Lifestyle Intervention in Patients with Gastric Bypass Surgery

A Randomized Controlled Trial Focusing on Weight, Energy Intake and Quality of life

Master Thesis by

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May 2011
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Eva Rustad

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Oslo, 26 May 2011

Eva Rustad
Summary

Background and aims: The increasing rate of obesity is evident in both the world in general and in Norway. The consequences of obesity are well documented, including diabetes mellitus (DM) type 2, cardiovascular diseases, social stigma, and shortened life expectancy. Bariatric surgery is the most effective long-term successful treatment for the morbidly obese and the only documented treatment to maintain a substantial weight loss in this group over time. However, weight regain after surgery is a well recognized problem, also at Oslo University Hospital (OUH) Aker. Weight loss after bariatric surgery has a major positive impact on both somatic and mental health. Simultaneously, weight regain is shown to deteriorate these positive effects. Thus, an adequate follow-up regimen to avoid substantial weight regain is important to establish. Health related quality of life (HRQoL) is known to be poorer in morbidly obese subjects compared to the population norm, to improve with a significant weight loss and to deteriorate in association with the magnitude of weight regain. The purpose of the present study was to investigate whether additional follow-up prevents or lessen the degree of weight regain and whether it has a positive effect on HRQoL compared to controls who receive usual postoperative care.

Subjects and methods: Recruitment letters were sent to 714 eligible participants 14 months – 2 ½ years after Roux-en-Y gastric bypass (RYGBP) surgery from 2008 – 2010 for participation in a two-year study. Participants were randomized into a control and an intervention group according to sex and percentage of excess weight loss (EWL).The intervention was mainly based on group meetings, 16 in total. Results are based on data from individual study visits at baseline, 4 and 24 months. Food diaries to assess energy intake and the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) questionnaire to assess HRQoL were collected together with measures of weight and waist circumference. The study was approved by The Privacy Ombudsman, The Regional Committee of Medical Ethics, and Biohealth Norway.

Results: A total of 166 participants (23.2%) were recruited to the study. The completion rate was 93.4% at the 4 month visit and 83.0% at the 24 month visit. From baseline to the 4 month visit, the intervention group showed a significant weight increase (p-value = 0.007), whereas a tendency to weight increase was seen from baseline to 24 months (p-value = 0.08). There was
no significant difference in weight or waist circumference between the control and intervention group at 4 months or at 24 months (p-values > 0.05). There was no difference in energy intake between the two groups at 24 months (p-value = 0.96) and there was no significant association between change in energy intake and change in weight (p-value = 0.45). HRQoL analyses between baseline and 4 months showed that the intervention group had a tendency of decrease in the mental health measure (p-value = 0.09) whereas the control group showed a significant decrease in both the total score and the mental health measure (p-values = < 0.001 for both). No HRQoL score was statistically significant between the groups after 4 months (all p-values > 0.05). The control group had a significantly larger decline in mental health measure score than the intervention group (p-value = 0.04). No association between change in weight and change in any of the aggregated scores of the SF-36 were found (all p-values > 0.05).

**Conclusion:** The study subjects in both groups showed a tendency to increase their weight after 24 months of study and the control group showed a decrease in HRQoL total and mental scores. As these factors have been shown to correlate, it is important to prevent as much weight regain as possible, both concerning somatic and mental health. Future results from this study may reveal whether a group intervention should be a part of the usual care after RYGBP surgery or not.
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<td>Acceptable daily intake</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<td>BMR</td>
<td>Basal metabolic rate</td>
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<tr>
<td>BP</td>
<td>Bodily pain</td>
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<tr>
<td>CI</td>
<td>Confidence intervals</td>
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<tr>
<td>Cm</td>
<td>Centimeter</td>
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<tr>
<td>DM</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>DS</td>
<td>(Biliopancreatic diversion with) Duodenal switch</td>
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<tr>
<td>EI</td>
<td>Energy intake</td>
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<tr>
<td>E-mail</td>
<td>Electronic mail</td>
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<tr>
<td>EWL</td>
<td>Excessive weight loss</td>
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<tr>
<td>FFQ</td>
<td>Food frequency questionnaire</td>
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<tr>
<td>GH</td>
<td>General health</td>
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<tr>
<td>GLP-1</td>
<td>Glucagon-like peptide 1</td>
</tr>
<tr>
<td>HDL</td>
<td>High density lipoprotein</td>
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<tr>
<td>HRQoL</td>
<td>Health related quality of life</td>
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<tr>
<td>HSE</td>
<td>South-Eastern Norway Regional Health Authority</td>
</tr>
<tr>
<td>HUNT</td>
<td>Nord-Trøndelag Health Study (Helseundersøkelsen i Nord-Trøndelag)</td>
</tr>
<tr>
<td>IQOLA Project</td>
<td>International Quality of Life Assessment Project</td>
</tr>
<tr>
<td>IWQoL-Lite</td>
<td>Impact of Weight on Quality of Life-Lite</td>
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<tr>
<td>KBS</td>
<td>Kostbergningssystem</td>
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<tr>
<td>Kcal</td>
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<td>Kg</td>
<td>Kilograms</td>
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<td>kJ</td>
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<td>MC4R</td>
<td>Melanocortin 4 receptor</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>MH</td>
<td>Mental health</td>
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<tr>
<td>NAFD</td>
<td>Nonalcoholic fatty liver disease</td>
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<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>OUH</td>
<td>Oslo University Hospital</td>
</tr>
<tr>
<td>P25 – P75</td>
<td>25 to 75 percentiles</td>
</tr>
<tr>
<td>PAL</td>
<td>Physical activity level</td>
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<tr>
<td>PC1</td>
<td>Prohormone convertase 1</td>
</tr>
<tr>
<td>PF</td>
<td>Physical functioning</td>
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<tr>
<td>POMC</td>
<td>Proopiomelanocortin</td>
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<tr>
<td>PYY</td>
<td>Peptide YY</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
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<tr>
<td>RD</td>
<td>Registered dietitian</td>
</tr>
<tr>
<td>RE</td>
<td>Role-emotional</td>
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<tr>
<td>RMR</td>
<td>Resting metabolic rate</td>
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<tr>
<td>RP</td>
<td>Role-physical</td>
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<tr>
<td>RR</td>
<td>Relative risk</td>
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<tr>
<td>RYGB</td>
<td>Roux-en-Y gastric bypass</td>
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<tr>
<td>SD</td>
<td>Standard deviation</td>
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<tr>
<td>SES</td>
<td>Socio-economic status</td>
</tr>
<tr>
<td>SF</td>
<td>Social functioning</td>
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<tr>
<td>SF-36</td>
<td>The Medical Outcomes Study 36-item Short-Form Health Survey</td>
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<tr>
<td>SOS</td>
<td>Swedish obese subjects</td>
</tr>
<tr>
<td>UiO</td>
<td>University of Oslo</td>
</tr>
<tr>
<td>VGB</td>
<td>Vertical banded gastroplasty</td>
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<tr>
<td>VT</td>
<td>Vitality</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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1 Introduction

1.1 Obesity – definition and development

To describe and classify the degree of obesity, the World Health Organization (WHO) uses a weight-for-height index, the body mass index (BMI). It is defined as weight in kilos per square meter body mass (kg/m²). The normal range is a BMI between 18.5 – 24.99 kg/m², overweight is classified at a BMI between 25.0 – 29.99 kg/m² and obesity is classified at a BMI range > 30 kg/m². Further, obesity is divided into three subclasses; class I (BMI 30 – 34.99 kg/m²), class II (35 – 39.99 kg/m²) and class III (BMI ≥ 40 kg/m²) (1). The increasing rate of obesity is evident in both the world in general and in Norway. New estimates from WHO is in progress, but the latest projections indicated in 2005 that minimum 400 million adults from the age of 15 years were obese and that this number would rise to 700 million in 2015. Overweight and obesity was considered a disease of affluence which occurred only in high income countries, but this has now changed. Overweight and obesity are on the rise in low- and middle-income countries, particularly in urban areas (2). The most updated numbers on obesity from Statistics Norway is their latest Living-condition research in 2008. It showed that among Norwegians above 16 years of age, 12% of the men and 9% of the women were obese whereas in 1995 those same numbers were 6% and 5%, respectively (3). These numbers are supported by the Nord-Trøndelag Health Study (HUNT). This major survey in the Nord-Trøndelag county of Norway was carried out in 1984-1987 (HUNT 1) with a follow up in 1995-1997 (HUNT 2) and the last part of this study was carried out in 2006-2008 (HUNT 3). The development in BMI change is based on data collections from nearly 25 000 individuals. It shows that in only 11 years from 1984 to 1995, the total BMI has increased nearly two units from 24.79 – 26.70 kg/m² (4). A recent report from the HUNT study showed that among men, the average BMI (kg/m²) increased from 25.3 (HUNT 1) to 26.5 (HUNT 2) and 27.5 (HUNT 3). The corresponding numbers for women were 25.1, 26.2 and 26.9 kg/m². In the HUNT 1 study, 50% of the men and 43% of the women had a BMI > 25 kg/m². These numbers increased to 75% and 61% respectively in the HUNT 3. The largest increase was in the BMI group ≥ 30 kg/m² (5). This shows that the prevalence of obesity has steadily been increasing and will continue to be a major health problem.
1.1.1 Causes of obesity

Heredity and environmental influences are both contributors to the development of obesity. The causes of obesity are mainly multifactorial, where environmental factors play a significant part. However, obesity has a high heritability. The most common genetic variants of heritable obesity are so-called polymorphisms. These are susceptible genes for developing overweight and obesity (6). Studies have shown that genetic factors explain up to 90% of the variance in BMI in twin studies and up to 80% in family studies (7). Another review found a heritability of weight change 58% in men and 64% in women (8). The development of obesity is consequently not, for most people, determined by his or hers genes only. In addition to susceptible genes, the right environmental factors must exist (6). WHO attribute the excess intake of calories to two main factors: A global shift in diet towards increased intake of energy-dense foods high in sugars and fat, but low in micronutrients and decreased physical activity due to more sedentary work and transportation (2). Overweight and obesity are, in addition to genetic factors, associated with physiological characteristics such as age, gender and ethnicity, socio-economic status (SES), level of education, psychological conditions, social and physical environment and behavioral characteristics such as diet and physical activity. Chronic conditions are also linked to overweight and obesity. Such conditions include arthritis, high blood pressure, diabetes mellitus (DM) and anxiety or other psychological disorders (9). The amount of energy intake and level of activity, expressed as energy expenditure, is an important predictor of BMI. An imbalance between energy intake and energy expenditure, i.e., energy intake exceeds energy expenditure, results in a higher BMI (9). Physical activity appears to be lower in obese individuals, and one study found that leisure-time physical activity was nil in 46.7% of the obese women (10). Another study among men, investigating the association of dietary and behavioral factors with gain in waist circumference, showed that an increase in vigorous activity and weight training both were associated with a decrease in waist circumference (11). Gender and age are also known to be significant predictors of weight. BMI tends to increase with age, and males have larger average BMI’s than their female counterparts (9). This difference seems to be evident up to the age of 80 years. In the age group 80+, females tend to have a greater average BMI than the males (5). On the contrary, in females with an anxiety or mood disorder, a higher BMI was found among them compared to their male counterparts. SES and level of education are inversely related to BMI both for men and women and play a substantial role in explaining differences in BMI among different groups of society (9).
In the media in particular and among people in general, there is a great interest in the debate concerning high-protein/low-carbohydrate versus traditional low-fat diets. The media discussions focus on which of the diet regimens is the best to lose weight and/or to maintain a healthy weight. The popular high-protein/low-carbohydrate diets seem to have a greater short-term effect on weight loss, but with no difference achieved after one year. There is also little evidence on the long-term effect and safety of these diets (12). One study compared the effect on weight loss in four different popular diets after one year of intervention. They only found a significant difference in mean weight loss between two diets; the Atkins diet (very low in carbohydrate) and the Zone diet (low in carbohydrate). On the other hand, there was no significant difference between the diet very low in carbohydrates (Atkins) and the diet very high in carbohydrates (Ornish) (13). Other studies have investigated the dietary pattern of people who maintain an optimal body weight in an obesogenic environment. Prospective studies of large samples have shown that a high intake of carbohydrates and fiber is associated with a greater probability of maintaining an optimal body weight. An increment in trans fatty acid intake and a higher intake of protein from red and processed meat and poultry has been linked to weight gain and an increase in waist circumference (11, 14, 15).

In comparison to the multifactorial causes of obesity, monogenetic causes of obesity are much more rare and the most frequent monogenetic mutation, in the melanocortin 4 receptor (MC4R), has a frequency of about 5% in obese adults with a BMI > 40 kg/m² (16, 17). There are five known genes where mutations may occur and lead to monogenic forms of obesity in humans. Over 100 gene variants of the MC4R are known and 42 different functional mutations are described. There are variants found in both lean and obese subjects, others are only found in lean or only found in obese subjects. This suggests that the MC4R gene may influence body weight in several ways. There is still no causal therapy to treat this condition (6, 18). The other four mutations are in the gene coding for leptin production causing leptin deficiency, mutation of the leptin receptor gene, mutations in the gene for producing the peptide proopiomelanocortin (POMC) and prohormone convertase 1 (PC1) (6).

Factors during pregnancy are also believed to affect the offspring’s risk of developing overweight and the metabolic syndrome as adult. The probabilities of such conditions depend on genetic susceptibility of the individual, but are also affected by both pre- and postnatal factors (19, 20). Gestational DM and DM 1 are associated with a higher risk for the offspring to develop overweight as an adult. The hypothesis is that maternal glucose leads to
intrauterine hyperglycemia and hence hyperinsulinemia in the fetus. This may affect the development of the fetus. Offspring of women with diet-treated gestational DM or DM 1 were found to have doubled risk of overweight compared to offspring of pregnant women who were not exposed (19).

1.1.2 Consequences of obesity

The effects of overweight have been known for more than 2000 years when Hippocrates discovered that “sudden death is more common in those who are naturally fat than in the lean”. The consequences of obesity are today well documented and recognized and are often termed the comorbidities of obesity. These included widespread diseases like DM type 2, hypertension, atherosclerosis, dyslipidemia, and supplementing a range of heart diseases, sleep apnea, gallbladder disease, stroke, sudden death and shortened life expectancy, arthritis of weight-bearing joints, nonalcoholic fatty liver disease (NAFD), infertility, some cancers, social stigma, and psychological problems (figure 1). In addition are physical problems prominent such as the inability to move greater distances without motorized transportation, to put on socks, to tie shoelaces, to cut toenails and to fit in small airplane seats (21).

When obesity is present, the fat cells are enlarged which in turn leads to increased secretion of free fatty acids and several peptides. Importantly, the adipose tissue is an endocrine organ (21). As the adipose tissue is an endocrine organ, it has a substantial role in the development of DM type 2. The Nurses Health Study found that the relationship between BMI and the risk of DM to be increasing exponentially with increasing BMI. The study showed that women with a BMI $\geq 35$ kg/m² had a relative risk (RR) increase of 93.2 of developing DM type 2 compared to women with a BMI < 22 kg/m² (RR = 1.0). Weight gain per se also increases the risk of developing DM regardless of the initial BMI, whilst weight loss decreases the risk (22). Results from a large Dutch cohort study also showed that persons who gained a substantial amount of weight (> 6 kg) during 5 years more than doubled the risk of DM compared with persons who had a stable weight (± 2kg). This study also showed increasing Odds Ratios (OR) with increasing BMI (23). WHO predicts that deaths related to DM will increase by over 50% worldwide in the next 10 years (2). Lipid abnormalities and coronary artery disease are also correlated with an increase in BMI in relation to an increase in triglycerides and decrease in “the good cholesterol” high density lipoprotein (HDL). Blood pressure is also often increased in obese subjects. High blood pressure leads to hypertrophy of
the heart which in turn leads to a thickening of the ventricular wall and thus a larger heart volume. This increases the risk of developing a heart disease (21). Heart disease and stroke are the world’s number one cause of death, killing 17 million people every year (2). Certain forms of cancer are also significantly more prominent in people with overweight and obesity and several of them are also linked to endocrine disturbances. In women, cancers of the reproductive system (the endometrium) are related to increasing BMI and increasing estrogen production as well as postmenopausal breast cancer. Among other cancers who are linked to an increasing body fatness are cancers in the colon, rectum, gallbladder, pancreas, and kidneys (24). Other consequences of an altered endocrine secretion are hirsutism in women and irregular menses and reduction in fertility rate (21).

**Figure 1.** Medical consequences of obesity. NAFLD = nonalcoholic fatty liver disease, CVD = cardiovascular disease, GB disease = gallbladder disease. Adapted from Bray (21).

### 1.2 Bariatric surgery

Oslo University Hospital (OUH), Aker started performing bariatric surgery in 2004 and had 26 surgeries carried through that year. Since then the number of patients who have undergone surgery have steadily increased, and in the last two years stabilized at around 250 surgeries.
per year. To be considered for surgery, the candidate must meet certain criterions. The patient must suffer from either extreme obesity, defined by a BMI $\geq 40$ kg/m$^2$ (class III), or a BMI $\geq 35$ kg/m$^2$ (class II) with additional comorbidities related to the overweight which are likely to be significantly improved by bariatric surgery. Such comorbidities include sleep apnea, a serious cardiopulmonary condition, DM type 2, arthritis, and hypertension which are poorly regulated by antihypertensives. Contraindications for bariatric surgery are mental illnesses and abuse of any narcotics or alcohol (25). These conditions are contraindications to bariatric surgery because patients must be able to engage in a long-term follow-up. Non-compliance with the follow-up schedules can lead to serious complications and possible death (26). Thus, severe mental and/or cognitive retardation and hyperphagia are also viewed as contraindications. Although minor psychological problems are common in morbidly obese individuals, they are not found to be a predictor of long-term successful outcome. On the other hand, preoperative motivation has been found to be a predictor of weight loss. The patient should therefore be examined prior to surgery and evaluated with a view to mental health together with the aspects of physical health. Surgical candidates must also have tried conventional treatment of obesity before bariatric surgery can be performed (26). The guiding age range for the surgical candidates was between 18-60 years of age. This age range has been the guiding range since the start at OUH Aker in 2004 (25). However, the South-Eastern Norway Regional Health Authority (HSE) will not allow an upper limit of age for granting surgeries anymore. This is because an upper age limit of treatment is viewed as age discrimination (27). A fixed age limit can not be set based on the evidence available, but children with immature skeleton should not undergo bariatric surgery. When it comes to the upper age limit, findings have shown that patients over 60 or 65 years has more pronounced comorbidities making them less reversible than at a earlier stage/younger age. However, patients aged up to 70 years have been documented to have a beneficial effect of the surgery on weight and some comorbidities (26).

At OUH Aker there are two types of bariatric surgery performed. One alternative is a restrictive surgery (gastric sleeve) and the other alternative is a combination of both restrictive and malabsorptive surgery (gastric bypass and duodenal switch). The latter category is by far the most common type of bariatric surgery at OUH Aker (27). Among the combination surgeries, gastric bypass is the most common type in Norway (28). Gastric bypass is the preferred surgery for patients with a BMI of 40-50 kg/m$^2$. In patients with a BMI between 50-60 kg/m$^2$, gastric bypass and duodenal switch are both considered, and in patients with a BMI
> 60 kg/m² duodenal switch is the preferred option. This is because the latter surgery causes more weight loss (26) and thus is more suitable for the patients in the highest BMI category. Restrictive surgeries cause a limited food intake due to reduction in gastric capacity and thus a quickly filled stomach. The malabsorptive surgeries interrupt with normal digestion and absorption of nutrients and thus limit the amount of calories absorbed. The expected excess weight-loss (EWL) after restrictive and malabsorptive surgeries is 60-80% (26, 29). The word excess refers to the amount of weight above the normal range of the BMI scale defined by WHO (1). Thus, weight is in excess from BMI 25 kg/m² (initial weight - weight at BMI 25 kg/m²). It is normal to indicate the EWL as a percentage of the excess weight lost ((preoperative weight – current weight)/(preoperative weight – weight at BMI 25 kg/m²) x 100) (30). An EWL of minimum 50% maintained for at least five years after surgery is viewed as a success (26, 28). Some publications indicate the weight loss as a percentage or part of the total weight. Bariatric surgery is the most effective long-term treatment for the morbidly obese (28, 29).

1.2.1 Roux-en-Y gastric bypass surgery

Roux-en-Y gastric bypass (RYGB) is the most common surgery in Norway and is performed at every hospital who offers bariatric surgery (28). It is also the most common bariatric procedure worldwide (26). The procedure is both restrictive and malabsorptive with a high degree of restriction and moderate malabsorption. The gastric capacity is reduced by 90-95% to a pouch containing 15-30 mL, the rest of the stomach is left as a “blind” pouch. After this surgery is performed the pyloric sphincter is not a part of the digestion system anymore, hence the control mechanism for the pace of food from the stomach to the intestine is gone. The fundus, corpus and antrum of the stomach are also left out. The small gastric pouch is anastomosed with the distal end of the jejunum (26, 28). This limb is called Roux limb or alimentary limb and carries the ingested food. The limb which carries digestive enzymes and drains bile is called the biliopancreatic limb. The biliopancreatic limb includes, in addition to bile acids and digestive enzymes, the duodenum and proximal part of jejunum. This limb is connected to the “blind” pouch of the stomach (figure 2). Digestion takes place when these limbs are connected by an anastomosis of the biliopancreatic limb to the alimentary limb and creates a common limb. The standard length of the Roux limb is normally 75-100 cm and the biliopancreatic limb normally runs until 40 cm distal to the ligament of Treitz’. The common limb is normally 3-3.5 meters long (26, 28, 29). The uptake of several nutrients and calories
is reduced due to the small area of the common limb for food and enzymes to be mixed. The degree of malabsorption is dependent on where the Roux and biliopancreatic limbs are anastomosed to create the common limb. The standard procedure with the Roux limb of about 75 cm is recommended in patients with a BMI of less than 50 kg/m². In cases of a higher BMI, it is recommended to create a Roux limb of 150 cm (long limb) or up to as much as 250 cm (very long limb) to further induce weight loss and a better weight maintenance. Expected EWL after RYGB range from 60-70% (26, 28, 29, 31).

**Figure 2.** The Roux-en-Y gastric bypass procedure. A small gastric pouch is separated from the rest of the stomach. Food is led through the alimentary limb, bile acids and pancreatic enzymes are led through the biliopancreatic limb. The alimentary limb can have different lengths depending on the desired degree of malabsorption. The biliopancreatic limb runs until 40 cm distal to the ligament of Treitz’ until two limbs are joint together in a common limb for digestion and absorption. From Aasheim ET et al (28). The illustration is made by Ole-Jacob Berge and used with permit ion of article author and The Journal of the Norwegian Medical Association.
1.2.2 Biliopancreatic diversion with duodenal switch

Biliopancreatic diversion with duodenal switch (DS), hereafter termed duodenal switch (DS), is not performed at every hospital with a bariatric surgery team in Norway, but it is offered at OUH Aker (28). The procedure is both restrictive and malabsorptive with moderate food restriction and a high degree of malabsorption (26). The gastric capacity is reduced to a pouch containing 100-200 ml. The gastric volume is reduced by vertical gastroectomy (figure 3) (26, 28, 29). Unlike the RYGBP procedure, the DS preserves the pylorus and about five cm of the duodenum. The duodenum is cut proximal to the papilla of Vater which is the exit opening to the bile acids and digestive enzymes. Preservation of the pylorus and the proximal duodenum is very important for absorption of micronutrients. The distal jejunum is anastomosed to the proximal duodenum (duodenal switch) creating an alimentary limb. The standard length of the alimentary limb is 200-300 cm. The biliopancreatic limb is created when the proximal ileum is anastomosed with the distal jejunum about 100 cm above the ileocecal valve, which in turn creates the common limb (26, 32). As the common limb is very short, DS is a considerably malabsorptive procedure and the malabsorption of fat, fat-soluble vitamins and starch is more pronounced than in RYGBP. Malabsorption of iron, vitamin B_{12}, folate and calcium is more pronounced in RYGBP than in DS, but the levels of iron and calcium must also be monitored in DS. Expected EWL after DS range from 65-80% (26, 28, 31, 32).

The DS may be done in two operations to reduce the risk of adverse effects. In that case the first step is to do the vertical gastroectomy and then wait a while before performing step two, the duodenal switch (28). In this period weight loss is shown to occur. This first step is also performed to decrease the hemodynamic instability during surgery (26).

DS is known to cause a greater weight loss than RYGBP. One Norwegian study found a significantly superior weight loss in patients with a BMI range of 50-60 kg/m² comparing DS to RYGBP one year after surgery (32). However, DS has also been associated with a higher risk of developing nutritional deficiencies due to the more malabsorptive nature of DS compared to RYGBP (26). The DS is also more complicated for the surgeons to execute than the RYGBP, but both procedures are regarded as safe with acceptable levels of surgical complications and low mortality (26, 32). Thus, DS is mostly performed in patients with a BMI > 50 kg/m². This is to enhance EWL for the larger patients and to avoid unnecessary complications and adverse effects for those with a lower initial BMI (table 1) (26, 32).
Figure 3. The biliopancreatic diversion with duodenal switch procedure. A gastric pouch is separated from the rest of the stomach with vertical gastroectomy. The pylorus is kept intact and is anastomosed with proximal ileum (duodenal switch). Food is led through the alimentary limb and bile and digestive enzymes from the pancreas are led through the biliopancreatic limb. When these limbs are anastomosed, they create a common limb of only about 100 cm for digestion and absorption. From Aasheim ET et.al (28). The illustration is made by Ole-Jacob Berge and used with permission of article author and The Journal of the Norwegian Medical Association.
Table 1. Examples of excess weight loss after gastric bypass and duodenal switch.

<table>
<thead>
<tr>
<th>Data</th>
<th>RYGBP</th>
<th>DS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>Female, 117 kg, 167 cm, BMI 42</td>
<td>Female, 150 kg, 167 cm, BMI 54</td>
</tr>
<tr>
<td>Normal weight, kg (BMI 20(^1)-24.9)</td>
<td>56-70</td>
<td>56-70</td>
</tr>
<tr>
<td>Excess weight, kg</td>
<td>47</td>
<td>80</td>
</tr>
<tr>
<td>Expected EWL, kg</td>
<td>28-33 (60-70%(^2))</td>
<td>52-64 (65-80%(^3))</td>
</tr>
<tr>
<td>New weight, kg</td>
<td>84-89</td>
<td>86-98</td>
</tr>
</tbody>
</table>

1 A lower BMI range of 20 kg/m\(^2\) was chosen because the optimal BMI range for longevity and avoidance of obesity-related diseases have been proven to fall between 20 – 24.9 kg/m\(^2\) (30, 33).

2References: (26, 28, 29, 31).

3References: (26, 28, 29, 31, 32).

1.2.3 Pre and post surgery routines at Oslo University Hospital Aker

OUH Aker follows a certain treatment regimen regarding examination of the patients, preparations before surgery and post surgery follow-up, based on international guidelines (28). Before surgery can be performed, the patient must be evaluated by a surgeon, anesthesiologist, nurse and registered dietitian (RD). The evaluation of the patient is based on weight development, age when obesity emerged, weight related comorbidities, spirometry, lifestyle, expectations and motivation. Possible eating disorders are also examined. In addition, anthropometric measures like BMI, weight and waist circumference and blood samples are performed and evaluated. If required, other supplemental examinations are carried out, e.g. gastroscopy and abdominal ultrasound (28). The family doctor may also order a glucose tolerance test (26). The goal is to get a general over view of the patient’s somatic diseases, psychosocial situation and the patient’s mortality and morbidity risks during surgery. It is important that the patient has enough information to make an informed decision on whether to undergo the surgery or not (26). Thus, the patients are taught about the surgical procedures, demands to lifestyle changes to obtain a successful surgery, possible complications and the follow-up routines at the hospital (28). At the preoperative mandatory course at OUH Aker, the patient is told and taught to complete a low-calorie diet of 4200 kilojoules (kJ) (1000 kcal) per day the last three weeks before surgery. This is due to the high prevalence of enlarged livers among the obese as a result of fat accumulation. An enlarged liver increases the risk of surgery because the liver is lifted during the procedure (34, 35). As described in detail below, the short-term after-care at OUH Aker includes different diets. Patients must be on a liquid diet the first week after surgery. Thereafter follows two weeks of
pureed food together with the initiation of micronutrient supplementation. Finally, the patient may eat normal food from four weeks on after surgery (36). The post surgery follow-up is mostly conducted by the RD and sessions at the surgeons when needed. The RD sees the patient at the ward before return to home and at called in sessions 2 and 6 months, 1, 2 and 5 years post surgery. During these sessions, the vitamin and mineral status is evaluated on the basis of blood samples and individual nutritional advices are given accordingly. Anthropometric measurements are taken and the RD also performs a food anamnesis to guide the patient on fluid, energy and protein intake and to assess the pattern of food intake. If required, the patient is also called in for a session with the surgeon. In addition to the individual consultation, the patients are offered a group meeting three and four years after surgery (37). However, due to lack of capacity, the decision has been made to cancel the four year group meeting (27).

1.2.4 Surgical after-care

A multidisciplinary approach to aftercare is recommended. Patients should be assigned for out-patient clinic appointments 3-8 times during the first postoperative year, 1-4 times during the second year and once or twice the following years. Further visits to specialist consultation should be done when needed. The healthcare team should assess the following outcomes; weight loss, weight maintenance, quality of life, comorbidities and nutritional status (26). Since malabsorption is a desired consequence of RYGBP and DS, nutritional management and compliance to diet regimen post surgery is crucial to avoid serious complications and severe malnutrition. In addition many patients already had nutritionally inadequate diets prior to surgery, a condition that is more likely to be worsened than improved after surgery due to malabsorption (26). After the surgery, food intake is limited which leads to a diet high in demands to its content. This normally requires an extensive change in dieting habits for the patient. The food must be nutritious, varied and at suitable portion sizes. Proteins must be prioritized in the beginning when food intake is limited. In addition, patients are advised to have one dose of multivitamins every day which covers the micronutrient recommendations together with iron, calcium and vitamin B₁₂ supplements (26, 28).

Weight loss is normally most rapid the first six months and the weight is usually at its lowest one year after surgery. The reduction in weight tends to stop between one and two years after surgery (38). The mechanisms for the great weight loss are not fully understood, but several
mechanisms are researched and investigated. The food intake is restricted due to lower gastric capacity, and the pouch volume is believed to be a key aspect of the RYGBP procedure (26). In DS malabsorption plays the most significant role in the weight loss mechanism with reduction of net energy absorption (29). In long-limb RYGBP, malabsorption is an important contribution to the weight loss in addition to gastric restriction. It is also shown superior EWL in the super-obese compared to a shorter length of the Roux-limb (29, 39). Odstrcil et al. found that malabsorption accounted for 6% of the total reduction in energy absorption five months after surgery. This fraction increased to 11% 14 months after long-limb RYGBP surgery. At the same time, the effect of restricted gastric capacity on energy intake decreased successively with time after the procedure (40).

There are also changes in hunger, satiety and appetite, possibly due to decreased secretion of appetite stimulating hormones like ghrelin and an increased secretion of appetite inhibitory hormones such as glucagon-like peptide 1 (GLP-1) and peptide YY (PYY) (41-43). The orexogenic hormone (i.e. having a stimulating effect on appetite) ghrelin is thought to increase significantly after diet-induced weight loss (41). This may explain why substantial weight loss by conventional methods is very difficult. Ghrelin is produced primarily in the stomach, and thus the RYGBP procedure in itself may affect the ghrelin secretion (41). Cummings et al. found interesting results, although their study results came from a small study group. They compared diet-induced weight loss to weight loss after RYGBP in relation to ghrelin secretion. The results showed that plasma ghrelin levels were 72% lower in the surgery group compared to the matched obese controls, despite the fact that the loss of total body weight was 36% and 17% respectively (41). This study, carried out in 2002, was the first to report reduced ghrelin levels in patients who had undergone RYGBP compared with normal weight and matched obese controls. There has been an extensive research on ghrelin in bariatric surgery since then. There have been various results and a recent study found a significant increase in the fasting ghrelin plasma levels three years after RYGBP (44). However, a review article concluded that overall, ghrelin is considerably reduced after RYGBP surgery compared to people with normal weight, overweight, obesity, or people who had other weight loss surgeries (45).

The role of the hormones GLP-1 and PYY is still somewhat controversial when it comes to their effect on appetite and satiety. However, postprandial GLP-1 and PYY seem to rise early after the surgery and is thought to cause a change in appetite. This happens quickly and is
evident before any substantial weight loss occurs. It is also suggested that when GLP-1 and PYY are inhibited, appetite returns (42, 43). Studies of the gut hormones after bariatric surgery may lead to the knowledge that there are other factors than restriction and malabsorption contributing to the prolonged weight loss seen. Such knowledge may change the management of the obesity epidemic. However, a more straightforward cause of prolonged weight reduction is still evident; it is shown that patients with bariatric surgery have a higher physical activity during leisure time compared to obese individuals left to conventional treatment (38).

Some patients also experience unpleasant physical reactions to eating too fast or eating foods high in sugar (RYGBP-patients) or fats (DS-patients). A high intake of refined sugar or simple carbohydrates, or rapid food intake may cause a condition called dumping syndrome. The pathophysiology is not fully understood, but it is believed that with the absence of the pyloric sphincter the food content of the stomach is delivered too rapidly into the small intestine. Thus the food particles may be too large and together with a content rich in sugar, a hyperosmolaric state occurs in the small intestine (46). This causes fluid to move into the intestinal lumen, which in turn may lead to a decrease in the circulating blood volume, tachycardia and syncope. The fluid shift may also cause a distention of the small intestine followed by a sensation of cramps. In addition to fluid shifts, the release of gastrointestinal peptide hormones, like GLP-1 among others, is thought to be of importance in the mechanisms of dumping syndrome. A rise in GLP-1 secretion may lead to increased motility of the intestines (46). Hypoglycemia is also a part of the dumping syndrome. A rapid delivery of refined carbohydrates to the small intestine causes insulin to exceed its normal secretion level and this causes a state of hypoglycemia. The symptoms of dumping syndrome include abdominal pain, diarrhea, nausea, bloating, fatigue, flushing, perspiration and hypoglycemia (46). Prevention of dumping syndrome implies small, frequent meals, avoidance of meals rich in sugar, eating and drinking slowly, chewing the food thoroughly and drinking in between meals in stead of together with meals (47).

The Swedish obese subjects (SOS) study compares different bariatric surgeries to conventionally treated obese subjects and follow them for 10 years. Although only a small part of the surgery group had gastric bypass surgery, the results are interesting because there are very few studies which have followed patients for such a long time. Among the surgery subgroups (gastric banding, vertical banded gastroplasty, and gastric bypass), the results are
most favorable for the gastric bypass-group. The study found that the surgery group together had better recovery from DM, a lower weight and waist circumference, and better values of uric acid, glucose and triglycerides 10 years after surgery. They also had a lower energy intake and higher level of physical activity (38). This shows that morbid obesity is treatable. However, weight regain may threat these benefits. Thus it is important with patient follow-up to try to maintain lifestyle changes and to avoid weight regain and relapse of comorbidities.

**Short-term after-care**

At OUH Aker the patient starts on a liquid diet during the first week after surgery, normally within 1-2 days. The second week, the patient upgrade the food to puréed consistency and starts with micronutrient supplements. The supplement regimen for the RYGBP-patients at OUH Aker consists of multivitamins, iron and calcium. The patients should also be on the prescribed medicine Ursofalk (ursodeoxycholic acid) the first six months when the weight loss is most rapid to reduce the risk of gallstone. In addition, injections of vitamin B₁₂ every third to fourth month are recommended. Patients can eat normal food four weeks after surgery, but they have to explore different foods carefully due to individual reactions to food items (36). The patients should also drink one high protein energy drink each day the first four weeks. It is recommended to have an intake of at least 60 grams of proteins every day to avoid protein energy malnutrition. Another important advice is to drink fluids between meals and not with the meals to avoid dehydration or insufficient food intake due to small gastric capacity. This information is given to the patient both during consultation and in writing (36).

**Long-term after-care**

The bariatric surgery patient must be willing to engage in long-term care and to change eating and exercise behavior compared to pre-surgery lifestyle. The patient care is recommended to last for life with support groups, counseling to reinforce change of life style and involvement of the general physician (29). Complications have a tendency to decrease with time after surgery and the unpleasant reactions to poor food choices lessen. Dumping syndrome commonly diminishes 12-18 months after surgery (47). This means that the “guard dog” of poor food choices disappears. Hence, the patient must have acquired a change of life style to maintain the achieved weight loss.
Bariatric surgery and its subsequent weight loss can lead to improvement or resolution of the obesity-related comorbidities (29). The weight loss the bariatric patients achieve has a major positive impact on both physical and psychological aspects of the patients' lives, and thus weight regain deteriorates these positive effects (38, 48, 49). However, bariatric surgery is an expensive solution to the obesity problem. Accordingly, it is important to have an adequate follow-up regimen to achieve the best results possible. A qualified multidisciplinary team must be available to best potentiate and manage this task (26, 29).

Further aspects elaborated in this thesis will emphasize on effects of and theory on RYGBP, because the patients studied all went through this procedure.

### 1.3 Energy intake

As earlier mentioned, weight loss after RYGBP is at its greatest after 12-16 months and is maintained up to two years postoperatively (38, 50, 51). Participants in the SOS-study showed a decrease of 25% of total body weight 10 years after RYGBP (38).

**Table 2.** Levels of energy intake before and after Roux-en-Y gastric bypass surgery

<table>
<thead>
<tr>
<th>Article</th>
<th>kJ (Kcal)/day</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odstrcil <em>et al.</em> (40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Before RYGBP</td>
<td>15708 (3754)</td>
<td>Weighed food registration 7-10 days prior to study visits</td>
</tr>
<tr>
<td>• After 5 months</td>
<td>6510 (1556)</td>
<td></td>
</tr>
<tr>
<td>• After 14 months</td>
<td>9376 (2241)</td>
<td></td>
</tr>
<tr>
<td>Lindroos <em>et al.</em> (51)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Before RYGBP</td>
<td>11401 (2725)</td>
<td>Dietary questionnaire that covered food consumed the past three months, especially developed for the SOS-study</td>
</tr>
<tr>
<td>• After 6 months</td>
<td>5899 (1410)</td>
<td></td>
</tr>
<tr>
<td>• After 1 year</td>
<td>7531 (1800)</td>
<td></td>
</tr>
<tr>
<td>• After 2 years</td>
<td>7887 (1885)</td>
<td></td>
</tr>
<tr>
<td>Olbers <em>et al.</em> (52)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Before RYGBP</td>
<td>11255 (2690)</td>
<td>Same as Lindroos <em>et al.</em></td>
</tr>
<tr>
<td>• After 1 year</td>
<td>5250 (1225)</td>
<td></td>
</tr>
<tr>
<td>Kruseman <em>et al.</em> (53)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Before RYGBP</td>
<td>9853 (2355)</td>
<td>4-day dietary food record</td>
</tr>
<tr>
<td>• After 1 year</td>
<td>6033 (1442)</td>
<td>after instruction by a registered dietitian</td>
</tr>
<tr>
<td>• After 8 years</td>
<td>7029 (1680)</td>
<td></td>
</tr>
</tbody>
</table>
The restriction of the gastric capacity limits the food intake (26), and is thus one important explanation for the major weight loss seen after undergoing this surgery. Various levels of daily energy intake before and after RYGBP-surgery are reported as shown in table 2.

The SOS-study reports an intake of 11 401 kJ (2725 kcal) per day before surgery (51). Other studies report daily intakes ranging from 9853 to 15708 kJ (2355 to 3754 kcal) prior to surgery. Different methods for collection of energy intake were used (table 2) (40, 51-53). Regardless of these differences, all studies show a significant decrease in energy intake in the patients after surgery. In the SOS-Study the level of energy intake decreased to 5899 kJ (1410 kcal) six months after surgery, and thereafter increased to 7887 kJ (1885 kcal) two years post surgery (51). The other studies also showed an initial decrease in energy intake followed by an increase one year after surgery, but never to the same level as before surgery (40, 52, 53) (table 2).

Macronutrients

When the energy intake decreases, as a consequence the absolute intake of macronutrients is also reduced. Although studies do not show consistent results on the different macronutrients’ contribution to the total energy intake, it appears to be a significant decrease in the proportional contribution of fat to the total energy intake and an increase in percentage of energy from protein and carbohydrates (40, 51, 53). It also looks like RYGBP patients steer towards a more advantageous diet with less dietary fat and more fruit and vegetables when compared to vertical banded gastroplasty patients. This might explain some of the advantage of the RYGBP compared to strictly restrictive bariatric procedures (52). A review indicates that high-calorie and high-fat foods have a reduced appeal after RYGBP surgery (54). If this is correct, and patients change their food preferences to less energy dense foods, it may be another explanatory factor behind a prolonged decreased energy intake. In addition, self reported dietary strategy after RYGBP shows that patients attempt to decrease total intake of calories and fat and they try especially to avoid soda and sweet desserts (50).

1.4 Quality of life

Health-related quality of Life (HRQoL) refers to the total effects of a medical condition on physical and mental functioning and mental well-being as subjectively evaluated by the
patient (55). To measure success of bariatric surgery, it has traditionally been focused on the percentage of EWL and remission of comorbidities such as DM (48). One may suggest that the effects of bariatric surgery on HRQoL is not emphasized enough in proportion to the improvements it has on daily living and ability to participate in normal activities (56). There is a growing awareness on HRQoL after bariatric surgery together with its importance in evaluating the effectiveness of the procedure. HRQoL is known to be poorer in morbidly obese subjects compared to the population norm, to improve with a significant weight loss (48, 49, 57, 58) and to deteriorate in association with the magnitude of weight regain (49). Thus, it is especially relevant to investigate and document changes in HRQoL in weight-loss research alongside EWL and remission of comorbidities after bariatric surgery. Apart from being an important goal after bariatric surgery, it may be suggested that an improved HRQoL motivate patients to maintain the new weight achieved and thus be compliant to beneficial health behaviors.

1.4.1 Effects of obesity on general health and physical functioning

HRQoL or QoL among the bariatric patients can be measured by either generic or obesity specific instruments. A generic instrument can be used to measure HRQoL in many different groups, diverse conditions and diseases, and at any age. The generic instruments also make it possible to draw comparisons between the study group and the general population (59). Consequently, it is possible to compare the relative burden of different diseases with a generic instrument, while obesity specific instruments only can be used to measure HRQoL in obese groups. The most frequently used and validated generic health questionnaire is The Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) (56, 59). It measures both physical and mental health in eight domain scores (59). Another example of a generic health questionnaire is the Current health scale. It includes nine general statements on perceived current health, and items are aggregated into a total score (60). An example of an obesity specific HRQoL instrument is the Impact of Weight on Quality of Life-Lite (IWQoL-Lite). This 31-item questionnaire has five domain scores which measures physical and psychological burdens of obesity (61).

The strength of general health questionnaires is that in contrast to disease specific measurements, the general health forms may be used to compare a specific group with the population norm. It can also be used to investigate the perception of a subgroup on their
general health, instead of more disease specific perceptions and to compare the effect of different liabilities and disabilities in subgroups (59).

Many studies have consistently found that obesity significantly deteriorates different aspects of HRQoL, compared to the age and gender standardized population norm (48, 55, 57, 62). This is evident in the majority of the tested domains, which includes both physical and psychological elements. The adverse effects of obesity is most pronounced in aspects regarding physical functioning, vitality and bodily pain and less pronounced in emotional roles, social functioning and mental health (55). Especially bodily pain is documented to differ largely between the obese and the norm population. For this reason, Fontaine et.al compared the SF-36 bodily pain scores to data from several chronic conditions: clinical depression, congestive heart failure, symptomatic patients positive for human immunodeficiency virus and migraineurs. Surprisingly, the obese participants reported significantly greater bodily pain than all other chronic conditions except for migraine. The bodily pain scores in the obese and the migrainous population did not differ significantly (55). The SF-36 bodily pain scale measures both the degree of pain and how it affects normal daily activities. For this reason, it may be a good predictor to which extent obesity limits the normal day-to-day life. The general health, bodily pain, vitality and physical problems of people tend to increase in correlation with the degree of obesity (55). This may be expected as the load on weight bearing joints intensify, the severity of comorbidities increase and the general burden of obesity related problems enhances. The poor general HRQoL is highly significant and clinically important, both to health personnel and of course to the patient herself. Evidence from the literature also implies a great potential for improvements in HRQoL when obesity is treated adequately (49).

1.4.2 Effects of obesity on psychological functioning

Our culture today is very focused on the exterior character of an individual and this adds to the psychological burden of obesity. The beauty ideal is to be fit and slim. This ideal is relayed to all of us via the media and advertisements every day. We find evidence of the major influence this has on our society in the prevalence of book shelves brimming with books on dieting, and in commercials with a vast variety of dieting products and weight-loss programs. In a society with these ideals, it is not unlikely that individuals suffering from obesity are discriminated against. Conspicuousness is potentially an additional burden of
obesity as it can not be hidden like other “flaws”. Obesity is also connected to stigma. Friedman et.al investigated stigma experiences the last month prior to clinical interview in subjects seeking weight-loss surgery. Interestingly, all of the 94 participants had experienced at least one situation of stigma in this period of time. The most frequent stigmatizing situation, experienced by 88% of the study group, was physical barriers. Examples of such barriers include too small chairs and inappropriate medical equipment among others. Other frequently experienced stigmatizing situations were nasty comments from others, nasty comments from family and inappropriate comments from doctors (63). In contrast, another study of subjects seeking bariatric surgery, reported few episodes with stigmatization of the participating individuals. However, the total stigmatization experience was associated with worse weight-related quality of life (64).

Unflattering characterizations of obese individuals such as “weaked-willed”, “sloppy”, “lazy”, “bad” and “lack of personal control” can be attributed to their obesity alone (65). Unfortunately, these attitudes against people with overweight are also evidently shared by health-care professionals (66, 67). These recurrent negative attitudes include the perception that the condition is self-induced and that managing of the problem is not professionally gratifying (66). Negative attitudes tend to increase with patient BMI. On the contrary, it seems like knowledge and information about weight loss and its treatments decrease the negative attitudes among physicians. It is also noteworthy that physicians are less likely to be obese than the population norm (66, 67). This may contribute to the negative attitudes and characterizations of obese patients as described. One might believe that younger doctors and medical students are more likely to show less prejudice and to have less negative attitudes towards obese patients than older doctors. However, doctors with high age showed less negative attitudes (67) and medical students were found to make derogatory comments and jokes about health problems that they believed were self-inflicted, such as obesity. In clinical settings, this behavior was most often initiated by resident and attending doctors (68). Due to the evidence of negative attitudes among some health professionals, it is a possibility that obese patients may receive poorer quality of care than normal weight patients.

The effect of obesity on psychosocial aspects of quality of life is not as strong as the effects on general health and physical functioning. Nevertheless, studies have shown that compared to population norm, obese persons score significantly worse also in psychological domains of generic HRQoL questionnaires. This includes social functioning, role-emotional, depression,
distress and mental health (55, 62). Although the obese population score significantly worse in these domains, the impact of obesity on psychological dimensions does not follow the degree of obesity as it does in physical dimensions. However, the obese population only scored the 32\textsuperscript{nd} percentile on mental health compared to the norm population (55).

An interesting problem for discussion is how to measure the difficulty and despair people associate with different handicaps or disabilities. Normally, most subjects would prefer their own worst handicap compared to others worst handicap because they know how to handle it (69). Through comparison between own handicap and others (“mine-thine problem”), being forced to chose the worst one, obese subjects who had undergone bariatric surgery made some thought-provoking choices in one study. The questions asked for a comparison of being morbidly obese and being normal weight together with different handicaps such as being deaf, dyslexic, diabetic requiring insulin, blind, having very bad acne, and having one leg amputated. Strikingly, no patient chose to be morbidly obese compared to be deaf, dyslexic, diabetic, having bad acne or heart disease with a normal weight. About 90\% of the study subjects also chose being blind and having one leg amputated over being morbidly obese. All patients also chose to be normal weight over the possibility of being a morbidly obese multi-millionaire (69). A finding from Sullivan et.al which indicates the heavy psychological burden of being obese. They showed that the psychological functioning of obese subjects was similar to those who had survived cancer but were experiencing a recurrence and being worse than four years after a spinal cord injury (70).

1.4.3 Health related quality of life after weight loss surgery

Due to the significant adverse effects of obesity on HRQoL, it is necessary to assess whether weight loss improves HRQoL after bariatric surgery. Both generic and obesity related questionnaires are used in the literature for this purpose. To go through bariatric surgery is to take a dramatic step due to the invasive nature of the procedure. For this reason, it is important to investigate both its short- and long-term effect on HRQoL.

During the first year after weight loss surgery, the HRQoL improves significantly (48, 49). Not only do scores improve from baseline, but it is also found that scores on overall mood are significantly better than in the reference population one year after surgery (49). Rea et.al also showed significantly better scores than the population norm in all the SF-36 domains one year after surgery and in three of the eight SF-36 domains two years after surgery (48).
significant improvement was also found two years after RYGBP surgery in all of the SF-36 domains, compared to those subjects who sought but did not undergo surgery and population-based obese subjects (57). To exemplify, Karlsson et.al showed improvements in current health perception by 48% the first year, 16% after 6 years and 11% after 10 years. They also found improvement in obesity related psychosocial problems by 63% the first year and 49% after 10 years. Noteworthy, the surgical group improved significantly more than the conventionally treated group after 10 years. This study also reported significant changes in both anxiety and depression after weight loss, but both were within normal range (49). A limitation of many studies is that they only compare mean scores and does not look at clinical significance. However, when Karlsson et.al assessed only those bariatric candidates who were classified with a probable anxiety or depression disorder, the proportion of individuals in each category decreased with 10% and 9% respectively (49).

A comparison of obese subgroups gave a good opportunity to test the effects on HRQoL between those who sought surgery but did not undergo it (the non-surgery group) and those who did go through a RYGBP surgery. The difference between the groups was striking. As much as 97% of the surgery group had meaningful improvements compared to 43% in the non-surgery group. In addition, no surgery patients reported meaningful deterioration on HRQoL after two years, but in the non-surgery group about 19% had meaningful deterioration during the follow-up period (57). In the light of this comparison, it is natural to emphasize the dramatic improvement in the HRQoL with surgical intervention as a major benefit compared to non-surgical intervention. Interestingly, even bariatric patients who experience complications within the first year following surgery have reported significant improvements in all eight scales of the SF-36 compared to preoperative levels and to population norm. Compared to patients without complications however, they score lower in one domain, vitality. Those who were experiencing complications two years after surgery had significant improvements in five of the eight domains. Compared to patients without complications, they scored lower in six of eight domains. Nevertheless, this shows that even with complications two years after surgery, patients experience a significant improvement in HRQoL in all but three domains over preoperative scores (48).

A dose-response relationship between the magnitude of weight loss and HRQoL exists. Karlsson et al. findings of ten-years of follow up from the SOS-study showed that during this long period, the HRQoL largely followed the phases of weight loss. Those treated with weight
loss surgery had a peak in HRQoL during the first year after surgery. This corresponded to the great weight loss seen this first year. With the weight regain phase, one to six years after surgery, the HRQoL declined together with the gradual increase in weight. The body weight then remained quite stable six to ten years after surgery, while the HRQoL also remained stable. Although the HRQoL deteriorated from the highest measurement, net gains were noted for all domains ten years after surgery. Findings from this study, proposes that a sustained weight loss of ≥ 10% of total body weight is sufficient for a prolonged positive effect on HRQoL (49).

A common cut-off used to determine whether a surgery was a success or not is whether at least 50% of the EWL is maintained for at least five years after surgery (26, 28, 31). Thus it is noteworthy to investigate whether this cut-off also is appropriate when it comes to HRQoL. One study found that both those who had more or less than 50% EWL had significant improvement over preoperative scores in HRQoL. The difference between the groups was not significant (48). Unfortunately, these patients were only followed for two years. As a consequence, it can not be concluded whether these findings support the cut-off point of success. On the contrary, Kruseman et.al found that those who had ≥ 50% EWL after eight years had significantly better scores regarding depression, pain, body dissatisfaction and mobility compared to those who had < 50% EWL. However, results from both groups joined together showed significant improvements from baseline values (53). The studies mentioned differ greatly in follow-up time and do not intend to investigate whether the 50% EWL cut-off point is adequate for measure of success in HRQoL. Thus, one may only speculate whether the cut-off value of success is appropriate or not. Nonetheless, it is interesting that a sustained long-term weight loss in the morbidly obese achieved by bariatric surgery has an overall long-term positive effect on HRQoL even after 10 years (49).
2 Aims of the study

This master thesis is a part of a PhD study at OUH Aker and comprehends inclusion of the last sample of study subjects and the final session for two years follow-up subjects. After seven years with bariatric surgery at OUH Aker, experience has shown that many patients steadily regain weight from their lowest level. The PhD study’s purpose is to investigate if additional follow-up prevents or lessens the degree of weight regain and improves the health profile compared with post surgery controls.

2.1 Study rationale

The thesis aims to investigate whether additional follow-up of post surgery RYGBP patients prevents weight regain in the time between baseline and completion of a two-year intervention compared with a surgery control group. The period between baseline and study termination is from 14 months to 4 years after surgery. Achieved weight is normally maintained up to two years (38, 50, 51), thus the intervention starts when weight regain is expected to emerge. Further, the thesis aims to identify change in energy intake and to evaluate change in HRQoL.

2.2 Study objective

2.2.1 Specific aims of this master thesis

The specific aims of the thesis were

a. to investigate the effect on body weight after 4 and 24 months of group intervention

b. to identify and evaluate change in energy intake after 24 months of intervention

c. to evaluate change in HRQoL after 4 months of intervention

2.2.2 Areas for research investigation

Specific research questions to be studied in this thesis were whether:
a. additional follow-up prevents or lessens weight regain and increase in waist circumference:
   i. from baseline until 4 and 24 months of intervention within the intervention group
   ii. in the intervention group compared with the control group 4 and 24 months from baseline

b. additional follow-up prevents or lessens an increase in energy intake and thus contributes to weight stability after 24 months of intervention

c. Health related quality of life shows
   i. that the intervention group achieves a better HRQoL measured 4 months after intervention start compared to the control group
   ii. change in health related quality of life is linked to weight change
3 Subjects and methods

The master thesis, as a part of a larger PhD study, was approved by The Privacy Ombudsman in April 2008 and by The Regional Committee of Medical Ethics and Biohealth Norway in June 2008. See appendices 1 and 2.

Signed informed consent was obtained form all the participants (appendix 3).

3.1 Study design

The master thesis was a prospective intervention study with equal randomization [1:1] conducted at the OUH Aker, Norway. Data were collected on patients who had undergone RYGBP surgery 14 months – 2 ½ year prior to inclusion. Approximately half of the study subjects were randomized to a two-year group intervention, while the other half continued the standard follow-up regimen at OUH Aker. In addition to the standard regimen, the control group had extra individual sessions at baseline, 4 and 24 months. The intervention consisted of individual sessions at baseline, 4, 12 and 24 months together with 16 group meetings during these two years. At the individual sessions anthropometric measurements were taken and the SF-36 questionnaire was handed in. Because the master thesis was a part of a larger study, the master students used previous collected data in addition to own collected data. The master students collected data from two different sampling occasions. Sample 1 was included into the study during fall of 2008, sample 3 was included in during fall of 2010. Sample 1 finished the study during the fall of 2010 and the master students collected the last data from these subjects at 24 months. For sample 3, data were collected by the master students during individual sessions at baseline and 4 months. The master students also led the first seven group meetings for this sample. Figure 4 provides an overview over the entire study and Figure 5 shows a simple overview of the study subjects.
Figure 4. Overview over the study’s time and type of data collection, and time and number of group meetings.

Figure 5. Overview over the randomization of sample 1, 2 and 3 into intervention and control group.

1Finished the 24 month study period fall 2010
2Preliminary followed for 12 months
3Preliminary followed for 4 months
3.2 Subjects

Inclusion criteria
Eligible participants were all patients who had undergone RYGBP surgery at OUH Aker 14 months – 2 ½ years prior to each of the three inclusion periods. Data from all three samples contributed to the findings in this master thesis. The participants from sample 1 went through surgery between January 2006 and June 2007, the ones from sample 2 between January 2007 and June 2008 and finally participants from sample 3 went through surgery between January 2008 and June 2009. To be included, participants had to be willing and able to participate in regular group meetings at OUH Aker.

Exclusion criteria
The intervention, group meetings, required a rather good command of the Norwegian language. Physical activity was also an important part of these group meetings. For these reasons, patients who did not master Norwegian and immobile patients were excluded from the study. Patients who had experienced serious complications due to the gastric bypass procedure and individuals suffering from conditions associated with poor compliance (drug or alcohol abuse) were also excluded.

Study recruitment
The data collection for the master study took place at the Morbid Obesity Center OUH Aker, Norway from June 2010 to February 2011, while the main study started the fall of 2008. The Morbid Obesity Center at OUH Aker is a regional center that treats persons from the counties of Hedmark, Oppland, Akershus, Østfold, Buskerud, Vestfold, Telemark, and Oslo. Participation in the study was voluntary and all patients were informed in advance about the purpose and the hypotheses of the study. Data for use in this master thesis were both collected by two previous and by two present master students. All study subjects were recruited in approximately the same manner to ensure equality between all subjects even if the study recruiters were different. All patients at OUH Aker who had undergone RYGBP surgery between January 2008 and June 2009 were enquired to participate in the study, as the third and last sample to be included. They were enquired by an information letter via postal services (appendix 4). See figures 7 and 8 (p. 47 and 48) for a flow diagram of the study.
Information letters were sent to 315 eligible participants during the spring of 2010 to recruit individuals to sampling occasion 3. A total of 714 information letters have been sent to eligible participants during the entire recruitment period ranging from 2008 to 2010. Individuals who were interested in participation in the study were requested to announce participation at one of the two information meetings if desired. They were asked to reply via the study’s e-mail or telephone. At the information meeting, the subjects decided whether to accept or decline participation in the study.

### 3.3 Methods

During the summer and fall of 2010, subjects were recruited for participation in the study. From the two previous inclusion periods, 113 study subjects were already included. A minimum of 160 participants were needed to be included in the main study in total.

At the information meetings, the participants were informed about the purpose and the execution of the study. Food diaries *(appendix 5)*, picture booklets *(appendix 6)* and The SF-36 *(appendix 7)* were handed out to the participants. The participants were given both oral and written information on how to fill in these questionnaires correctly. A detailed guide on how to fill in the food diaries was also given *(appendix 8)*. At the end of this meeting, participants were signed up for individual sessions to collect anthropometric data, the questionnaires handed out at the information meeting and blood samples (baseline data). The patients were then again phoned by the master students one week prior to the individual session in case they had any questions regarding the questionnaires. The patients were at the same time reminded about the time of the individual session, to be fasting when blood samples were taken, and not to forget to bring the completed questionnaires to the session. The participant could at all times reach the master students via mobile phone or electronic mail (e-mail) for questions.

See *figure 6* for an overview of the time line for the master students’ data collection.
3.3.1 Data collection and randomization

The specific data collected at every individual session for use in this master thesis were anthropometric measurements and SF-36 questionnaires. At the baseline and 24 month sessions, a four-day food diary was also collected. The participants in the intervention group were additionally weighed at every group meeting. During the period between baseline and the four month individual session, seven group meetings were held. Until the next individual session, 12 months after inclusion, four group meetings were held. During the last year of the
intervention between the 12 and 24 months individual sessions, participants in the intervention group were offered to participate in four additional group meetings (figure 4). Randomization of study participants into control and intervention group took place right after their baseline individual session. The participants were randomized to either control group or intervention group. The study subjects were randomized according to sex and percentage of EWL. Average weight loss one and two years after surgery at OUH Aker is 66% of the excess body weight. This information was given after oral discussion with staff at the Morbid Obesity Center at OUH Aker. For this reason, the cut-off value in the randomization process was set to 66% of EWL. Randomization lists were prepared by statistician Lien My Diep and administered by RD Eline Birkeland at OUH Aker. The lists were made on the principles of block randomization and were stratified according to sex and EWL of $\geq$ or $< 66\%$. The study participants were informed about which group they were randomized into at the end of the baseline individual session.

**Control group**

Data were collected at baseline and four months for sample 3 and at 24 months for sample 1 by the master students. At baseline body weight, BMI, and waist circumference were measured. The participants also handed in the four-day food diary and the SF-36 questionnaires. Data collections at 24 months were identical to baseline data collection. Data collection at the four month visit included the same as the baseline and 24 month visit except for collection of food diaries.

The control group only had individual sessions at baseline, four and 24 months. It was desirable that the control group followed the normal regimen at OUH Aker as closely as possible, thus they were called in for as few extra sessions as possible.

**Intervention group**

There was no difference in data collection between the control and intervention group at baseline, four and 24 months. However, the intervention group had an additional individual session at 12 months. During this master thesis, sample 1 finished their participation in the study and 24 months data were collected from these study subjects. In addition to the four individual sessions, participants in the intervention group had the opportunity to attend in a total of 16 group meetings during the two years of intervention.
During the individual sessions, the master students did all the anthropometric measurements and registrations.

### 3.3.2 Anthropometry

Preoperative body weight and date of surgery were gathered from the patient’s electronic journal prior to the individual baseline session. The patient’s height was measured to the nearest centimeter by wall-mounted height rods at the offices of the Morbid Obesity Center at OUH Aker. Waist circumference was measured twice. The waist circumference measure was taken at the widest area of the waist because the waist tends to loose its “normal” curves after substantial weight loss.

Body weight and percentage of body fat were measured by the Tanita scale BC-418MA Segmental Body Composition Analyzer. This is an advanced scale which measures body weight and calculates the body fat percentage, body fat mass, fat free mass, estimated muscle mass, total body water, BMI, and the basal metabolic rate. The Tanita scale’s max capacity is 200 kilograms (kg) and its increments is 0.1 kg (71). The patients were weighed without shoes and socks and with light clothing. To compensate for the remaining clothes, 1 kg was subtracted from the body weight. Due to the electrical impulses needed to measure body fat percentage, the participant needed to be barefoot on the scale. For the same reason, study participants were asked if they had a pacemaker. If they did, they were not put on the scale due to fear of possible interference between electrical signals. The Tanita weight separates body mass readings for the right arm and left arm, the trunk, and the right and left leg.

Weight was also measured at every group meeting in the intervention group. Then the participants were weighed without shoes and outer garments and 1 kg was also here subtracted to compensate for clothing. The weight used at the group meetings was a Seca Alpha 770 floor scale with a weight increment of 0.1 kg and maximum capacity of 200 kg.

### 3.3.3 Food diary registration

The food diary is only validated for children (72). A validation among adults was initiated, but no results have been published (73). The study participants registered their food intake in four consecutive days from Wednesday to Saturday and thus one weekend day was included. The food diary (appendix 5) is pre-coded, consisting of 18 pages and with 277 food items
listed according to food groups and drinks. Each food group had open-ended alternatives to fill in consumption of items not listed. The food diary also registered at which time slot the study participants had consumed food or beverages within a range of five time slots. To indicate amounts of food ingested, the food diary used standard household measurements for the participants to fill in such as tablespoon, pieces and glasses. It was also possible to estimate portion sizes with help from a picture booklet (appendix 6). This booklet consisted of 13 pages with colored pictures with two alternative sizes for glasses and four alternative sizes for each food or dish. The participants were instructed on how to fill in the food diary correctly at the information meeting prior to the baseline individual session. It was emphasized that it was important to eat as normal as possible during the registration period. To ease completion of the food diary, a “help sheet” was handed out to the study subjects for notation when the food diary was not appropriate to bring along. It was one sheet for each day with a table with the same time slots as in the diary for quick notation instead of turning pages in the food diary.

The food diaries were collected and checked with the study subjects present at baseline and 24 month individual sessions by the master students. Further, the food diaries were scanned with the software program Teleform version 6.0 (Datascan Oslo, Norway) at the Department of Nutrition, University of Oslo (UiO), Norway with guidance from post doctor Inger Therese Lillegaard. Contents of the open fields were coded separately and merged together with the pre-coded food items. Energy intake and the distribution of energy from macronutrients were computed using the diet calculation system KBS version 7.0 and the food database AE10. The KBS is a diet calculation software system developed at the Department of Nutrition, UiO. The nutritional values of the food items in the KBS AE10 are mainly based on the official Norwegian Food Composition Table 2006 (www.norwegianfoodcomp.no). When the Food Composition Table was insufficient, values from recipes and food composition tables from other countries were used.

When converting kJ to kcal and vice versa, the factor of 4.184 was used.

3.3.4 Health-related quality of life – The SF-36

The Norwegian SF-36 version 2.0 was used in this study. It has not been validated under Norwegian conditions, but the Swedish SF-36 version 2.0 has been validated in Sweden. Thus, the comparison of study group to population norm is based on the ethnic Swedish
background population (74). The SF-36 is a generic questionnaire to measure HRQoL. The 36 items in the SF-36 are grouped into eight subscales (table 3). These subscales include physical functioning (PF), social functioning (SF), role limitations due to physical problems (RP), bodily pain (BP), general mental health (MH), role limitations due to emotional problems (RE), vitality (VT) and general health perceptions (GH). An additional item reports health transition over the last year (59). The different items were summarized into two component measures of physical and mental health. PF, RP, BP and GH scales were aggregated to make total score of physical health measure while RE, SF, MH and VT scales were aggregated to make total score of mental health measure. The items VT, SF and GH had most pronounced correlations with both summary measures (75).

**Table 3.** Description of the SF-36 questionnaire and interpretation of low and high scores (59).

<table>
<thead>
<tr>
<th>Item</th>
<th>No of items</th>
<th>Meaning of scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lowest</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>10</td>
<td>Limited a lot in performing all physical activities, including body care and dressing</td>
</tr>
<tr>
<td>Role-physical</td>
<td>4</td>
<td>Problems with work or other daily activities as a result of physical health</td>
</tr>
<tr>
<td>Social functioning</td>
<td>2</td>
<td>Frequent interference with normal social activities due to physical and emotional problems</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>2</td>
<td>Very severe and limiting pain</td>
</tr>
<tr>
<td>Mental health</td>
<td>5</td>
<td>Feels depressed and nervous all of the time</td>
</tr>
<tr>
<td>Role-emotional</td>
<td>3</td>
<td>Problems with work or other daily activities due to emotional problems</td>
</tr>
<tr>
<td>Vitality</td>
<td>4</td>
<td>Feelings of being tired and worn out all the time</td>
</tr>
<tr>
<td>General health</td>
<td>5</td>
<td>Believes that personal health is poorer and will deteriorate further</td>
</tr>
</tbody>
</table>
Every item (question) had response choices on a three – six point category scale. For each item, a score was given according to the answer. This score made up the raw score. As indicated in the scoring manual, 10 items were to be recoded before summed and transformed to the eight scales. The scores range from 0 – 100 (0 = poorest possible health state, 100 = the best possible health state) according to the SF-36 scoring algorithms (76). If there were missing data in half or less than half of the items aggregating to a scale in the SF-36 questionnaires, the missing values were replaced with the respondent’s mean score from the completed items in the same scale according to the SF-36 scoring algorithms (76). Effect size for clinical treatment effect was decided by calculating the difference between average baseline score and four months score divided by the study group’s standard deviation at baseline. Effect sizes of < 0.2, 0.2, 0.5 and ≥ 0.8 indicated a trivial, small, moderate or large effect respectively (77).

The questionnaires were self-administered. Key-punch entry was used as method to administrate the data from the SF-36 questionnaires. Proof reading of data was done by randomly choosing 5% of the data before analyzes were done. As no errors were found, further proof reading was not considered necessary.

### 3.3.5 Intervention

The study subjects in the intervention group had the choice of participating in either a day or an evening group. All group meetings were held by the master students with additional contributions from other health personnel. The day group met 1300-1500 and the evening group 1700-1900. The themes of the group meetings were already prepared by RD Eline Birkeland and previous master student Rose-Linn Bø. Their work was based on experience with this patient group and a handbook by Ingela Melin on practical clinical treatment of overweight, obesity and the metabolic syndrome based on cognitive behavior alteration and conventional treatment (78). Small alterations were made on request from the participants.

The main purpose of the group sessions was to enhance behavioral change among the study subjects to prevent (further) weight regain and to implement good health choices. In this respect, the participants were sometimes given home assignments or challenged by other group members to change a habit. At other occasions, discussion over own and group problems made the basis for change and reflection. In addition, 30 minutes of the two hour group session were reserved for physical activity. When the weather conditions allowed it,
walking with or without Nordic walking poles were preferred. Other activities were weight training using own body weight or stairs.

In sample 1, the evening group had few participants and it could not be sustained because too few participants showed each time. This led to a merging of the two groups after the first seven meetings.

Prior to every meeting, the participants received a text message as a reminder of the meeting and its time and place. Participants who were prevented from participating were given written information at the next meeting. Sliced fruit, coffee, tea and water were served at every meeting.

**Group meeting 1. Presentation, aims and intermediate aims**

The meeting started with a presentation of every participant with personal information such as marital status and location of residence, time of surgery and positive and/or negative experiences after surgery. A presentation of the theme schedule of the group sessions was also given together with a discussion of expectations on group dynamics and participation both in discussions and physical activity. To identify the participants’ long-term and intermediate aims, a questionnaire that surveyed the aims was handed out. It was collected at the end of the meeting and promised to be returned at group meeting 8.

**Group meeting 2. Physical Activity I**

The meeting was held by Kirsti Bjerkan, RD and sports coach. This was the first of two meetings to be held by Bjerkan on physical activity. She invited the participants for an open discussion about their own level of physical activity. An important goal for this session was to reveal the diversity of activity level within the group and to have the participants discuss their experiences regarding physical activity. In light of this discussion, a lot of time was spent on debating problems with physical activity and motivation for it. The goal was to find a solution to the problems. Another important aspect emphasized by Bjerkan was to increase the everyday activity of the participants. Participants were given these suggestions to improve their activity level: always using the stairs instead of elevators and escalators, to walk instead of taking the bus or car and to stroll with friends instead of sitting down in a coffee house.
To increase motivation and visualize the importance of everyday activity, the participants were given a pedometer. They were also instructed on how to adjust it according to personal length of steps and the usage of it in general. The 30 minute physical activity consisted this time of practical training with Nordic walking poles.

**Group meeting 3. Fiber, fruit and vegetables**

This meeting focused on the benefits of increasing the intake of fiber, fruit and vegetables and how to manage this in everyday life. We also had a discussion on which food items contain significant amounts of fiber and which food items contain very little. The Norwegian “bread scale”, which indicates the proportion of coarse flour or whole grains in the bread (79), was also presented and discussed. This scale was also used when comparing different types of bread, pasta and rice.

Fruits and vegetables were also emphasized as good sources of fiber, in addition to vitamins. The participants discussed their own regular intake and the group evaluated if it was sufficient according to public guidelines or not. As a part of this discussion, the participants were given a home assignment. They had to set a goal for increasing their fruit and vegetable intake and they were asked to list the types of bread, pasta and rice they had at home or normally bought according to the bread scale. They were also asked to share tip and experiences from the home assignment at the next group meeting. It was emphasized that the participant had to work with the assignment at home to achieve his or her aims.

**Group meeting 4. Fat and fat reduced products**

The topic of this meeting was introduced with questions to the participants about their knowledge on healthy and unhealthy types of fat and sources of these respectively. The meeting then continued with a presentation of the different fatty acids, both saturated fatty acids and unsaturated fatty acids. The health benefits of plant based unsaturated fatty acids were emphasized and its mechanisms were explained. An illustration of different food items were given, comparing them on the basis of fat content. It was also discussed how to reduce the fat content of the food when cooking, grocery shopping, and eating out.

The denominations “fat reduced products” or “low calorie food” were also debated. It was explained that a food item labeled “light” or “fat reduced” is not necessarily low in energy or
healthy and that it is easy to be misled by advertisements and labels of the food items. In this regard we discussed food declarations, how they are written and how to read them. Finally, it was accentuated that fat reduced products are beneficial for the entire family and not only the study participants.

**Group meeting 5. Physical activity II**

This meeting was a continuation of Kirsti Bjerkan’s previous meeting on physical activity, but it was held by the master students. At this session, several of the participants had set new aims to reach a certain level of physical activity. Some of the subjects also sought support from other group members. We discussed the outcome of working with and being aware of these goals and we visualized change and achievements that actually had been made. In addition, Bjerkan had also provided the master students with a task for the participants. The subjects were set to fill in an “activity account” where they were asked to fill in 1) the advantages and disadvantages of being physically active and 2) the advantages and disadvantages of being physically inactive. If the subject’s sum of questions 1) were positive and 2) negative, the subject was regarded as susceptible to start with physical activity. If the subject’s sum of the questions were the opposite, the subject were not yet susceptible for physical activity, and were encouraged to work with awareness and motivation for it.

**Group meeting 6. Food during holidays and celebrations**

This was the last meeting before Christmas. Naturally, the traditional Christmas food, cakes and other accessories to the Christmas celebration were in focus. To raise the awareness of the study subjects on how easy it is to overeat during Christmas, different plates filled with typical Norwegian Christmas food were presented. Christmas food such as pork ribs, salted mutton ribs, lutefisk, turkey, and salmon were compared. As the big differences in energy content was revealed, the importance of having a diverse food intake during the holidays was discussed. Another important issue that was debated was the frequency of Christmas parties prior to the holidays. The importance of being aware of the food intake during these events was also emphasized. The availability of candy and Christmas cookies also increases near Christmas and there are more occasions were alcohol containing beverages are offered. The energy content of these items was presented and the participants discussed strategies on how to reduce their intake. At the end of the meeting, a summary of the food items’ energy content
was handed out and aims for the Christmas holiday regarding physical activity and indulgences were set.

**Group meeting 7. New-year resolutions and cravings**

In the first meeting after New Year, the main topic was new-year resolutions. All group members were asked to think through own aims and barriers to reaching those aims. They were also challenged to list three actions they perceived as realistic to complete and tell how they were going to carry them out. A sheet with suggestions of new-year resolutions was handed out.

Sweet and salt cravings were also a topic of discussion, both the frequency of them and how to handle them. Tips were given on what to eat or drink when one can not keep the cravings at bay, for example sugar reduced hot chocolate, mints and fat reduced salty products. As a motivation to avoid sweets and salty snacks, examples of how much physical activity that is required to burn off different snacking items were given.

**Group meeting 8. Self-help groups**

During this meeting, the participants learned about what a self-help group is, why it can be of help, how it works and how to get started. After a presentation, the study subjects were split into small groups to discuss the topic. The purpose of this meeting was to inform the participants about the possibility of starting groups on their own as the frequency of the study group meetings decline.

The questions from group meeting 1 were returned, as promised, but first the participants had to fill in the same questions again to compare with the answers given four months earlier. For the most part, the participants had the same answers. However, some said that they had changed their way of thinking from focusing on what they did not achieve, to focusing on things they had actually mastered.

**Group meeting 9. Physical activity III**

This meeting was the third with the topic of physical activity and the second held by Kirsti Bjerkan. The main subject of discussion was motivation for physical activity. How to motivate and challenge our selves and how to gain motivation from others. The goal was to
have an open discussion and to get the group members to motivate both themselves and each other. Each member also set a personal goal for physical activity level until the next meeting.

**Group meeting 10. Sweeteners**

Artificial sweeteners were a topic that occupied the study subjects. This meeting was dedicated to define and classify different types of sweeteners, both artificial and natural, energy containing and non-energy containing. The food safety of sweeteners was presented together with the numbers and quantities of maximum acceptable daily intake (ADI) with examples of artificially sweetened soft drinks and other items. The skepticism towards artificial sweeteners was debated and scientific facts were presented to help the group participants make informed choices about food and drink items in their everyday life.

**Group meeting 11. Body image I**

This meeting was held by psychologist Ingela Lundin Kvalem. She talked about strategies on how to handle change in body and soul, relapse of weight, and adversity in life without turning to food as an answer. The participants were also taught about how perception and thoughts of own body image has psychological effects on behavior. Another important theme was the stigma of overweight and obesity and its psychological consequences. At the end, the group members were challenged on the importance of having a body image that is realistic to achieve and to be critical of the ideals of the mass media.

**Group meeting 12. Summer food and end of term**

This was the last meeting before the summer holiday and quite a long time without any group meetings was ahead. The meeting’s main topics were barbecue food, ice cream, other desserts, and physical activity suitable in the summer time. A comparison of lean versus rich food items for barbecuing was given together with examples of beneficial and less beneficial trimmings to go with it. A comparison of typical summer time desserts was also presented.

**Group meeting 13. “Café table”**

The participants were split into small groups where they discussed relevant themes such as motivation, physical activity, and change in lifestyle and health behavior. At the end of the meeting, all the participants came together again and summarized the discussions.
Group meeting 14. Body image II

This was a follow-up of group meeting 11. Psychologist Ingela Lundin Kvalem was again invited to lead the meeting on this topic. The same topics as the last time were discussed and questions from the group members were debated.

Group meeting 15. “Food for the entire family”

This meeting was joined together with the ordinary three year group session that all bariatric patients are offered as a part of the usual post operative care at OUH Aker. This session was held by RD Eline Birkeland.

Group meeting 16. Cooking class and farewell

The cooking class was held by the RDs Eline Birkeland and Susanna Hanvold. It emphasized how to cook healthy meals in a practical and simple way. Guidance was given during the class on nutritional values and how to prepare the food items and dishes. The participants were split into suitable groups and set to make different dishes high in protein and low in fat. At the end of the class, the participants ate together and had a free conversation as the group intervention period was over with the termination of this meeting.

3.4 Statistical analysis

All statistical analyses were performed using PSAW Statistics version 18.0 for Windows (IBM Corporation, Somers, New York, USA).

A p-value < 0.05 was considered statistically significant. For all analyses, the upper limit for a tendency of difference was set at p-value < 0.1. Statistical significant p-values were written in tables in bold, while p-values indicating a tendency of difference were written in tables as italics.

The desired effect of intervention to detect in this study was a difference in weight change between the intervention and control groups of 2.5 kg from baseline to the end of the study. As no comparable studies were available, there were uncertainties about what level of standard deviation (SD) to expect. Statistician at OUH Aker Lien My Diep performed the statistical calculations. It was presumed that large individual differences between the
participants could occur. Thus, the standard deviation was put at 5 kg with a power of 80% and a 5% probability of type I errors. As a basis of these calculations a total of 160 study participants were needed, i.e. 80 individuals in both the intervention and the control group. With 160 subjects, a drop-out rate of 20-30% was taken into consideration to achieve the strength of data indicated.

3.4.1 Continuous variables

Histograms and Normal Q-Q plots were used to evaluate whether the data material was Normally distributed. Data that were Normally distributed were analyzed using the Independent-sample *t*-test and data not Normally distributed were analyzed using the Mann-Whitney U test. To detect change within one group, the paired *t*-test was used with Normally distributed data while the Wilcoxon signed rank sum test was used for analyses when the data was not Normally distributed or with several extreme values present. If only one group was Normally distributed when comparing two groups, it was decided to use non-parametric tests. When performing correlation analyses, the standard method of Pearson’s correlation coefficient was used when the data showed Normality and the Spearman’s correlation coefficient when the data was not Normally distributed. Partial correlation was performed to test for confounding variables and multiple regression analysis were done when controlling for variables.

Results from parametric tests were given in text and tables as mean values with (SD). Non-parametric test results were presented as median values with 25 and 75 percentiles (P25 – P75).

3.4.2 Categorical variables

Differences in categorical variables were assessed by Chi-square test for independence when assumptions for Chi-square tests distribution (*χ²*) were made (80). When the assumptions required for using the Chi-square test could not be fulfilled, the Fisher’s exact test was performed. The significance level was considered at p-value < 0.05.

Categorical variables were presented as count with percentage of total count.
Some values were missing in a few analyses. When analyzing the 4 and 24 month data, cases were excluded pair-wise and not list-wise. No other adjustments were done.

Mifflin’s formula was used in calculation of the basal metabolic rate (BMR) as this is the recommended formula in obese and overweight individuals (81):

\[
\text{BMR (in kJ)} = ((9.99 \times \text{weight in kg}) + (6.25 \times \text{height in cm}) - (4.92 \times \text{age}) + (166 \times 1 \text{ if man and } 0 \text{ if woman}) - 161) \times 4.184
\]

The BMR factor was calculated by dividing the mean energy intake (kJ) from the four-day period of food diary completion on the BMR. Cut-off values of under- and over-reporters on individual and group levels were calculated on the bases of Goldberg and Black’s formulas (82):

\[
\begin{align*}
\text{EI}_{\text{rep}: \text{BMR}} > \text{PAL} \times \exp \left[ s.d_{\min} \times \frac{S}{\sqrt{n}} \right] \\
\text{EI}_{\text{rep}: \text{BMR}} < \text{PAL} \times \exp \left[ s.d_{\max} \times \frac{S}{\sqrt{n}} \right]
\end{align*}
\]

\[
S = \sqrt{(CV^2_{\text{wEI}}/d) + CV^2_{\text{wB}} + CV^2_{\text{tP}}}
\]

Acceptable reporters were defined as having a ratio \(\text{EI}_{\text{rep}: \text{BMR}}\) in the range between lower and upper cut-off values, under-reporters as \(\text{EI}_{\text{rep}: \text{BMR}}\)-ratio less than the cut-off range and over-reporters as \(\text{EI}_{\text{rep}: \text{BMR}}\)-ratio above the cut-off range.

\(\text{PAL} = 1.55\), indicates “light activity”, a rather conservative estimate of the PAL.

\(s.d_{\min} = -2\), for the lower 95% confidence limit.

\(s.d_{\max} = 2\), for the upper 95% confidence limit.

\(CV_{\text{wEI}} = 23\), a rather large within-subject variation, suggested by Black on the basis of the pooled mean of several studies.

\(CV_{\text{wB}} = 8.5\), suggested suitable by Black.

\(CV_{\text{tP}} = 15\), the variation found in several studies and suggested for use in the Goldberg’s formula by Black.

\(\exp = \text{exponential function (e}^x\text{)}\)

\(\text{PAL} = \text{the presumed mean physical activity level}\)
EI:BMR = PAL

$EI_{rep}$ = the reported energy intake.

$S$ = the factor that takes account of the variation in intake, BMR and energy requirements.

$CV_{wEI}$ = the within-subject coefficient of day-to-day variation in food intake.

$d$ = the number of days of diet assessment.

$CV_{wB}$ = the coefficient of the variation of repeated BMR measurements or the precision of estimated compared with measured BMR.

$CV_{tP}$ = the total variation in PAL.

As indicated, all the values chosen were the values suggested by A. E. Black (82).

After calculations the cut-off values at individual level, both at baseline and 24 months, were 1.02 – 2.35. This indicates that individuals with a ratio $EI_{rep}:BMR$ lower than 1.02 will be classified as under-reporters, individuals with ratio of $EI_{rep}:BMR$ above 2.35 will be classified as over-reporters and the remaining participants as acceptable reporters. At baseline group level with $n = 52$, the cut-off values were calculated to be 1.46 – 1.64 and at 24 months group level with $n = 42$, the cut-off values were 1.45 – 1.65. The classification of acceptable, under-, and over-reporters is the same as explained above.
4 Results

4.1 The study group and data collection

4.1.1 From baseline to 4 months

Flow of participants
In total, 714 letters were sent to eligible participants, 180 (25.2%) came to the information meeting and 166 (23.2%) subjects were recruited to the study; 81 in the control group and 85 in the intervention group (figure 7). The corresponding numbers for sample 3, which the master students recruited the summer of 2010, were that 58 (18.4%) out of 315 eligible participants met at the information meeting and 53 (16.8%) participants were enrolled in the study. These were the last subjects to be included in the study. Between baseline and 4 months follow-up, 11 participants from the total study group withdrew from the study (figure 7). Reasons for withdrawal were not always given. Among those who did give reasons, workload both professionally and at home and management of weight and surgery-related problems on their own were mentioned.

Anthropometric measurements
At baseline, all participants included were weighed and waist circumference was measured (n = 166). At 4 months follow-up weight and waist circumference measurements were collected from the remaining participants (n = 155).

The SF-36 questionnaires
Data from the SF-36 HRQoL questionnaires used in this thesis were collected from sample 1 and 2 which included 113 participants.

Completion rate
All participants in the study from sample 1, 2 and 3 have finished the 4 months individual session and the completion rate at this point was 93.4% (155 out of 166)
4.1.2 From baseline to 24 months

Flow of participants

The data collection for sample 1 was completed during the fall of 2010 and the flow of participants is shown in figure 8. In this sample, 60 (34.3%) of the 175 eligible participants came to the information meeting and 53 (30.3%) wanted to participate in the study. Between baseline and 24 months follow-up a total of seven participants withdrew from the study and another two were lost to follow-up as they repeatedly did not show up for the arranged individual session (figure 8). The reasons for withdrawal were the same as indicated above.

Anthropometric measurements and food diaries

At 24 months, weight data was collected from 44 participants as nine subjects in sample 1 had withdrawn from the study or were lost to follow-up. Waist circumference was only measured in 43 participants due to lack of measurement in one participant at the individual session.

At baseline, food diaries from 52 of the 53 participants were received as the food diary from one participant was sent via postal services and was lost. After 24 months follow-up, 42 of the 44 remaining participants delivered food diaries. The missing food diaries were requested sent via postal services, but they were not received.

Completion rate

Among the study subjects in sample 1, 83.0% (44 out of 53) completed the study after 24 months.
Figure 7. Flow diagram baseline – 4 months of the study including all three sampling occasions.
Figure 8. Flow diagram baseline – 24 months of the study, including only sample 1.

1Two participants have been contacted, but not yet met to the 24 months individual session nor have they officially withdrawn from the study.
4.1.3 Baseline characteristics

Table 4. Baseline characteristics of the intervention and control group

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(^1)</td>
<td>(±SD / P25 – P75)</td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>23</td>
<td>27.1%</td>
</tr>
<tr>
<td>Age at baseline(^2), years</td>
<td>85</td>
<td>45 (8.8)</td>
</tr>
<tr>
<td>Range</td>
<td>22-62</td>
<td></td>
</tr>
<tr>
<td>Age group:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29 or less</td>
<td>4</td>
<td>4.7%</td>
</tr>
<tr>
<td>30-39</td>
<td>21</td>
<td>24.7%</td>
</tr>
<tr>
<td>40-49</td>
<td>36</td>
<td>42.4%</td>
</tr>
<tr>
<td>50-59</td>
<td>18</td>
<td>21.2%</td>
</tr>
<tr>
<td>60-69</td>
<td>6</td>
<td>7.1%</td>
</tr>
<tr>
<td><strong>Anthropometry</strong>(^2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative weight, kg</td>
<td>85</td>
<td>130.4 (19.4)</td>
</tr>
<tr>
<td>Pre-operative BMI, kg/m(^2)</td>
<td>85</td>
<td>44.3 (4.9)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>85</td>
<td>90.8 (17.9)</td>
</tr>
<tr>
<td>BMI, kg/m(^2)</td>
<td>85</td>
<td>30.8 (4.9)</td>
</tr>
<tr>
<td>EWL &lt; 66%</td>
<td>31</td>
<td>36.5%</td>
</tr>
<tr>
<td>EWL ≥ 66%</td>
<td>54</td>
<td>63.5%</td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td>85</td>
<td>104.7 (14.0)</td>
</tr>
<tr>
<td><strong>Energy intake</strong>(^3,(^4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>kJ/day</td>
<td>27</td>
<td>7972 (6247 – 9410)</td>
</tr>
<tr>
<td>Kcal/day</td>
<td></td>
<td>1905 (1493 – 2249)</td>
</tr>
<tr>
<td>Males</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>kJ/day</td>
<td>8286 (7368 – 9501)</td>
<td>8641 (6037 – 8641)</td>
</tr>
<tr>
<td>kcal/day</td>
<td>1980 (1761 – 2271)</td>
<td>2065 (1443 – 2065)</td>
</tr>
<tr>
<td>Females</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>kJ/day</td>
<td>7255 (6246 – 9410)</td>
<td>6530 (5544 – 7243)</td>
</tr>
<tr>
<td>kcal/day</td>
<td>1734 (1493 – 2249)</td>
<td>1561 (1325 – 1731)</td>
</tr>
<tr>
<td><strong>SF-36</strong>(^3,(^5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>21.8%</td>
</tr>
<tr>
<td>Total score</td>
<td>48</td>
<td>72.2 (15.3)</td>
</tr>
<tr>
<td>Physical health score</td>
<td>48</td>
<td>77.3 (60.9 – 87.6)</td>
</tr>
<tr>
<td>Mental health score</td>
<td>49</td>
<td>78.9 (63.6 – 85.3)</td>
</tr>
</tbody>
</table>

\(^1\) n indicates number of individuals in each category.

\(^2\) Age and anthropometry are given as mean with standard deviation.

\(^3\) Data are presented as mean with SD when Normally distributed and as median with P25-75 when assumption for Normality was violated.

\(^4\) Results from analyzing data from sample 1.

\(^5\) Results from analyzing data from sample 1 and 2.

kJ = kilojoules, Kcal = kilocalories, SF-36 = The Medical Outcomes Study 36-item Short-Form Health Survey
Characterization of the subjects, divided into intervention and control group, is shown in table 4. As displayed, the males were in minority among the study subjects and the largest age group was between 40 – 49 years of age. The majority of the group had lost more than 66% of their excess weight at baseline.

4.2 Group meeting attendance

Table 5 shows an overview over the group meeting attendance in all three samples from baseline to 4 months and in sample 1 from 4 months to 24 months.

As shown, the total attendance percentage was by far largest at the first group meeting. At the three next meetings, the total attendance percentage was above 50%. The total attendance the last year, group meetings 8-16, was quite stable with 30-37%. However, group meetings 10 and 11 stand out with an attendance over 50%. The average group meeting attendance in sample 1 for all 16 group meetings was 47.0%. After seven meetings the total average meeting attendance in sample 1, 2 and 3 was 57.7% (54.5%, 55.7% and 63.1% respectively). The average number of attended group meetings was 7.3 out of 16 possible in sample 1. In sample 2 and 3 the average numbers of attended group meetings were 3.9 and 4.4 out of seven possible respectively.

The effect of group meeting attendance on change in weight and waist circumference was also investigated as shown in table 6. The intervention group was divided into two groups; one with subjects who had a group meeting attendance of $\geq 50\%$ and one with subjects who had a group meeting attendance of $< 50\%$. No significant difference was found neither in change in weight nor in waist circumference between the ones who had participated in $\geq 50\%$ compared to those who had participated in $< 50\%$ of the group meetings.
Table 5. Group meeting attendance

<table>
<thead>
<tr>
<th>Samples</th>
<th>Topic of the meeting</th>
<th>Number of attendants</th>
<th>Attendance percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample 1, 2 and 3 (n = 85)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group meeting 1</td>
<td>Presentation, aims and intermediate aims</td>
<td>71</td>
<td>84%</td>
</tr>
<tr>
<td>Group meeting 2</td>
<td>Physical activity I</td>
<td>59</td>
<td>69%</td>
</tr>
<tr>
<td>Group meeting 3</td>
<td>Fiber, fruit and vegetables</td>
<td>53</td>
<td>62%</td>
</tr>
<tr>
<td>Group meeting 4</td>
<td>Fat and fat reduced products</td>
<td>46</td>
<td>54%</td>
</tr>
<tr>
<td>Group meeting 5</td>
<td>Physical activity II</td>
<td>38</td>
<td>45%</td>
</tr>
<tr>
<td>Group meeting 6</td>
<td>Food during holidays and celebrations</td>
<td>42</td>
<td>49%</td>
</tr>
<tr>
<td>Group meeting 7</td>
<td>New-year resolutions and cravings</td>
<td>35</td>
<td>41%</td>
</tr>
<tr>
<td><strong>Sample 1 (n = 27)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group meeting 8</td>
<td>Self-help groups</td>
<td>10</td>
<td>37%</td>
</tr>
<tr>
<td>Group meeting 9</td>
<td>Physical activity III</td>
<td>10</td>
<td>37%</td>
</tr>
<tr>
<td>Group meeting 10</td>
<td>Sweeteners</td>
<td>15</td>
<td>56%</td>
</tr>
<tr>
<td>Group meeting 11</td>
<td>Body image I</td>
<td>14</td>
<td>52%</td>
</tr>
<tr>
<td>Group meeting 12</td>
<td>Summer food and end of term</td>
<td>10</td>
<td>37%</td>
</tr>
<tr>
<td>Group meeting 13</td>
<td>“Café table”</td>
<td>9</td>
<td>33%</td>
</tr>
<tr>
<td>Group meeting 14</td>
<td>Body image II</td>
<td>9</td>
<td>33%</td>
</tr>
<tr>
<td>Group meeting 15</td>
<td>“Food for the entire family”</td>
<td>8</td>
<td>30%</td>
</tr>
<tr>
<td>Group meeting 16</td>
<td>Cooking class and farewell</td>
<td>9</td>
<td>33%</td>
</tr>
</tbody>
</table>
Table 6. Comparison of change in weight and waist circumference according to group meeting attendance

<table>
<thead>
<tr>
<th></th>
<th>Mean (±SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥ 50%</td>
<td>&lt; 50%</td>
</tr>
<tr>
<td>Change from baseline to 4 months</td>
<td>n¹ = 55</td>
<td>n = 24</td>
</tr>
<tr>
<td>Change in weight</td>
<td>0.9 (3.1)</td>
<td>1.1 (2.8)</td>
</tr>
<tr>
<td>Change in waist circumference</td>
<td>0.21 (3.9)</td>
<td>0.16 (5.8)</td>
</tr>
<tr>
<td>Change from baseline to 24 months</td>
<td>n¹ = 12</td>
<td>n = 12</td>
</tr>
<tr>
<td>Change in weight</td>
<td>1.6 (8.2)</td>
<td>3.9 (6.5)</td>
</tr>
<tr>
<td>Change in waist circumference</td>
<td>0.11 (6.5)</td>
<td>1.1 (9.6)</td>
</tr>
</tbody>
</table>

¹n indicates the number of participants included in the pair wise analyses.

4.3 Anthropometric outcomes

4.3.1 Changes in weight and waist circumference from baseline to 4 and 24 months within the intervention group

Between baseline and 4 months data collection, the intervention group increased their mean weight from 91.1 kg to 92.0 kg (table 7). Although this was a small increase, the difference in weight between the two data collection points was statistically significant (p-value = 0.007).

In the smaller group who had finished the intervention (participants from sample 1), there was a tendency of weight increase from baseline until 24 months data collection (p-value = 0.08) (table 7). Figure 9 shows every individual’s weight development in the intervention group of sample 1. As displayed, most of the individuals increased their weight from baseline, but not near to the preoperative level. Some individuals also lost weight between the two sampling points. When comparing the weight increase in sample 1 between baseline and 4 months and between 4 months and 24 months, there was a tendency to a greater increase during the latter period than the first (p-value = 0.07). However, when dividing the weight increase from 4 months to 24 months data collection into periods of four months, the weight increase each four months was 0.46 kg. This is the same increase as the mean increase of 0.45 kg from baseline to 4 months.
Table 7. Comparison of weight and waist circumference within the intervention group from baseline to 4 and 24 months of intervention

<table>
<thead>
<tr>
<th></th>
<th>n&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Mean /median (±SD / P25-75)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline&lt;sup&gt;2&lt;/sup&gt;</td>
<td>4 months</td>
</tr>
<tr>
<td><strong>Comparison baseline – 4 months</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight, kg</td>
<td>79</td>
<td>91.1 (17.5)</td>
<td>92.0 (18.3)</td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td>79</td>
<td>104.3 (96.8-113.0)</td>
<td>104.0 (96.0-112.0)</td>
</tr>
<tr>
<td><strong>Comparison baseline – 24 months</strong>&lt;sup&gt;4&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight, kg</td>
<td>24</td>
<td>93.6 (19.4)</td>
<td>96.3 (21.1)</td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td>24</td>
<td>106.0 (97.5-117.8)</td>
<td>108.8 (89.9 – 118.0)</td>
</tr>
</tbody>
</table>

<sup>1</sup>n indicates the number of participants included in the pair wise analyses  
<sup>2</sup>Baseline mean and median values from subjects who were included in the pair wise analyses  
<sup>3</sup>Data includes sample 1, 2 and 3  
<sup>4</sup>Data includes only sample 1

As shown in table 7, there was not a significant difference in waist circumference between baseline and 4 months (p-value = 0.47), nor between baseline and 24 months data collection in the intervention group (p-value = 0.77).

The control group showed much of the same pattern of weight development as the intervention group (table 8). Although the control group did not increase their weight significantly from baseline until 4 months, they had a tendency of weight increase from baseline until 24 months data collection (p-values = 0.28 and 0.06 respectively). The weight development within the control group is shown in a similar figure as for the intervention group (figure 10). Whereas none of the participants in the intervention group were near regaining weight to the pre-operative level, one person in the control group regained the entire amount of weight lost except for one kg.
Figure 9. Weight development in the intervention group of sample 1 from the preoperative weight to weight at 24 months of intervention (n at baseline = 27).

Pre op. = preoperative weight, i.e. 14-24 months before baseline, 0 = weight at baseline, 4 = weight at 4 months, 24 = weight at 24 months and end of study
Figure 10. Weight development in the control group of sample 1 from preoperative weight to weight at 24 months of intervention (n at baseline = 26).

Pre op. = preoperative weight, i.e. 14-24 months before baseline, 0 = weight at baseline, 4 = weight at 4 months, 24 = weight at 24 months and end of study

Symbol indicates the weight development for the individual with total weight regain to pre-operative level.
4.3.2 Comparison of weight and waist circumference between the control and intervention group

There was no significant difference in weight between the two groups at either of the data collection points or in change in weight between the data collections. The same was the case for waist circumference (table 8). When excluding the three study subjects who had removed abdominal skin folds, were pregnant or had abdominal hernia at the actual time points, the changes in waist circumference was still not statistically significant between the intervention and control group (data not shown). As expected, baseline to 24 months change in weight and waist circumference was found to be highly correlated (r = 0.85, p-value < 0.001).

Table 8. Comparison of weight and waist circumference between the intervention and control group from baseline and 4 months and baseline and 24 months data collection

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n¹</td>
<td>Mean/median (±SD/P25-P75)</td>
<td>n²</td>
</tr>
<tr>
<td>Weight, kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>85</td>
<td>90.8 (17.9)</td>
<td>81</td>
</tr>
<tr>
<td>4 months</td>
<td>79</td>
<td>92.0 (18.3)</td>
<td>76</td>
</tr>
<tr>
<td>24 months</td>
<td>24</td>
<td>96.3 (21.1)</td>
<td>20</td>
</tr>
<tr>
<td>Change in weight, kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From BL – 4 m</td>
<td>79</td>
<td>0.93 (3.0)</td>
<td>76</td>
</tr>
<tr>
<td>From BL – 24 m</td>
<td>24</td>
<td>2.8 (7.4)</td>
<td>20</td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>85</td>
<td>104.7 (14.0)</td>
<td>81</td>
</tr>
<tr>
<td>4 months</td>
<td>79</td>
<td>104.0 (98.0-112.0)</td>
<td>76</td>
</tr>
<tr>
<td>24 months</td>
<td>24</td>
<td>108.8 (89.9-118.0)</td>
<td>19</td>
</tr>
<tr>
<td>Change in waist circumference, cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From BL – 4 m</td>
<td>79</td>
<td>-0.20 (4.5)</td>
<td>76</td>
</tr>
<tr>
<td>From BL – 24 m</td>
<td>24</td>
<td>0.63 (8.0)</td>
<td>19</td>
</tr>
</tbody>
</table>

¹n indicates the number of participants in the intervention group at the different data collection points
²n indicates the number of participants in the control group at the different data collection points
BL =baseline, 4 m = 4 months, 24 m = 24 months

In subgroup analyses of the total study group, males were found to have a tendency of increasing their weight more than females (p-value = 0.06) between baseline and 4 months data collection. However, in sample 1, a significant difference between males and females in
weight increase between baseline and 24 months was not found (p-value = 0.73). When comparing the drop-outs between baseline and 24 months data collection with the participants who completed the study, there was no significant difference between them in weight at baseline (p-value = 0.63).

### 4.4 Energy intake

#### 4.4.1 Comparison of energy intake

The median energy intake per day of the control and intervention group at 4 and 24 months is shown in *figure 11*. The control group increased their median energy intake from 6539 kJ (1563 kcal) per day to 7599 kJ (1816 kcal) per day from baseline to 24 months data collection which was statistically significant (p-value = 0.03). The corresponding data for the intervention group was 7972 kJ (1905 kcal) per day to 7184 kJ (1717 kcal) per day, a change that was not significant (p-value = 0.57). There was no difference in energy intake between the two groups at 24 months (p-value = 0.96).

To investigate the association between change in energy intake and change in weight, correlation analyses were performed. Pearson’s correlation coefficient (r) was only found to be 0.12 and not significant with a p-value = 0.45. However, the correlation between weight and energy intake at 24 months data collection was found to be significant (p-value = 0.001), with a correlation coefficient (r_{sp}) = 0.48. In addition, the explained variance (r^2) of 0.16 indicates that 16% of the weight at 24 months was explained by energy intake.
The median energy intake in the control and intervention group at baseline and 24 months.

The energy intake between the intervention and control group was also compared after two participants with outlier values were removed. Still, there was no significant difference in energy intake at 24 months (p-value = 0.94). The energy intake of each individual in the control and intervention group at baseline and 24 months is displayed in figures 12a and 12b.

When investigating the energy intake between men and women, no significant difference was found between them in median energy intake at baseline (p-value = 0.11), but a tendency of higher energy intake for men was found at 24 months (p-value = 0.07). Neither the males nor the females increased their intake significantly from baseline to 24 months. Analyses comparing the seven drop-outs to the study completers in baseline energy level, showed a significant difference in energy intake at baseline (p-value = 0.02) with a lower energy intake in the drop-outs than in the continuing participants.
Figure 12a. Each individual’s energy intake in the intervention group at baseline and 24 months
Star indicates outlier

Figure 12b. Each individual’s energy intake in the control group at baseline and 24 months
The marked column is not an outlier. The calculation for determining the validity of a person’s energy report is based on the individual’s BMR. The factors included in this calculation are weight, height, age and sex. Even though the marked energy intake is very high, this person had an EI_{rep}:BMR ratio of 2.03, which is within the individual cut-off range for acceptable reporters (table 9).
4.4.2 Evaluation of the energy intake

The group mean baseline EI_{rep:BMR} ratio was 1.12 (0.34). As the group level cut-off values, based on the Goldeberg and Black formula (82), for acceptable reporters were 1.46 – 1.64 at baseline, the participants were deemed under-reporters at group level. When subgroup analyses at baseline were performed, no significant differences in reporting validity were detected between the intervention and control group or between men and women (p-values = 0.33 and 0.51 respectively).

At 24 months, the group’s mean EI_{rep:BMR} ratio was 1.15 (0.38). With the same cut-off values as at baseline, this classified the group in total as under-reporters also at 24 months. As was the case at baseline, there was no significant differences in validity of food diaries between the intervention and control group or male and female at 24 months either (p-values = 0.95 and 0.81 respectively).

Paired tests between baseline and 24 months data within the control group and the intervention group were performed separately. This was done to investigate if the degree of under-reporting was significantly different at these two data collection points within the groups. Neither the control group (p-value = 0.11) nor the intervention group (p-value = 0.86) showed significant differences in reporting energy intake when comparing the EI_{rep:BMR} ratio at the two data collection points. When a paired test was done within the whole study group, the result was the same with a p-value = 0.44.

At the individual level, cut-offs were used to identify invalid reports which were also based on the Goldberg and Black formula (82). The results are shown in table 9. More than 50% of the study participants were classified as acceptable reporters at both 4- and 24 months, while only one person was classified as an over-reporter. This was at 24 months and the over-reporter had no unusual days according to the food diaries. However, this person gained 5.8 kg from baseline to 24 months.
Table 9. Evaluation of reported energy intake at individual level.

<table>
<thead>
<tr>
<th></th>
<th>Cut-off values</th>
<th>n¹</th>
<th>Percentage of total</th>
<th>Min - max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptable reporters</td>
<td>1.02 – 2.35</td>
<td>29</td>
<td>55.8%</td>
<td>1.04 – 2.08</td>
</tr>
<tr>
<td>Under-reporters</td>
<td>&lt; 1.02</td>
<td>23</td>
<td>44.2%</td>
<td>0.45 – 1.01</td>
</tr>
<tr>
<td>Over-reporters</td>
<td>&gt; 2.35</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptable reporters</td>
<td>1.02 – 2.35</td>
<td>25</td>
<td>59.5%</td>
<td>1.02 – 2.03</td>
</tr>
<tr>
<td>Under-reporters</td>
<td>&lt; 1.02</td>
<td>16</td>
<td>38.1%</td>
<td>0.54 – 1.01</td>
</tr>
<tr>
<td>Over-reporters</td>
<td>&gt; 2.35</td>
<td>1</td>
<td>2.4%</td>
<td>2.61</td>
</tr>
</tbody>
</table>

¹n = number of individuals in total at baseline and 24 months data collection and in each category of reporters.

4.5 Health-related quality of life

4.5.1 Data quality

The approval for usage of the HRQoL questionnaire was received after baseline data collection had started. As a result, the first nine (8.0%) participants did not fill in this questionnaire at baseline. All of these participants were women, four (7.2%) in the intervention group and five (8.6%) in the control group. An additional three (2.7%) of the participants did not deliver the questionnaire at the baseline data collection.

At the 4 months data collection, a total of eight (7.1%) had withdrawn from the study, and six (5.7%) questionnaires from the remaining participants were not delivered to the master students. The withdrawal rate was 3.6% in the intervention group and 10.3% in the control group. The difference in drop-outs between the intervention and the control group was not significant (p-value = 0.27). Neither was there a significant difference in total score, physical and mental health measure between the drop-outs and the participants who continued the study at 4 months data collection (p-values = 0.57, 0.71 and 0.24 respectively). Answers were in 7.1% of the questionnaires which led to the inability of aggregating a total score from these questionnaires. There was no significant difference in inability to aggregate total scores between women and men (p = 0.31) or between the intervention and control group (p-value = 0.72). A total of 11 participants (9.7%) had one or several missing items in their
questionnaires at both baseline and 4 months follow-up. Across the board, the percentage of missing items from completed questionnaires ranged from 0.0 – 5.0%. Among the 36 items in the questionnaire, 12 items had 0% missing, 20 items had 1-3% missing and three items had 4.0% missing (belonging to the MH and GH dimensions) and one item had 5.0% missing (belonging to the VT dimension).

No statistically significant difference was found between men and women in change of any of the scores from baseline to 4 months. Neither was a significant difference found at 4 months follow-up in mental health summary, in physical health summary or in total scores (data not shown). However, a tendency of difference between men and women was found in total scores at baseline (p = 0.09) with a tendency to a higher score in women than in men. This tendency was sustained after controlling for age.

In the RP, SF and the RE dimensions, more than one third of the study group had maximum scores (= 100, “ceiling effect”) at baseline while the dimension with most pronounced minimum score (= 0, “floor effect”) was BP (Table 10). The ceiling effect seemed to decline somewhat after four months, but was still prominent in the RP, SF, and the RE. The BP was still the dimension with the most prominent flooring effect.

Table 10. Percentage of participants in both the control and intervention group with minimum/maximum scores of the SF-36 dimensions.

<table>
<thead>
<tr>
<th></th>
<th>No of items</th>
<th>% minimum / maximum score</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Baseline</td>
<td>4 months</td>
</tr>
<tr>
<td>Physical function (PF)</td>
<td>10</td>
<td>0.0 / 16.8</td>
<td>0.0 / 14.3</td>
<td></td>
</tr>
<tr>
<td>Role-physical (RP)</td>
<td>4</td>
<td>1.0 / 35.6</td>
<td>2.0 / 30.6</td>
<td></td>
</tr>
<tr>
<td>Bodily pain (BP)</td>
<td>3</td>
<td>3.0 / 19.2</td>
<td>4.1 / 17.3</td>
<td></td>
</tr>
<tr>
<td>General health (GH)</td>
<td>2</td>
<td>1.0 / 5.0</td>
<td>0.0 / 0.0</td>
<td></td>
</tr>
<tr>
<td>Vitality (VT)</td>
<td>2</td>
<td>1.0 / 2.0</td>
<td>2.1 / 1.0</td>
<td></td>
</tr>
<tr>
<td>Social function (SF)</td>
<td>5</td>
<td>0.0 / 42.0</td>
<td>1.0 / 34.7</td>
<td></td>
</tr>
<tr>
<td>Role-emotional (RE)</td>
<td>4</td>
<td>0.0 / 52.0</td>
<td>1.0 / 43.9</td>
<td></td>
</tr>
<tr>
<td>Mental health (MH)</td>
<td>5</td>
<td>0.0 / 6.1</td>
<td>0.0 / 2.1</td>
<td></td>
</tr>
</tbody>
</table>
The correlations between the SF-36 dimensions’ average scores from the two data collection time points ranged from 0.074 (PF and MH) to 0.78 (RP and BP). The correlations between the scales aggregating the mental health summary measure (VT, SF, RE and MH) ranged from 0.61 (VT and SF) to 0.75 (RE and MH). Between the scales aggregating the physical health summary measure (PF, RP, BP and GH), the correlations ranged from 0.59 (PF and BP) to 0.78 (RP and BP). The correlations between scales across the two summary measures ranged from 0.074 (PF and MH) to 0.55 (GH and VT).

### 4.5.2 Comparison of health related quality of life after 4 months

The 4-months changes within the intervention and control groups are presented in table 11.

The results in the intervention group on change in the VT (p-value = 0.02) dimension, showed a statistical significance but did not differ in mean score. The same was the case with the tendency of difference in the SF (p-value = 0.08) and MH (p-value = 0.09) dimensions. However, the significant difference in GH (p-value = 0.008) showed a decrease in scores. When aggregating the scores into physical and mental health measures and total score, there was no statistically significant decrease in the HRQoL scores, only a tendency of decrease in the mental health measure (p = 0.09). The subjects in the control group showed statistically significant decline in HRQoL in the GH (p-value = 0.04), VT (p-value = < 0.001), RE (p-value = 0.003) and MH (p-value = < 0.001) dimensions. Whereas the SF dimension increased (p-value = 0.01). When aggregating the scores, both the total score and the mental health measure showed a significant decrease in HRQoL while the change in the physical health measure was not significant (p-values = < 0.001, < 0.001 and 0.23) respectively.

The baseline total scores and the physical and health measure scores for both the intervention and control group are shown in table 4. The total score, physical health measure and mental health measure scores, together with the dimension scores were not statistically significant between the groups after 4 months (table 12). However when analyzing change in scores, the control group had a significantly larger decline in mental health measure score from baseline to 4 months compared to the intervention group. The same was found in total score when six outlier values were removed. There were two outliers in the control group and four outliers in the intervention group. The change in total scores, mental and physical health measure within each group is shown in figure 13.
Table 11. Change in SF-36 dimensions and aggregated scores within the groups from baseline to 4 months

<table>
<thead>
<tr>
<th>Dimension scores median (P25-75)</th>
<th></th>
<th>Intervention group</th>
<th>P-value</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
<td>4 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>45</td>
<td>90.0 (80.0 – 96.3)</td>
<td>90.0 (78.8 – 95.0)</td>
<td>0.49</td>
<td>44</td>
</tr>
<tr>
<td>Role-physical</td>
<td>45</td>
<td>90.6 (62.5 – 100)</td>
<td>87.5 (50.0 – 100)</td>
<td>0.25</td>
<td>44</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>43</td>
<td>56.0 (32.0 – 74.0)</td>
<td>51.0 (32.0 – 84.0)</td>
<td>0.45</td>
<td>44</td>
</tr>
<tr>
<td>General health</td>
<td>45</td>
<td>72.0 (52.0 – 87.0)</td>
<td>59.5 (44.3 – 87.0)</td>
<td><strong>0.008</strong></td>
<td>44</td>
</tr>
<tr>
<td>Vitality</td>
<td>43</td>
<td>50.0 (37.5 – 65.6)</td>
<td>50.0 (31.3 – 62.5)</td>
<td><strong>0.02</strong></td>
<td>43</td>
</tr>
<tr>
<td>Social function</td>
<td>44</td>
<td>75.0 (62.5 – 100)</td>
<td>75.0 (50.0 – 100)</td>
<td><strong>0.08</strong></td>
<td>44</td>
</tr>
<tr>
<td>Role-emotional</td>
<td>44</td>
<td>100 (75.0 – 100)</td>
<td>91.7 (66.7 – 100)</td>
<td>0.72</td>
<td>44</td>
</tr>
<tr>
<td>Mental health</td>
<td>43</td>
<td>75.0 (65.0-90.0)</td>
<td>75.0 (60.0 – 90.0)</td>
<td><strong>0.09</strong></td>
<td>43</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total scores median (P25-75)</th>
<th></th>
<th>Intervention group</th>
<th>P-value</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
<td>4 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>42</td>
<td>73.5 (61.1 – 82.5)</td>
<td>63.8 (58.4 – 79.8)</td>
<td>0.11</td>
<td>43</td>
</tr>
<tr>
<td>Mental health measure</td>
<td>43</td>
<td>78.9 (63.6 – 85.3)</td>
<td>69.4 (57.0 – 83.2)</td>
<td><strong>0.09</strong></td>
<td>43</td>
</tr>
<tr>
<td>Physical health measure</td>
<td>42</td>
<td>77.3 (60.9 – 87.6)</td>
<td>74.4 (53.6 – 87.1)</td>
<td>0.38</td>
<td>43</td>
</tr>
</tbody>
</table>

n indicates the number of participants included in the pair wise analyses
Compared to a Swedish norm population’s mean scores, the control group had lower median scores in all the dimensions at the 4 months data collection except for PF which was a little higher. The intervention group had lower median scores in five of the eight dimensions. PF and RE was a little higher and RP was approximately the same as the norm population (table 12).

**Table 12.** Comparison of SF-36 4 months dimension scores between intervention group, control group and norm data.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (±SD/P25-75)</th>
<th>Control group (±SD/P25-75)</th>
<th>Norm data (±SD)</th>
<th>P-value²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimension scores</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>90.0 (78.8 – 95.0)</td>
<td>90.0 (71.3 – 95.0)</td>
<td>89.0 (0.4)</td>
<td>0.97</td>
</tr>
<tr>
<td>Role-physical</td>
<td>87.5 (50.0 – 100)</td>
<td>75.0 (43.8 – 100)</td>
<td>87.6 (0.6)</td>
<td>0.22</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>51.0 (32.0 – 84.0)</td>
<td>41.0 (22.0 – 84.0)</td>
<td>74.2 (0.6)</td>
<td>0.13</td>
</tr>
<tr>
<td>General health</td>
<td>59.5 (44.3 – 87.0)</td>
<td>54.5 (35.0 – 87.0)</td>
<td>74.9 (0.5)</td>
<td>0.34</td>
</tr>
<tr>
<td>Vitality</td>
<td>50.0 (31.3 – 62.5)</td>
<td>40.6 (25.0 – 56.3)</td>
<td>64.8 (0.5)</td>
<td>0.32</td>
</tr>
<tr>
<td>Social function</td>
<td>75.0 (50.0 – 100)</td>
<td>81.3 (50.0 – 100)</td>
<td>87.5 (0.5)</td>
<td>0.69</td>
</tr>
<tr>
<td>Role-emotional</td>
<td>91.7 (66.7 – 100)</td>
<td>83.3 (50.0 – 100)</td>
<td>88.8 (0.5)</td>
<td>0.24</td>
</tr>
<tr>
<td>Mental health</td>
<td>75.0 (60.0 – 90.0)</td>
<td>70.0 (45.0 – 85.0)</td>
<td>79.3 (0.4)</td>
<td>0.28</td>
</tr>
<tr>
<td><strong>Total scores</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>63.8 (58.4 – 79.8)</td>
<td>65.9 (44.4 – 78.7)</td>
<td></td>
<td>0.18</td>
</tr>
<tr>
<td>Mental health measure</td>
<td>69.4 (57.0 – 83.2)</td>
<td>65.3 (44.3 – 80.5)</td>
<td></td>
<td>0.26</td>
</tr>
<tr>
<td>Physical health measure</td>
<td>74.4 (53.6 – 87.1)</td>
<td>68.6 (46.2 – 82.9)</td>
<td></td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Change in scores BL – 4 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Δ in total score</td>
<td>-4.1 (14.2)</td>
<td>-7.0 (11.5)</td>
<td></td>
<td>0.11</td>
</tr>
<tr>
<td>Δ in total without outliers</td>
<td>-1.8 (9.3)</td>
<td>-6.8 (9.5)</td>
<td></td>
<td>0.02</td>
</tr>
<tr>
<td>Δ in mental health measure</td>
<td>-1.6 (-11.3 – 4.1)</td>
<td>-11.3 (-24.1 – 1.6)</td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td>Δ in physical health measure</td>
<td>-1.3 (-8.8 – 6.3)</td>
<td>-2.9 (-8.1 – 4.9)</td>
<td></td>
<td>0.90³</td>
</tr>
</tbody>
</table>

¹The norm data used for comparison is the Swedish norm data (74) because there is no published Norwegian norm data on the SF-36 version 2.0.
²P-values from analyses between the control and the intervention group
³No statistical difference was found when removing outlier values
N = 50 intervention group, n = 48 in the control group and n = 1715 in the norm data. N = 43 in both control and intervention groups in change calculations, including outliers.
Δ = change, BL = baseline
Figure 13. Median change in the SF-36 scores from baseline to the 4 months data collection, based on table 12.

The effect size for the clinical treatment effect was not equally distributed in the control and the intervention group as shown in Figure 14. The physical health measure scores showed the least reduction in both groups with -0.15 in the control group and -0.06 in the intervention group, both which indicates a trivial effect (77). In the intervention group, the total score showed the largest effect reduction (-0.23), although regarded as a small effect (77). In the control group, the mental health measure score had the largest reduction in effect size, showing a moderate effect reduction with a score of -0.61 (77). The difference between the groups in both physical health measure and total score treatment effect reduction was not significant with p-values = 0.90 and 0.11 respectively. However, the treatment effect reduction score for the mental health measure showed a statistically significant difference between the groups (p-value = 0.04).
4.5.3 Change in health related quality of life in relation to change in body weight

Correlation and regression analyses between total score, physical and mental health measures with change in weight, age and sex is shown in table 13. No association between change in weight and change in any of the aggregated scores was found. It was a statistically significant association between change in total scores and age and a tendency of association between age and physical and mental health measures. The regression analysis showed that there were statistically significant relations between increase in HRQoL of total scores and mental health measures with age. Per one year of increasing age, the change in total score and mental health measure was 0.35 and 0.44 respectively. However, when adjusting the results for change in weight, age and sex in a multiple regression analysis, no relation between the variables was statistically significant. There were only a tendency of relation between age and change in total score (p-value = 0.06) and age and change in mental health measure and age (p-value = 0.07).
Table 13. Change in health-related quality of life scores in relation to weight change from baseline to 4 months, age and sex (n = 79).

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted effect</th>
<th>SD</th>
<th>P-value</th>
<th>Adjusted effect</th>
<th>SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change in total score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in weight</td>
<td>0.06</td>
<td>0.47</td>
<td>0.59</td>
<td>-0.54</td>
<td>0.47</td>
<td>0.25</td>
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<tr>
<td>Age</td>
<td>0.23</td>
<td>0.35</td>
<td>0.17</td>
<td>0.33</td>
<td>0.17</td>
<td>0.06</td>
</tr>
<tr>
<td>Sex</td>
<td>-5.6</td>
<td>3.1</td>
<td>0.08</td>
<td>-4.8</td>
<td>3.2</td>
<td>0.13</td>
</tr>
<tr>
<td><strong>Change in mental health measure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in weight</td>
<td>0.09</td>
<td>0.61</td>
<td>0.58</td>
<td>-0.75</td>
<td>0.61</td>
<td>0.22</td>
</tr>
<tr>
<td>Age</td>
<td>0.21</td>
<td>0.44</td>
<td>0.21</td>
<td>0.42</td>
<td>0.22</td>
<td>0.07</td>
</tr>
<tr>
<td>Sex</td>
<td>-6.8</td>
<td>4.0</td>
<td>0.10</td>
<td>-5.8</td>
<td>4.2</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>Change in physical health measure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in weight</td>
<td>0.03</td>
<td>0.44</td>
<td>0.43</td>
<td>-0.53</td>
<td>0.45</td>
<td>0.24</td>
</tr>
<tr>
<td>Age</td>
<td>0.19</td>
<td>0.24</td>
<td>0.16</td>
<td>0.23</td>
<td>0.17</td>
<td>0.18</td>
</tr>
<tr>
<td>Sex</td>
<td>-3.5</td>
<td>3.1</td>
<td>0.27</td>
<td>-3.2</td>
<td>3.3</td>
<td>0.32</td>
</tr>
</tbody>
</table>

1 Pearson’s (r) and Spearman’s (rs) correlation coefficients to study the possible association between the variables
2 Regression analysis to describe the relation between the variables
3 Adjusted for all the variables in the table in a multiple regression analysis
4 Sex is a categorical variable not suitable for correlation analysis
5 Discussion

Brief synopsis of key findings

A significant increase in weight between baseline and 4 months was found within the intervention group and a tendency of increase in weight from baseline to 24 months was also found. There were no significant changes in waist circumference within the intervention group and there were no significant difference in anthropometric measures between the subjects who had participated in more or less than 50% of the group meetings. When weight and waist circumference were compared between the intervention and control group, no statistical differences were found at any data collection point. There was no significant difference in energy intake between the intervention and control group at 24 months data collection. However, the control group had a significant increase in median energy intake from baseline to 24 months while the intervention group had a non-significant change in median energy intake. There was no significant difference between the intervention and control group in HRQoL at 4 months in any of the eight dimension scores, total score or physical and mental component measures. However most of the dimension scores differentiated from the norm scores except for physical function and mental health dimensions in the intervention group and physical function in the control group. The control group had a significantly larger deterioration in mental health scores than the intervention group. When investigating the relationship between change in weight and change in HRQoL-scores, no significant association was found.

5.1 Subjects and methods

5.1.1 Study design

With current knowledge, no studies have conducted a postoperative, randomized study based mainly on group intervention after RYGBP surgery. Whereas some other studies have investigated the effect of support group meetings after bariatric surgery on anthropometric measures (83-86), none have been randomized into an intervention and a control group. Having a control group makes it possible to compare the results of the intervention to the usual care and additionally, randomization reduces the risk of bias (80). Table 4 showed that
the two groups did not differ in any systematic way, which is good as statistical theory is based on the idea of random sampling (80).

Several studies have investigated subjects who have undergone RYGBP procedure or other bariatric surgeries with focus on anthropometric, dietary, and HRQoL changes before and after surgery (49-51, 53). Papalazarou *et al.* randomized female surgery candidates into groups of usual care or life style intervention that began immediately after vertical banded gastroplasty (VGB) surgery. After 30 sessions during three years, they found favorable effects of life style intervention (87). Another study initiated intensive nutritional management with follow-ups once every 15 days for at least 3 months. This study started at least two years after RYGBP surgery and found that weight was reduced in patients who had had a previous weight regain (88).

The effect of support group meeting attendance after bariatric surgery has also been investigated by different methods such as retrospective chart review (86), questionnaires on anthropometric data and support group meeting attendance (83, 84), and retrospective study on encouraged attendance and effect on weight (85), but none of them were randomized. The present study could then be a valuable contribution to the data that already exists on extra support and guidance after RYGBP surgery.

The intervention in the present study was less comprehensive with 16 group meetings and four individual sessions over a two year period compared to three individual sessions in the control group for data collection. This scheme was chosen as it was believed to be more easily implemented as a general scheme to prevent weight regain, and thus maybe contribute to a greater generalization on the effect of intensive follow-up starting 14-24 months after RYGBP surgery.

The intervention of this study was based on group participation with peers. A difference in weight and energy intake between the control and intervention group for the time being is not evident. It might have been a more effective intervention if the participants in the intervention group were offered an extra individual session in addition to the group meetings to discuss the content of the food diary with the master student. Even though the exact energy intake is hard to estimate with just a quick look at the food diary, it is possible to say something about intake of disadvantageous food items and the frequency or amounts of intake of these items and give advice to the participant accordingly. With this approach, it would also have been
possible to compare choice of food items and discuss low-fat versus regular variants of the same products. Another possibility is to identify certain time points which constitute more risk than others and together with the participant work out strategies regarding food intake when the risk for disadvantageous eating patterns is at its greatest. It might be a lot of potential in guidance according to the items in the food diary which could influence the result on energy intake (89) and thus body weight.

A limitation to be considered is that the data collection was done by four different master students and one RD. For this reason, possible inter-observer variability may occur. Intra-observer reliability is known to be better than inter-observer reliability in anthropometric measurements both in adults and children (90, 91). In the review by Ulijaszek and Kerr they stated that measurement error has mainly two types of effects on the quality of data collected to the extent which: 1) repeated measurements give the same value; and 2) measurements depart from the true values (90). The ideal would have been to have one person who performed all the anthropometric measurements, but this was not possible as the participants were included over three years and the measurements were taken by master students. To minimize the intra- and inter-observer errors, the master students were taught how to perform the measurements correctly with the supervisor ahead of data collection. It has been found that the measurement errors are largest, among other things, when the anthropometrist are recently trained with limited experience (90). Stomfai et.al, found that the reliability of intra-observer measurements increased from 69% to 95% from the first to the second training session when measuring children (91). However, intra- and inter-observer reliability values have been shown to be similar to each other for measures of weight. Acceptable levels of inter-observer measurement error (R > 0.95) was generally achieved for weight and lower levels of reliability was achieved for waist circumference (mean R = 0.94) (90).

As only 23.2% of the eligible participants signed up for participation, there was a risk of response bias. Those who wanted to participate could have been more motivated to keep a health promoting lifestyle, more concerned about weight development, and knowledgeable about the risk of weight regain after surgery. This potentially made the participants more likely to follow a more restrictive eating pattern and to be further aware of food choices and physical activity. Consequently, the present results may not be representative for the entire population of those who have undergone RYGBP surgery at OUH Aker. This also creates the possibility of not detecting a true effect of the intervention because the participants in the
control group might be more aware of the lifestyle choices they made to avoid significant weight regain than the average post RYGBP candidate.

Since OUH Aker is a regional center for bariatric surgery, some study subjects had to travel a long distance to participate. This may both limit the possibility of joining the study for some of the eligible candidates and affect the group meeting attendance. It may also be a challenge for some that the study period lasts for two years. Nevertheless, the statistician expected a rate of withdrawal from the study of 20-30%, and so far 83% have completed the study after 24 months.

5.1.2 Data assessment

Food diaries

To eliminate errors in completing the food diaries as much as possible, the study participants were thoroughly informed about how to complete them both orally and in writing. The master students also proof read each food diary during the scanning process. In addition, peculiar amounts of different food items, or values of macro- and micronutrients were screened for and consequently scanning errors were detected and corrected.

The food diary used to collect data on energy intake has not been validated for adults, but for children. This validation showed that both under- and over-reporting of energy intake did occur (72). A dietary questionnaire that covered food intake over the past three months has been developed for use in the SOS-study and validated in obese subjects. This validation showed that it gave more valid information than four-day food records in obese subjects (92). However, choosing the four-day food diary also had its advantages. It is pre-coded and has an extensive list of typical Norwegian food items categorized in a typical Norwegian food pattern (93). It is also accompanied with a photographic booklet. In addition it has been shown, although in the elderly, that food records collected during the first days were less likely to under-report high intakes as this was an increasing problem by the fifth, sixth, and seventh day (94). Hence, this implies that as the number of days of food records increase, the validity of the food records decrease. However, another study found that the number of days of diet record needed to ensure a correlation between observed and true mean of energy intake \( \geq 0.9 \), was found to be 4-5 days in adult men and 5-6 days in adult women (95). Thus, the four-day food diary in the present study may be sufficient for satisfactory energy estimates in
males but possibly insufficient in females. A seven-day food diary may therefore have been more adequate to achieve good energy estimates for both sexes. However, such a conclusion can not be drawn due to the ambiguous findings from the scientific literature.

The food registration itself may influence the energy intake as registration of all food and drink intake might increase the awareness of ingestion. It might also be the case that participants avoid food items high in fat and sugar during the registration days to be “good” or limit their intake because it is more cumbersome to register more items. Many subjects also indicated that one or several of the recorded days were unusual. While some definitions of unusual days certainly were rare occasions, such as confirmation, party/celebration or having surgery, others were of more normal daily variations. This may reflect that some subjects still excuse intake of snacks and energy dense food as unusual happenings even if it occurs several times a week.

SF-36 questionnaires

The SF-36 survey is a generic instrument. It was chosen for use in this study due to the advantages of generic instruments and its extensive use in scientific literature. Generic instruments are most useful when diverse groups are compared and create the possibility to compare the study group to a norm population. With a generic instrument, it is also possible to compare the relative burden of different diseases (59). On the contrary, obesity specific instruments can only be used to measure HRQoL in obese groups. To avoid an extensive length of the questionnaire, the creators chose the most frequently used health concepts in health surveys when developing the SF-36 (59). These concepts were also regarded as the most affected by disease and treatment (75). The items in the SF-36 questionnaire have been standardized and proven suitable for self administration (59).

The SF-36 has been translated into Norwegian by Loge et.al. following the procedures developed by the International Quality of Life Assessment (IQOLA) Project (96). It was tested for reliability, scaling assumptions, and construct validity. The evidence for the construct validity of the questionnaire was good. However minor deficiencies were detected and changed (Norwegian SF-36 version 1.2) (96). The Norwegian SF-36 version 2.0 used in this study, is the last version of the SF-36 and is mostly similar to the previous one except for two scales, RP and RE. In these scales, the scoring is changed from a dichotomous “yes/no” response to a five-step format (74). The Norwegian SF-36 version 2.0 is unfortunately not
validated under Norwegian conditions. Nevertheless, the Swedish SF-36 version 2.0 has been validated in Sweden. Here the researchers concluded that the changes in response formats, improved the precision, reliability and validity without deteriorating the structure of the original SF-36 (74).

We used a key punch entry to administer the data from the SF-36 questionnaire. This is a method of administration that has been used successfully (59).

**Group meetings**

The European guidelines on long-term after-care recommend that bariatric patients should be seen 1-4 times per year from the third year post surgery and after that. This follow-up should not only focus on weight, but also QoL (26). As the participants in the intervention group was offered 16 group meetings and four individual sessions during the two years of the study, our follow-up may be regarded as quite frequent compared to usual care. The topics of the group meetings reflected challenges concerning healthy, nutritious and low energy density food as well as psychological and physical activity issues. A goal expressed at the first group meeting by all participants was to either keep current weight loss or to loose more weight. Thus, the master students emphasized that research has shown that to maintain a great weight loss, ingestion of food with low energy density and engagement in physical activity for 60 minutes every day is necessary (97).

Participants in sample 1 and 2 had low participation rates in the physical activity part of the group meetings, while most of the participants in sample 3 joined the physical activity. When participants did not engage in the physical activity, bodily pain or sickness was given as reasons for absence. The reason for this different attitude may be different group dynamics. It might also have been an increasing awareness in the bariatric surgery patient milieu about the great risk of weight regain that modified the attitudes towards physical activity. Another possible explanation is that the latter group leaders set other ground rules for participation in the physical activity part than the previous group leaders.

Many of the participants showed quite good knowledge about nutrition. The nutritional advices given during the meetings were also often applicable to the general population. It may thus not be a lack of knowledge on advantageous nutrition to avoid weight regain, but rather a lack of realization of this knowledge into action. The opinion in the group on whether it was
useful to refresh the nutritional knowledge differed. Some participants felt they knew all they
needed about nutrition and others felt that it was useful to be reminded of healthful food
choices. However, nutritional topics seemed to be valuable at some occasions. The high
energy content of the traditional Christmas food surprised the group members, and motivated
the study subjects to set goals for weight development and indulgence during Christmas. After
Christmas, the group members felt that these goals had helped them to keep focus during the
holidays.

The nutritional advices might have felt more relevant to even more of the group participants if
we instead of focusing on general nutritional advices for a healthy weight, had focused on
very specific diet schemes relevant for this group. Orth et.al have investigated the effect of
attendance in support group meetings on weight in addition to reasons for not attending them.
They produced a list of topics that patients desired to be discussed during these meetings.
Examples were adjusting to a new self after surgery, best food for individual needs, diet,
eating less years after surgery, exercise, how to deal with plateaus, life altering changes and
plastic surgery (83). How to, where to and the official guidelines for removing excess skin
was one of the most frequently discussed topics in the group. Many participants in the present
study stated that the most rewarding outcome from the group meetings was that they had a
safe forum where they could share their thoughts and experiences with peers.

It is possible that since the group meetings were held by four different master students, some
minor differences in presentation, accentuation of topics, and level of physical activity might
have occurred.

5.1.3 Statistics

Several values analyzed were skewed and not strictly Normally distributed. The non-
parametric techniques Mann-Whitney U and Wilcoxon signed rank sum tests were chosen
when this condition occurred. Non-parametric techniques takes into consideration outliers in
the data set using median as the middle value of the data and not comparing means as in
parametric tests. However, non-parametric test are less powerful than parametric tests (98). In
addition, the parametric techniques are quite robust in regard to violations of the assumption
of Normality. With a sample size > 30, the violation of this assumption normally does not
cause any large problems (98). In this regard, interpretation of whether data was Normally
distributed or not might have been too strict. Thus, there was a potential risk of missing
statistically significant p-values. To account for this possible bias, Independent sample t-tests and Paired sample t-tests were performed in addition to the non-parametric tests to detect possible differences in the results obtained. Such differences did not occur.

The PAL value chosen for calculation of accurate-, under- and over-reporters was suggested by Black (82). There were several reasons for using 1.55 as the PAL value in the present study group. Since the physical activity level of the participants was unknown, choosing a too high value might exaggerate the extent of under-reporting. A PAL of 1.55 has been shown to be a probable minimum energy requirement for a sedentary population, but with the ability to perform normal activities. If the PAL is raised, not only would more under-reporters have been identified, but also more acceptable reporters would have been misclassified as under-reporters (82).

The ideal would have been to collect the actual PAL of each individual. A physical activity questionnaire was collected from all the participants at the individual sessions, but due to the size of this master thesis, the master student has not analyzed the data from these questionnaires. However, it would be recommendable to include data from these questionnaires when calculating cut-off values for under- and over-reporters in the future.

The number of participants included in the baseline and 4 months analyses was acceptable in comparison to other published studies on HRQoL, energy intake and anthropometric measures carried out after RYGBP surgery (50, 52, 53, 99). The 4 months data fulfill the power assumption of 80% and 5% probability of type I errors in this study. On the other hand, the number of participants included in the 24 months analyses may imply limited power. This is especially applicable in the sub-analyses of gender as there were only four men in the intervention group and three in the control group of sample 1. This number is too small to be representative and very unlikely to produce any significant differences between the groups even if the difference is really true.

5.2 Results

5.2.1 Group meeting attendance

The first four group meetings had an attendance of over 50%, and thereafter it steadily declined to a steady level of 30-37%. This is probably explained by that the novelty has worn
off. However, two group meetings stand out with a substantially higher group meeting attendance than the previous and following meetings; number 10 on the topic of sweeteners and number 11 on the topic of body image held by a psychologist. It was evident from the food diaries that many participants had a very high and frequent intake of artificially sweetened soft drinks, tea, and coffee. Lindroos _et al._ found that despite the reduction of total energy intake two years after gastroplasty and gastric bypass, there was a relative increase of sugar intake (51). Thus, many subjects might be aware of their high intake of sweet food and drink. These factors may explain the rather great interest in this topic. Artificial sweeteners are often front page topic in the most popular tabloid news papers. This may cause some extra interest in what is regarded as acceptable amount of intake without causing any health risks.

Body image is related to the excess skin after surgery (100). Some participants mentioned that excess skin caused rashes, made hygiene difficult and that it caused great dissatisfaction with their own body. This has also been found in the literature (100). A few in the intervention group said that they were more unlikely to wear a swimming suit in public after the surgery than before. The excess skin may be a reminder of the previous weight and body shape (101). As excess skin and body image preoccupied the participants a lot, this may explain the high attendance percentage at the meeting on body image. Besides, patients’ perception of themselves have shown to be significantly improved with body contouring surgery (100).

Many of the group members had to travel quite a distance to get to the group meetings. It is possible that this may have affected the group meeting attendance percentage, but analyses on distance from the participant’s residence to OUH Aker and attendance percentage was not performed. Lara _et al._ have found that patients in a one year study who lived > 160 kilometers away had a significantly poorer compliance at the 9 month visit, but not at the 12 month visit (102). Thus, it is difficult to speculate whether this may have had an influence on the present study group’s meeting attendance or not.

No differences were found in weight or waist circumference among those with a meeting attendance ≥ 50% compared to an attendance < 50% at any of the data collection points. The 4 months data included a sufficient amount of participants, but four months may not be long enough to create any significant differences. Song _et al._ found no difference in weight loss between patients who attended support groups compared to those who did not the first six months. However, they found a significant difference after nine months (85). Any systematic differences at 24 months between those with ≥ 50% and < 50% attendance in the present
study, may not be revealed due to lack of power. The present findings are not consistent with conclusions in a recent systematic review that attending support group meetings appeared to be associated with greater degree of weight loss after bariatric surgery (103).

Lara et al. have suggested that, among other possible reasons, not attending follow-up visits may be due to weight regain and non-compliance with diet (102). Participants who experience weight regain may also feel less successful than the other participants who “manage it”. However, this effect was not found in the present study as there was no difference in weight between those who had attended ≥ or < 50%.

Even though we tried to minimize non-compliance by sending every group member a reminder via text message one day prior to every group meeting, the average attendance after 16 group meetings was 45.6%. However, according to Orth et al. such low rates are not uncommon (83).

5.2.2 Anthropometric measures

As it appears from the baseline characteristics, the anthropometric results were quite similar between the intervention and control group. Thus the randomization process has created quite equal groups.

No statistically significant differences were found between the groups in weight or waist circumference at either 4- or 24 months. Change in waist circumference was found to be highly correlated to change in weight. Between baseline and 4 months follow-up in the intervention group the change in waist circumference was not significant, whereas the weight change was significantly different. A mean increase of 0.9 kg may not be enough to create a significant difference in waist circumference, or this may be caused by measurement errors.

As one would expect due to the difference in time span, there was a tendency to a greater weight increase the last 20 months than the first four months in sample 1. However, no evidence of higher weight gain per four months was found between 4 and 24 months compared to the first four months.

Weight regain is common between one and two years after RYGBP (38, 104, 105). Several mechanisms of weight regain have been investigated and proposed; a decreased resting metabolic rate (RMR) (106), abnormal eating habits (107), sweet- and snack-eating patterns
(108), increased energy intake (40, 51, 53), and greater gastric capacity (40). It was expected that participation in an intervention group would lead to less weight regain compared study controls as concluded in a review by Livhits et al. where the mean length of follow-up in the included studies varied from 12-33 months (103). As four months is a rather short period of intervention, this probably explains why the present results do not match others regarding support group participation. The absence of significant differences after 24 months may be explained by the lack of statistical power due to the smaller sample size.

The Swedish SOS-study, who followed the participants for 10 years after bariatric surgery, found that the maximal weight loss occurred one year after surgery and that the weight regain started between one and two years after surgery (38). Another study found that weight regain became significant within 48 months after surgery (105). This means that the present study subjects were included around the point where weight regain often begins. The SOS-study also suggested some return of comorbidities along with the weight regain (38), thus it is important to try to control this problem as early as possible. It is observed that about 50% of the patients experience weight regain within 24 months after surgery (105). Factors associated with successful outcome (i.e. long-term EWL ≥ 50%) are EWL and body composition 1 year post surgery, total energy intake, and better social security (53). Cook and Edwards formulated six key concepts of habits in the most successful long-term gastric bypass patients; five well-balanced meals a day (three main and two snack), drinking water and not carbonated beverages, vitamin supplements, sleep seven hours per night on the average, exercising regularly, and to taking personal responsibility for their body weight and viewing the surgery as a tool, not a cure (109). Since the problem of weight regain after bariatric surgery is well known (38, 105), it is very important for the study subjects to take responsibility for their own body weight and personal habits.

It may be possible to reverse the development of weight regain. An intervention study by Faria et al. on subjects who sought treatment for weight regain more than two years after RYGBP, used a prescribed low-glycemic-load diet moderate in carbohydrates, but rich in whole grains, high in protein and low in fat. It lasted for three months and the patients were seen every 15th day. The result was considered good as half of the sample with unsuccessful weight loss (i.e. EWL < 50%) achieved at least 50% EWL after the intervention (88). The similarity to the present study is that both studies included participants who wanted extra follow-up, and who were followed closely with a group meeting about every 2 ½ week. On
the contrary, already existing weight regain was not a criterion to be included in the present study and a specific diet was not prescribed in the present study. The long-term effect of such a specific diet after RYGBP was not investigated, as the study only followed their participants for three months (88). It is uncertain for how long bariatric patients would be compliant to such a diet regimen. Hence it is difficult to determine whether this could have been a more effective approach in the present study group.

As the participants may already have experienced adversity with weight regain, motivation for life style habits that counteract this may be hard to retrieve. During the group meetings we repeatedly focused on factors for maintaining weight loss. However, several of the participants asked for more psychological guidance from a professional. Abnormal eating habits and low body image are highly present in obesity (110, 111). A psychologist was only offered at two of the 16 group meetings, and a psychologist present to address abnormal eating habits could maybe have yielded a greater effect on weight. Eating habits and meal patterns were not analyzed in this study. Thus, it is unknown whether these factors influenced the weight regain seen in the present study.

5.2.3 Energy intake and its evaluation

The results from the analyses of energy intake showed that the control group had a significant increase in median energy intake while the intervention group had a non-significant change. There was no difference between the groups in energy intake at 24 months.

As the weight did not differ between the groups, it is natural to assume that the energy intake did not differ either. However, both groups showed a tendency to weight increase which could explain the increase in energy intake in the control group but not the unchanged energy intake in the intervention group. Nevertheless, one would expect that change in weight and change in energy intake would correlate, but this was not evident in the present analyses. One possible explanation for the lack of correlation is that body weight is a result of personal habits over a longer period, while the energy intake only measures four days. Another possibility is that the correlation disappears due to under-reporting.

In the subgroup analysis of difference in energy intake between men and women, no significant difference was found. Obese men were found to have a higher RMR than women, due to a larger lean body mass (112). This was not found in a study of normal weight men and
women as the difference in RMR between the sexes became non-significant when adjusted for lean body mass. However, the difference in RMR remained significantly different after adjusted for body cell mass (113). This implies that men most often will have a higher energy requirement than women, but the difference in weight between men and women in the present study was not investigated and hence conclusion can not be drawn. In addition, as there were only seven men in sample 1, it was not a sufficient number of subjects to obtain the significant difference in daily energy intake between the sexes that would have been expected.

When the drop-outs were compared with the continuing study participants in baseline energy intake, the drop-outs had significantly lower energy intake than the ones who completed the study. Hence, high food and energy intake did not seem to have had an influence on withdrawal.

It was found that the present study participants were under-reporters at a group level both at baseline and 24 months data collection. There was no significant difference in reporting validity at group level between baseline and 24 months, or between the intervention and control group at 24 months. At the individual, level the majority of the study population was classified as accurate reporters at both data collection points. When evaluating the validity of the reported energy intake at group level, the cut-off values become narrower as the \( n \) increases (82). Hence, at the individual level where \( n = 1 \), the cut-off values become significantly wider. This means that more of the subjects studied were classified as under-reporters at group level than at an individual level. In addition, the sensitivity for detecting under-reporting when using a mean PAL of 1.55 was 0.50 and 0.52 while the specificity was 1.00 and 0.98 in men and women respectively (114). This means that there is about 50% chance of miss-classifying an actual under-reporter to another category than under-reporter when the energy requirement is high. However it is a very good chance, nearly 100%, to classify an accurate-reporter in the correct category. When evaluating the energy intake of all subjects with an equal PAL for all, around 20% are misclassified (82).

It is possible that some of the under-reporters actually were under-eaters as some of the participants previously said that they wanted to loose more weight and some did. Nevertheless, sample 1 had a tendency to increase their weight at the same time as the group was found to be under-reporters. This probably means that many of the subjects actually did under-report their intake.
The over-reporter at 24 months belonged to the intervention group, did not indicate any unusual days, increased the energy intake substantially from baseline and gained nearly six kg between the two data collection points. This might mean that this person did not over-report but were in a state where energy intake exceeded the requirement. The food diaries from this person were checked especially, and the intake of fast food and different desserts was very high. One person in the control group also had a very high energy intake. This person was not classified as an over-reporter, and gained over 7 kg during the two years between data collection. This could mean that this person was an over-eater in proportion to the requirement. However, the classification of this study participant as an acceptable reporter might also illustrate the problem with wide cut-off values at the individual level.

The present results in energy intake was found to be about the same as Lindroos’ findings two years after gastric bypass surgery (51). Their data corresponds to the present baseline data with respect to time after surgery. The energy findings from the present study were lower than Odstrcil’s data 14 months after RYGBP (40). Results from yet another study which investigated the energy intake 18-48 months after RYGBP surgery found an average energy intake of 7251 kJ (1733 kcal) (115), which is quite similar to the 24 months data of the present study. When comparing the results from energy intake reports in the present study to other findings, it is a limitation of consideration that different methods are used and that the proportion of men differs between the samples. In sample 1 in the present study, there were 13% men. In Lindroos et.al, there were 35% men (51) and the method was previously described in table 2 together with Odstrcil et.al which study group consisted of 22% men (40). The study with the 18-48 month post surgery data only had 7.2% men. This study used 24-hour recall as method of dietary assessment (115). However, both prospective methods like four-day food diaries and weighed food records and retrospective methods such as the dietary questionnaires, have been shown to have a bias of under-reporting. Additionally, none of the methods were found to be better than the other (116). In the light of these findings and the fact that the men were in minority in the referred studies, energy intake was chosen to be compared even though the methods differed.

With current knowledge, no other study has investigated the difference in energy intake and it relation to attendance in support groups of any kind after bariatric surgery. Nonetheless, participation in support groups is associated with greater weight loss compared to non-
participation (87, 103), and hence the energy intake probably also differs between attenders and non-attenders. However, no such differences were found.

During the last two decades of the 20th century, biomarkers of intake and measures of energy expenditure revealed a frequent bias of under-reporting actual energy intake. It is today an acknowledged problem that invalid reporting of energy intake in studies of nutrition and health occur (82). Under-reporting is especially a problem in dietary assessments of obese (117-120). This phenomenon is also found in monozygotic twin pairs with one obese and one normal weight twin, where under-reporting of energy intake and over-reporting of physical activity was found in the obese twin but not in the normal weight twin (121). It was found that, at an individual level, the present study group under-reported both at baseline and 24 months. A review article stated that most studies appear to have a lower reported energy intake than the measured energy expenditure (120). This review also found an average of under-reporters of 41%, while others found under- and over-reporting respectively to be 35% and 2% among Danish men (117), and 33.2% and 11.9% in a large Irish study (119). The average of under-reporters corresponds well with present findings and the study among Danish men corresponds well with present percentage of over-reporting at 24 months. The level of under-reporting does not change statistically from baseline to 24 months in the present study. Nevertheless, results from another study showed that the prevalence of under-reporting and the severity of the misreporting significantly increased in overweight and obese women who followed a behavioral weight-loss program for six months (122). As this study only followed their participants for six months, it is not possible to predict if this reporting bias would have continued, but it is of interest that participation in a treatment program may influence the degree of under-reporting. The participants in the present study were special because they have lost a lot of weight and several of the subjects were not obese anymore. A study in Denmark has investigated whether previous and current body size affected the validity of reporting energy intake among men. They found that current obese men were more likely to under-report than the non-obese, and most interesting, they found that among those who were not currently obese, under-reporting was more pronounced among those who had previously been obese than those who had not (117). In women, a higher prevalence of under-reporting was found in those with a higher BMI compared to the ones with lower BMI (118).

In the present study a significant difference between men and women in the validity of energy reporting was not found. This may be due to the lack of power since there are few men.
included in the analysis. However, the findings in the literature are not consistent. In the study of a large Irish population, using a food frequency questionnaire (FFQ) as dietary assessment method, they found that men were more likely to be under-reporters than women (119). However, the present result is consistent with other findings (114, 120).

The food diary could have been collected for seven days, including all week days, instead of just four days in a week. However, the mean cut-off value did not improve with increasing the number of days above four at group level. On the contrary, at an individual level the ability to detect invalid reports increased up to seven days (82). The actual PAL of each participant was not analyzed in this thesis and that raises the question whether the sensitivity would improve if the BMR was measured rather than estimated. When the sensitivity between reported and estimated PALs have been investigated, a very small difference in sensitivity between the two methods was found at an individual level (114). Nevertheless, using measured BMR in small samples as in the present study may lead to fewer misclassifications which might be important in small studies were each individual have greater influence on the results (114).

In summary, there is not yet an accurate method for determination of energy intake (120). A possible solution is to confront study subjects with earlier results from food diary validation. The validity of food reporting improved in a group of dietitians when they were confronted with previous invalidity (123). Although this group is very special and not comparable to the study participants in the present study, confronting the subjects with poor validity may yield some of the same effect. Nonetheless, it is still very difficult to obtain accurate data on energy intake at the individual level.

5.2.4 Health related quality of life

The level of withdrawal and missing items in the SF-36 did not differ between the control and intervention group. Some of the items were missing in certain cases. It might be that some items were harder to answer than others, either because it was difficult or because it was a sensitive question for the individual. Items may also have been forgotten when the questionnaires were completed.

We found that the RP, SF and RE dimensions had quite a prominent ceiling effect and that the BP dimension had some floor effect. When measuring several health concepts in a short questionnaire, this does not allow a great level of detail (59). This might mean that the
questionnaire does not differentiate well enough between the study subjects and thus not
capture the differences between subjects. The RP and RE scales ask for limitations in the
performance of these domains. Consequently, healthy people will score the highest score
possible and thus would have scored 100% even with a larger scale. BP is more pronounced
in subjects experiencing current health problems (124), which might explain the ceiling effect
seen in present data. However, ceiling and floor effect are not an unknown result of the SF-
36. RP and RE are usually the two dimensions with most problem with this effect, while PF,
GH, VT and MH are often most precise (75). The reliability of the RP and RE scales
improved in the Swedish validation of the SF-36 version 2.0 when the response format was
changed (74). However, the RP, RE and SF still had a ceiling effect over 60%. The floor
effect was on the contrary very limited with RP as the highest with 1.5%. The BP scale had a
floor effect of 1.0% (74). The present study showed less ceiling effect than the Swedish norm,
but some higher floor effect in the BP dimension and about the same floor effect in the RP
dimension. Also in the present study were the PF, GH, VT, and MH dimensions the most
precise ones.

The strongest correlation between dimensions and within the physical health summary in the
present study was between RP and BP while the weakest correlation was found between PF
and MH. The strongest correlation within the mental health summary was between RE and
MH and the strongest correlation across the two summaries was found between GH and VT.
The same pattern of association as in the present study, both across summaries and between
summaries, is also most frequently seen by others (74, 75, 124).

Several of the dimension scores showed a statistically significant decrease within each group
without a great discrepancy between the scores. The VT dimension in the intervention group
even had a statistically significant result with equal median scores at baseline and 4 months.
This is due to the comparison of ranks in the non-parametric test. As previously mentioned,
all comparisons were done with both parametric and non-parametric tests to see if there was
any difference, and there was none between the tests in this case either. Since this
phenomenon occur, it is important to separate between statistical significance and clinical
significance (125). A difference of 15 points from one score to another is regarded as clinical
significance (99). The only dimension with a clinical significant decrease, is the VT
dimension of the control group. This dimension belongs to the mental health summary when
aggregating scores. However, the negative changes in scores that occurred in both groups
happened over a time span of just four months, and if the deterioration was to continue in the same pattern it would be of great concern. We might also see a greater difference between the intervention and control group as the control group already had a greater decrease in mental health summary. If so, a group intervention might not only have a positive effect on weight and other health measures, but also on life quality.

We did not find a statistical difference in scores between the groups at 4 months, but a significant difference in change in mental health measure and change in total scores when outliers were removed was found. The control group also had a significantly more reduced treatment effect in mental health measure than the intervention group.

No significant correlation between change in weight and HRQoL was found. On the other hand there was a significant correlation between age and total scores. The significant results found from regression analysis were lost when adjusting for the different variables, although a tendency of relation was seen between increasing age and total score and mental health measure. Nevertheless, due to lack of strong results, the causes of the decline in HRQoL scores can not be determined. In the study by Karlsson et.al they found that two years after surgery, improvements in HRQoL and weight loss were significantly associated and weight regain showed the opposite (49). Higher age is associated with poorer SF-36 scores, but this is applicable for those over 70 years (124), and no one of that age was included in the present analyses. More than 2/3 of the present study group was between 40-59 years. Those between 40-49 years are shown to score highest in the RE dimension and those between 50-59 highest in the dimensions that aggregate to the mental health summary (124). This may explain why age was seen to have a tendency of relation to increased scores after adjusting for sex and weight change. The effects of sex were in favor of being female, but disappeared after adjusting for other variables. However, women have been found to score significantly lower than men in all scores except for the GH scale (124).

When comparing the intervention and the control group to the Swedish norm, several scores were lower. However, not all have a clinical significant difference (99). The intervention group had median scores that were >15 points lower than the norm data in the BP and GH dimensions whereas the control group had median scores that were >15 points lower than the norm data in the BP, GH and VT dimensions. This means that the participants in the intervention group and control group had clinically worse scores than the norm population in two and three dimensions respectively. However, the HRQoL before surgery was not
investigated but it can be assumed, based on background data, that the pre-operative scores would have been significantly lower. The present data was collected 18-28 months after surgery. Another study also compared RYGBP patients in the same time span after surgery as the present study. It found statistically significant better scores in the VT, PF, and GH domains compared to the norm population (48). None of the domains were found to be significantly worse or with a clinical significant difference of ≥15 points.

It is shown that weight regain decreases the HRQoL (49), and both the intervention and the control group had a tendency to weight increase. The weight regain is shown to flatten from six years after surgery and hence the HRQoL scores stabilizes (49). This implicates that if the weight regain can be stopped, a decline in HRQoL might also be prevented. That possibility just adds to the importance of avoiding significant weight regain to achieve the best long-term result possible both in health and life quality. Nonetheless, the intervention group had significantly less deterioration in the mental summary score compared to the control group. Thus it may seem like the intervention group had a better result in the mental part of HRQoL compared to the control group even though they did not loose significantly more weight. A possible explanation is that just to be in contact with and seen by health professionals and peers have a positive effect on mental HRQoL.

Several studies have found a significant improvement in HRQoL after bariatric surgery compared to the pre-surgery level (48, 57, 99, 126) and one found that this effect sustained even 10 years after surgery (49). However, with current knowledge, no studies have investigated the effect of post-surgical group intervention on QoL either with or without a control group. The effect of attendance in support groups after surgery has focused mainly on weight loss (83, 85, 86). Although weight loss magnitude and HRQoL have shown to correlate (49) and support group attendance is associated with greater weight loss than to not attend (84, 103), it would have been interesting to solely investigate the effect on QoL of such groups. One study investigated the effect of group therapy to enhance motivation and decision making for treatment of obesity in a small group of obese who had a mental disorder. The results showed positive effects on mental QoL after 12 group meetings. Despite that it was not an intention of this study, the participants also lost weight during this period (127). For that reason it is difficult to determine whether the positive results occurred due to the weight loss, the group therapy or both. Even so, there was an improvement in mental QoL in a group of
people struggling with psychological problems. This might implicate that benefits of group sessions on QoL do occur.

5.3 Future research

Future research directions should probably focus more on individual nutritional counseling and hence enhance compliance to nutritional and behavioral advices to ultimately improve weight loss. It might also be of a greater clinical significance to identify the individuals with the most pronounced weight regain, for example from the follow-up sessions in the usual post-surgery care scheme, and start intervention among these subjects in stead of recruiting from the total population of post RYGBP patients. This might improve the success of the surgery in a larger part of participants who have undergone RYGBP surgery. As there is a great possibility of self-selection bias in the present and similar studies, future research should make an effort to collect information about eligible candidates who do not want to participate. Only then can research make assumption about its generalizeability.

We know that obesity and HRQoL are inversely related, but there is no evidence on whether participation in groups of peers led by health personnel may improve HRQoL regardless of weight change. Thus, further research on possible benefits of group interventions after RYGBP surgery on HRQoL matched with a control group is needed. Perhaps the challenge of defining success criterions on long-term HRQoL should be assessed. Without consensus about this, it is difficult to compare scientific results.

There is a continuous need for studies with longer follow-up. More knowledge about the long-term outcomes will both identify positive and negative results and maybe give an indication on when relapse of comorbidities and other adverse effects begins and who is at risk for such events. Only with this knowledge are we able to get the best long-term results possible.
6 Conclusion

In the present study we have shown that

a. change in weight and waist circumference
   i. within the intervention group showed different patterns. The weight increased significantly from baseline to 4 months, while the increase from baseline to 24 months only showed a tendency to increase. Waist circumference did not change significantly between baseline and 4 months or between baseline and 24 months of intervention.
   ii. did not differ between the control and intervention group at neither the 4 months nor the 24 months data collection.

b. the energy intake did not change significantly in the intervention group after 24 months of additional follow-up while the energy intake increased significantly between baseline and 24 months in the control group. However, the energy intake did not differ significantly between the two groups at the 24 months data collection. The change in energy intake and change in weight did not correlate.

c. evaluation of health related quality of life
   i. showed that there were no significant differences between the groups in either total, mental or physical scores at 4 months. However, the control group decreased their mental scores significantly more than the intervention group. The total score was also significantly more reduced in the control group compared to the intervention group when outliers were removed.
   ii. change in weight and change in HRQoL was not found to be correlated neither in total score, mental or physical health measures.

In conclusion, present data did not show statistical differences between the groups in measures or scores at either 4 months or 24 months after study start. Nonetheless, we found some differences within the groups; the control group significantly reduced their mental health scores more than the intervention group and they also had a significant increase in
energy intake during the 24 months of study. However, only one third of the total study population has finished the study at 24 months. Thus, the 24 month data suffers from lack of power to be able to reveal possible systematic differences.

The study subjects in both groups showed a tendency to increase their weight during the study and the control group had lower HRQoL total and mental scores after 4 months. As these factors have been shown by others to correlate, it is important to prevent as much weight regain as possible, both concerning somatic and mental health. Future results from this study may reveal whether a group intervention should be a part of the usual care after RYGBP surgery or not.
References


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73. Løken EB. Personal Communication. Oslo;2011.


Appendices

Appendix 1. Approval from the Regional Committee of Medical Ethics

Klinisk ernæringstidolog Susanna Elisabeth Hanevold
Aker universitetssykehus
Trondheimsveien 235
0514 Oslo

Dato: 25.06.08
Deres ref.: 08/302d, 2008/6365

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Ost D (REK Sør-Ost D)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 85 05 93
Telefaks: 22 85 05 90
E-post: t.middelthon@medisin.uio.no
Nettadresse: www.etikkom.no

Kost- og aktivitetsveiledning etter gastric bypass-operasjon
Søknad om opprettelse av forskningsbiobank

Vi viser til svar på merknader (udørert) mottatt 16.06.2008 med følgende vedlegg: Reviderte informasjonskrav.


Komiteen finner at dens merknader er tilfredsstillende besvart.

Komiteen har følgende merknader til søknad om opprettelse av forskningsbiobank:
Komiteen har ingen innvendinger mot opprettelse av forskningsbiobank og videre sender søknaden om opprettelse av denne sammen med kopi av dette vedtaket til Helsedirektoratet for endelig godkjenning.

Vedtak:
Komiteen godkjener at prosjektet gjennomføres slik det nå foreligger

Med vennlig hilsen

Stein A. Evensen (sign.)
Professor dr.med.
Leder

Ingrid Middelthon
Komitésekretær

Kopi:
- Forskningscenteret, Trondheimsveien 235, 0514 Oslo
Appendix 2. Approval from Biohealth Norway

Klinisk ernæringsfysiolog Susanna E Hanevold
Aker universitetssykehus
Trindhemsveien 235
0514 OSLO

Vedrørende opprettelse av forskningsbiobank - Kost- og aktivitetsveiledning etter gastric bypass-operasjon

Helsedirektoratet viser til brev om ovennevnte, som vi mottok 1. juli 2008.

Direktoratet er delegert myndighet til å vurdere meldinger om opprettelse av forskningsbiobanker i enhold til biobankloven § 4.

Direktoratet har ingen innvendinger mot at forskningsbiobanken opprettes. Vi forutsetter at opprettelse av forskningsbiobanken oppfyller eventuelle krav til godkjenning, konsesjon mv, som følger av annet regelverk.

Vi har registrert at man ønsker å benytte personopplysninger til eventuelle oppfølgingsstudier uten at det innhentes samtykke, jf pkt 14 i biobankmeldingen. Det er uklart hva som menes med dette. Dersom ønsket bruk av opplysninger/biobankmateriale som er innhentet i forbindelse med studien faller utenfor det opprinnelige samtykke det må innhentes nytt samtykke, jf biobankloven § 13. Innhenting av helseopplysninger ut over det som framgår av informasjonskravet krever også nytt samtykke fra deltakerne, eller dispensasjon fra taushetsplikten.

Biobankregisteret orienteres om direktoratets vurdering.

Vennlig hilsen

Rolf Dalseg e.f. seniorrådgiver

Anne Forus seniorrådgiver

Dokumentet er godkjent elektronisk

Kopi:
Biobankregisteret melding nr 2336
Rek Ser-Øst D 08/302d, 2008/6365

Helsedirektoratet - Divisjon spesialisthelsetjenestor
Avd. bioteknologi og generelle helsetil enver.
Anne Forus, tlf.: 24 16 31 99
Postadresse: Postboks 7000. St. Olavs plass, 0130 Oslo • Besøksadresse: Universitetsgata 2, Oslo
Tlf.: 810 20 050 • Faks: 24 16 30 01 • Org. nr.: 983 544 622 • postmottak@helsedir.no • www.shdir.no
Appendix 3. Information about the study and written informed consent given to the study subjects.

Kost- og aktivitetsveileddning etter gastric bypass-operasjon
Hoveddel 10.06.2010
Forespørsel om deltakelse i forskningsprosjektet

"Kost- og aktivitetsveileddning etter gastric bypass-operasjon"
forebygging av ny vektøkning etter at maksimalt vekttap er oppnådd

Bakgrunn og hensikt

Formålet med studien er å undersøke sammenhengen mellom vektendring etter gastric bypass-operasjon og utvikling/tilbakefall av overvektrelaterte sykdommer, spesielt diabetes type II. Fedmekirurgi er en effektiv behandling av diabetes type II, men ved ny vektøkning er det igjen risiko for tilbakefall. Vi ønsker derfor å registrere forekomst av diabetes type II og blodglukosekontroll ved inklusjon og studieslutt ved hjelp av glukoselastningstest, blodskuker, HbA1c (mål på blodukkerkornivå over tid) og inkretninormoner (har betydning for blodukkerreguleringen). Vi vil innhente informasjon fra din journal som kan være av interesse i forbindelse med sykelig overvekt og gjennomført fedmeoperasjon. Informasjon av interesse er for eksempel vektsrelaterte- og antropometriske mål, diabetesrelaterte mål, laboratorieverdier og medikamentbruk.

Vi ønsker også å undersøke om vektendring påvirker livskvaliteten. Deltakerne skal derfor underveis i intervensionen fylle ut livskvalitetskjema.


Hva innebærer studien?
Dere som inkluderes i studien deles inn i 2 grupper (gruppe A og B). Begge gruppene følger vanlig prosedyre, det vil si individuelle konsultasjoner 2 år og 5 år etter operasjon, samt gruppemøter 3 og 4 år etter operasjon. I tillegg skal begge grupper, ved studiestart og studieslutt, fylle ut matbøker, fylle ut aktivitetskjema og livskvalitetskjema, registrere bruk av medikamenter (blodtrykk, kolesterol, diabetesmedisiner), måle blodtrykket, ta blodprøver og registrere midje- og hofteomkrets, vekt, BMI og festprosent (gruppe B skal gjenta dette underveis i studien). Noen av deltakerne vil også bli bedt om å gjennomføre en glukosebelastningstest for å undersøke endringer i insulinfølsomheten.

Gruppe B skal i tillegg delta på 12 regelmessige gruppemøter det første året, deretter 4 gruppemøter det andre året. På møtene vil ulike tema tas opp. Det er 30 minutter med fysiske aktivitet hver gang. Deltakelse i studien krever derfor at du er istand til å delta i fysisk aktivitet.

Mulige forderer og ulemper
Fordelen med å delta i studien er at du får ekstra oppfølgning sammenlignet med dagens tilbud. Ekstra oppfølgning kan redusere risikoen for ny vektøkning etter fedmeoperasjonen. Deltakelse i studien krever at du møter til regelmessige konsultasjoner på Aker Universitetssykehus HF.

Hva skjer med prøvene og informasjonen om deg?
Prøvene tatt av deg og informasjonen som registreres om deg, skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjenende opplysninger. En kode knytter deg til dine opplysninger og prøver
Kost- og aktivitetsveiledning etter gastric bypass-operasjon
Hoveddel 10.06.2010
gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til
navnelisten og som kan finne tilbake til deg.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke
til å delta. Dette vil ikke få konsekvenser for din videre behandling. Om du nå sier ja til å delta i studien,
kun du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere
ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Susanna Hanvold på e-mail
prosjekt.ern@oslo-universitetssykehus.no eller på tlf: 22894872.

Ytterligere informasjon om studien finnes i Kapittel A - utdypende forklaring om hva studien innebærer.
Ytterligere informasjon om biobank, personvern og dine rettigheter finnes i Kapittel B - Personvern,
Biobank og økonomi.
Samtykkeerklæring følger etter kapittel B.

Kost- og aktivitetsveiledning etter gastric bypass-operasjon
Hoveddel 10.06.2010

Kapittel A- utdypende forklaring om hva studien innebærer

Etter en fedmeoperasjon oppnår de fleste et tilfredsstillende vekttap, men det er viktig med varig
livsstilendring for å opprettholde dette vektapet. Ønsker du å delta i denne studien får du en tettere
oppfølging enn dagens regime tilsier. Tettere oppfølging kan gjøre det lettere å opprettholde oppnådd
vektap.

Ønsker du ikke å delta i studien vil du likevel få tilbud om å fortsette å følge dagens
oppfølgingsregime. Dagens regime går ut på at fedmeopererte følges opp med individuelle
konsultasjoner av klinisk ernæringsfysiolog 2 mnd., 6 mnd., 1år, 2 år og 5 år etter operasjon. I tillegg
tilsyn gruppermøter 3 og 4 år etter operasjon.

For å kunne delta er det flere kriterier som må oppfylles:

- Inklusjonskriterier
  o Gastric bypass-operert for 1 ½ - 2 ½ år siden.
- Ekklusjonskriterier
  o Pasienter med alvorlige komplikasjoner som følge av fedmeoperasjonen
  o Immobile pasienter
  o Fremmedspråklige pasienter som ikke forstår norsk.
Hva forventer vi av deg som ønsker å delta i studien?
Vi forventer at du, så langt det er mulig, møter opp til avtalt time. Dette innebærer følgene:

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                • Livskvalitetsskjema  
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                • Midje/hofteomkrets, vekt, fettprosent  
                • Registrere medikamentbruk  
                • Glukosebelastningstest/Clamp* | |
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                • Blodtrykk  
                • Midje/hofteomkrets, vekt, fettprosent  
                • Registrere medikamentbruk | |
| 12 mnd.       | • Matdagbøker  
                • Aktivitetsskjema  
                • Livskvalitetsskjema  
                • Fastende blodprøver  
                • Blodtrykk  
                • Midje/hofteomkrets, vekt, fettprosent  
                • Registrere medikamentbruk | • Matdagbøker  
                • Aktivitetsskjema  
                • Livskvalitetsskjema  
                • Fastende blodprøver  
                • Blodtrykk  
                • Midje/hofteomkrets, vekt, fettprosent  
                • Registrere medikamentbruk |
| 18 mnd.       | Gruppeundervisning (dagens regime) | Gruppeundervisning (dagens regime) + vekt |
| 2 år          | • Matdagbøker  
                • Aktivitetsskjema  
                • Livskvalitetsskjema  
                • Fastende blodprøver  
                • Blodtrykk  
                • Midje/hofteomkrets, vekt, fettprosent  
                • Registrere medikamentbruk  
                • Glukosebelastningstest/Clamp* | |


- Blodprøvene skal tas etter 12 timers faste. I tillegg til de standard blodprøvene som blir tatt ved vanlig kontroll, ønsker vi blant annet å måle nivå av homocystein og cystein.
Kapittel B - Personvern, biobank og økonomi.

Personvern

Oslo Universitetssykehus HF ved administrerende direktør er databehandlingsansvarlig.

Biobank

Rett til innsyn og sletting av opplysninger og prøver
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er innlagt i analyser eller brukt i vitenskapelige publikasjoner.

Informasjon om utfallet av studien
Deltakerne har etter at alle analyser er fuldført, rett til å få informasjon om resultatet av studien.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien "Kost- og aktivitetsveileddning etter gastric bypass-operasjon". Jeg godtar også at innsamlet materiale kan benyttes til videre forskning etter at hovedstudien er avsluttet.

(Signet av prosjektleder, dato)

Jeg bekrerter å ha gitt informasjon om studien

(Signatur, dato)
Appendix 4. Information letter to eligible subjects.

Forespørsel om deltakelse i forskningsprosjektet

"Kost- og aktivitetsveiledning etter gastric bypass-operasjon"
forebygging av ny vektøkning etter at maksimalt vekttap er oppnådd

Bakgrunn og hensikt

Formålet med studien er å undersøke sammenhengen mellom vektendring etter gastric bypass-operasjon og utvikling/tilbakefall av overvektsrelaterte sykdommer, spesielt diabetes type II. Fedmekirurgi er en effektiv behandling av diabetes type II, men ved ny vektøkning er det igjen risiko for tilbakefall. Vi ønsker derfor å registrere forekomst av diabetes type II og blodglukosekontroll ved inklusjon og studieslutt ved hjelp av glukosebelastningstest, blodsukker, HbA1c (mål på blodsukkernivå over tid) og inkretinhormoner (hårbetydning for blodsukkerreguleringen). Vi vil innta informasjon fra din journal som kan være av interesse i forbindelse med sykelig overvekt og gjennomført fedmeoperasjon. Informasjon av interesse er for eksempel vektrelaterte- og antropometriske mål, diabetesrelaterte mål, laboratorieverdier og medikamentbruk.

Vi ønsker også å undersøke om vektendring påvirker livskvaliteten. Deltakere skal derfor underveis i intervensionen fylle ut livskvalitetskjemene.

Hva innebærer studien?

Mulige fordeler og ulemper
Fordelen med å delta i studien er at du får ekstra oppfølgning sammenlignet med dagens tilbud. Ekstra oppfølgning kan redusere risikoen for ny vektøkning etter fedmeoperasjonen. Deltakelse i studien krever at du møter til regelmessige konsultasjoner på Oslo Universitetssykehus Aker.

Hva skjer med prøvene og informasjonen om deg?
Prøvene tatt av deg og informasjonen som registreres om deg, skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.
**Frivillig deltakelse**

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta. Dette vil ikke få konsekvenser for din videre behandling. Om du nå sier ja til å delta i studien, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling.

**Er dette noe for deg?**


Meld din interesse på følgende måte:
1. E-post: til prosjekt.ern@oslo-universitetssykehus.no (merk e-posten med “prosjekt 2010”)
2. Brev: fyll inn opplysninger i skjemaet på neste side
3. Telefon: 22894872 (Vær oppmerksom på at det kan være vanskelig å oppnå kontakt på tlf).

Husk å oppgi hvilket informasjonsmøte som passer best:

1. Jeg ønsker å delta på informasjonsmøtet onsdag 16. juni kl 14
2. Jeg ønsker å delta på informasjonsmøtet onsdag 23. juni kl 14
3. Jeg ønsker å delta på informasjonsmøtet onsdag 25. august kl 16
4. Jeg ønsker å delta, men kan ikke komme på informasjonsmøtet

Når passer det evt å komme:

(Vedlagt følger et livskvalitetsskjema (SF 36). Hvis du ønsker kan dette medbringes ferdig utfylt til informasjonsmøtet.)

Med vennlig hilsen

Susanna Hanvold, Klinisk ernæringsfysiolog
Oslo universitetssykehus Aker
Tlf: 22894872
Fyll inn kontaktinformasjonen og send til følgende adresse:

Susanna Hanvold
Seksjon for klinisk ernæring
Oslo universitetssykehus Aker
Trondheimsveien 235
0514 Oslo

Ja, jeg ønsker å delta på informasjonsmøtet om forskningsprosjektet "Kost- og aktivitetsveiledning etter gastric bypass-operasjon".

Navn:__________________________________________

Adresse:________________________________________

Tlf:____________________________________________

E-mail:_________________________________________

Kryss av:

1. Jeg ønsker å delta på informasjonsmøtet **onsdag 16. juni kl 14**  □
2. Jeg ønsker å delta på informasjonsmøtet **onsdag 23. juni kl 14**  □
3. Jeg ønsker å delta på informasjonsmøtet **onsdag 25. august kl 16**  □
4. Jeg ønsker å delta, men kan ikke komme på informasjonsmøtet  □
   Når passer det evt å komme:______________________
   (Det blir satt opp ekstra informasjonsmøter ved behov)

_________________________________________________________________________

111
Appendix 5. Extract of the food diary

Dagbok

Fyll inn:

Kjønn

Alder år

Ukedag 1=mandag, 2=tirsdag, 3=onsdag, 4=torsdag, 5=fredag, 6=lørdag og 7=søndag

Dato . . .

Var denne dagen en vanlig dag? Skriv ja eller nei i rutene.

Hvis det var en uvanlig dag, forklar hvorfor denne dagen var uvanlig:

Hvor finner jeg matvarene i dagboken?

<table>
<thead>
<tr>
<th>Drikke</th>
<th>Side</th>
<th>Side</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brød</td>
<td>4</td>
<td>Grønnsaker</td>
</tr>
<tr>
<td>Smør/margarin</td>
<td>5</td>
<td>Saus/dressing</td>
</tr>
<tr>
<td>Pølleg</td>
<td>5-7</td>
<td>Is/dessert</td>
</tr>
<tr>
<td>Yoghurt</td>
<td>7</td>
<td>Kaker/kjeks</td>
</tr>
<tr>
<td>Frokostgryn/grøt</td>
<td>8</td>
<td>Frukt/bær</td>
</tr>
<tr>
<td>Kjøttretter</td>
<td>9-10</td>
<td>Snacks</td>
</tr>
<tr>
<td>Fiskeretter</td>
<td>11</td>
<td>Godterier</td>
</tr>
<tr>
<td>Andre retter/salater</td>
<td>12</td>
<td>Tran/kosttilskudd</td>
</tr>
</tbody>
</table>

HUSK:

Alt du spiser/drikker skal skrives opp
Sett ikke kryss i dagboken
Sett bare bokstaver i de orange rutene
Sett bare tall i de sorte rutene

20003822
### Drikke

For størrelsen på glasset du drikker av, se bildenserie 1. Fyll inn bokstaven i den orange ruten.

<table>
<thead>
<tr>
<th></th>
<th>Antall</th>
<th>kl. 6-10</th>
<th>kl. 10-14</th>
<th>kl. 14-18</th>
<th>kl. 18-22</th>
<th>kl. 22-6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vann</td>
<td>glass</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Helsmelk, søt/sur (eks. helmelk, kefir)</td>
<td>glass</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Lettmelk, søt/sur (eks. lettmelk, Cultura)</td>
<td>glass</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ekstra lett lettmelk</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Skummet melk</td>
<td>glass</td>
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<tr>
<td>Dramke/ogurt</td>
<td>glass</td>
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<tr>
<td>Sjokolademelk av helmelk (eks. O'boy, Nesquik)</td>
<td>glass</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sjokolademelk av lettmelk (eks. Nesquik, Litago)</td>
<td>glass</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sjokolademelk av ekstra lett lettmelk (eks. O'boy)</td>
<td>glass</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sjokolademelk av skummet melk (eks. O'boy, Nesquik)</td>
<td>glass</td>
<td></td>
<td></td>
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<tr>
<td>Litago sjokolademelk</td>
<td>1/2 liter</td>
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<tr>
<td>Kakao av helmelk</td>
<td>kopp</td>
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<tr>
<td>Kakao av lettmelk</td>
<td>kopp</td>
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<tr>
<td>Kakao av ekstra lett lettmelk</td>
<td>kopp</td>
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<td>Kakao av skummet melk</td>
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<tr>
<td>Appelsinjuice</td>
<td>glass</td>
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<tr>
<td>Eplesjuice/plemost</td>
<td>glass</td>
<td></td>
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<tr>
<td>Nektar (eks. eple, tropisk frukt, annen frukt)</td>
<td>glass</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Brus med sukker (eks. Cola, Solo)</td>
<td>glass</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Brus med sukker (eks. Cola, Solo)</td>
<td>1/2 liter</td>
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<tr>
<td>Brus, k unstig spet (eks. Cola light, Solo lett)</td>
<td>glass</td>
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<tr>
<td>Brus, k unstig spet (eks. Cola light, Solo lett)</td>
<td>1/2 liter</td>
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<td>Ost</td>
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<td>kl. 22-6</td>
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<tr>
<td>Hvitost helvet 27% fett (eks. Jarlsberg, Norge)</td>
<td>til antall skiver</td>
<td></td>
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<tr>
<td>Hvitost halvhet 16% fett (eks. Norvegia katterø)</td>
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<td>Brunost helvet (eks. Geitost, G35, Fjelmsyost)</td>
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<td>Smøreost, vanlig (eks. Bæcomost, Snøfrisk)</td>
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<td>Smøreost, mager (eks. mager skinkost)</td>
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<td>Kremost (eks. Philadelphia, Gourmetoster)</td>
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<td>Dessertost (eks. Brie, Gräddost, Riddrøst)</td>
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<td>Makrell i tomat, rakt makrell</td>
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<td>Sardiner, sursild, angsos</td>
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Annet
beskriv best mulig hva, hvor mye og når:  

20003822
### Frukt/bær

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<td>Melon, vann</td>
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<td>Melon, eks. cantalup</td>
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<td>Jordbær (friske/frosne)</td>
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<td>Kiwi</td>
<td>stk</td>
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**Anmerkung:**
Beskriv best mulig hva, hvor mye og når.

### Snacks

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<th>kl. 18-22</th>
<th>kl. 22-6</th>
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</thead>
<tbody>
<tr>
<td>Potetgull, vanlig (1 neve = 8 flak)</td>
<td>neve</td>
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<td>Potetgull, vanlig</td>
<td>pose (300g)</td>
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<tr>
<td>Potetgull, lett/ potetskrueer (1 neve = 8 flak)</td>
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<tr>
<td>Potetgull, lett/ potetskrueer</td>
<td>pose (300g)</td>
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<td>Ostekøk (1 neve = 8 ostebuer)</td>
<td>neve</td>
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<tr>
<td>Macchips (1 neve = 8 flak)</td>
<td>neve</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peanutter</td>
<td>pose (100g)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Popcorn</td>
<td>neve</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dip (eks. remme mydpmix)</td>
<td>spiseskjæer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Anmerkung:**
Beskriv best mulig hva, hvor mye og når.

---

20003822

17
Appendix 6. Extract of the picture booklet.

1. GLASS
2. BRØDTYKKELSE

3. SMØR/MARGARIN PÅ BRØD
4. CORNFLAKES (FROKOSTBLANDING)

5. GRØT
6. SPAGHETTI / PASTA (RIS)

7. POTETMOS
10. SALAT

11. KJØTTSAUS (LAPSKAUS)
12. PIZZA, TREKANTSTYKKER

13. PIZZA, FIRKANTSTYKKER
14. FISK

15. IS (PUDDING)
Appendix 7. The Medical Outcomes Study 36-item Short-Form Health Survey

SF-36 SPØRRESKJEMA OM HELE


Hvert spørsmål skal besvares ved å sette et kryss (X) i den boksen som passer best for deg. Hvis du er usikker på hva du vil svare, vennligst svar så godt du kan.

1. Stort sett, vil du si at din helse er

<table>
<thead>
<tr>
<th>Utnyttet</th>
<th>Meget god</th>
<th>God</th>
<th>Nokså god</th>
<th>Dårlig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Sammenlignet med for ett år siden, hvordan vil du si at din helse stort sett er nå?

<table>
<thead>
<tr>
<th>Mye bedre nå enn for ett år siden</th>
<th>Litt bedre nå enn for ett år siden</th>
<th>Omtrent den samme som for ett år siden</th>
<th>Litt dårligere nå enn for ett år siden</th>
<th>Mye dårligere nå enn for ett år siden</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrænser deg i utførelsen af disse aktivitetene nå? Hvis ja, hvor mye?

<table>
<thead>
<tr>
<th>a. Anstrengende aktiviteter som å løpe, løfte mange gjenstander, delta i anstrengende idrett</th>
<th>Ja, begrenser meg mye</th>
<th>Ja, begrenser meg litt</th>
<th>Nei, begrenser meg ikke i det hele tatt</th>
</tr>
</thead>
<tbody>
<tr>
<td>b. Moderate aktiviteter som å flytte et bord, støvle, gå en tur eller drive med hagenbeid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Løfte eller bære en handlekar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Gå opp trappen flere etasjer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Gå opp trappen en etasje</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Bøye deg eller sitte på lut</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. Gå mer enn 10 kilometer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. Gå noen hundre meter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Gå hundre meter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j. Vask eller klei på deg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(SF-36 Norwegian Version 2 - preliminary version)
Copyright 1992 The Health Institute, New England Medical Center, Boston, Massachusetts.
All rights reserved.
4. I løpet av de siste 4 ukene, hvor ofte har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

<table>
<thead>
<tr>
<th></th>
<th>Hele tiden</th>
<th>Mye av tiden</th>
<th>En del av tiden</th>
<th>Litt av tiden</th>
<th>Ikke i det hele tatt</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Du har måttet redusere tiden du har brukt på arbeid eller på andre gjøremål</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Du har utrettet mindre enn du hadde ønsket</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Du har vært hindret i å utføre visse typer arbeid eller gjøremål</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Du har hatt problemer med å gjennomføre arbeidet eller andre gjøremål (for eksempel fordi det krevede ekstra anstrengelser)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. I løpet av de 4 siste ukene, hvor ofte har du hatt noen av de følgende problemer i ditt arbeid eller andre av dine daglige gjøremål på grunn av følelsesmessige problemer, (som for eksempel å være deprimert eller engstelig) ?

<table>
<thead>
<tr>
<th></th>
<th>Hele tiden</th>
<th>Mye av tiden</th>
<th>En del av tiden</th>
<th>Litt av tiden</th>
<th>Ikke i det hele tatt</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Du har måttet redusere tiden du har brukt på arbeid eller på andre gjøremål</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Du har utrettet mindre enn du hadde ønsket</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Du har utford arbeidet eller andre gjøremål mindre grundig enn vanlig</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

<table>
<thead>
<tr>
<th></th>
<th>Ikke i det hele tatt</th>
<th>Litt</th>
<th>En del</th>
<th>Mye</th>
<th>Svært mye</th>
</tr>
</thead>
</table>

7. Hvor sterke kroppelige smerten har du hatt i løpet av de siste 4 ukene?

<table>
<thead>
<tr>
<th></th>
<th>Ingen</th>
<th>Meget svake</th>
<th>Svake</th>
<th>Moderne</th>
<th>Sterke</th>
<th>Meget sterke</th>
</tr>
</thead>
</table>

8. I løpet av de siste 4 ukene, hvor mye har smerten påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

<table>
<thead>
<tr>
<th></th>
<th>Ikke i det hele tatt</th>
<th>Litt</th>
<th>En del</th>
<th>Mye</th>
<th>Svært mye</th>
</tr>
</thead>
</table>
For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. 
Hvor ofte i løpet av de siste 4 ukene har du:

<table>
<thead>
<tr>
<th></th>
<th>Hele tiden</th>
<th>Mye av tiden</th>
<th>En del av tiden</th>
<th>Litt av tiden</th>
<th>Ikke i det hele tatt</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Felt deg full av liv?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b. Felt deg veldig nervøs?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c. Vært så langt nede at ingenting har kunnet mantre deg opp?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d. Felt deg rolig og harmonisk?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>e. Hatt nye overskudd?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>f. Felt deg nødfor og depriment?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>g. Felt deg slien?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>h. Felt deg glad?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>i. Felt deg trett?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følesemessige problemer påvirket din sosiale omgåing (som det å besøke venner, slektnings osv.) ?

<table>
<thead>
<tr>
<th></th>
<th>Hele tiden</th>
<th>Mye av tiden</th>
<th>En del av tiden</th>
<th>Litt av tiden</th>
<th>Ikke i det hele tatt</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

11. Hvor RIKTIG eller GAL er hvert av de følgende påstander for deg?

<table>
<thead>
<tr>
<th></th>
<th>Helt riktig</th>
<th>Devis riktig</th>
<th>Vet ikke</th>
<th>Devis gall</th>
<th>Helt gall</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Det virker som om jeg blir syk litt lettere enn andre</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b. Jeg er like frisk som de fleste jeg kjenner</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c. Jeg tror at helsen min vil forverres</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d. Jeg har utmøntet helse</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Vennligst kontroller at du har besvart alle spørsmålene
Appendix 8. Instruction guide on how to fill in the food diaries.

Råd om utfylling av kostdagboken

Spis og drikk som du pleier. Det er meget viktig at du ikke endrer noe på vanene dine i forbindelse med denne undersøkelsen. Det er også meget viktig at du skriver ned alt du spiser og drikker i løpet av disse dagene.

Hvordan fyller jeg ut dagboken?
Bla gjennom dagboken og bildeheftet slik at du blir kjent med innholdet. På de siste sidene i denne informasjonen er det et eksempel på hvordan dagboken fylles ut.

Forsiden
På forsiden av hver dagbok skal du fylle inn kjønn, alder, hvilken ukedag det er, dato og om det var en vanlig eller uvanlig dag. På forsiden finner du også en oversikt over hvor du finner de ulike matvarene i heftet. Bruk gjerne penn (sort eller blå) til å skrive med.

Tidsbolker
Legg merke til at en dag er delt inn i 5 tidsbolker (eks. kl. 6-10, kl. 10-14). Fire av disse er på 4 timer, mens den siste strekker seg fra kl. 22 om kvelden til kl. 06 neste morgen. Du skal skrive ned hvor mye du har spist eller drukket i de aktuelle tidsbolkene. Har du begynt å spise i en tidsbolk og sluttet i den neste, skriver du alt i den tidsboken du begynte.

Absolutt alt du spiser og drikker skal registreres
For hver matvare/drikke er det oppgitt en enhet. For eksempel kan drikke angis i antall glass, og brød i antall skiver. Du skal for alle matvarene angi hvor mange enheter du har spist/drukket. Du kan skrive hele tall som 1, 2, 3 eller deler som
¼ eller 1½ for alle matvarer og drikker i dagboken. Antallet skal fylles inn i de sorte rutene.

Bare bokstaver i de orange rutene

Ikke kryss i dagboken
Det skal aldri brukes kryss i dagboken. Det skal kun brukes bokstaver og tall.

Når matvaren ikke er i dagboken
Spiser du matvarer/matretter som ikke finnes oppført i dagboken, må du beskrive nøye det du har spist, hvor mye og når du har spist i de åpne boksene "Annet – beskriv best mulig hva, hvor mye og når:"

Eksempel


Kari finner linjen med soya soft margarin og skriver "1/2" i kolonnen "kl. 14-18". Deretter ser Kari i bildeboken og finner at hun brukte samme mengde margarin som på bilde B. Under "Hvor mye smurte du på brødet?" skriver Kari "B" i den orange ruten.


I tillegg skriver hun hvor mye pølser hun hadde i tomatsovsen. Kari finner linjen med "Grillpølse/wienerpølse vanlig" og skriver "1" i kolonnen "kl. 14-18"

Kari finner ikke mango blant fruktene som er nevnt i dagboken. I boksen "Annet" etter frukt skriver hun "Mango, 1/2 stk, kl. 17.45".