17% (95% CI = 12.66 to 21.34) fulfilled the criteria for Avoidant Personality Disorder (30). In comparison, about 15% (95% CI = 14.08 to 15.50) of adult Americans have at least one personality disorder and 2% (95% CI = 2.14 to 2.58) have Avoidant Personality Disorder (34).

Comorbid eating disorders

Binge eating behaviour and Binge Eating Disorder (BED) are common in bariatric surgery candidates (30-32). The reported prevalence rate of BED among patients seeking bariatric surgery depends on the diagnostic criteria and instruments used to collect data; the literature shows as little as 3% to as much as 50%. Studies that used the research criteria for BED which appears in an appendix of the DSM-IV and

structured interviews for the assessment of eating disorders (SCID and/ or Eating Disorder Examination (EDE) have found prevalence rates for BED to be between 3% and 23% (30-33, 35, 36) in patients seeking bariatric surgery. This variation in prevalence is mainly caused by variation in diagnostic criteria and particularly “diagnostic cut-offs”. One study reported a low prevalence rate of BED but reported a high prevalence rate of atypical binges (an atypical binge is a binge that does not meet DSM-IV definition of a “binge”, which is eating in a discrete period of time (e.g., within any two hour period) an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances) (37). Prevalence rates of BED in the normal-weight population range from 1% to 3% and in the obese general population from 4% to 10% (38).

Comorbid substance abuse

There are few published studies that report the prevalence rates of lifetime or current substance abuse among patients seeking bariatric surgery. One study found a 33% prevalence rate of lifetime substance abuse and a 2% prevalence rate of current substance abuse among patients seeking bariatric surgery (30). Another study confirmed a 1% prevalence rate of current substance abuse, with alcohol as the most commonly abused substance (39).

1.3 Obesity treatment

Treatment for obesity includes life style interventions, behavioural therapy, pharmacotherapy, surgery, or combinations of these. In a review of obesity treatments, published in 2007, the evidence from randomized controlled trials was evaluated regarding efficacy in producing sustained and significant reductions in weight (40). Studies with a randomized controlled design that had weight loss as the

outcome measure and a follow-up of two years or more from the intervention initiation were included in this review.

1.3.1 Life style interventions for obesity

Life style interventions include a combination of dietary changes, caloric restrictions, and exercise and often result in modest reductions in weight, but this modest weight reduction appears to be clinically important for outcomes like reduction in blood pressure and reduction in incident diabetes. Average sustained weight loss following life style interventions is 3.2 kg (40). However, there is no evidence that calorie restricting diets alone lead to lasting weight loss or health benefits (41). In a recently published review by Kirk et al., evidence for life style interventions were examined (42). In accordance with this review, evidence based life style interventions should include a multi-component treatment (such as targeting diet, physical activity, and counselling) that takes a long term approach (at least six months). Further, the study reported that motivation and encouragement by the health care professionals seem to be key components in life style interventions. Life style interventions were effective with an initial weight loss of about 5% to 10% of body weight (42).

Inclusion of exercise in a life style intervention is important for sustaining weight loss (43, 44). Long term maintenance of physical activity has been found to decrease weight gain (43), and 30 minutes of aerobic activity daily seem to promote weight loss and reduce obesity related comorbidities (44). Successful lifestyle interventions are continuous; a key factor in sustaining weight loss seems to be that the treatment becomes the person's daily routines (40).

1.3.2 Psychological treatment

Behavioural weight loss treatment

Behavioural Weight Loss Treatment (BWL) aims at long term change of eating and physical exercise habits. BWL seeks to identify and challenge eating, activity, and thinking habits that contribute to the patients' weight problem. Traditionally, these programmes relied on education for behaviour change. Self-monitoring, stimulus control, problem solving (45), and self-regulation (46) skills seem to be essential for behaviour change. A previous study showed that engagement in self-monitoring is associated with sustaining weight loss at approximately two years after gastric bypass surgery (47). BWL is effective in inducing and maintaining losses of approximately 5% to 10% of initial weight (45).

Cognitive therapy

It has been argued that incorporation of cognitive therapy in weight loss programmes would increase the effectiveness of reducing comorbid psychological problems and facilitating weight loss (48-50). Several studies support this assumption. Inclusion of cognitive-behavioural approaches in treatment programmes seems to improve the participants' physical activity and nutrition (48). In one study, two groups of patients, patients with obesity and BED and patients with obesity without BED, received either cognitive or behavioural treatment (51). Cognitive treatment was more effective than behavioural treatment in reducing concerns about shape, weight, and eating as well as in improving self esteem. Further, patients who received cognitive treatment were more abstinent from binge eating compared to patients who received behavioural treatment. Patients who participated in a cognitive group treatment (10-week programme) in another study had significantly greater weight loss, which was maintained at follow-up 18 months after treatment, compared to patients in the control group (waiting list) (49). Werrij et al. compared cognitive treatment added to dietetic treatment with physical exercise added to dietetic treatment in patients with obesity

(50). The treatment that included cognitive therapy was superior to treatment that included physical exercise with regard to maintenance of weight loss.

Mindfulness based therapy

Mindfulness based therapy is an educational approach that uses training in mindfulness meditation to increase the ability to respond skilfully to experiences that contribute to emotional distress and maladaptive behaviour (52). There are several reasons to study the effects of Mindfulness based training in patients with obesity. Psychological distress has been shown to play a role in binge-eating behaviour (53). Many individuals with obesity seem to have lost the ability to recognize and respond to internal cues of hunger, satiety, and fullness (54). Avoidance of unpleasant emotions and reduced coping skills may also play a role in eating behaviours (55).

In a study by Alberts et al., participants in a dietary group treatment for overweight received manual based mindfulness training (56). This training aimed to increase awareness of automatic patterns that usually emerge in response to food cravings, i.e. to observe and accept food cravings without acting on them. After the intervention, these patients reported lower cravings for food compared to patients who had not received this training. Further, there is some preliminary evidence that mindfulness based therapy can promote weight loss, decrease psychological distress, reduce eating pathology in patients in weight loss treatment (57), and improve quality of life in patients with obesity who have completed a weight loss treatment programme (58). In the study by Lillis et al., changes in distress and quality of life could not be attributed to changes in weight, suggesting that the Acceptance and Commitment Therapy (ACT), which includes mindfulness training, had a positive effect on these outcome measures (distress and quality of life) independent of weight loss (58).

1.3.3 Pharmacotherapy

Pharmacotherapy for weight loss includes drugs that lead to reduction in appetite and drugs that lead to fat malabsorption. Sibutramine is a B-phenethylamine derivate that inhibits reuptake of serotonin and norepinephrine and suppresses appetite and causes satiety (59). In a meta-analysis, sibutramine promoted weight loss of about 4.5 kg in patients with BMI $>25\text{kg/m}^2$ at one year follow-up and improved risk factors associated with obesity (i.e. plasma levels of glucose, triglycerides, and cholesterol) (60). However, in the Sibutramine Cardiovascular Outcomes trial (double-blind and placebo-controlled study involving 10,742 overweight or obese patients), long term sibutramine treatment was associated with an increase risk of myocardial infarction and stroke in overweight or obese patients with pre-existing cardiovascular diseases (61). Sibutramine has been withdrawn from many markets including Norway because of concerns about these serious side effects.

Rimonabant is a CB₁ receptor antagonist (cannabinoid receptor type 1). Studies have demonstrated that the endocannabinoid system is overactive in obesity (62). Rimonabant promoted weight loss of about 4.7 kg at 1-year follow-up and reduced cardiovascular risk factors (63). However, it has been reported that use of rimonabant was associated with psychiatric side effects including anxiety, depression, and suicidal ideation (64). Therefore, it has been suspended from the market.

Orlistat is the only anti-obesity drug allowed in Norway. It is a reversible gastrointestinal lipase inhibitor that blocks fat absorption (65). In a meta-analysis of 29 studies, orlistat reduced body weight by about 2.6 kg at six months follow-up and 2.9 kg at one year follow-up (66). Treatment with orlistat also reduced obesity related risk factors (67, 68). The more common side effects of orlistat include diarrhea, flatulence, bloating, abdominal pain, and dyspepsia (69). Adequate vitamin supplementation (fat-soluble vitamins: vitamins A, D, E, and K) may be necessary for patients on orlistat.

Drug interventions achieve modest weight loss that is comparable to weight loss by life style interventions (40). Weight loss following drug interventions seems to also be associated with reduction in obesity related comorbidities. Sustained drug treatment is necessary to prevent weight regain (40).

1.3.4 Surgical treatment

Bariatric surgery is an effective treatment for patients with severe obesity as it leads to significant and sustainable weight loss and improvement in obesity-related comorbid conditions (70). There are three main approaches: restrictive procedure, malabsorptive procedure, or a combination of these two (71). Successful weight loss is defined as more than 50% Excess Weight Loss (EWL). In a review of the clinical effectiveness of bariatric surgery, %EWL was reported to be between 63% and 78% following Gastric Bypass surgery (70). Life style change is a key factor in both obtaining and sustaining a favourable outcome. The consensus view of surgical intervention is that surgery is a tool for weight loss and should be accompanied by behavioural and life style changes (72). Outcomes of the most common bariatric surgery procedures are summarized in Table 2. Laparoscopic Roux-en-Y gastric bypass (LRYGB) is considered to have the best “outcomes to risk” ratio (73) (Table 2).

Appropriate life style changes and bariatric surgery

Dietary guidelines

Dietary guidelines vary according to the specific kind of bariatric procedure that is performed (74). Generally, a multiple vitamin and mineral supplement (estimated for adults) is sufficient after pure gastric restrictive procedures since there is no malabsorption of specific nutrients. The RYGB procedure involves bypassing the gastric fundus, the duodenum, and a variable length of the proximal jejunum.

Consequently, patients are at risk for developing deficiencies of iron, B12, folate, and calcium. After biliopancreatic diversion, protein and fat mal-absorption can be more pronounced than after gastric bypass, and vitamin D supplementation is recommended. In addition, patients are recommended to ingest 90g of protein a day to counteract the protein mal-absorption (74).

After surgery, patients need to return to solid foods gradually. Four to six weeks after surgery most of the patients manage to eat regular textured food. After six weeks, the guidelines include the following: eat for at least 20 minutes and chew food well to allow feeling of satiety, drink liquids before meals or 30 minutes afterward, eat proteins before carbohydrates and fats (75, 76), and eat three balanced meals and two snacks daily (77).

Several studies have examined the role of postoperative eating behaviours as a means of influencing post-surgery outcome (78, 79). These studies have found associations between eating behaviour and weight loss. In a study by Sarwer et al. the patients who were “high adherers” to postoperative diet had 28% greater weight loss two years after surgery compared to patients who were “low adherers” to the postoperative diet (79).

Guidelines for physical exercise after bariatric surgery

Patients waiting for bariatric surgery have lower levels of physical activity compared to normal-weight controls (80) and spent 26% more of their time in sedentary behaviours (television, internet, sitting) compared to the general population (81). In a review paper about exercise after bariatric surgery, postoperative exercise was found to be associated with weight loss one and two years after surgery (82). Activity at levels > .5 hours each day has been reported to be associated with maintenance of %EWL at a follow-up period of more than 3 years after surgery (patients spending < .5 hour in activity/day had 78% EWL compared 85% EWL in patients spending > .5 hour in activity/day) (83). In a study by Rosenberger et al. moderate (fast walking, tennis) and strenuous (jogging, basketball) physical activity one year after surgery was

associated with weight loss and psychosocial outcomes (level of depressive symptoms and HRQoL) (84). In a recently published study, patients who participated in an endurance and strength training programme improved their aerobic capacity and prevented decrease in muscle strength following weight loss surgery compared to patients who had not participated in such a programme (85). Further, level of physical activity is associated with improved HRQoL one year after surgery (86).

Though there are no standard guidelines for the amount of physical exercise for bariatric surgery patients, the guidelines for the amount of physical activity necessary to promote weight loss and reduce comorbidities suggest at least 30 minutes of aerobic activity daily (44). In the study by Bond et al., 200 minutes of physical activity each week (assessed by The International Physical Activity Questionnaire, which includes walking and activities of a moderate and vigorous intensity performed continuously for at least 10 minutes) was associated with weight loss and HRQoL one year after surgery (86).

Adherence to the recommended life style after surgery varies among patients. In a study by Thomas et al., most patients (>85%) took the recommended vitamins as prescribed while only 5% had more than 5 meals each day, and 24% engaged in moderate to vigorous physical activity for ≥ 30 minutes daily 6 months after surgery (87). In a study by Forbush et al. 58% of the respondents performed < .5 hour of activity/day and 9% of the respondents reported no activity of consequence in a typical day (83). According to these findings, research should focus on ways to help individuals who undergo bariatric surgery to initiate and maintain appropriate levels of physical activity after surgery.

Post-surgical outcomes

Weight loss, quality of life, improvement in mental and physical health, and side effects/ complications are included as outcome measures in the evaluation of bariatric surgery.

Weight loss

Patients who undergo bariatric surgery lose substantial weight. The use of EWL is a common metric for reporting weight loss after bariatric surgery. Successful weight loss is often defined as $\geq 50\%$ EWL. From 47% to 80% EWL is achieved after bariatric surgery; the lower %EWL is for restrictive procedures and the higher %EWL is for procedures combining restrictive and mal-absorptive procedures (Table 2) (88-91). About 20% to 30% fail to achieve successful weight loss or they regain much of the lost weight over time (92, 93). However, %EWL does not express health risk reduction unequivocally for all patients because %EWL can correspond with a wide range of possible BMI results depending on the patients initial BMI. There is a direct correlation between BMI and health risk (94). Further, it has been reported that %EWL is associated with initial BMI: the heavier the patient, the smaller the %EWL (95). In line with this, it has been argued that weight loss outcome following bariatric surgery should include a relative weight loss measure (96). In a study by van de Laar et al., percentage total weight loss (%TWL) is suggested as the relative weight loss measure (96).

There is significant long term variability in weight loss outcomes after surgery. For example, 83% EWL at a two year follow-up after gastric bypass was reported (90) and 75% EWL after biliopancreatic diversion in a study with more than a ten year follow-up (91). One study with a participation rate of 96% found an average BMI reduction of 28% and a mean EWL of 61% at the seven year follow-up after surgery (gastric banding and gastric bypass surgery) (97).

Somatic comorbidity

Persons with overweight and obesity are known to have increased risk of several somatic comorbidities compared to persons with normal weight (7). After surgery there is a significant reduction in metabolic syndrome, hypertension, and diabetes (88-91). Of the patients with preoperative conditions, reduction in body weight was associated with a clinically significant reduction in diabetes (84%), hypertension

(68%), sleep apnoea (80%), and hyperlipidemia (97%) at follow-up two years after surgery (98) (Table 2).

Life expectancy

Two studies, by Sjostrom et al. and Adams et al., with mean follow-up of 10 and 7 years, respectively, showed that weight loss lowers the rate of death in persons suffering from severe obesity (99, 100). Particularly, the number of deaths from diabetes, heart disease, and cancers were lowered, yet another study found that deaths from non-disease related causes, like accidents and suicides, are significantly higher in the surgery group compared to a control group (100). In a study by Omalu et al., a substantial excess of deaths owing to suicide (compared to age and gender adjusted general population) was found (101). Careful assessment and intense follow-up are recommended.

Quality of life

Patients with obesity have impaired HRQoL compared to the general population (102, 103). However, HRQoL in patients with obesity seems to vary widely with increasing age, higher BMI, and comorbid psychiatric disorders (30, 31); all three of these were found to be associated with more impaired HRQoL. The relationship between obesity and HRQoL is complex. In a study by Cameron et al., they found that reduced HRQoL was not only a consequence of obesity, impaired HRQoL was also a predictor of weight gain (104). This study was a longitudinal population-based study with surveys conducted with five years interval. In particular, mental health related aspects of HRQoL at baseline were associated with weight gain at follow-up five years later (104). Further, some of the associations between BMI and HRQoL were confounded by age. The predictive value of obesity at baseline for reduction in social functioning at follow-up was limited to patients younger than 65 years old, and the predictive value of bodily pain at baseline for weight gain at follow-up was limited to patients over 65 (104).

HRQoL improves after bariatric surgery (105). In a study by Andersen et al., HRQoL two years after bariatric surgery was found to be in the normal range (103). In a study by Karlsson et al., HRQoL was found to follow phases of weight loss, weight regain, and weight stability. Long-lasting weight reduction was associated with long-standing improvements in HRQoL (106). This study compared conventional treatment to surgical treatment for obesity with a ten year follow-up time (106).

In a five year prospective study, levels of Disease specific quality of life (DSQoL) was also improved (105). Levels of DSQoL are reported to be significantly higher after weight loss surgery when compared to levels in morbidly obese patients not yet operated (107). However, about one-third of surgically treated patients do not manage to maintain weight loss sufficient for a positive long term effect on quality of life (106). Preoperative comorbid psychiatric disorders seem to have predictive value for less improvement in HRQoL after surgery (108, 109).

Mental health

Psychological and psychosocial difficulties improve after weight loss treatment and the improvements seem to be sustained (110-113). Prevalence rates of Axis I Disorders are found to be from 0% to 50% of the presurgical status; however, prevalence rates for Axis II Disorders are reported to be more stable (108). In one study, the 50 patients with severe obesity who were examined at a six year follow-up had sustained improvements in anxiety, depression, and quality of life (111). Several studies find that symptoms of depression are more reduced than symptoms of anxiety (110, 114). It is perhaps possible that the anxiety symptoms were unrelated to obesity before treatment, and are, thereby, not reduced by weight loss. Another possibility is that some patients face serious challenges after surgery, such as changed self concepts and social relationships or fear of regaining weight. In accordance with earlier research, a tentative conclusion is that psychopathology directly related to weight issues improves after surgery, but psychopathology not secondary to the degree of obesity is persistent (115).

In a recently published study by de Zwaan et al., psychiatric disorders were assessed by structured clinical interviews (SCID-I) prior to and after bariatric surgery (gastric banding or gastric bypass) (116). They found a significant decrease in the prevalence of current depressive disorders from preoperative assessment to follow-up 6-12 months and 24-36 months (32.7%, 16.5%, and 14.3%, respectively) after surgery. However, prevalence rates for anxiety disorders were stable from preoperative assessment to follow-up (16.8%, 15.3%, and 14.3%, respectively).

It has been discussed whether substance abuse and weight problems share a common causality: where substance abuse decreases when eating behavior predominates (117). Patients unable to overeat may be at increased risk for substance abuse. This “transfer” of addictive behavior between substances has not been strongly supported by empirical data. Only about one percent met criteria for alcohol abuse 2.5 years after gastric bypass surgery (118). In comparison, prevalence rates (12-month prevalence) for alcohol abuse in a Norwegian urban area was 6% for men and 3% for women (119).

Side effects/complications

Side effects/complications of bariatric surgery are dependent on several factors: bariatric surgery procedure, patient characteristics, and quality of the bariatric surgery team (71). Common side effects after bariatric surgery include nutritional deficiencies, nausea, vomiting, dumping syndrome, abdominal pain, and diarrhoea (71). Vomiting is reported by a substantial proportion of the patients during the first postoperative months, and dumping syndrome initially occurs in about 50% of the patients who have undergone gastric bypass surgery (71). Postoperative complications of particular concern include thromboembolism (0.4-3.1%) and anastomotic leaks (0.5-3.0%) (71). Anastomotic ulcer is an occasional complication after gastric bypass (120). Ulcers that occur early (< one year after surgery) are common (6% in a large prospective study (120)) and those that occur late (> one year after surgery) have been reported in only a small proportion of the patients (1%) (120, 121). LRYGB is

associated with increased incidence (0.8–5%) of internal hernias (122). Internal hernias have been reported to be associated with small bowel obstruction occurring after LRYGB (123).

The early mortality rate of bariatric surgery (i.e. death <30 days) is 0.1% to 2% (71). Risk factors for early mortality are BMI >50, male gender, hypertension, age >45 years, and presentation of risk factors for pulmonary embolism (124). Pulmonary embolism is the leading cause of death after undergoing gastric bypass (124). In the study by DeMaria et al., patients without any of the previous mentioned risk factors had practically no risk for mortality (124).

1.4 The significance of psychosocial factors for clinical and patient rated post-surgery outcomes

Post-surgery outcome is dependent on nonsurgical factors such as the patients' ability to implement and adhere to life style changes like healthy eating and exercising (125). Several studies have investigated how pre-surgical psychosocial factors influence post-surgery outcome (126-130). However, methodological differences in these studies make them difficult to compare. Few studies have incorporated ICD or DSM diagnostic criteria in assessing preoperative psychiatric disorders.

The predictive value of psychiatric comorbidity for post-surgery outcome

There are only three prospective studies that used structured diagnostic interviews when assessing the role of psychiatric comorbidity for treatment outcome in bariatric surgery. The first of the three prospective studies found that patients with a lifetime history of depression or anxiety had less weight loss six months after surgery compared to patients who had never had such disorders (131). The second prospective study found that having more than two preoperative psychiatric disorders compared to having only one or no preoperative psychiatric disorders was associated with less

weight loss after surgery (average BMI loss 10.8, 14.0, and 16.1, respectively, $p=.047$) (132). Post-surgical quality of life was also assessed in the same study population. The study demonstrated that a combination of Axis I and Axis II Disorders predicted poorer quality of life after surgery. Female patients with preoperative comorbid psychiatric disorders had more impaired quality of life in four of six domains: self esteem, physical activity, social relationships, and sexuality compared to female patients without preoperative comorbid psychiatric disorders (109). In the third of the three prospective studies, current and lifetime depressive disorders were negative predictors for weight loss at follow-up four years after a restrictive bariatric surgery procedure (127). In addition, depressive disorders had no impact on short term weight loss after surgery (127). An earlier study by Powers et al., reported that presence of multiple pre-surgical Axis I psychiatric diagnoses, presurgical untreated Axis I diagnosis, or presurgical psychiatric hospitalization were associated with post-surgical psychiatric hospitalization (133). There is some evidence that postoperative psychiatric disorders are associated with weight loss (116, 134). In the study by de Zwaan et al., postoperative depressive disorders, but not postoperative anxiety disorders, were associated with weight loss at follow-up 24-36 months after surgery (116).

In contrast, other studies have reported no association between psychiatric disorders and weight loss after bariatric surgery (108, 126, 135). In a recently published study by Steinmann et al., patients with bipolar disorders had weight loss comparable to patients with other psychiatric disorders (mainly depression and anxiety disorder) as well as patients without any psychiatric disorders (136). This study was limited by a retrospective design and a small percentage of patients with bipolar disorders. Perhaps there has been a selection bias against surgery in patients with bipolar disorder.

Personality disorders as predictors of outcome after surgery

In general, personality appears to have substantial influence on health behaviour (137). Accordingly, several studies have focused on the influence of personality

disorders on the results of bariatric surgery. One study, using structured interview based diagnosis for Axis II Disorders (SCID-II), found that narcissistic personality disorder was associated with poor compliance to diet, to exercise, to attendance of scheduled visits, and to amount of weight loss (138). However, this was only apparent at short term follow-up, and not at follow-up two, three and four years after surgery. Other Axis I or Axis II Disorders were not associated with treatment adherence and weight loss in this study. This finding is in accordance with findings in previous studies that have shown that presence or absence of personality disorders is not predictive of bariatric surgery outcome, while the extent and quality of these problems seem to be associated with success or failure (129). In line with this are findings in a Norwegian study by Larsen et al. (128). They were able to define a group of patients with negative psychosocial outcome, characterized by personality disorders and a higher frequency of preoperative psychiatric help-seeking. These patients had a negative psychosocial reaction despite sufficient weight loss.

Substance abuse and outcome

Patients who are currently abusing or are dependent on drugs or alcohol are excluded from bariatric surgery. Because of this, there is limited amount of information about how substance abuse can affect postoperative outcome. There has been some focus on the misuse of alcohol after bariatric surgery, but evidence regarding alcohol misuse after surgery is also limited (139).

The predictive value of comorbid eating disorders for post-surgical outcome

Naturally, there has been a particular focus on whether patients with BED have problems with eating behaviour adaption and treatment adherence after bariatric surgery (140-148). Pre-treatment BED is associated with less weight loss after non-surgical weight loss treatments (150). In a recent meta-analysis of non-surgical approaches, patients with pre-treatment BED lost 2% of their initial weight compared to patients without pre-treatment BED who lost 11% (149).

Methodology for assessment of BED varies across studies, and findings regarding the impact of preoperative BED on post-surgical outcome, including weight loss, are inconsistent. Four prospective studies did not find any association between preoperative BED and weight loss after surgery (140-143); however, one prospective and several retrospective studies did find an association between BED and both weight loss and quality of life after surgery (144-147). A recently published study, in which BED was assessed using criteria proposed for the Diagnostic and Statistical Manual (DSM-IV), found that preoperative presence of BED does not attenuate weight loss or improvements in cardiovascular risk factors at one year follow-up in surgically treated patients (148). A review of the literature of binge eating in the bariatric surgery population concludes that clinically significant binge eating is related to poorer surgical outcomes (150, 151). However, this finding seems confined to patients that retain eating pathology after surgery (150). The same conclusion is supported by the findings of a recently published prospective study: LOC after surgery is associated with weight loss, higher depression score, more eating disturbances, and more impaired mental aspects of HRQoL (134).

In a recently published review, emergence of classical eating disorders and “subsyndromal” eating pathology after weight loss surgery was examined (152). The conclusion was that the development of eating disorders after surgery seemed to be rare, but development of subsyndromal eating problems like grazing and sense of “lack of control” are more prevalent. (151). Classification of postsurgical eating problems is complicated for several reasons. Firstly, side effects after bariatric surgery (e.g., purging, constipation, decreased appetite) may mimic eating disorder behavior or symptoms and secondly, postoperative symptoms (e.g., dumping, dysphagia) may lead patients to engage in compensatory or restrictive behaviors to compensate for the feeling of having overeaten or having consumed foods that are difficult to tolerate. Finally, patients are instructed to follow specialized diets, to limit meal size and to extensively chew food. Such eating habits could be regarded as ritualistic, and it may be difficult to distinguish from eating behaviors motivated by eating, weight, and shape concerns.

To summarize, BED at baseline is not a stable predictor for short term weight loss, and the impact of BED on the long term course of weight after treatment remains unclear. Evidence suggests that only some patients with preoperative BED return to this behavior after surgery, but for those who do, there is likely to be more weight gain (152). It seems reasonable to assume that patients with preoperative BED who undergo bariatric surgery achieve an overall better outcome than they would have without bariatric surgery (153).

Psychological symptom level and caseness as predictor of post-surgery outcome

Herpertz et al. reviewed 29 studies that examined potential psychosocial predictors of weight loss and mental health after bariatric surgery. The review concluded that psychological symptoms seemed to be of predictive value for HRQoL as well as mental and physical well-being, but not for weight loss after bariatric surgery (108). This findings are confirmed in a study by Van Hout et al. (126). On the topic of weight loss, depressive and anxiety symptoms as correlates of psychological stress with regard to obesity seem to be positive predictors of weight loss post-surgery. However, Rutledge et al. have found that there is a natural selection process of patients that pursue bariatric surgery (154). Bariatric surgery patients reported greater self-rated health, lower depression level, and fewer cardiovascular risk factors compared to patients pursuing non-surgical treatment for obesity. In accordance with this, the bariatric surgery group is not a random group, and this might have limited the findings in earlier studies that psychosocial factors did not predict weight related surgery outcomes.

The associations between preoperative psychological symptoms and postoperative HRQoL were confirmed in a more recently published study; In 2007, Masheb et al. concluded that lower baseline depression score and greater improvement in depression score predict better HRQL one year after gastric bypass surgery (155). In contrast, another study showed that patients with more severe binge eating compared

to patients with moderate or non binge eating benefited the most in terms of quality of life one year after surgery (156).

Other psychosocial variables and their relation to outcome after surgery

Several studies have investigated the impact of past sexual abuse on post-surgery outcome (157-162). Studies have reported a negative impact of sexual abuse in the past on weight loss (157), depression (161) and an increased risk of psychiatric hospitalisation (162) after bariatric surgery. It has been speculated that patients with a history of sexual abuse will maintain excess weight as a defence against potential future abuse (159). However, in a study published in 2009, no impact of past sexual abuse was found in long term follow-up of patients who had undergone bariatric surgery (159).

To summarize, evidence suggests that patients with past sexual abuse did not differ with regard to weight loss (158-162); however, they seem to have more impaired mental health after surgery compared to patients without past sexual abuse (161, 162).

Evidence for the impact of emotional eating (EE) (tendency to eat in response to emotional distress and during stressful life situations) on post-surgery outcome is mixed (163, 164). In one prospective study, with one year follow-up, emotional eating was found to predict weight loss and improvement in quality of life in bariatric surgery patients (163), and accordingly EE is suggested to be an important variable to consider when patients do not do well in weight loss treatment. In contrast, one study reported no differences regarding weight loss in “high emotional eaters” compared to “low emotional eaters” eight months after surgery (164). Weight regain after surgery may not occur until 18-24 months after surgery, and these studies did not have any follow-up after one year and eight months, respectively.

The NICE guidelines for bariatric surgery suggest that psychological factors influence outcome after bariatric surgery (165). However, these guidelines do not specify which

psychological factors are associated with postsurgery outcome. Earlier studies have reported that psychological symptoms that persist or reoccur after bariatric surgery might have strong impact on the course of weight loss and quality of life (116, 134). One study by de Zwaan et al. found that preoperative Axis I psychiatric disorders were related to postoperative psychiatric disorders, and postoperative psychiatric disorders were related to postoperative weight loss (116). White et al. reported that postoperative, but not preoperative loss of control over eating was a negative predictor for postsurgical weight loss and psychosocial outcomes at follow-up one and two years after surgery (134). In accordance with this, further research is needed to identify maintaining factors for psychiatric disorders in patients undergoing bariatric surgery, in order to develop effective individual psychosocial intervention strategies to improve outcome.

1.5 Shame and obesity

Definition of shame

Shame is related primarily to perceptions of personal inadequacy, inferiority, and weakness. The concept is described as an unpleasant emotion that arises when an individual experiences some defect in oneself (166). Shame is called “the affect of inferiority” (167) and is linked to fear of negative evaluations, submissive behaviour, and coping strategies of avoidance and withdrawal (168, 169). Shame and guilt are often considered to be the same emotions, but they seem to represent distinct affective experiences. Guilt is linked to the experience of the bad thing I did, however, shame is linked to experiencing the whole self as bad. Accordingly, guilt motivates for engaging corrective responses, and shame for more disengaging responses such as self-criticism and problem avoidance (166, 170).

Shame, but not guilt, is associated with higher prevalence of psychiatric disorders (depression, anxiety, eating disorders, and Cluster C personality disorders) (171). One study reported that shame plays a significant role in the onset and course of

depression (172). A central cognition in depression is the tendency to over-generalize from one specific failure to a broader sense of worthlessness (173). This may be the case for patients with obesity: perhaps they internalize societal prejudices of obese people as being lazy, incompetent, and lacking self discipline (174, 175). In social psychology, shame has been linked to public self-consciousness and fear of negative evaluation by others (176). In other words, internal judgements about how the individual believes they exist in the minds of others.

Shame and obesity

Shame is under the heading of stigma in sociological literature, and self-objectification theory may contribute to explaining differences in stigma and body shame in patients with obesity (177). Self-objectification distinguishes between two types of body evaluation: appearance based and competence based (health, strength, physical fitness). An appearance based body evaluation is associated with feelings of shame (178). One study examined associations between exposure to idealized body images and body shame and exposure anxiety. Such exposure led to increased body shame and exposure anxiety in all participants, but the effect of this type of exposure on appearance anxiety was greatest for high self objectifiers (appearance based self view) compared to low self objectifiers (179).

Shame typically arises in response to personal failure to live up to esteemed standards. In accordance with this are findings of associations between experience of body shame and the experience of falling short of cultural appearance standards (178). People actively seek to defend themselves against negative evaluations, and shame is possibly one of the key affects that induce conformity (180). Gilbert makes the distinction between external and internal shame (180). He proposed that external shame is related to what we believe others think of us (others consider us unattractive and devalued) and internal shame is related to how we see ourselves. Obese people experience a pervasive pattern of condemnation in society; however, patients with obesity also have negative attitudes toward obesity and blame themselves for the

condition (181). Thereby, it is reasonable to assume that patients with obesity experience both external and internal shame. Evaluating body appearance using cultural standards for thinness is found to be associated with feelings of shame. Stigmatizing experiences or higher level of body shame may serve as a trigger for psychological distress (182). There is evidence that stigma associated with being overweight is more negative for women than for men (183), which may explain why women, more often than men, seek treatment for their obesity (30).

The role of shame in predicting outcome of obesity treatments

Patients with obesity who seek treatment report more psychological problems than patients who do not seek treatment (25). In patients who undergo bariatric surgery, negative self attitudes played an important role in preoperative depression scores (184). Shame and self-critical thinking are associated psychiatric disorders, and shame and, in particular, self-critical thinking are related to problem maintenance and inadequate treatment response (185-187). In a qualitative study that investigated differences between patients who maintained weight and patients who regained weight after an initial weight reduction, “weight- regainers” reported that weight and shape unduly influenced their self-worth. The patients described more preoccupation with weight and shape compared to “weight maintainers” (55).

Coping strategies associated with shame may be a negative predictor for outcome after weight loss treatments (188). In general, two major ways of coping strategies are identified: coping that alleviates emotional distress (emotion-focused coping) and coping that attempts to manage or alter the problem causing distress (problem-focused coping) (189). Problem-focused coping is linked to improved mental health, end emotion-focused coping to increased distress (190). Patients with obesity and weight related shame seem to display lower levels of problem-focused coping compared to patients with obesity and weight related guilt (181). Patients who choose surgery as their treatment preference for obesity have lower levels of problem-focused coping

and higher levels of emotion-focused coping compared to patients who choose conventional treatment (191). Problem-focused coping, in contrast to coping strategies characterized by avoidance and escape, is associated with better ability to maintain weight loss after initial weight loss (188).

To summarize, shame-prone people appear to be vulnerable to a variety of psychiatric disorders, including depression (172), anxiety (192), eating disorders (193), and Cluster C personality disorders (194). Shame and, in particular, self-critical thinking contribute to maintenance of psychiatric problems (185, 187). Further, shame is associated with low self esteem, low self-efficacy and with coping strategies of avoidance and withdrawal (168, 169, 195). Hence, shame could be important in understanding the individual differences in improvement of mental health and in engagement in health promoting activities after surgery.

1.6 Psychological counselling and bariatric surgery

Psychological well-being, physical exercise, and healthy eating habits are associated with weight loss and postoperative sustained improvement in quality of life (82, 108, 134, 196, 197). After bariatric surgery, patients must learn to handle their new self image and barriers to behavioural/life style changes to improve the likelihood of sustaining weight loss and improved quality of life. A review of relevant literature, published in 2010, that focused on factors associated with outcome and adequate follow-up of patients who underwent bariatric surgery concluded that patients should have full understanding of postoperative dietary requirements and the importance of stress management strategies (198). Patients with disordered eating should receive preoperative dietary, psychological, and psychiatric care. Preoperative and postoperative counselling and education to assist with life style changes are suggested for all candidates (198). Accordingly, centres for bariatric surgery are supposed to

make available organized and supervised support groups for patients who have undergone bariatric surgery (199).

Postoperative eating behaviours and postoperative exercise seem to predict weight loss (78, 79, 82). Preoperative instructions about exercise and identification and minimization of barriers to exercise are intended to increase postoperative compliance with exercise guidelines (82). In a study by Wouters et al., preoperative cognitions about exercise, such as not regarding oneself as a sportive type of person and not perceiving physical exercise as something beneficial for health, were negative predictors for physical activity after surgery (200). Presurgical interventions targeting these cognitions are meant to increase physical activity after surgery (200). Some patients have problems with adherence to postoperative eating behaviour guidelines (79). Boeka et al. published a pilot study in 2010 that examined which factors increase intention to comply with eating behaviour recommendations after surgery (201). The participants in this study were randomly assigned to either a group session based on Protection Motivation Theory (PMT), an intervention that focused on the importance of adhering to post-surgical eating behaviour guidelines and how best to adhere to these guidelines, or a control group. The PMT intervention did not increase patients' intentions to comply with post-surgical eating behaviours. However, self efficacy and perceived threat factors (e.g., perceived poor eating behaviours after surgery as a threat) were predictors for intention to comply with post-surgical eating behaviours. Intention to engage in a behaviour is assumed to be a predictor of actual behaviour (202-204). In accordance with this, it has been suggested that preoperative interventions should ensure that patients understand the consequences of not following recommendations and should strengthen patients' confidence in their ability to adhere to these guidelines (201). However, no studies have evaluated preoperative interventions and their relationship with engagement in health-promoting behaviours such as exercise and eating behaviour after surgery.

The factors that influence long term weight loss differ from those that influence weight loss the first year after surgery (130). Factors associated with weight loss one to three years after surgery are coping skills (e.g., problem-focused and emotion-

focused coping), functional eating, information/support, and expectation of increased self-confidence (the belief that one is capable of performing in a certain manner or attaining certain goals) (130).

Previous studies on the effect of counselling groups adjuvant to bariatric surgery

Support groups for patients who undergo bariatric surgery are assumed to be important for outcome. Weight loss after bariatric surgery is associated with regular attendance to postoperative follow-up (97, 197, 205-208). In a study by Steffen et al. with a multi-intervention programme that combined bariatric surgery, an intensive programme for life style changes, and regular consultations with obesity specialists, the EWL was 61% seven years after surgery (97). They also had a significant decrease in prevalence of metabolic syndrome, hypertension, and Type 2 Diabetes and significant improvements in quality of life at follow-up seven years after surgery. This study showed a significant relationship between number of consultations per patient during the follow-up period and weight loss at follow-up seven years after surgery. Several studies have reported an effect from attendance to group sessions aimed at support and guidance for postoperative life style changes on weight loss after surgery (197, 205-206, 209). Attendance to such groups is related to degree of postoperative weight loss as described by Song et al. (206). Song et al. found that attendance to such groups is related to degree of postoperative weight loss, and this can be seen in the results: the patients who had attended five or more support group meetings had 56% EWL and the patients who had attended less than five group meetings had 47% EWL ($p < .05$). Further, one study reported a significant positive linear relationship between the number of postoperative support group meetings the patients had attended and %EWL one year after gastric banding (205).

Preoperative group counselling has been studied in patients with comorbid psychiatric disorders. In one study patients with preoperative Binge Eating Disorder (BED) had a significant reduction in episodes of binge eating following preoperative cognitive-

behavioural group treatment (210). Further, positive responders to a cognitive behavioural group treatment for binge eating behaviours before surgery had greater %EWL at follow-up 6 and 12 months after surgery compared to non responders (211). Patients with preoperative comorbid psychiatric disorders had a reduction in level of depression, improvement in mental quality of life, and enhancement of treatment motivation following preoperative group intervention (212). It is noteworthy that Wild's study included a small number of patients (N=10), pre and post measurements were reported, and confidence intervals for change in level of depression and mental quality of life were given. Confidence intervals for change in level of depression and mental quality of life did not include zero, and therefore change in level of depression and mental quality of life was considered to be significant. Overview of studies that assessed the associations between participation in support groups and bariatric surgery outcome is presented in Table 3.

In another study, patients went through a mandatory preoperative education programme (a notebook with relevant information, two appointments with the surgeon) (213). In addition, they were offered preoperative educational seminars and postoperative support groups. They also had to pass a preoperative test of their knowledge of the bariatric procedure and the necessary life style changes before bariatric surgery. The patients had the same test one year after surgery. The central findings were that many patients did not remember essential information from their preoperative education, and 17% of the patients thought they would lose weight regardless of what they ate or did (213).

There is evidence that factors associated with long term outcome (continuing weight loss at two and three years follow-up after surgery) may be skills that can be learned (130). Ability to make life style changes in preparation for surgery (143), preoperative motivation (214), and engagement in self-monitoring (47) are associated with postoperative weight loss. Adherence to scheduled post-surgery clinic visits supersedes the predictive role of pre-surgical binge eating status in predicting weight

loss after surgery (143). However, unrealistic expectations regarding weight loss predict low compliance with postoperative guidelines (215).

With these studies in mind, it would be reasonable to focus on the following factors in a preoperative intervention: treatment adherence with guidelines for dieting and exercise, realistic expectations for post-surgery outcome, and stress management strategies. Another preoperative intervention factor could be cognitive behavioural therapy (CBT). It has been used for the treatment of BED in patients with obesity and obesity without Eating Disorders (216) and as a preoperative intervention for patients with BED on a waiting list for bariatric surgery (210). CBT for binge eating incorporates many techniques already used in behavioural weight loss treatments (217). It includes goal setting, self-monitoring of food intake, establishing a pattern of regular meals, implementing stimulus control procedures, and problem solving techniques. In line with this, we assume that a comprehensive programme consisting of preoperative intervention based on CBT and surgery would improve outcome (treatment adherence and weight loss) in patients who undergo surgical treatment.

2. Aims and research questions

The primary objectives of this study were:

To examine prevalence rates of psychiatric disorders in patients with severe obesity referred to bariatric surgery (Paper I)

To examine if the prevalence rates of comorbid psychiatric disorders were higher in patients participating in (voluntary) preoperative counselling groups compared to patients not participating in preoperative counselling groups (Paper I)

To examine prevalence rates of psychiatric disorders before and one year after bariatric surgery (Paper II)

To study if the level of preoperative shame could be a maintaining factor for psychiatric disorders at one year follow-up. (Paper II)

To investigate HRQoL (as reported by patients) and its relation to mental health both prior to and at follow-up one year after bariatric surgery (Paper III)

To examine the effect of participation in counselling groups based on cognitive behavioural therapy with regard to weight loss and engagement in health promoting behaviours one year after surgery (Paper IV)

3. Methods

3.1 Material

A total of 169 patients with obesity were screened for participation in the study. One-hundred-and-forty-one patients were included. The patients were all referred from general practitioners (GPs) to the Department of Surgery at Haugesund Hospital on the West coast of Norway. This region includes both urban and rural areas. Procedures for recruitment, screening, and inclusion of participants are shown in Figure 2. A total of 150 patients had a psychiatric assessment (19 patients were excluded: psychiatric assessment not relevant (n=16), did not meet for psychiatric assessment (n=3)). Two patients refused to participate in the study and three patients retracted their consent. Descriptively, mean age was higher in the subgroup of patients who refused to participate compared to the study population (56.4 vs. 42.0 years, $p < .001$) and there was no difference in female/male ratio or in BMI. A total of 141 patients were included. Of these, 122 (87%) filled in the self-report questionnaires. Two of the 141 patients did not fulfil the general criteria for bariatric surgery. The general criteria for bariatric surgery are BMI >40 or BMI >35 with significant somatic comorbidity. These patients were, however, still accepted for surgery and included in the present study. Forty-nine patients were randomised to the preoperative counselling groups. Forty-two patients (86%) participated (seven patients either changed minds about participating or did not meet for counselling) (Figure 2).

3.2 Counselling

The objectives of the intervention in the present study were to teach the patients about the consequences of bariatric surgery and support them in being compliant with treatment recommendations regarding diet and physical exercise.

The intervention was a cognitive behavioural treatment programme with one preoperative group session weekly for six weeks and three postoperative group sessions (about six months, one year, and two years after surgery). Each group had six to ten participants, and a total of five groups completed the programme. The intervention was given by a team of three professionals (psychiatrist, psychologist, and physiotherapist) who applied a semi-structured therapy manual based on principles from cognitive therapy and mindfulness training. Each session lasted for about three hours including mindfulness training (one hour).

The main components of the intervention were:

- ✓ Information about bariatric surgery and appropriate eating and physical exercise behaviour change.
- ✓ Mindfulness training focused on stress reduction techniques such as breathing and yoga exercises and mindfulness-based practices regarding food consumption.
- ✓ Problem solving skills and cognitive restructuring techniques.
- ✓ Introduction of diary for eating behaviour, physical activity, and mindfulness training. Real-time self-monitoring of eating behaviour was initiated when counselling began and continued throughout treatment.
- ✓ Homework: diary for food intake, diary for planned and executed exercise, and mindfulness training (instruction on a CD for 20-30 minutes, six days a week). We encouraged the participants to eat three to four balanced meals and two snacks daily, to chew food thoroughly, to consume food slowly, and respond appropriately to satiety cues as well as engage in physical activities for at least 30 minutes daily (physical activity that they were able to perform with their physical limitations).
- ✓ A person who had undergone bariatric surgery and agreed to participate in one of the sessions to share with the participants his/her personal story about the challenges that follow surgery.

Patients in the Control group received “treatment as usual”, which included two four hour educational seminars: one preoperative and one postoperative. These seminars included information about the surgical procedure from the surgeon and information about dietary strategies and behaviours associated with beneficial nutritional outcomes from a dietician. In addition, a former patient who had undergone bariatric surgery told them about the experiences and the challenges after the operation. The preoperative, but not the postoperative, seminar was mandatory.

3.3 Design

Treatment intervention study

A two armed randomised clinical trial of preoperative cognitive therapy and treatment as usual was conducted to investigate treatment effects in patients undergoing bariatric surgery at Haugesund Hospital. Assessment was done three months and one year after bariatric surgery.

The protocols and design adhered to the standards of the CONSORT statement of randomised clinical trials (218, 219).

Patients who fulfilled the inclusion criteria were divided into two groups based on their willingness to participate in counselling groups. They were given consecutively assigned ascending numbers from 100 to 199 for those willing to participate in counselling groups and from 200 to 299 for those willing to participate in the study but not in the counselling groups.

Inclusion criteria

The inclusion criteria in the present study were the same criteria as the general criteria for bariatric surgery, i.e. BMI >40 or BMI >35 with significant somatic comorbidity (220). Of the 141 patients, two patients did not fulfil these general criteria; they had

BMI <35, but had several obesity related comorbidities (diabetes, hypertension, and sleep apnoea). They were accepted for surgery and included in the present study.

Exclusion criteria

Exclusion criteria were severe psychopathology (psychotic disorder, severe mood disorder), severe eating disorder, risk of suicidal behaviour, severe substance abuse, or severe cognitive dysfunction, and all were based on psychiatric assessment of psychopathology and impaired psychosocial functioning using structured diagnostic interviews and clinical assessment. Four patients, three women and one man (with mean age of 51.0 years), were deferred for surgery and excluded from this study. These patients had inadequately treated mood disorder and eating disorder, and were deferred surgical treatment until various treatment recommendations were met (including psychological treatment and psychopharmacological treatment).

Randomisation

Of the invited patients, 99 (69%) accepted randomization (Intervention group) to either group counselling (Treatment group) or control condition (Control group). Patients willing to participate in counselling groups were randomised by concealed randomisation at an external research site, by blocked randomisation with a block size of ten. Comparison groups were determined to a ratio of 1:1. The randomisation yielded no significant differences in demographic and clinical characteristics. The patients who did not accept randomization, n=45 (31%), gave consent to assessment before and after surgery; they comprised the Reference group.

3.4 Instruments

Psychiatric disorders

Current and lifetime DSM-IV Axis I diagnoses (clinical syndromes) (221) were assessed with the MINI International Neuropsychiatric Interview for DSM-IV (M.I.N.I. Norwegian version 5.0.0) (222). Reliability, sensitivity, and validity were explored in a clinical population in a comparison with the Composite International Diagnostic Interview (CIDI) and against the Structured Clinical Interview for DSM-IV (SCID-P) (223). The performance of the M.I.N.I. was reliable and valid in eliciting symptom criteria for diagnosis. It has been widely used and translated into numerous languages (223).

Axis II personality disorders (221) were assessed with a Norwegian revised and shortened form (Pedersen and Karterud (2004) of the Structured Clinical Interview for DSM-IV Axis II Disorders (SCID-II) (224). SCID-II is widely used and has good diagnostic reliability (225).

Depression

Level of depressive symptoms was assessed by The Beck Depression Inventory (BDI-II). This is a 21-item self-report questionnaire that measures depressive symptoms over two weeks prior to assessment (226). The BDI has well established psychometric properties and is considered to be a valid and reliable screening tool for depression (227, 228). Higher total scores indicate more severe depressive symptoms; 0 to 13 represent “minimal” depression, scores from 14 to 19 are “mild”, scores from 20 to 28 are “moderate”, and scores from 29 to 63 are “severe” depression (229). The BDI scale has good internal consistency, with Cronbach’s alpha reported from .73 to .95 (228).

Anxiety

The Beck Anxiety Inventory (BAI) is a 21 item self-report questionnaire measuring the subjective, somatic, or panic-related symptoms of anxiety (230, 231). Psychometric evaluations have reported adequate internal consistency (Cronbach's alpha ranges .83-.93), and several studies have supported the good reliability and validity of this instrument (232). The scoring of the BAI ranges from a normal level of anxiety (scores <7), mild anxiety (score range 8-15), moderate anxiety (score range 16-25) to severe anxiety (scores >26).

Eating disorders

The Eating Disorder Examination Questionnaire (EDE-Q) provides frequency data on key behavioural features for eating disorders and subscale scores, reflecting the severity of aspects of the psychopathology of eating disorders (233-235).

The Eating Disorders in Obesity (EDO) questionnaire, is a self rating questionnaire for eating disorders based on the DSM IV. The questionnaire includes 11 items and has been adjusted for application in patients seeking weight loss treatment as items referring to anorectic symptoms have been excluded. It has been reported that EDO has good psychometric properties which makes it suitable in assessing eating disorders and binge eating in patients that undergo weight loss treatment (236).

The assessment of Binge Eating Disorder was done using a clinical checklist based on the DSM-IV research criteria (221, 237).

Shame

Shame was measured using a Norwegian translation of the Cook's Internalized Shame Scale (ISS) (238). This scale measures shame as related primarily to perceptions of personal inadequacy, inferiority, and weakness. The ISS comprises 24 negatively worded items, which were interspersed with six positively worded items from Rosenberg's twelve item Self-Esteem Scale; these two instruments were combined in

this way to counteract an acquiescence bias and a negative response set. All items are rated on a five-point scale from “never” to “almost always”. The ISS is a reliable and construct-valid instrument for both clinical and nonclinical populations (239). Psychometric evaluations have reported high internal consistency ($\alpha = .96$), and a comparable high value (i.e. α of .93) was found in the present study.

Quality of life

Short Form Health Survey 36 (SF-36) is a well validated self-rating questionnaire that measures HRQoL (240). The SF-36 comprises 36 items that describe the following eight dimensions of functioning: Physical Functioning, Physical Role Limitation, Bodily Pain, General Health, Vitality, Social Functioning, Emotional Role Limitation, and Mental Health. The validity of the Norwegian version of SF-36 has been tested and found satisfactory, and norm data were obtained from this Norwegian study (241). A higher score on the subscales represents better HRQoL. In the present study, changes in HRQoL were calculated by subtracting the one year post-surgery SF-36 scores from the baseline SF-36 scores.

Health-related behaviors and weight status

The patients were asked about frequency of daily meals, use of recommended vitamins and minerals, and amount of physical activity. The patients filled in a self developed survey with the following questions;

- a. Eating habits: “How many meals do you have each day?”, and “If there is variation in eating habits from day to day, please describe.”
- b. Vitamin use: “Do you take the recommended vitamins?”
 - i. Every day
 - ii. More than 50% of the days
 - iii. Less than 50% of the days

iv. Never

- c. Physical exercise: “Describe how many minutes you spend being physical active each week?” Reported Physical activity should include a level of activity of moderate intensity (activity affecting breathing).

Patients were also asked about their satisfaction with bariatric surgery (satisfied, unsure, and dissatisfied). Preoperatively and at follow-up one year after surgery, body weight was measured in light clothing without shoes to the nearest 0.5 kg using an electronic scale (or self-reported (telephone interview) at one year follow-up). Weight loss was self-reported at the three month follow-up. Body height was self-reported throughout and was used to calculate BMI.

3.5 Intervention

Forty-nine patients were randomized to the Treatment group. Seven of these patients did not receive allocated treatment (did not meet for intervention). Of the patients in the Treatment group, 35 patients (83%) attended at least 5 of the preoperative sessions, and 23 patients (55%) attended at least 2 of the post-surgery sessions. Thirty-four patients (81%) registered their food intake more than 50% of the days in the preoperative counselling programme, 2 patients (5%) for less than 50% of the days in the preoperative counselling programme, 6 patients (14%) did not answer the question about registration of food intake. During the preoperative counselling programme, 17 patients (40%) practiced mindfulness training as recommended for more than 50% of the days, 14 patients (33%) did some mindfulness training, 4 patients (10%) reported no mindfulness training at all and 7 patients (17%) did not answer the question about registration of mindfulness training. Thirty-three patients (79%) found the counselling programme to be a useful tool in preparing for bariatric surgery, and they reported a better understanding of the consequences of bariatric surgery and treatment recommendations regarding eating habits and physical exercise.

Three patients from the Treatment group withdrew from the surgical intervention after finishing the preoperative counselling programme. One of the patients died in the preoperative period; the death was unrelated to bariatric surgery.

3.6 Statistical methods

We applied the software package Statistical Package for the Social Sciences (SPSS) version 15 for the analyses in the first paper, and version 17 and 18 for the analyses in Papers II, III and IV.

In Paper I, group comparisons between the Intervention and Reference group with regard to psychiatric disorders and demographic data were performed using Pearson's Chi-square Test and Student's *t*-Test for Independent Samples.

In Paper II, McNemars test for dependent proportions was used to analyse whether the percentages of Axis I and Axis II Disorders were significantly different from each other at preoperative assessment and follow-up assessment. Wilcoxon Signed Rank Test was used to analyze change in BMI and change in scores of psychological symptoms from preoperative assessment to follow-up assessment one year after surgery. Mann-Whitney U-test was used to compare preoperative scores of psychological symptoms in patients with and without postoperative psychiatric disorders.

In Paper III, group comparisons between groups with and without comorbid psychiatric disorders were performed using Pearson's Chi-square Test and Mann-Whitney U-Test (continuous variables were not normally distributed). Further, Wilcoxon Signed Rank Test was used to analyze differences in SF-36 subscales from preoperative assessment to assessment one year after surgery. The Kruskal-Wallis Test was conducted to evaluate differences among three groups of the study population (patients without comorbid psychiatric disorders, patients with psychiatric disorders that persist after surgery, and patients with psychiatric disorders that

resolved after surgery) with regard to preoperative and postoperative HRQoL and the change in score for HRQoL (preoperative score minus postoperative score of SF-36 subscales). Effect size indices (d) were computed for the difference in mean scores of SF-36 subscales from preoperative assessment to follow-up for all three groups. Effect sizes $< .2$ are considered trivial, from $.2$ to $< .5$ small, from $.5$ to $< .8$ moderate, and $> .8$ large (242, 243). Further, Z-scores for change for each SF-36 subscales within the three patient groups were presented.

HRQoL in groups with and without comorbid psychiatric disorders was compared to the population norm. The population norm data were adjusted by age and gender. We calculated effect sizes (Cohen's d) to compare the mean values of SF-36 subscales in this study population to the population norm by subtracting the mean scores of the population norm from the mean score of the patient group divided by the standard deviation of the patient group. Effect sizes $< .2$ are considered trivial, from $.2$ to $< .5$ small, from $.5$ to $< .8$ moderate, and $> .8$ large (242).

In Paper IV, a one way analysis of variance was conducted to compare the groups (Intervention, Control, and Reference group) on the continuous variables at baseline and at follow-up. A two way contingency table analysis was conducted to compare the groups on categorical variables.

Tests were two-tailed setting the α -level to 0.05 divided by number of tests.

3.7 Ethics

The study was approved by the Regional Committees for Medical and Health Research Ethics and the Norwegian Social Science Data Services (NSD). The trial was registered at www.clinicaltrials.gov prior to patient inclusion. The study was performed in accordance with The Helsinki Declaration. All participants provided written informed consent prior to assessment.

4. Results and summary of the papers

In the first paper, the overall prevalence of current psychiatric disorders was found to be 49% among patients with severe obesity referred from GPs to gastrobariatric surgery. Thirty-one percent of the invited patients refused to participate in counselling groups. Patients who were unwilling to participate in counselling groups had significantly higher prevalence of Social Phobia and Avoidant Personality Disorder than patients who agreed to participate. Prevalence rates for Social Phobia were 32% and 12%, respectively and prevalence rates for Avoidant Personality Disorder were 27% and 12%, respectively.

In the second paper we found that for patients undergoing bariatric surgery, the prevalence of comorbid psychiatric disorders was significantly lower at follow-up one year after surgery compared to the prevalence rate at preoperative assessment. Significant predictors for postoperative psychiatric disorder were preoperative psychiatric disorder and preoperative level of shame.

In the third paper we found a significant improvement in HRQoL from preoperative assessment to follow-up one year after bariatric surgery. Patients without preoperative and postoperative psychiatric disorders had no impairment in HRQoL compared to the population norm at follow-up one year after surgery. However, in patients with postoperative psychiatric disorders, only a trend toward improvement could be detected in several of the subscales that measured HRQoL, and these patients still had impaired HRQoL compared to the population norm one year after surgery.

In the fourth paper we studied if preoperative counselling focusing on preparing patients for the life style changes required after surgery influenced weight loss, eating habits, and physical exercise one year after surgery. Eating habits, taking recommended vitamins and minerals, physical activity, and weight loss were not different in patients who participated in preoperative counselling groups compared to patients who did not participate in such groups. Preoperative counselling groups did

not improve postsurgical outcomes relevant for maintenance of weight in bariatric surgery patients.

5. Discussion

5.1 General discussion

5.1.1 Prevalence of comorbid psychiatric disorders before bariatric surgery

In this study 43% of the patients waiting for bariatric surgery had a current Axis I psychiatric disorder and 26% an Axis II personality disorder. The most prevalent diagnoses were Social Phobia (18%), Dysthymic Disorder (17%), and Avoidant Personality Disorder (17%). Thirty-one percent of the bariatric surgery patients refused to participate in a preoperative and postoperative counselling group. The prevalence rates of Social Phobia (32% vs. 12%, $p = .006$) and Avoidant Personality Disorder (27% vs. 12%, $p = .029$) were significantly higher in this group than among the patients who were willing to participate (Paper I). Preoperative assessment was done three to eight months prior to surgery (number of days between preoperative assessment and bariatric surgery: 157 ± 67 (mean \pm SD)).

The findings in this thesis add to the body of data that shows the prevalence of psychiatric disorders to be higher in studies based on bariatric surgery samples (30-32) compared to studies based on epidemiological surveys (26, 119, 244). Five studies that assessed comorbid psychiatric disorders with structured interviews in large bariatric surgery samples compared the prevalence of psychiatric disorders to normal-weight individuals and obese individuals with and without weight loss treatment (37) or to the general population (30-33). Only in the study by Rosenberger et al., was the prevalence of comorbid psychiatric disorders in patients waiting for bariatric surgery comparable to the prevalence of psychiatric disorders in the general population (33). Muhlhans et al., Kalarchian et al., and Mauri et al. reported higher prevalence of comorbid psychiatric disorders in patients waiting for bariatric surgery compared to the prevalence of psychiatric disorders in the general population (30-32). For instance

prevalence rates of lifetime mood disorders were 55%, and 46%, and 22%, respectively (30-32).

The present study showed descriptively higher prevalence rates of current mood disorders (24% vs. 16%) and anxiety disorders (30% vs. 24%), while the prevalence rates for lifetime mood disorder and personality disorders were similar compared to the study by Kalarchian et al. of bariatric surgery patients (30). Compared to two other studies of bariatric surgery patients (31, 33) our study showed higher prevalence of both lifetime and current Axis I Disorders. Only in the study by Muhlans et al., prevalence rates for both current and lifetime psychiatric disorders were higher compared to our study (32).

Though most of the studies found that patients waiting for bariatric surgery have higher prevalence of comorbid psychiatric disorders in comparison to the general population, great variability in the reported prevalence rates exists (prevalence rates of 21%-56% for any current Axis I Disorder and of 20%-29% for any Axis II Disorder). Differences in sample characteristics and methods for assessment may partly account for these differences (32).

Possible explanations for the discrepancy in the literature in prevalence of psychiatric disorders

The study by Muhlans et al. includes a review of the literature regarding psychiatric disorders in bariatric surgery samples (32). They concluded that direct comparison between the studies was misleading because there were differences in demographic characteristics and in methodology. Gender distribution, mean age, and mean BMI are descriptively similar among the studies of bariatric surgery patients (Table 1). However, level of education seems to be different in the studies. Our sample and the sample described by Muhlans et al. (32) were characterized by a low education level compared to the education level in the three other study samples (30, 31, 33). In our study, only 18% reported more than thirteen years of education. In comparison 22%, 70%, 73%, and 45% reported an education beyond high school (more than 13 years)

in the other studies of bariatric surgery patients (30-33). In the general population (26, 119, 244) as well as in persons with obesity in epidemiological surveys (8, 20), fewer years of education correlate with increased risk for psychiatric disorders. In accordance with this, the higher prevalence of comorbid psychiatric disorders in our study can to a degree be explained by a lower education level in our study compared to the education level in the studies by Kalarchian et al., Mauri et al., and Rosenberger et al. (30, 31, 33).

Differences in methods of assessment of psychiatric disorders can explain differences in prevalence rates of comorbid psychiatric disorders among studies. The main difference between these earlier studies and our study is the evaluation instruments used. The diagnostic tool used in the four earlier studies was SCID-I, whereas in our study psychiatric disorders were assessed by M.I.N.I. We could speculate that the use of M.I.N.I. in our study might explain the higher prevalence rates of comorbid psychiatric disorders compared to several other studies (30, 31, 33). However, one study that used SCID-I in to assess psychiatric disorders (32) reported higher prevalence rates than in our study. In light of this, it is not clear that the use of SCID-I is related to higher or lower prevalence rates of psychiatric disorders compared to the use of M.I.N.I.

In the present study the psychological assessment was part of the approval process for bariatric surgery, and the patients were informed that serious psychopathology could be an exclusion criterion for surgery. The psychological assessment sometimes results in deferral or rejection for bariatric surgery. Because of this practise, participants may underreport psychological problems so as to receive this treatment. Higher prevalence rates of comorbid psychiatric disorders are found in studies where the evaluation process is independent from the approval process for bariatric surgery (30, 32) compared to studies where psychological evaluation is a part the approval process for bariatric surgery (31, 33). However, prevalence rates for comorbid psychiatric disorders in our study were comparable to prevalence rates in studies where psychological assessment was independent of surgical approval (30).

There may be other selection biases in our study. Bariatric surgery is a new treatment option in the area where the study was conducted, and the availability for surgery is still limited. Earlier studies have suggested that patients with obesity and psychiatric comorbidity more often seek treatment for their obesity compared to patients without psychiatric comorbidity (24, 25). Our study may have recruited patients from “the top of the iceberg”, i.e. when the new treatment option was introduced in the area, patients who experienced the greatest burden of obesity were referred for treatment earlier than patients who reported less burden of their obesity.

Prevalence of multiple comorbid psychiatric disorders

In the present study, 43% of the patients waiting for bariatric surgery had a current Axis I psychiatric disorder and 26% had an Axis II personality disorder. Further, 28% of the patients fulfilled the diagnostic criteria for more than one psychiatric disorder at preoperative assessment. For instance, we found a significant overlap between patients who fulfilled criteria for Social Phobia and patients who fulfilled criteria for Dysthymic Disorder (42% of the patients who fulfilled the diagnostic criteria for Dysthymic Disorder also fulfilled the diagnostic criteria for Social Phobia and 40% of the patients who fulfilled the diagnostic criteria for Social Phobia also fulfilled the diagnostic criteria for Dysthymic Disorder). Comorbidity among psychiatric disorders is common (245), and the trend in successive editions of the diagnostic manuals has been to reduce diagnostic hierarchies and increase comorbidity (246). One study examined patients with principal diagnosis of Major Depressive Disorder or Dysthymic Disorder referred to an outpatient clinic (247). They found that of people with the diagnosis Dysthymic Disorder, over 66% of the patients had at least one additional psychiatric diagnosis. The more common disorders for this group were Anxiety Disorder (48%), Social Phobia (27%), and Generalized Anxiety Disorder (22%). The way the DSM and ICD incorporate comorbidity could be seen as a description of the various aspects and manifestations of psychiatric illness (248). Our findings are consistent with our clinical experience that patients with severe obesity

report several and different kinds of suffering such as low self-esteem, feelings of hopelessness and helplessness, limitation of physical activity, less ability to engage in activities, social isolation, loss of energy, sleep problems, and the experience of being critically observed in addition to somatic health complaints. For some patients the severity of these obesity related complaints will most likely exceed the diagnostic threshold level for one or more psychiatric disorders.

This joint occurrence of multiple disorders may be of clinical importance. One study found that having more than two preoperative psychiatric disorders, compared to having none or only one preoperative psychiatric disorders, was associated with less weight loss after bariatric surgery (minimum follow-up of 30 months) (132). Based upon this finding it could be suggested that persons suffering from two or more psychiatric disorders are in need of a more complex and broad treatment than those suffering from just one psychiatric disorder. However, we may also speculate that co-occurrence between disorders can in part be explained by a shared risk factor (obesity), and the problem is related to a categorical classification or the effect that one disorder could affect the onset of other disorders. Perhaps patients who perceive their obesity as caused by being lazy or personal inadequacy will avoid experiences of being observed or judged by others, which causes social isolation and social anxiety which in turn can affect the onset of depressive symptoms. Treatment for obesity, which is a stigmatising and disabling condition, might reduce social inhibition, negative self-evaluation, and self-criticism and thereby reduce symptoms of social anxiety, depression, and avoidance tendencies. When prioritizing patients for treatment, assessment of the severity of the individual's dysfunction may be of greater importance than specifying the precise nature of the disorder. In our study, there were no significant differences between mean BMI loss, change in SF-36 subscales from preoperative assessment to follow-up, or between score on SF-36 subscales at follow-up between patients with one preoperative psychiatric disorder and patients with two or more preoperative comorbid psychiatric disorders (analyses not shown). We suggest that it is not merely a matter of the number of psychiatric disorders, but that it is more related to whether or not and how psychopathology is related to obesity that

can affect outcome of surgery. However, there is need for more knowledge about how psychiatric comorbidity is related to treatment complexity and course of illness in patients with obesity.

5.1.2 Prevalence of psychiatric disorders one year after surgery

Follow-up assessment was one year after surgery (number of days between bariatric surgery and follow-up; 373 ± 24 (mean \pm SD)). At follow-up, 16 patients (18%) fulfilled the diagnostic criteria for at least one current psychiatric disorder. Of these 16 patients, 15 patients had a preoperative comorbid psychiatric disorder. Sixteen patients (18%) fulfilled the diagnostic criteria for at least one current Axis I Disorder and 7 patients (8%) for at least one Axis II Disorder (Paper II). The prevalence of psychiatric disorders in the present study sample at follow-up and in three Norwegian samples from the general population are presented in Table 4. There are several methodological differences between the Norwegian epidemiological studies that have assessed Axis I Disorders and our study. The most obvious is that Kringlen et al. reported 12 month prevalence rates of psychiatric disorders using the Composite International Diagnostic Interview (CIDI) (119, 244). In our study, we reported point prevalence rates of psychiatric disorders using the M.I.N.I. It is reasonable to expect higher 12 month rates of psychiatric disorders than point prevalence rates. However, the concordance and psychometric values of the M.I.N.I. analysed by reference to CIDI have been found to be satisfactory for most diagnoses (249).

To summarize, prevalence of current Axis I psychiatric disorders one year after surgery is comparable to the annual rate of any Axis I Disorder in Norwegian rural areas (244), and prevalence of any Axis II Disorder is descriptively lower than prevalence of any Axis II Disorder in the Norwegian general population (250). However, prevalence rates for the most prevalent disorders in the postsurgical population are descriptively higher than annual rates for the same disorders in both urban and rural areas in Norway (119, 244). These results are somewhat better than

expected, especially considering that 55% of the patients are still obese with a BMI >30 one year after surgery.

In the present study, the point prevalence of any mood disorder was reduced from 24% to 13%, and the point prevalence of any anxiety disorder was reduced from 30% to 13% from baseline to one year after surgery. To our knowledge, only one study has assessed psychiatric disorders using structured diagnostic interviews before and after bariatric surgery (116). De Zwaan et al. reported prevalence rates of Axis I Disorders prior to bariatric surgery and 6-12 months and 24-36 months after bariatric surgery. Prevalence of current depressive disorders were 33%, 17%, and 14% and prevalence of current anxiety disorders were 17%, 15%, and 14% prior to, 6-12 months, and 24-36 months after bariatric surgery. That is, prevalence rates of current anxiety and depressive disorders were descriptively similar in our study and in the study by de Zwaan et al. at follow-up one year after surgery (116). A review of prevalence rates of postsurgical psychiatric disorders have found prevalence of postsurgical psychiatric disorders to be from 0% to 50% of presurgical status (108).

Although the increase in prevalence of major depressive disorder in our study from preoperative assessment to follow-up (from 6% to 9%) was not significant, it may be an important finding (Paper II). It has been emphasised in several studies that there is an increased risk of suicide after surgery (100, 101). One study found that deaths from non-disease related causes, like accidents and suicides, are significantly higher in the surgery group compared to a control group (100). Further, in a study by Omalu et al., a substantial excess of deaths owing to suicide (compared to age and gender adjusted general population) was found at follow-up one and five years after surgery (101). We can speculate that when the “hope factor” postoperatively diminishes, major depression and suicidal ideation might follow. In the present study, 90% of the patients with a major depressive disorder one year after surgery had either current or lifetime depressive disorder at preoperative assessment (analyses not shown). Careful monitoring of bariatric surgery patients and more intense follow-up may help to reduce the long term case fatality rate in this patient population.

In contrast to the finding in our study of a significant reduction in prevalence of personality disorders, earlier research has reported personality pathology as largely unchanged after bariatric surgery (108). In the present study, Avoidant Personality Disorder was the most prevalent preoperative Axis II Disorder (Paper I). There is significant overlap of diagnostic criteria between Social Phobia and Avoidant Personality Disorder (251). In our study, 67% of the patients with preoperative Social Phobia also fulfilled the diagnostic criteria for Avoidant Personality Disorder. We are inclined to think that treatment for obesity, which is a stigmatising condition, might reduce social inhibition, negative self-evaluation, and self-criticism and, thereby, reduce both Social Phobia and avoidance tendencies. This is in line with earlier research. Liebowitz et al. found that effective treatment for Social Phobia was associated with a reduction of patients who fulfilled the criteria for Avoidant Personality Disorder (252). Similarly, the observed reduction in prevalence rate of Avoidant Personality Disorder in our study can be partly explained by the reduction in prevalence of Social Phobia.

Although individuals with obesity experience a pervasive pattern of condemnation in the society, many patients with obesity also seem to predict the standards that the “audience” holds for them. Many of the patients with Social Phobia in our study reported a sense of being “on stage” when in the presence of others, whether the situation was swimming at a pool, eating at a restaurant, shopping for clothes or food, or another situations in which the person might be observed by others. They perceived the “audience” as critical. According to the studies by Gilbert and Trower (253, 254), patients with Social Phobia view their audience as competitors in hierarchies where dominant and subordinate roles are established. As a consequence of this view, patients with Social Phobia avoid a range of social, interpersonal, and professional situations because they fear their own or others’ critical evaluation of their appearance. In addition, Avoidant Personality Disorder is characterized by longstanding patterns of social inhibition, feelings of inadequacy and hypersensitivity to negative evaluation.

Most treatments for Social Phobia and Avoidant Personality Disorder involve a combination of exposure, social skills training, and cognitive restructuring (255, 256). Exposure allows the patients to practice long avoided behaviours and to engage in behaviours consistent with their goals. We can speculate that a consequence of weight loss (and the experienced reduction in social stigmatisation) after bariatric surgery is that most the patients will view social situations as less threatening and will be more willing to confront and expose themselves to social situations. Further, as a consequence of exposure to situations involving social interaction, the prevalence of patients that met criteria for Social Phobia and Avoidant Personality Disorder decreased from preoperative assessment to follow-up. This reduction in Avoidant Personality Disorder following bariatric surgery was valuable to the patients being that Avoidant Personality Disorder is associated with severe dysfunction and subjective distress (257). This was quite likely reflected in the increase in HRQoL demonstrated in the present study.

In our study, 41% of the subjects with Avoidant Personality Disorder remained above diagnostic threshold from preoperative assessment to follow-up one year after surgery (Paper II). The significant reduction in prevalence of personality disorders from preoperative assessment to follow-up in our study is in contrast to the assumption of diagnostic stability of personality disorders. In one longitudinal study, short term diagnostic stability (one year) of Avoidant Personality Disorder was examined as was the numbers of diagnostic criteria met from baseline to follow-up examined (258). Fifty-six percent of the subjects with Avoidant Personality Disorder remained at diagnostic threshold during the one year follow-up, and there was a significant decrease in number of criteria met from baseline to follow-up. In a study with a two year follow-up interval, the criteria for Avoidant Personality Disorder were tracked and variation in prevalence and remission over time for the diagnostic criteria were examined (259). The most prevalent and least changeable criteria for Avoidant Personality Disorder over the two years were feeling inadequate and socially inept; the most changeable criteria for Avoidant Personality Disorder were avoiding jobs that are interpersonal and avoiding potentially embarrassing situations.

The finding about the criterion changeability of “avoiding potentially embarrassing situations” for Avoidant Personality Disorder is of special interest in regard to our study. According to earlier research, personality disorders may be hybrids of more stable traits and less stable symptomatic behaviours. For instance, avoidance of various social situations could be viewed as symptomatic behaviour (based on internalization of societal prejudices that obese people are lazy, incompetent, and lack self discipline). For most patients, weight loss creates considerable freedom to become physically and socially active. For such patients, these symptomatic behaviours highlight aspects of a disorder (being obese) and the criteria are remitted at follow-up.

However, some patients wait or wish for further improvement in appearance or greater weight loss before facing challenges in social activity or physical exercise. It could very well be the person’s self-view is what matters the most. For these patients, it seems essential that weight loss is reinforced by positive changes in self-image in order to attain behavioural changes related to an overall positive outcome. Patients’ self-image, including both specific perceptions of their appearance and physical attractiveness as well as more general feelings of worthiness or shame, should be assessed and challenged. For this type of patient, the criteria highlight more stable personality traits, and as such the criteria are less changeable over time.

Change in scores of shame and depression and anxiety symptoms from preoperative to postoperative assessment

In our study, there was a significant reduction in BDI score and ISS score from preoperative assessment to one year follow-up in all patients (mean scores 10.9 and 5.9, $p = .001$ and mean scores 27.1 and 15.2, $p = .001$, respectively). There was no significant change in BAI score (mean scores 7.6 and 6.1, $p = .250$) (Paper II). The reduction in score of depressive symptoms is in line with earlier research (111, 112, 260, 261). Several longitudinal studies have assessed the course of anxiety and depressive symptoms using instruments such as Hospital Anxiety and Depression

Scale (111, 114, 262), and BDI (112, 260, 261). Most studies report sustained improvements in scores of anxiety and depression symptoms (111, 184, 262). Some studies find that symptoms of depression are more reduced than symptoms of anxiety (110, 114). Burgmer et al. reported that 41% of their patients had depressive symptoms of clinical relevance before surgery and only 18% one year after surgery (114).

As the preoperative level of anxiety symptoms was in the normal range in our study, a decline in anxiety symptoms could not be expected. However, high prevalence of anxiety disorder as determined by M.I.N.I. and preoperative level of anxiety symptoms in the normal range as assessed by the BAI in our study seem to be contradicting findings (Paper I). The BAI was created to assess the severity of an individual's anxiety as well as to be largely independent of the symptoms of depression (230). However, the strongest quality of BAI has been found to be its ability to assess panic symptomatology (263). Agoraphobia and Social Phobia were the most prevalent preoperative anxiety diagnoses in our study. According to earlier research, BAI does not have high enough sensitivity to capture these Anxiety Disorders. Perhaps this explains why a high prevalence of Anxiety Disorders is not reflected in high BAI scores in our study.

The preoperative mean level of shame in the study population was significantly higher compared to the mean level in a Norwegian non-clinical sample (mean values 27.1 vs. 21.9, $p = .019$) (238). One year after the operation, the mean level of shame was significantly reduced and lower than the mean level in a Norwegian non-clinical sample (mean values 15.2 vs. 21.9, $p = .003$) (Paper II). We suggest that this reduction of shame score is of clinical importance. Patients with obesity and weight related shame seem to display lower levels of problem-focused coping compared to patients with obesity and weight related guilt (182). Problem-focused coping, in contrast to coping strategies characterized by avoidance and escape, is associated with better ability to maintain weight loss after initial weight loss (188). However, we have no data measuring coping strategies. We can only speculate that lower levels of shame

can be related to more appropriate coping and a positive predictor for maintenance of weight loss.

5.1.3 Quality of life before and after surgery

In the present study, patients with severe obesity who were waiting for bariatric surgery reported impaired quality of life compared to the general population, greater impairment was reported by patients with comorbid psychiatric disorders. We found a significant improvement in HRQoL from preoperative assessment to follow-up one year after bariatric surgery. Patients without postoperative psychiatric disorders achieved HRQoL comparable to the general population at follow-up one year after surgery. In patients with psychiatric disorders that persisted after surgery, only a trend toward improvement could be detected in several of the subscales that measured HRQoL, and these patients still had impaired HRQoL on all subscales compared to the population norm one year after surgery (Paper III).

We found that patients with comorbid psychiatric disorders had greater impairment in preoperative HRQoL compared to patients without comorbid psychiatric disorders (Paper III). This association between preoperative comorbid psychiatric disorders and impaired HRQoL is in accordance with earlier research (30, 31, 155, 264). Kalarchian et al. (2007) found that lifetime Axis I Disorders were associated with significantly lower scores on each subscale of SF-36 (30). Mauri et al. (2008) found that having both Axis I and II disorders was significantly associated with impaired HRQoL, while having only Axis I or Axis II Disorders did not predict lower scores on HRQoL (31). The association between preoperative psychiatric disorders and quality of life is known; however, virtually nothing is known about the association between post-surgery psychiatric comorbidity and quality of life outcome.

Notably, patients without postoperative psychiatric disorders achieved HRQoL comparable to the general population at follow-up one year after surgery. Patients who had preoperative psychiatric disorders that resolved after surgery showed great

quality of life improvement (Paper III). A number of studies have examined the role of preoperative psychological factors in predicting outcome of bariatric surgery (126, 127, 129, 130). An association of preoperative mental health with HRQoL and mental and physical wellbeing after bariatric surgery has been found in earlier research (108, 126, 135). In accordance with our findings, the association between preoperative psychiatric disorders and postoperative quality of life seemed to be limited to patients with psychiatric disorders that persisted after surgery (Paper III).

Patients with postoperative psychiatric disorders had impaired HRQoL compared to the population norm one year after bariatric surgery. Earlier studies have reported that psychological symptoms that persist or reoccur after bariatric surgery might have strong impact on the course of weight loss and quality of life (116, 134, 155). One study by de Zwaan et al. found that postoperative Axis I psychiatric disorders were related to weight loss (116). White et al. reported that postoperative, not preoperative loss of control over eating, was a negative predictor for postsurgical weight loss and psychosocial outcomes at follow-up one and two years after surgery (134). Further, improvements in HRQoL one year after surgery were found to be largely related to improvement of depressive symptoms (155). However, no published studies have presented results on how postoperative psychiatric disorders are related to quality of life after bariatric surgery. Post-surgery psychiatric symptoms may be a potential mediator for poorer quality of life outcome after surgery. Close monitoring of patients after surgery could help identify the patients that would benefit from adjunctive treatment for psychiatric disorders.

Surprisingly, improvement in quality of life was not correlated with change in BMI from preoperative assessment to follow-up in any of the three groups in the present study (patients without psychiatric disorders, patients with psychiatric disorders that resolve after surgery, and patients with psychiatric disorders that persist after surgery) (Paper III). Patients with psychiatric disorders that persisted after surgery had descriptively smaller change in BMI compared to patients without postoperative psychiatric disorders. However, the difference in change of BMI did not reach statistical significance. Previous studies have reported associations between weight

loss and quality of life (106, 265) and between postoperative psychiatric disorders and weight loss (116). In the study that had ten years of follow-up by Karlsson et al., improvements and deteriorations in HRQoL were associated with the amount of weight loss or regain (106). Further, in the study by de Zwan et al., an association between weight loss and depressive disorders was found at follow-up 24 to 36 months after surgery, but not at follow-up 6 to 12 months after surgery (116). The lack of association between weight loss and improvement in quality of life and the finding of no differences in weight loss between the three groups of patients are probably explained by the short follow-up period in our study. In line with earlier research, we speculate that such associations between weight loss and quality of life and between weight loss and postoperative psychiatric comorbidity become more clear in studies that have longer than one year follow-up after surgery.

In our study, level of postoperative HRQoL in patients without postoperative psychiatric disorders was comparable to or better than the population norm one year after surgery (Paper III). Patients without preoperative psychiatric disorders in our study reported HRQoL similar or even better than general population norm despite the fact that 47% of these patients still had a BMI ≥ 30 kg/m² at follow-up. This finding is in line with several studies that have reported improvements in HRQoL after various bariatric procedures (103, 105, 106, 266) despite the fact that many patients still have overweight and obesity (103). The population norm is based on the general population, which includes patients with and without psychiatric disorders. Our group of patients without postoperative psychiatric disorders is probably healthier with regard to psychiatric illness than the general population. It is, therefore, not unexpected that HRQoL in patients without postoperative psychiatric disorders one year after surgery was better than the population norm. Some have also suggested that improvements in HRQoL shortly after surgery are related to a short-term euphoria caused by relief from a long term disability (266). It has been shown that this effect is transient, yet, the fall in HRQoL with time after surgery is small and long term improvement in HRQoL has also been reported (106, 266).

It is well established that variability exists in the quality of life outcome after bariatric surgery (47, 93). The reasons for this variability in bariatric surgery outcomes appear to be related in part to differences in follow-up time and bariatric procedures. In a study by Andersen et al., patients who had Duodenal Switch had a HRQoL two years after surgery that was comparable to that of the general population (103). Chang et al.'s study reported that the patients reached levels of HRQoL one year after RYGBP similar to those of healthy individuals (267). However, in a recently published study where both disease-specific and general health-related HRQoL were measured, level of postoperative HRQoL did not reach the level of the general population (105). Bariatric procedures combining restrictive and malabsorptive techniques like gastric bypass and duodenal switch report greater weight loss and larger improvements in HRQoL compared to procedures with only restrictive techniques like gastric banding. In a study by Campos et al., patients who had gastric bypass had higher HRQoL measures one year after surgery compared to patients who had gastric banding (268). In our study, patients received a bariatric procedure that combined restrictive and malabsorptive techniques (RYGBP).

To summarize, we found a significant improvement in HRQoL from preoperative assessment to follow-up one year after bariatric surgery. A positive finding for this group in our study showed that patients without postoperative psychiatric disorders achieved a HRQoL one year after bariatric surgery that is comparable to the general population. However, in patients with postoperative psychiatric disorders, only a trend toward improvement could be detected in several of the subscales that measured HRQoL. These patients still had impaired HRQoL one year after surgery compared to the population norm. The findings in our study emphasise that patients with psychiatric disorders that resolve after surgery show large improvements in quality of life. In light of this, they might be given priority for bariatric surgery. However, further research is needed to identify maintaining factors for psychiatric disorders in patients who undergo bariatric surgery so that effective individual psychosocial intervention strategies to improve outcome can be developed.

5.1.4 The role of shame in maintenance of psychiatric disorders in patients undergoing bariatric surgery

Forty-two percent of the patients in our sample had a psychiatric disorder that persisted after surgery. Significant predictors for postoperative psychiatric disorder were preoperative psychiatric disorder and preoperative level of shame (Paper II).

The finding of an association between shame and psychiatric disorders is in line with several other studies that have shown associations between psychiatric disorders and shame (172, 192, 238). Shame and in particular self-critical thinking are related to problem maintenance and inadequate treatment response (186, 187). In accordance with our findings, level of shame and self-perceived inadequacy could be maintaining factors for psychiatric disorders in patients with obesity who undergo bariatric surgery (Paper II).

It has been speculated that maintenance of psychiatric symptoms in shame-prone persons can be explained by the perceived unavailability of appropriate treatment to repair the “bad self” (269). According to this view, people with negative self-views will often act in ways that verify their own negative view of themselves (270), and they may deem themselves ineligible for various forms of participation in life (271). This perceptual process is understood as a safety strategy and a way in which people can exert control (270, 272). The negative aspect of this strategy is that negative self-views can sabotage people’s ability to cope successfully with events in their lives.

Our findings suggest that it is important to assess level of shame in patients who will undergo bariatric surgery. Higher level of shame is a predictor for postoperative psychiatric disorders. Postoperative psychiatric comorbidity is found to have impact on the post-surgery outcomes weight loss (116) and quality of life (Paper III). This group of patients may benefit from adjunctive treatment.

5.1.5 Preoperative counselling and post-surgery outcome

In our study, 69% chose to participate in the counselling groups. They were randomized to a Treatment group (N=49) and a Control group (N=48). Thirty-one

percent chose not to participate in the counselling. They did, however, give their consent to assessment before and after surgery, and as such comprised the Reference group. In the entire study sample, 88% of the patients achieved 50% EWL, 74% had more than the 5 recommended meals a day, and 37% of the patients reported daily physical exercise for more than 30 minutes at follow-up one year after surgery. We found no differences regarding patient behaviours (eating habits, taking recommended vitamins, and physical activity) and weight loss between the patients who participated in a preoperative counselling programme and the patients who did not participate in a preoperative programme at follow-up one year after surgery. In other words: The preoperative counselling programme had no measurable effect on relevant postoperative outcomes (Paper IV).

Willingness and ability to adopt life style changes are key components of long term success (93, 273). Inadequate behavioural changes may partly explain the observed variability in bariatric surgery outcomes (93, 274). Level of physical activity is associated with maintenance of weight loss (82) and HRQoL (86) after bariatric surgery. We did not have information about the patients' preoperative physical exercise, so we were not able to examine changes in amount of physical exercise from preoperative assessment to follow-up one year after surgery. However, only 37% of the patients reported daily physical exercise for more than 30 minutes at follow-up one year after surgery (Paper IV). Although, there are no standard guidelines for the amount of physical exercise for bariatric surgery patients, the guidelines for the amount of physical activity necessary to promote weight loss and reduce comorbidities suggest at least 30 minutes of aerobic activity daily (44). Further, in a study by Bond et al., 200 minutes of physical activity each week was associated with weight loss and HRQoL one year after surgery (86).

The finding in our study and several other studies (86, 87) underline the need to focus on ways that help individuals adhere to treatment guidelines, in particular, ways that help them initiate and maintain higher levels of physical activity. There is also a need for specific guidelines concerning the recommended amount and measurement method of physical exercise for patients after bariatric surgery. Variability in reported

rates of compliance with treatment guidelines can be partly explained by methodological differences within studies. For instance, Bond et al. reported that 76% of the patients were physically active more than 200 minutes weekly one year after surgery and Thomas et al. reported that only 24% of the patients were physically active more than 30 minutes daily six months after surgery (86, 87). Differences in measurement of physical activity and the cut-off criterion for categorisation of active/inactive may explain differences in level of physical activity in our study and the studies by Thomas et al. and Bond et al. In the present study, activity was defined as activity that affected breathing. In the study by Thomas et al., participants were instructed to report number of minutes spent in moderate physical activity (breathing definitely affected) and vigorous physical activity (breathing heavily affected) each day (87). In the study by Bond et al., they assessed walking and activities of moderate and vigorous intensity in all domains of everyday life (86). The high proportion of patients who reported more than 200 minutes of physical activity weekly in the Bond et al. study can most likely be explained by their inclusion of low intensity physical activity (86). Thomas et al. had a higher cut-off for identifying patients as active compared to both the present study and the study by Bond et al.

Low level of physical activity after bariatric surgery has been reported in earlier studies, and several studies have reported that adherence to healthy behavioural changes diminishes with time (79, 275-277). Kafri et al. found that 25% of the patients with longer follow-up than one year reported no physical activity compared to 12% of the patients with shorter follow-up than one year (275). In addition, the same study found that 14% of the patients with longer follow-up than one year reported that they did not have regular meals compared to 6% of the patients with shorter follow-up than one year. Results such as these gave rise to interventions that prepare patients for life style changes, which are suggested for all patients who undergo bariatric surgery.

And yet, we found no differences in adherence to treatment guidelines or weight loss between patients in the Treatment group, the Control group, and the Reference group. This is in contrast to earlier studies that have reported a positive relationship between

attendance to support groups and degree of weight loss after bariatric surgery (97, 197, 205-208).

Several factors may explain the difference between our study and the earlier studies (97, 197, 205-208). First, the participation rate in support groups was generally low in some of the previous studies, varying between 26% and 39% (205, 207, 208), while in our study 69% accepted randomization to either counselling or control condition. Patients who attend postoperative support groups are more likely to think that attendance to such groups will be supportive in helping them lose weight than patients who do not attend such groups (207). We speculate that earlier studies have a selection bias of participants who were more motivated for behavioural changes and patients who think that attendance to support groups will be helpful in life style change.

Second, in the earlier studies patients were offered to attend mainly post-surgical support groups (205, 207, 208). A study from 2005 (213), reported that many patients did not remember essential information from their preoperative education one year after surgery. Further, of the patients randomized to the treatment group in our study, 14% did not attend any of the preoperative sessions. There was also great variability in attendance to the intervention strategies; 80% registered their food intake for more than 50% of the days in the preoperative counselling while only 40% conducted the mindfulness training as recommended (Paper IV). In accordance with this, the lack of benefit from participating in preoperative counselling can be explained by the choice of intervention strategies or attendance to intervention strategies in the present study. However, our findings are in line with findings in a study that examined whether patients with problematic eating behaviours were more likely to attend and complete behavioural interventions preoperatively or postoperatively (278). They found that patients who were referred to the counselling after surgery were significantly more likely to complete the treatment and they attended significantly more treatment sessions than did the patients who were referred for preoperative treatment (278). A review of the interventions for weight loss maintenance showed that maintaining contact with participants is essential for success (279), and in a study by Steffen et al.,

a significant relationship between number of consultations per patient during the follow-up period and weight loss at follow-up seven years after surgery was found (97). Perhaps more intensive continued contact with the participants after surgery might have increased compliance with treatment guidelines in our study.

Third, in general, to change a maladaptive behaviour, individuals must perceive the behaviour as a substantial threat to their health and also be provided with an effective way to avert the threat (280). Madan et al. reported that one year after weight loss surgery, 17% of the patients thought they would lose weight regardless of what they ate or did (213). This might have been the case for the patients in our study too. If patients do not perceive the adverse consequences of not following eating and exercise guidelines as a serious threat, adherence to treatment guidelines will generally be low (280). In a study by Boeka et al., a preoperative intervention, which was based on “the Protection motivation theory”, focused on the importance of adhering to postsurgical eating behaviour guidelines and how best to adhere to these guidelines. The intervention did not increase patients intention to comply with postsurgical eating behaviours (201).

Finally, all patients in our study attended a mandatory preoperative educational seminar and were offered a similar seminar after the operation. In addition, all patients were given a preoperative psychiatric assessment. The main objective of this assessment was to evaluate eligibility for bariatric surgery and to determine prevalence of comorbid psychiatric disorders, but information about how to increase compliance with treatment guidelines and enhance self efficacy, i.e. the belief that one has the ability to implement the behaviours needed to obtain a desired effect, were also included in this preoperative assessment. Hence, the patients in the Control group and the Reference group had been given some information and counselling as well. We assume that an educational seminar in addition to the pre-surgical psychological evaluation is an opportunity for education and intervention in and of itself and are important parts of the treatment program. We believe that the pre-surgical evaluation could be expanded beyond that of a screening process, and be an opportunity to strengthen the patients expectations to cope with a challenge, known to

reduce stress and helplessness (281). However, overlap between information presented in the intervention and information that all patients received (regardless of which group they were in) may have affected the comparison of effectiveness of the intervention with the two other groups in the present study (Paper IV).

Despite poor evidence of effect, preoperative interventions that are meant to prepare patients for life style changes are generally suggested for all patients who will undergo bariatric surgery (198). In particular, preoperative instructions about exercise and identification and minimization of barriers to exercise are supposed to increase postoperative compliance with exercise guidelines (82). In a study by Wouters et al., preoperative cognitions about exercise, such as not regarding oneself as a sportive type of person and not perceiving physical exercise as something beneficial for health, were negative predictors for physical activity after surgery (200). Presurgical interventions targeting these cognitions are supposed to increase physical activity after surgery (200). Considering the findings in earlier studies and in the present study (Paper IV), it is reasonable to question the effect of preoperative interventions for all patients who will undergo bariatric surgery. There seems to be better evidence for postsurgical interventions with the treatment guidelines that target patients with low compliance.

5.2 Discussion of methodological issues

Study design

A two armed randomised clinical trial was conducted to investigate treatment effect of a preoperative counselling programme in patients who underwent bariatric surgery. However, the aims in paper I, II, and III required study designs with different methodological approaches that were appropriate to answer the specific research questions. In paper I, a cross sectional design was used to study prevalence of comorbid psychiatric disorders and the possible influence of comorbid psychiatric disorders on willingness to participate in preoperative and postoperative group

counselling in patients accepted for bariatric surgery. A cross sectional design is appropriate to find prevalence of psychiatric disorders at one point in time. No conclusion regarding causality between comorbid psychiatric disorders and participation in counselling can be drawn. However, we were able to see an association between comorbid psychiatric disorders and participation in counselling.

Papers II and III were based on a follow-up study that used repeated measures design. The goal of the study was to determine whether the patients changed significantly from preoperative assessment to follow-up one year after surgery with regard to comorbid psychiatric disorders and quality of life.

Paper IV was based on a randomised controlled trial, which is considered to be the optimal design to assess treatment effects. This design enabled us to answer the research question about whether an approach with preoperative counselling gave better results than no such intervention. As earlier studies have used a variety of designs to assess the effect of counselling in patients who undergo bariatric surgery (retrospective, pre-post intervention) (97, 197, 205-208, 212), studies with randomised controlled design have been requested in this field.

The study evaluates the effect of a complex intervention, which had several interacting components (282): preoperative and postoperative counselling using a multidisciplinary team, surgery, and a counselling programme based on cognitive behavioural therapy. As in all complex interventions, it is difficult to know which ingredients of the programme are the active ingredients. Furthermore, process evaluation of the counselling programme showed considerable variation in the implementation of the programme, including attendance and compliance with the programme and individual timing of the counselling programme before surgery. However, process evaluation is reported in Paper IV, which enables replication of the study.

Sample selection, selection bias

A total of 169 patients with obesity were screened for participation in the study. Twenty-five patients were excluded for several reasons (pregnancy, bariatric surgery at private hospitals, did not want bariatric surgery, lack of consent, or severe mood or eating disorder), which left the 144 patients who were included in the study. Of these, three patients retracted their consent. Of the invited patients, 99 (69%) accepted randomization (Intervention group) to either group counselling (Treatment group) or control condition (Control group). The patients who did not accept randomization, n=45 (31%) gave their consent to assessment before and after surgery; they comprised the Reference group. A total of 127 patients underwent surgery. Fourteen patients were excluded for the following reasons: bariatric surgery at private hospitals, did not want bariatric surgery, or serious comorbid somatic disorders. We were able to get some information from 91 patients (72%) at follow-up one year after surgery. However, four of these patients did not complete the psychiatric assessment (not possible to make an appointment for the diagnostic interviews), hence, postoperative data on both psychiatric disorders and quality of life were available from 87 patients (69%) (Figure 2).

It is important to know where the study subjects come from and if they are a representative group to study to address the research question of interest. Our study sample comprised patients who were referred from general practitioners (GPs) to the Department of Surgery at Haugesund Hospital on the West coast of Norway. Psychiatric assessment was required as a part of the preoperative evaluation process for bariatric surgery.

There may be some selection bias in our study. Four patients with severe eating and mood disorders were excluded from the study at preoperative assessment (Paper I). Patients who accepted randomisation to the RCT had significantly lower prevalence of Social Phobia and Avoidant Personality Disorders compared to patients who did not accept randomisation. Further, 31% did not meet for psychiatric assessment one year after surgery. When there are subjects who cannot be found or who refuse to

participate, the question arises as to whether they constitute biased subsamples with poorer outcome or with better outcome. It is impossible to know exactly how the inclusion of non-attenders would have affected the results in our study. In general, non-responders have higher prevalence of severe mental disorders (283). Further, it has been suggested that patients lost to follow-up have poorer outcome than patients who participate in follow-up (284, 285). Consequently, we can speculate that inclusion of non-attenders would have reduced the magnitude of change in prevalence of psychiatric disorders from preoperative assessment to follow-up one year after surgery.

In our study, preoperative group counselling did not increase treatment adherence to recommended life style changes. It is reasonable to question if the participants in this RCT are representative for other bariatric surgery samples. In the present study, 69% of the patients attended the RCT. In earlier studies that assessed the effect of adjuvant counselling (97, 197, 205-208), the participation rate was generally low, varying between 26% and 39% (205, 207, 208). Perhaps the association between attendance to group counselling and post-surgical weight loss that was found in these earlier studies was biased by a selection of patients who were more motivated for change, which in turn made them more motivated to attend group counselling (207). Considering this, it is reasonable to speculate that our results are more representative for bariatric surgery samples compared to earlier studies with lower participation rates (205, 207, 208).

The process of referral in our study may have caused a selection of patients with psychological distress to be referred to bariatric surgery. Only a small proportion of patients with severe obesity are offered bariatric surgery in our area (it was a new treatment option in the area where the study was conducted), and given this, the argument for being selected is of the utmost importance. It is reasonable to assume that treatment seeking individuals with obesity might report psychological distress to increase his or her chances of being selected for this type of effective treatment. These patients may have been referred to this surgery as an appropriate treatment choice because their general practitioners had noticed that they experienced impaired

quality of life and impaired social and occupational functioning. If this is the case, then prevalence of psychiatric disorders might be higher in our study compared to studies conducted in areas with more access to bariatric surgery.

The bariatric surgery sample in the present study may be biased concerning sociodemographic factors compared to the general population. The direct comparison of prevalence rates of psychiatric disorders in patients seeking bariatric surgery and the normal population can be misleading. Gender, age, marital status (244), and years of education (8, 20, 26, 119, 244) have been found to be associated with prevalence of psychiatric disorders. Our sample was characterized by a low education level in comparison to the general population in Norway (286). In the general population, education level increases with younger age. It is reasonable to compare our study sample with the age cohort 25-64 years. The percent of individuals with an education that exceeds 13 years seems to be lower in our study sample compared to the age cohort 25-64 years of the general population (18% (95% CI: 11.49; 24.11) vs. 28%). In line with this, a higher prevalence of psychiatric disorders is expected in our study sample compared to the general population.

A study sample can also be gender-biased and this can affect, for instance, prevalence rates of psychiatric disorders. In our study population (preoperative assessment) 27% were men and 73% were women. In two Norwegian psychiatric epidemiological studies, the study conducted in a rural area was 50% men and 50% women (244) and the study conducted in an urban area was 45% men and 55% women (119). In these two studies, women had higher lifetime prevalence and higher 12-month prevalence of both Anxiety Disorders and Affective Disorders compared to men. The prevalence of Social Phobia and Dysthymic Disorders was about twice as high in women than in men (119, 244). Social Phobia and Dysthymic Disorder were the most prevalent Axis I Disorders in the present study, and there were no significant differences in prevalence of Social Phobia and Dysthymic Disorder between men and women (13% vs. 18%, $p > .05$ and 16% vs. 20%, $p > .05$). The high prevalence rates of Social Phobia and Dysthymic Disorder did not seem to be explained by differences in gender distribution in our study compared to the population studies.

Age and marital status are also associated with prevalence of psychiatric disorders. In the Norwegian population studies, age between 30 and 39 years seemed to heighten the susceptibility for mental disorders, and psychiatric disorders were less common in married persons (119, 244). In the present study, mean age was 42.0 years (SD±10.4) and 61% were cohabitant. In comparison, mean age was 39.3 years (SD=12.5) and 64% were cohabitant in the Norwegian psychiatric epidemiological study that assessed prevalence of psychiatric disorders (119). Mean age in our study is significantly higher compared to Kringlen's Norwegian psychiatric epidemiological study ($p = .003$). With this in mind and based on differences in mean age, we would expect lower rates of psychiatric disorders. Difference in marital status is small and does not seem to contribute to the explanation of differences in prevalence rates of psychiatric disorders in Paper I and the epidemiological studies (119, 244).

Finally, bariatric surgery samples are biased with high prevalence rates of somatic disorders and this can also affect prevalence rates of psychiatric disorders (287). Obesity is associated with increased prevalence of physical disorders (7), and patients with serious obesity related somatic disorders are given priority to bariatric surgery. In our study sample, 43% of the patients reported that they had hypertension and 27% reported that they had diabetes. Several physical disorders are associated with psychiatric disorders such as cardiovascular disease (288) and type 2 diabetes (289) are associated with higher rates of depression. In the Norwegian general population, 3.4% of individuals older than 30 years old had diabetes (290), and 25% of patients between 40 and 49 years old had hypertension (291). Thus, the increased prevalence of comorbid somatic disorders in patients referred to bariatric surgery may explain the higher prevalence of psychiatric disorders compared to the general population.

Confounding factors

Many factors can confound the association between psychiatric disorders and participation in group counselling. Factors known to influence participation in, for instance, epidemiological surveys (292) might also influence participation in group

counselling. Examples of such factors are age, gender, level of education, and employment status. For instance, participation may be higher among women than men, lower among the youngest and oldest patients, and lower among those with the lowest level of education. These types of factors make the translation of inference from this study sample to other study samples of patients who seek bariatric surgery difficult. Age, gender, and level of education are also associated with psychiatric comorbidity. In our study, the group of patients who refused to participate had a descriptively higher female/male ratio (80/21 vs. 70/30), a descriptively higher proportion of people who had more than 13 years of education (24% vs. 15%), and a descriptively lower proportion of employed people (52% vs. 61%) compared to the group of patients who was willing to participate. These differences in sociodemographic factors between the two groups were not statistically significant. All of these potentially confounding factors (gender, level of education) may exist independently of psychiatric disorders and may affect participation in counselling groups.

In Paper IV, no significant group differences were found between patients who participated in group counselling and patients who did not participate in group counselling with regard to level of physical exercise, eating habits, or weight loss one year after surgery. Level of physical activity (minutes of physical activity each week) was significantly higher in patients without preoperative psychiatric disorders compared to patients with one or more preoperative psychiatric disorders ($p = .046$, Mann-Whitney U-test, analyses not shown). Differences in prevalence of psychiatric disorders in the two groups could confound the association between participation in counselling and life style changes and weight loss one year after surgery. In the intervention group, 48% had one or more preoperative psychiatric disorders compared to 42% in the control group ($p = .582$, Pearson's Chi-square Test). As differences in prevalence of psychiatric disorders between the intervention group and control group were non-significant, we assume that differences in psychiatric comorbidity have not confounded the result in this paper.

Randomisation

A limitation of the randomisation approach in the RCT was that the block sizes were fixed to only ten. A disadvantage of small block size is that it is possible for the investigators to guess some allocations, thus reducing blinding in the trial. An equal distribution between Treatment and Control group of known potential confounders (sociodemographic factors and prevalence of comorbid psychiatric disorders) was found (Paper IV). We can assume that the blinding was adequate and that effect of intervention was accurately estimated.

Assessment

Psychiatric disorders were assessed by the standardized validated diagnostic interviews M.I.N.I. and SCID-II. In Paper I, the diagnostic process was discussed in a consensus meeting with members of the research group, which comprised one psychologist and two psychiatrists. At preoperative assessment, all included patients were interviewed by Lier. At postoperative assessment, three patients were interviewed by Lier and the others were interviewed by Parlati (research assistant). The prevalence rates at the two points of time in Paper II (preoperative, one year follow-up) could have been affected by low inter-rater reliability. Lier, the principal investigator, was available to supervise the research assistant concerning the diagnostic interviews the research assistant had completed. In addition, some of the interviews were reviewed by Lier. However, correlation on diagnosis between interviewers was not assessed, and we cannot exclude that low inter-rater reliability is a problem in this study.

Data on HRQoL

HRQoL was measured by the generic health status measure SF-36 for health situations during the last four weeks (241). HRQoL was compared to the population norm. The population norm data were adjusted by age and gender (293). SF-36 is

regarded as a valid measure for generic HRQoL in patients with severe obesity (294), and has been used in several studies of patients undergoing bariatric surgery (103, 264, 266).

A limitation of the present study is that a disease-specific health-related quality of life (DSQoL) was not incorporated in the assessment of quality of life. It might be advantageous to include both a disease-specific health-related quality of life (DSQoL) measure and a generic health-related quality of life (HRQoL) measure when exploring quality of life in a population. DSQoL instruments assess the special states and concerns of diagnostic groups (295). HRQoL is a domain of quality of life assessment that represents the individual's perception of the impact on his or her health status of an illness and/or its treatment and how an illness interferes with the patient's day-to-day life. Measurements of HRQoL include levels of psychological, physical, and social functioning (296). A DSQoL instrument may be more sensitive in detecting small changes in quality of life related to specific diagnostic groups compared to a HRQoL measurement (295). However, the benefit of HRQoL measurement is that it enable us to compare HRQoL between different diagnostic groups and to compare HRQoL in specific diagnostic groups with HRQoL in an age and gender adjusted general population (295).

Impact of weight on quality of life questionnaire short form (IWQoL) assesses obesity specific quality of life. However, the subscales of SF-36 correlate moderately to strongly with IWQoL (297). It is, thus, safe to assume that SF-36 is sufficiently sensitive to assess impact of obesity on health.

Data on depression, anxiety, and shame

Psychiatry traditionally focuses on categorical diagnoses. However, there might be several advantages to incorporate a dimensional component; the dimensional approach has methodological advantage in that it captures more of the variance in symptomatology than the categorical approach. As such, analyses performed with continuous scaled measures can provide stronger correlations between measures than

analyses performed with categorical measures. Further, continuous scaled measures avoid errors arising from misclassification of individuals caused by diagnostic cut-offs. Finally, psychiatric disorders are symptom continuous rather than categorical entities, and there is growing acknowledgement that whichever diagnostic criteria are satisfied and to what degree, the presence of mental symptoms may moderate the effect of treatment (298). In our study, both continuous scaled measures (BDI, BAI, and ISS) and categorical measures (M.I.N.I. and SCID-II) are included in preoperative and postoperative assessment.

BDI is probably the most commonly used psychological measure for evaluating depressive symptoms in patients who undergo bariatric surgery (299, 300). It has been argued that several of the BDI items may be measuring consequences of obesity rather than depressive symptoms (301). One example is that items that measure energy level may be related to depression, yet they may also be related to obstructive sleep apnoea, which is common among bariatric surgery patients. Findings in two recently published studies do not support the suggestion that physical symptoms play a central role in BDI scores of patients with severe obesity (184, 302). Negative attitudes towards one's self appear to play a more essential role in elevated depression score than overlap in physical symptoms between obesity and depression (184). Further, the use of BDI-II is considered to be more appropriate than BDI in patients with obesity because several of the somatic items are omitted and replaced by items that are more cognitive-affective in focus. In accordance with this, BDI-II appears to be a reasonable screening instrument for depressive symptoms among patients who undergo bariatric surgery.

A high prevalence of Anxiety Disorders was not reflected in high BAI scores in our study. BAI was created to assess the severity of an individual's anxiety as well as to be largely independent of the symptoms of depression (230). However, the strongest quality of BAI has been found to be its ability to assess panic symptomatology (263). Other psychological measures for evaluating anxiety symptoms, for instance Hospital Anxiety and Depression scale, might be more suitable for measuring anxiety symptoms in patients with obesity (106, 110).

ISS is reported to measure global and stable negative beliefs about how others view the self and self evaluations, strongly associated with psychopathology. However, a cut off for “shame pathology” is not established. Clinical samples that have been tested has yielded a sample mean of 50 or higher. In line with this a 50-point ISS score is suggested as a cut off for “shame pathology” (238), and this was used in our study (Paper II).

Cronbach’s alpha coefficient is one of the most commonly used indicators of internal consistency. Within measures, this refers to the degree to which the items that make up the scale are measuring the same underlying construct. Ideally, Cronbach’s alpha coefficient should be above .7. In the present study, Cronbach’s alpha was .92 for preoperative BDI score and .95 for postoperative score (one year after surgery). Cronbach’s alpha was .94 for preoperative BAI score and .96 for the postoperative BAI score. Cronbach’s alpha was .97 for preoperative ISS score and .98 for the postoperative ISS score. This indicates highly internally consistent scales in our study.

Data on post-surgery eating behaviour and physical exercise

The patients were asked to report frequency of daily meals, use of recommended vitamins and minerals, and amount of physical activity. Use of a self-report measure is subject to self-report bias (303). In one study they found that participants overestimated the number of days they exercised and underestimated exercise duration (304). We included questions about weekly duration of the exercise performed, and physical activity was defined as activity that affected breathing. There are few validated instruments used to measure activity levels and eating behaviour, and no gold standard instrument exists for measuring exercise and eating habits in bariatric surgery patients. Self-reported estimates of exercise duration and frequency and eating habits should perhaps not be taken at face value, though we can assume that errors in measurement of exercise and eating habits was the same in the two

groups (Treatment groups and Control group). Hence, the aim of the RCT, to find out the effect of an intervention, was achievable.

5.3 Further strengths and limitations of Papers I to IV

Paper I

Only univariate analyses were applied in Paper I. For instance, we did not control for factors known to be associated with attendance to support groups, such as travel distance (209), the patients' belief of necessity of support groups, and attendance difficulty because of obligations from patients' family (207). The present study population had great variation in travel distance to Haugesund hospital (travel time to the hospital was from 0 to four hours). Applying multiple regression analyses that control for these factors might have resulted in partialling out some of the effects of the association between comorbid psychiatric disorders and attendance to support groups. Further, the association between psychiatric comorbidity and participation in group counselling may be confounded by age, gender, and level of education. The analyses were not adjusted for these possible confounding factors because our intention was to describe the associations as they are in a model that was not over-adjusted.

Paper II

To the best of our knowledge, the present study is the first study that presents prevalence rates of both Axis I and Axis II Disorders assessed by structured clinical interviews prior to and after bariatric surgery. Only one previous study has examined the prevalence of structured clinical interview based diagnoses of Axis I Disorders prior to and after bariatric surgery (116). From previous research, structured clinical interviews have been assumed to be superior to traditional clinical assessment (305). In a study by Mitchell et al., the congruence between diagnoses assigned during a

routine clinical psychiatric evaluation and research assessment using the SCID was low (306).

Unfortunately, our study is limited by the amount of missing data at follow-up: Thirty-one percent did not attend follow-up one year after surgery. Patients who attended follow-up may differ in psychiatric comorbidity from those who did not attend follow-up; we have no knowledge of postoperative psychiatric comorbidity in non-completers of follow-up, and as such there is the possibility of a selection bias that may have affected the associations studied in our data.

Paper III

One of the strengths of this study is the use of structured diagnostic interviews in the assessment of psychiatric diagnosis not only prior to but also after surgery. An interview enables us to clarify questions. In addition, standardized clinical interviews, although far from perfect, are generally considered the most reliable and valid methods for the assessment of psychiatric disorders (307, 308). Further, we used a well-validated measure of HRQoL. Several studies have shown that SF-36 is sensitive to detect impact of obesity on health and changes after surgery (30, 103). Norwegian normative data were available for SF-36, which made it possible to compare this study population with the general population.

Some limitations of the study should be considered. First, one year follow-up may not be a long enough time to capture long term maintenance of outcome. Changes in HRQoL are reported to follow phases of weight loss, weight regain, and weight stability after bariatric surgery. Most patients report much weight loss the first year after surgery, and regain of weight is usually not reported until two or three years after surgery. Second, 31% of the patients did not complete the follow-up assessment one year after surgery. We found no differences in sociodemographic data, BMI, or prevalence of comorbid somatic or psychiatric disorders between completers and non-completers of the follow-up one year after surgery. Thus, it seems reasonable to assume that our findings are representative of patients who seek bariatric surgery.

Finally, we acknowledge that a DSQoL measure could have complemented our results.

Paper IV

In the present study we failed to reject the null hypothesis: There is no difference between patients participating in counselling and patients not participating in counselling with regard to weight loss and adherence to treatment guidelines one year after bariatric surgery. A Randomized controlled trial is generally regarded as the gold standard for hypothesis testing and finding the effect of an intervention. However, it is reasonable to question whether the data set is able to prove a null hypothesis. The power of a test is the probability to detect a wrong hypothesis, it depends on sample size, standard deviation, mean difference (effect sizes), and significance level. In our study there were large standard deviations for two of the outcome measures (physical activity and weight loss). Large variance in the outcome measures implies the need for a larger sample size in order to detect differences in the selected outcome measures. However, the small descriptive difference in amount of physical activity between Intervention and Control group was in favour of the patients in the Control group (they had a descriptively higher amount of physical activity than patients in the Intervention group). Consequently, our study does not yield evidence that supports the use of a mandatory preoperative counselling programme aimed at improving weight loss or compliance with treatment guidelines.

Further, we have no measure of baseline exercise (at preoperative assessment). And as such, there may be differences regarding change in amount of exercise performed from baseline to follow-up between the groups. However, the patients were randomised to the Intervention group and Control group, so we can assume that there are no major differences between the groups at baseline. Therefore, we assume no differences in the results had we used change in level of physical exercise from preoperative assessment to follow-up or post-surgical level of physical exercise as an outcome variable.

6. Conclusions and implications

- ✓ The present study confirmed high prevalence of comorbid psychiatric disorders in patients waiting for bariatric surgery compared to the general population. We can speculate that patients with obesity face a high mental health burden due to the high degree of stigmatisation, social isolation, suboptimal sleep, lack of exercise and high prevalence of comorbid somatic disorders. Patients with comorbid psychiatric disorders in this study population reported mean level of depressive symptoms and mean levels of anxiety symptoms corresponding to mild level of depressive and anxiety symptoms, but they reported large impairments in quality of life (Paper I and III). The high degree of impairment found among patients with relatively mild symptom severity highlights the degree to which psychosocial impairment can be associated with chronicity rather than severity of symptoms. This finding could influence how patients are prioritized for treatment.
- ✓ Higher prevalence of Social Phobia and Avoidant Personality Disorder was found among patients not willing to participate in counselling groups compared to those willing to participate in such groups (Paper I). It is probable that many patients with Social Phobia and Avoidant personality disorder found it too stressful to expose themselves to group settings.
- ✓ The present study also confirmed that most patients with severe obesity show significant and large reductions in BMI, significant improvements in mental health, and significant improvements in HRQoL at follow up one year after surgery (Paper II, III).
- ✓ Prevalence of comorbid psychiatric disorders was significantly lower at follow-up one year after surgery compared to the prevalence rate at preoperative assessment (Paper II). For most of the patients, having comorbid psychiatric disorders seemed associated with obesity-related psychological stress, and consequently the psychiatric disorders resolved after weight loss

treatment. Our data do not support that psychiatric disorders per se can be used as a criterion for denying gastrobariatric surgery. However, given the findings in our study of significant functional impairment associated with comorbid psychiatric disorders, and a significant decrease in prevalence of psychiatric disorders after surgical treatment, some psychological problems could be on the list of comorbid conditions that should lower threshold for surgery. It is important to note, however, that these results should not rule out the necessity for adjuvant treatment for some patients undergoing bariatric surgery, as bariatric surgery is not a treatment for psychiatric illness. For some patients, 17 % in the present study, psychopathology persisted after weight loss and seemed to not be related to the degree of obesity (Paper II).

- ✓ Preoperative level of shame was a significant predictor for maintenance of psychiatric problems (Paper II). Psychiatric disorders persisting after surgery were related to impairments in quality of life; patients with postoperative psychiatric disorders had only a trend toward improvement in several of the subscales that measured HRQoL, and they had impaired HRQoL compared to the population norm one year after surgery (Paper III). In accordance with this, patients with high preoperative level of shame should be given priority for postoperative follow-up, since they have a higher risk for persistence of psychiatric comorbidity compared to patients with low preoperative level of shame.
- ✓ There were no differences between patients who participated in preoperative counselling and patients who did not participate in counselling with regard to weight loss and adherence to treatment guidelines one year after bariatric surgery. The findings in this study do not support the necessity of preoperative counselling for all patients who undergo bariatric surgery (Paper IV).

Implications for future research

- ✓ Future research in the field of bariatric surgery should focus on early identification of patients who have risk of less favourable outcome after surgery and for whom accompanying psychological interventions could be beneficial. Treatment programmes should be established and studied systematically by evidence based methods.
- ✓ Studies should also explore resilience factors; which factors do characterize persons who cope successfully after surgery.
- ✓ Studies should be conducted that investigate the effect of support programmes which include outcome variables of self-efficacy, and coping skills of patients with the aim of effectively self-managing weight loss maintenance and improvements in quality of life. The participants' perceptions of the acceptability and perceived effectiveness of such interventions should be included when evaluating these programmes.
- ✓ Future studies should focus on identifying factors that can target those individuals who are likely to remain inactive after surgery. Treatment intervention to increase level of physical activity should be evaluated.
- ✓ The question about whether depression should be considered as an obesity related comorbidity and, thereby, a reason to lower the threshold for bariatric surgery needs clarification. It has been argued that preoperative comorbid depression should lower the threshold for surgical treatment. This is based on findings in several studies that weight loss in patients with severe obesity is associated with a decrease in mean level of depressive symptoms and a lower prevalence of clinically significant depression. A study with a long follow-up is needed and will likely add important information to this area.
- ✓ There is a need for more knowledge regarding the predictive role of shame in maintenance of psychological symptoms in bariatric surgery patients and in psychiatric conditions in general.

- ✓ There is also a need to focus on identifying factors that can prevent drop out in longitudinal studies of bariatric surgery patients. High rates of attrition are relatively common in longitudinal obesity studies, and consequently findings in several studies are limited.

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