

Mount Saint Vincent University
Department of Applied Human Nutrition

**Nutritional Intake and Quality of Life after
Laparoscopic Sleeve Gastrectomy**

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Abstract

Obesity has become an increasing health issue over the past several years. Weight loss surgery such as the Laparoscopic Sleeve Gastrectomy (LSG) is the only effective long term treatment option for morbid obesity. The nutritional intake and quality of life after LSG is not well known as it is a relatively new weight loss surgical procedure.

Nutritional intake and quality of life after LSG was investigated to determine the nutritional intake and adequacy of diet in patients ≥ 1 year after LSG and the effect quality of life has on nutritional intake and percentage weight loss. Nutritional status was measured through the use of four day food records, nutritional related laboratory parameters, and reported nutritional vitamin supplement intake. Diet quality was measured using the Healthy Eating Index (HEI). Quality of life was measured using Bariatric Quality of Life (BQL) questionnaire.

Participants were recruited through the Queen Elizabeth II Health Sciences Centre, Weight Loss Surgery Program, Halifax, Nova Scotia. Seventy-two patients who had the LSG between September 2008 and March 2010 and were able to read and write English were forwarded packages containing four day food record and Bariatric Quality of Life (BQL) Questionnaire.

Food intake was analyzed using a nutrient analysis program. Food record data were used to calculate HEI scores and individual risk of micronutrient adequacy. Cronbach's alpha was used to measure internal consistency of the BQL questionnaire.

Variables pertaining to socio-demographics, laboratory parameters, quality of life, diet quality, and dietary intake were included in the statistical analysis. Pearson Correlation analysis was used to measure associations between continuous variables and two-tailed t-tests were used to measure relationships between age group and continuous variables. Variables were dichotomized and Chi square test for independence was used to analyze categorical variables. Statistical significance was defined as $p < .05$.

Nineteen adults completed the four day food records and BQL questionnaires giving a response rate of 26%. Average percentage weight loss was $26.1 \pm 10.6\%$ 13 months after LSG. Average energy and protein intakes were 1256 ± 384.5 kilocalories and 77.3 ± 17.5 g per day respectively 22 months after surgery. Participants < 50 years of age lost more weight, had higher BQL scores, and consumed less energy than those ≥ 50 . Mean BQL and HEI scores were 78.1 ± 14.0 and 60.4 ± 8.8 respectively 22 months after surgery. All participants were at risk for at least one inadequate dietary micronutrient intake. The prevalence of nutrient deficiency was 10.5% with vitamin B₁₂ being the only micronutrient deficiency. Ninety-five percent of participants reported taking a multi-vitamin/mineral supplement.

Nutritional intake after LSG does not appear adequate to meet needs and multi-vitamin/mineral supplementation seems effective at preventing nutritional deficiencies. Risk of inadequate dietary micronutrient intake appears to be related to the number of food guide servings consumed. Quality of life is acceptable and is dependent on weight loss. There is no relationship between nutritional intake and quality of life. Diet quality

scores are considered “needs improvement” which is comparable to the rest of the Canadian population.

A combination of tools should be used when assessing the nutritional status of a population and more research is needed on the long term nutritional status after LSG. It is recommended to use tools that are specific to the bariatric surgery population when measuring quality of life.

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Chapter 1.0 Introduction

1.1 Problem Statement

Obesity has become a global health issue in recent years. According to the World Health Organization there are more than 1.6 billion over weight adults worldwide and of those approximately 400 million are considered obese (1). In Canada about one quarter (5.5 million) of citizens are obese and 2.7% are morbidly obese. Women are two times more likely to be morbidly obese compared to men. In Nova Scotia 30% of women and 19% of men are obese. Women are more likely to be obese between the ages of 55 and 64 and men are equally as likely to be obese between the ages of 45-54 and 55-64 (2). Obesity was responsible for 2.2% of total Canadian healthcare costs in 2001(3). It is obvious that obesity is a major health issue as it can lead to a number of health related consequences (1,2,4) and quality of life issues (5) .

Bariatric surgery is a treatment option for morbid obesity (6,7). Laparoscopic Sleeve Gastrectomy (LSG) is a new surgical procedure for weight management in patients who are morbidly obese. The LSG leads to significant weight loss within the first year post surgery (7-10) and greatly improves pre-existing diseases such as diabetes (8). It has also been shown that the surgery leads to an improved overall quality of life in 90% of patients (11).

The topic of nutritional intake in relation to quality of life after LSG is an area of research that has not been investigated extensively. Most of the research so far has focused on the gastric bypass procedure (induced malabsorption) which differs from the LSG (induced reduction is gastric volume) (9). The effect of the LSG on nutritional

status has not been well studied. This is an important area to research as alterations in anatomy as a result of surgery would likely lead to a decrease in consumption of food and a smaller stomach may affect the absorption of certain nutrients (7). It is unknown whether nutritional intake would be adequate to meet needs post surgery. In relation to quality of life, the literature has shown that in general bariatric surgery impacts quality of life in many patients and that quality of life tends to change over time (12-14). There have been a number of behavioural issues identified in the research which may impact quality of life (5,15) as well as nutritional intake post surgery (16). This research proposes to examine nutritional intake and quality of life through four day food records, Bariatric Quality of Life (BQL) questionnaire, and by calculating the Healthy Eating Index (HEI) scores in a group of LSG patients who are two years or less post-surgery. With the increasing incidence of obesity, bariatric surgery rates will continue to rise making the need for research in this area so significant.

1.2 Practical Importance of the Study

Information gained from the research will aid in the understanding of possible nutritional and quality of life issues that develop after LSG and knowing this information may improve patient care. The information learned from the research may assist with pre surgical assessments in choosing appropriate patients for surgery. In terms of nutrition, healthcare professionals will be able to use the information gained to increase awareness of the nutritional issues that develop following the surgery and address them with patients before they develop. The information gained from the research will be especially useful for dietitians as they will be able to provide education that will better meet the nutritional needs of the population. The quality of life aspect of the research

will give healthcare professionals a better understanding of the issues patients experience following surgery and this will allow for professionals to better address patient needs which may improve outcomes. Overall the research will provide healthcare professionals with additional tools to help meet the needs of the population and programs which are addressing patient needs could lead to savings in healthcare costs.

1.3 Research Questions

- Is the nutritional intake of patients ≥ 1 year following LSG adequate to meet nutritional needs?
- Does quality of life affect nutritional intake and percentage weight loss in patients ≥ 1 year following LSG?

1.4 Research Objectives

- To gain an understanding of the nutritional status of patients ≥ 1 year following LSG through four day food records and measuring lab parameters.
- To determine the relationship between dietary intake as measured by four day food records and diet quality scores measured using the HEI and nutritional lab parameters.
- To gain an understanding of quality of life issues after LSG using the BQL questionnaire.
- To determine the relationship between nutritional intake, quality of life, and percent weight loss.

Chapter 2.0 Literature Review

2.1 Overweight and Obesity Classification

“Overweight” and “obesity” are defined based on body mass index (BMI) (Kg/height m²) (4). According to Health Canada’s Canadian Guidelines for Body Weight Classification in Adults (4) overweight is defined as BMI 25-29.9. Obesity is divided into three classes: Class I BMI 30-34.9, Class II BMI 35-39.9, Class III (morbid obesity) BMI ≥ 40 (4). Health risk is directly proportional to BMI. Increased BMI is associated with an increase in risk of co-morbidities such as diabetes, dyslipidemia, hypertension, coronary artery disease, gallbladder disease, sleep apnea, musco-skeletal disorders, and cancer (1,2,4).

2.2 Treatment of Morbid Obesity

Morbid obesity is associated with significant health risks and will likely lead to mortality if left untreated due to the many co-morbidities mentioned above. Unfortunately, adherence to lifestyle changes in the morbid obese lead to minimal weight loss and adherence is often poor (17). For example, obese patients enrolled in weight management programs that provide continuous care and follow-up lose about 5% of body weight after 36 months. Patients who drop out of the programs achieve a weight loss of 3%. About half of the participants drop out of the program after the first year and only about 15.7% of individuals are still in the program after 36 months. A limitation identified to a study showing these results is that participants were enrolled in several different weight management programs and details on specific programs are not given (18). This research suggests that weight loss programs may not be an effective means for weight loss in some obese individuals.

Weight loss drugs have also been used to assist with obesity management. Currently, two areas are being investigated in pharmacology and nutrition to enhance weight loss through decreasing energy intake and increasing energy expenditure (19). Weight loss drugs generally lead to modest decreases in weight (10%) and are associated with several side effects (20) and are intended to be used short term to reduce associated risks (21). Continued research appears to be needed in this area.

Bariatric surgery is an effective long term treatment for weight loss in individuals with morbid obesity (16) and candidates need to be selected carefully. Weight loss after bariatric surgery is associated with major improvements in obesity related co-morbidities (8,9). There are about 200,000 bariatric procedures performed worldwide each year (22). It appears that in most centers, bariatric surgery is reserved for those with a BMI of 35 or greater with pre-existing uncontrolled medical conditions, or a BMI of 40 or greater without pre-existing chronic diseases (8,23,24). Bariatric surgery is a popular procedure that can lead to long term results and specific criteria is in place by many centres to allow for appropriate selection of candidates to ensure successful outcomes.

2.3 Types of Bariatric Procedures

The original bariatric surgery procedure, developed in 1954 created malabsorption and morbidity by joining the proximal jejunum to the distal ileum, thereby bypassing the duodenum (25). Bariatric surgery has since advanced into a number of different types of procedures and can be categorized as restrictive or restrictive and malabsorbative. Restrictive procedures cause weight loss through the reduction in the amount of food consumed. Examples of restrictive procedures that are widely used include the LSG and the laparoscopic adjustable gastric band (LAGB) (26,27).

Malabsorbative and restrictive procedures cause weight loss by reducing the amount of food consumed and by inducing malabsorption. The most commonly performed combined malabsorbative and restrictive procedure is the Roux-en-Y Gastric Bypass, commonly known as the gastric bypass procedure (28).

2.3.1 Laparoscopic Adjustable Gastric Band Procedure

The LAGB is a bariatric procedure where an adjustable silicone band is inserted around the gastric cardia to create a small gastric pouch. A reservoir is implanted under the skin in the abdomen. The band can be adjusted by removing or filling the reservoir with liquid until desired weight loss is achieved (27,28). The complication rate for this procedure can run as high as 11.3% however, the mortality rate is only 1/10th that of the gastric bypass procedure. The most common complications requiring re-operation include band removal due to intolerance, infection, slippage, or erosion. Weight loss is not as successful compared to other procedures, with mean weight loss at 24 months being about half that of the gastric bypass and LSG procedures (27).

2.3.2 Gastric Bypass Procedure

The gastric bypass procedure first performed in 1967, is the most commonly used bariatric surgical intervention and is considered the gold standard (30). The gastric bypass procedure involves dividing the stomach into a pouch with a capacity of about 15-30 millimetres. The proximal jejunum is then joined to the stomach creating a gastrojejunal anastomosis and a roux limb of 80-150 cm (27). This procedure reduces stomach capacity by 95% and food bypasses the duodenum and part of the jejunum leading to a number of nutritional deficiencies with 98% of patients requiring a supplement in addition to a multivitamin 24 months after surgery (30). Additional

supplements which are needed include vitamin B₁₂, iron, calcium, vitamin D, and folic acid (31). The mortality rate is estimated to be 0.3 – 1% (32). The gastric bypass procedure has many nutritional consequences and does not appear to be the “gold standard” from a nutrient deficiency perspective.

2.3.3 Laparoscopic Sleeve Gastrectomy

The LSG is a new surgical procedure that was initially introduced in the super-super morbidly obese (BMI >50) prior to performing malabsorptive procedures such as the gastric bypass. At the time, the purpose of the LSG was to cause weight loss so that patients could safely undergo further weight loss procedures (33). The LSG is now used as a single staged procedure (8). In the LSG, 60 to 80% of the stomach is removed, leaving a long narrow stomach which takes the shape of a sleeve (Figure 1) (7,24). By removing the fundus, secretion of ghrelin is reduced resulting in suppressed appetite (9,34). Appetite suppression combined with a smaller stomach ($\leq 300\text{mL}$) leads to weight loss (7,34). Because the pylorus is retained and the small bowel is not bypassed, patients are less likely to develop complications such as dumping syndrome and nutritional deficiencies occurring secondary to malabsorption. While the overall complication rate is low at 10%, (8) negative outcomes can include post operative bleeding (1-5% of patients), gastrointestinal leak (1-3% of patients), deep vein thrombosis (1-2% of patients), splenectomy (1% of patients), pulmonary embolus (0.5% of patients), and death within 30 days (less than 0.5% of patients) (24). The LSG appears to be a safe procedure with fewer alternations to the gastrointestinal tract compared to the gastric bypass procedure.

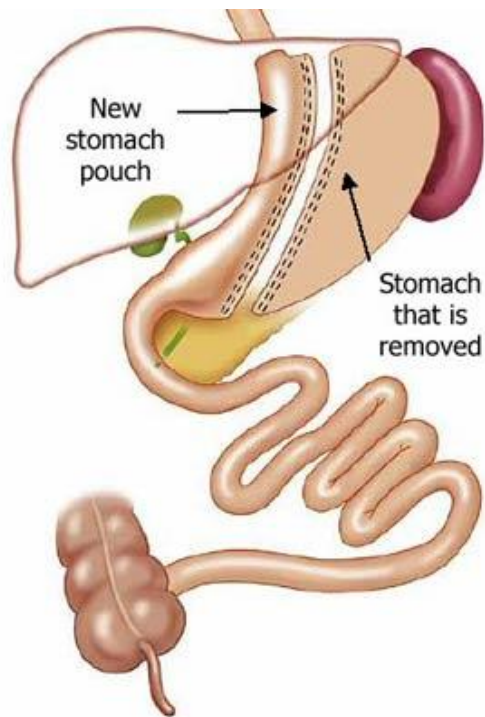


Figure 1 - Laparoscopic Sleeve Gastrectomy Diagram (35)

The LSG as a single staged procedure appears to be an effective approach for weight loss and resolving co-morbidities in morbidly obese patients. Weight loss of 50% or more in one year is the expected outcome (36). The average amount of excess weight lost ranges from 49% (10) to 63% (8) at one year follow-up. Patients with a pre-surgery BMI < 50 have a significantly higher weight loss at one year than those with a BMI \geq 50 (8). Perhaps those with lower BMI may have less behavioural issues associated with eating making it easier for them to lose weight after surgery compared to patients with higher BMI. Post operative weight loss has been associated with a decrease in the use of medications in about 75% of diabetics (8,36), 60% (8) to 78% (36) of individuals with hypertension, and 66.7% (36) resolution or decrease in lipid

disorders. The LSG leads to overall improvements in the physical health of patients by reducing morbidity.

Weight loss is similar in patients who have undergone either the LSG or the gastric bypass procedure. Lakdawaia et al (9) retrospectively compares patients who had undergone a laparoscopic gastric bypass with patients who had the LSG and found that median excess weight loss at one year is 76.1% for the LSG group and 62.2% for the laparoscopic gastric bypass group. Resolution of co-morbidities is similar between the two groups (9). In contrast, Gehrler et al (37) observes a greater weight loss after one year in laparoscopic gastric bypass patients (74%) in comparison to LSG patients (65%). Overall it appears that LSG is an effective procedure for weight loss in the short term but more long term studies are needed.

2.4 LSG at the Queen Elizabeth II Health Sciences Center

The LSG procedure has been performed for approximately 3 1/2 years at the Queen Elizabeth II (QEII) Health Sciences Center in Halifax, Nova Scotia. The criteria to be considered for the surgery are as follows: BMI \geq 40 or BMI \geq 35 with a serious medical condition related to weight, aged 19-65 (with some exceptions), long history of obesity, many failed attempts at weight loss, non-smoker for 6 months prior to surgery, no drug or alcohol abuse, no serious psychiatric illness that would impact ability to follow the program and make lifelong changes. Patients are thoroughly assessed by a dietitian, nurse practitioner, and psychologist to determine candidacy for the procedure. The patient is then referred to the surgeon for further assessment (24).

Patients must comply with a number of dietary changes before and after the LSG procedure. Before surgery patients must consume a full liquid diet for seven days followed by a clear liquid diet for one day. This diet prepares the patient for surgery and allows them to adjust to the post operative diet changes (38). Post LSG patients must follow a five stage diet as described in Table 1.

Table 1 - Diet Progression Following LSG*

Stage	Description	Duration	Energy
1	Sips water (1 oz per hour sipped)	1 day or less	_____
2	Clear fluids (2-4 oz per hour sipped)	1 day or less	_____
3	Full Fluids (4-8 oz per hour) Discharge from hospital at this stage	4 weeks	600-800 calories/day
4	Soft foods (mashed/ground, no bread, rice, pasta, raw vegetables)	4 weeks	700-1000 calories/day
5	Normal foods		800-1200 calories/day (Women) 1000-1600 calories/day (Men)

*Adapted from (39,40)

Post operatively, patients are asked to take a multivitamin/mineral supplement daily for the rest of their life depending on nutritional intake and blood work. Other supplements may be needed if nutritional deficiencies exist (24). Individuals are encouraged to eat 60-80 g/day of protein (40) which is 26-30% of energy intake for women and 20-24% of energy intake for men which is within the Acceptable Macronutrient Distribution Range (AMDR) for protein (41).

2.5 Nutrition after LSG

Little is known about the adequacy of nutritional intake after bariatric surgery. The most common deficiencies after surgery are zinc, vitamin D, folate, iron, and low albumin (37). Iron deficiency is more common in female patients and usually precedes surgery. Deficiencies are found as early as three months post operatively and peak at 6-12 months after surgery (37). Patients who have gastric bypass surgery have the same vitamin deficiencies as the LSG patients but the deficiencies are more prevalent (42). Nutrient deficiencies after bariatric surgery appear to be a fairly common issue although it is not always clear whether patients with deficiencies are taking nutrient supplements and whether dietary intake is adequate to meet nutritional needs (37,42).

2.5.1 Possible Causes of Nutritional Deficiencies after LSG

Poor pre operative nutritional status appears to play an important role in post operative nutritional status as 57% (37) of morbidly obese individuals have nutrient deficiencies before weight loss surgery. Deficiencies identified pre operatively are similar to those present post operatively (37) and include vitamin B₁₂, vitamin D, folic acid, and iron (43,44). Vitamin D deficiency seems common in the obese population with a prevalence of 61% in obese individuals compared to 32% in non-obese controls

(45). The risk of nutritional deficiency is inversely related to BMI, (44). The risk of nutrient deficiency in the obese is not related to education, income, or presence of co-morbidity (44). It appears that nutritional deficiencies found pre-operatively may be impact post-operative nutritional status.

Lack of compliance with taking nutritional supplements may contribute to post operative deficiencies. One study involving gastric bypass patients shows a compliance rate with oral supplements to be only 33% (31). The majority of deficiencies in patients post operatively are easily treated with supplementation of the deficient nutrient either orally, intramuscularly, or through intravenous therapy (37). It is important to consider compliance with taking nutritional supplements when assessing nutrient deficiencies.

Inflammation related to obesity can create an appearance of iron deficiency. The rationale for changes in iron indices after bariatric surgery is complex. Anemia of chronic inflammation can exist in obese populations as obesity is associated with an elevated C Reactive Protein level which is a measure of inflammatory status. Serum ferritin, an acute phase reactant increases during inflammation as BMI increases and serum iron and transferrin saturation decrease as BMI increases. Since serum ferritin is an acute phase reactant, levels increase during stress/inflammation, meaning it may increase as weight increases. In patients who have anemia of chronic inflammation, serum ferritin levels are often increased and serum iron and transferrin saturation are decreased with no changes in hemoglobin concentrations (46). Anemia of chronic inflammation can also exist with true iron deficiency when CRP levels are increased with low hemoglobin levels and low transferrin saturation (47). Anemia of chronic

inflammation must be assessed appropriately when evaluating obese patients for nutrient deficiencies.

The appearance of zinc deficiency may also be related to inflammation caused by morbid obesity. The rationale for the cause of zinc deficiency after LSG is not known however, zinc is transported on albumin which is a negative acute phase reactant and decreases during inflammatory states (48). Salle et al found a significant negative correlation between pre-surgery fat mass and zinc levels and a positive correlation between pre-surgery pre-albumin and zinc (49). The prevalence of zinc deficiency prior to LSG has been found to be 6.5% with the proportion increasing significantly to 14.3% and 18.5% at 6 and 12 months after surgery respectively (48). Risk of zinc deficiency in the Canadian population is slightly lower at 14.0% and 16.8% for females and males respectively (50). Chronic inflammation caused by obesity may cause albumin levels to fall, which in return will lead to a decrease in serum zinc levels. Changes in prealbumin levels account for 12.4% of variation in zinc levels in the first six months after weight loss surgery (48). Consumption of zinc rich foods may be limited after weight loss surgery leading to inadequate intake and possible deficiency. It would be interesting to have more long term studies on the nutritional status of individuals post LSG to determine if deficiencies resolve as weight and inflammation decrease. Zinc deficiency caused by the inflammatory effects of obesity must be evaluated with caution as it may not be a true deficiency.

Anatomical changes after LSG and physiological changes caused by obesity can also explain nutrient deficiencies such as vitamin B₁₂ and vitamin D. Vitamin B₁₂

deficiency may be explained by a lack of intrinsic factor as a result of removing the fundus during surgery since the fundus is responsible for producing intrinsic factor which is needed to absorb vitamin B₁₂ (40). In terms of vitamin D, it has been found that low levels of vitamin D are associated with secondary hyperparathyroidism in the obese population (36,44). While the cause of vitamin D deficiency is not completely known, one potential reason could be reduced release of vitamin D₃ from the skin into the blood during sunlight exposure due to excess adipose tissue (51). The causes of deficiencies often seen after weight loss surgery are multi-factorial and may not always be related to surgery.

Reduced ability to consume adequate food after surgery is another important factor contributing to nutritional deficiencies. As mentioned previously, the LSG procedure removes up to 80% of the stomach which drastically reduces the volume of food consumed (7,24). In addition, secretion of ghrelin, an-appetite stimulating hormone synthesized in the fundus of the stomach is reduced by approximately 70% (34). Lack of ghrelin may lead to appetite suppression and decreased intake (7,34). The expected energy intake after surgery is also quite diminished as shown in Table 1 above. It seems that appetite suppression along with reduction in stomach size may have an impact on nutritional intake.

Food intolerance is another factor that should be considered when assessing nutritional status after LSG. It appears LSG patients have greater tolerance to food after surgery compared to other types of bariatric surgery (52,53). 'Comfort with food' and 'diet experience' is better in LSG patients compared to LAGB at six months post

surgery (53). Ninety-five percent of post operative LSG patients describe their eating as acceptable to excellent even though they report consuming small frequent meals due to early satiety (54). However, LSG patients struggle with specific food intolerances especially to red meat, bread, rice, and pasta which have the lowest food tolerance scores (52,54). It is assumed that LSG patients are more likely to avoid foods that they do not tolerate which could account for the low iron, vitamin B₁₂, and folic acid levels seen in post operative LSG patients (36,40).

2.6 Body Composition and Metabolic Changes after Bariatric Surgery

Body composition and metabolism are altered by weight loss surgery. In response to the change in energy intake, both percent body fat and fat free mass decrease. After gastric bypass energy intake decreases from 1654-9745 kcal/day before surgery to 790-1418 kcal/day six months post operatively. Percentage of body fat also decreases from 51.6% \pm 5.4 to 41.2% \pm 6.2 and fat free mass also decreases from 56.1 \pm 10.2 kg to 48.0 \pm 7.3 kg at six months post operatively (55). It has been reported that no significant correlation exists between protein intake and degree of fat free mass relative to total weight loss (56). Up to six months after gastric bypass surgery the percentage of weight loss as fat is 66.9% and the percentage of weight loss as lean body mass is 33.1%. BMR stabilizes one month after surgery despite a continued decrease in weight and lean body mass. Participation in activities such as exercise may have been slowing down loss of lean tissue (57). It could be expected that patients undergoing LSG would have similar changes in body composition over time with decreased energy intake after surgery leading to metabolic shifts.

2.7 Predictors of Weight Regain After Bariatric Surgery

The long term effects of LSG on eating patterns and sustained weight loss are unknown. As time since surgery increases, weight increases over the long term but does not go back to pre-surgery weight. Sarela et al reports a 76% excess body weight loss at one year post surgery compared to 69% at ≥ 8 years post surgery (58). Mathieu et al reports a higher mean weight loss of 83% at 12 months after surgery but greater weight gain as evidenced by excess weight loss of 83.8%, 72.9%, and 55.9% at 24, 48, and 72 months respectively with mean pre-operative BMI of 39.3 kg/m² (54). Similar to the gastric bypass procedure, LSG patients have increased food consumption at one year post surgery including foods that are high in sugar and fat (59) which may contribute to weight gain. Also, increased age is related to a decrease in lean body mass and higher BMI (60). Perhaps poor eating patterns and age related body composition changes result in weight gain despite a decrease in gastric volume.

Behavioural predictors of weight regain after weight loss surgery are typically lack of control over food urges (such as emotional eating), addictive behaviours, decreased post operative well-being, lack of self monitoring, and fewer post operative follow-ups (13,61). Patients with the highest risk for depression pre operatively have the most post operative weight regain (61). Predictors of BMI after weight loss stabilization are age, weight at age 21, and duration of physical activity (61). Although the research is on the gastric bypass population, some of the behaviours of obese patients seeking other types of bariatric surgery could be similar. Behaviour controls eating and physical activity habits which can impact weight regain.

2.8 Characteristics of Bariatric Surgery Candidates

Individuals who pursue bariatric surgery have particular characteristics and reasons for wanting to pursue surgery, and perhaps understanding this may help weight loss surgery programs select appropriate individuals for the surgery to ensure successful outcomes. Abiles et al (5) shows that bariatric surgery candidates have higher levels of stress, anxiety, depression, and lower levels of self-esteem compared to normal weight controls. They have also have lower psychological and physical well being, less independence, worse relationship with the environment, and lower personal and spiritual well being. There are no studies available that compare bariatric surgery candidates to obese controls. The primary reason why morbidly obese patients pursue bariatric surgery is for medical health reasons (63). More women than men are seeking or have already had bariatric surgery. The rationale for this is that morbid obesity is recognized as a more important issue to women than to men and dissatisfaction with physical appearance is greater in women than it is in men (64). Bariatric surgery patients have a number of issues impacting their psychological health and they choose surgery for medical health reasons showing the impact that they perceive obesity having on their physical health.

2.9 Eating Disorder Behaviours in the Morbidly Obese

Disordered eating behaviours appear to be an issue in the morbidly obese population as 18.5% of individuals who seek surgery have an eating disorder (15). Specifically, binge eating behaviours are present in both bariatric surgery seeking and post surgery individuals. Binge eating behaviours are prevalent and can last for many years after surgery. It has been reported that 46-68% of individuals seeking bariatric

surgery have at least one binge episode per week during the previous month (5) and 51% of patients suffer from binge eating or night eating syndrome eight years after gastric bypass surgery (16) but do not have a diagnosed eating disorder. The incidence of binge eating before bariatric surgery remains similar after surgery. Interestingly, individuals who are less obese are more emotional, express more feelings, and have higher levels of dissimulation (5). Patients who do not display these traits may be more likely to use food to cope with emotions leading to obesity. A greater number of psychological consultations before surgery is associated with better outcomes post operatively (16). Binge eating is an issue in the morbidly obese and emotions are connected to eating behaviours and play a role in disordered eating patterns.

2.10 Quality of Life after Bariatric Surgery

Many individuals undergo bariatric surgery for quality of life purposes. Quality of Life is defined as,

“Individual’s perceptions of their position in life in the context of the culture and value system where they live, and in relation to their goals, expectations, standards and concerns.” World Health Organization, 1998 (65)

Overall, obese individuals have a decreased quality of life compared to normal weight individuals (5) and quality of life improves after bariatric surgery (12,13). Within three to six months after bariatric surgery patients report improvements in energy, pain, and physical mobility (66) and have increased physical and mental well-being scores up to three years after surgery compared to obese controls (12). Quality of life improves significantly one year after LSG in a variety of areas including social functioning, physical functioning, body pain, mental health, vitality, and general health (36). Eighty

six percent (86%) of post operative bariatric surgery patients who attend a post-surgery support group rate their quality of life as excellent or very good (67). It appears that in the short term quality of life improves after surgery.

Quality of life after bariatric surgery is dependent on weight loss and impacts overall well-being. However, few studies examine the long terms effects of bariatric surgery on quality of life. Health related quality of life improves during the first year of weight loss after surgery, then decreases during the weight regain phase (one to six years) and then is stable from years six to 10 when weight does not fluctuate. Over a 10 year study period, overall health perceptions, obesity - related psychosocial problems, and mood scores gradually decrease over time. Depression scores decrease at one year and then start to show improvement after six years. Anxiety scores show an improvement at year one, worsen, and then improve after six years (14). Factors related to health related quality of life change over time but it appears that quality of life decreases over the long term after bariatric surgery but likely demonstrates an overall improvement compared to before surgery.

Quality of life after bariatric surgery is also affected by the type of surgical procedure used. Gastric bypass patients have better quality of life scores compared to LSG patients. Overall, 94% of gastric bypass and 90% of LSG patients are satisfied with the results following surgery. Gastric bypass patients lose more weight compared to LSG patients which could explain the increased quality of life scores in the gastric bypass population (11). LSG patients have better quality of life scores compared to LAGB patients. LSG patients experience fewer physical symptoms and have better

social related quality of life compared to LAGB patients (64,68). Weight loss is greater in LSG compared to LAGB (64,68) and likely contributes to the differences in quality of life between the two groups. LSG patients have better quality of life after surgery compared to LAGB patients but it is not as good as gastric bypass patients.

Differences in quality of life after surgery could be due to the range of tools used to measure it. Various tools such as the Short Form 36, Gastrointestinal Quality of Life Index and/or other validated questionnaires to rate aspects such as depression and social functioning are often used to measure quality of life (11-14). Tools that are specifically designed to measure quality of life in the bariatric population appear to be used less often. The Bariatric Quality of Life (BQL) questionnaire (Appendix A) is one tool available to measure well being in obesity surgery patients. The BQL questionnaire is designed to assess quality of life pertaining to weight, weight related co-morbidity, and surgery related gastrointestinal symptoms. This questionnaire has been found to be reliable, valid, and responsive. The test retest reliability has an average variance of 14.2%. The internal consistency is acceptable (Cronbach's Alpha 0.71-0.86), there is a high construct validity and a high rate of responsiveness. The questionnaire is simple and only takes a few minutes to complete (69). It appears that the BQL questionnaire may be a useful tool to use on the bariatric surgery population. So far, the tool has been used in one study comparing quality of life after LSG and LAGB (68).

2.11 Nutrition Intake and Food Records

Underreporting of food intake is a challenge when assessing dietary intake regardless of the method used. Underreporting of energy intake in the Canadian Community Health Survey is about 10% (70) using 24 hour dietary recall. When

comparing 24 hour recall, three day food records, and food frequency questionnaires, less individuals underreport using three day food records compared to the other two methods of collection (71). In terms of comparing 24 hour recall to food records, it has been found that underreporting using the 24 hour recall is greater compared to using food records (72). There is also less underreporting with seven day food records compared to diet interviews (73). The literature appears to show that food intake records are more accurate in terms of underreporting than other forms of measurement.

Underreporting is an issue with recording dietary intake and it is influenced by several factors (71,73,74). Sixty-eight percent of individuals have an inclination to misreport and 32% indicate they would report food intake accurately. About half of the individuals who have a desire to misreport are obese. There is no relationship between restraint, depression, and intention to misreport (74). Underreporting of food intake also is associated with lower socioeconomic status and education level (71,76). In women, education level below postsecondary is associated with underreporting (70).

Overweight women report being ashamed of their intakes particularly to sweets and snack foods which causes them to under eat or correct their intake by eating fewer sweets (75). Under reporters have low intake of sweets, fried foods, pasta, meats, and pork (72,76). Age group is not a significant factor in underreporting (70). Underreporting appears to be affected most by BMI, female gender, and education level.

Underreporting occurs with all methods of dietary intake. Specifically, rates of underreporting for seven day food records range are 16% (73) using energy equations to estimate intake. Rationale for underreporting using food records include: under

eating while recording intake, portion size errors, burden of recording intake, and social desirability (75). Challenges involved with keeping a food record include: inconvenience, lack of time, difficulties estimating portions at restaurants, and confusion involving household measures (75). It appears that there are many contributing factors to underreporting of food intake and they are mainly related to inaccurate recording to show a more healthy eating pattern.

Food records may be the most reliable way to collect information on dietary intake in the bariatric surgery population. In particular, a seven day food record captures the variability of nutritional intake from day to day. Underreporting is often highest during the first day of recording food intake and decreases during subsequent days (77). However, given the challenges mentioned above for subjects to record intake over several days it seems that using a four day food record may be more realistic. A four day food record which includes a weekend day to help capture variability of eating during the weekend may be less of a burden for subjects to record resulting in possibly more individuals participating in the research. Regardless of the method used to record intakes, it must be kept in mind that recording of dietary intake is usually a small snapshot in time and may not reflect typical intakes (78).

2.12 The Healthy Eating Index

The Healthy Eating Index (HEI) is a scoring system that provides a single score to rate an individual's overall diet quality in terms of adequacy and moderation (79). The HEI was developed by the United States Department of Agriculture to assess whether a population's intake follows Federal Dietary Guidance (80). The HEI consists of several components with a possible range of scores for each component depending

on intake. The adequacy component has a maximum of 60 points and the moderation component consists of a maximum of 40 points for a total maximum HEI score of 100 (81). A grade is assigned depending on the HEI score as shown in Table 2.

Table 2 - HEI Grading Scale*

HEI Score	Grade
Greater than 80	Good
51-80	Needs Improvement
Less than 51	Poor

*Adapted from (82)

The HEI is a unique scoring system and assesses dietary intake based on density or a ratio to energy intake (79). Intakes of specific food groups or nutrients are expressed as a ratio of total energy for food groups or percentage of total intake for specific nutrients. Intakes of various foods are expressed out of 1000 calories of total energy intake (79,83). For example, individuals with excessively high energy intakes may meet recommendations for food group servings but could have an overall poor diet quality and HEI score. When total energy intake of unhealthy foods is high, the proportion of recommended food group servings for energy intake could be low resulting in a poor HEI score.

The HEI was chosen as the method to assess diet quality as it is based on American dietary guidelines which are similar to Canadian recommendations and have been adapted to Eating Well with Canada’s Food Guide. The Canadian adaptation has eight adequacy and three moderation components as described below. Some of the scores in the adequacy component and moderation components are expressed as a

percentage of total intake. Another adaptation that is made is to use the specified number of servings per food group according to age and sex as indicated in Canada's Food Guide (84).

Table 3 - Components of Canadian Adaptation of Healthy Eating Index, Range of Scores and Scoring Criteria*

Component	Range of Scores	Scoring Criteria
<i>Adequacy</i> ⁺	<i>0 – 60 points</i>	
Total vegetables and fruit	0-10 points	Minimum: 0 Maximum: 4-10 servings*
Whole fruit	0-5 points	Minimum: 0 Maximum: 0.8 to 2.1 servings (21% of recommendation for total vegetables and fruit)*
Dark green and orange vegetables	0-5 points	Minimum: 0 Maximum: 0.8 to 2.1 servings (21% of recommendation for total vegetables and fruit)*
Total grain products	0-5 points	Minimum: 0 Maximum: 3 to 8 servings*
Whole grains	0-5 points	Minimum: 0 Maximum: 1.5 to 4 servings (50% of recommended for total grain products)*
Milk and alternatives	0-10 points	Minimum: 0 Maximum: 2 to 4 servings*
Meat and alternatives	0-10 points	Minimum: 0 Maximum: 1 to 3 servings (75 to 225 grams)*
Unsaturated fats	0-10 points	Minimum: 0 Maximum: 30 to 45 grams*
<i>Moderation</i> [#]	<i>0-40 points</i>	
Saturated fats	8-10 points 0 -8 points	Minimum: 7% to 10% of total energy intake 10% to maximum 15% of total energy intake

Sodium	8-10 points	Adequate intake to tolerable upper intake level
	0-8 points	Tolerable upper intake level to twice tolerable upper intake level
Other food	0-20 points	Minimum: 5% or less of total energy intake Maximum: 40% or more of total intake
<p>*according to age and sex as specified by Canada's Food Guide</p> <p>+for adequacy components, 0 points for minimum or less, 5 to 10 for maximum or more, and proportional for amounts between minimum and maximum</p> <p># for moderation components, 10 or 20 points for minimum or less, 0 points for maximum or more, and proportional between minimum and maximum</p>		

*Adapted from (84)

Canadians need to improve their diet quality. Data from the Canadian Community Health Survey used to calculate Canadian adapted HEI scores shows that the average score for the population ages two and older is 58.8. Seventeen percent (17%) of the population have scores 50 or lower and only 1% scores more than 80. Females have higher scores compared to males. Scores increase as intake of vegetables and fruits increase. Components which raise index scores include grain products, meats and alternatives, and unsaturated fats. Lower scores are associated with lower intakes of dark green and orange vegetables, whole fruits, whole grains, and percent calories from other foods (85).

The likelihood of being obese increases as HEI scores decrease. The proportion of individuals with a HEI graded as “good” is lower in obese individuals compared to non-obese individuals. Obese individuals are more likely to have a HEI score graded as “poor” compared to non-obese individuals. However, these results did not reach statistical significance (85). In terms of abdominal obesity it has been found that as HEI score decrease, abdominal obesity increases. There is a 1.4% decrease in waist

circumference in men and a 0.8% decrease in waist circumference in women for every one point increase in HEI score. An increase of one point in the saturated fat component for men is associated with a decrease in abdominal obesity risk of 3.1%. An increase in one point on the fruit component for women results in 2.6% decrease in the risk for abdominal obesity (86). It appears that weight and waist circumference are related to HEI scores.

Diet quality using the HEI is related to biomarkers of nutritional status. Serum RBC folate levels, serum vitamin C, and serum vitamin E levels are positively correlated with HEI scores. The highest values of the nutrients are found in individuals who have HEI scores greater than 80. Surprisingly, vitamin D and ferritin levels are not associated with HEI scores (87). This is unusual as it would be expected that as HEI decrease vitamin D and ferritin levels would decrease as these are deficiencies that are often present in morbidly obese patients (4). However, a rationale given is that vitamin D levels can fluctuate according to sunlight exposure and external factors such as blood loss can affect ferritin levels. HEI scores are also associated with intake of nutritional supplements. As HEI scores increase, the amount of subjects taking supplements also increases. One rationale for this is that people who consume supplements may be more conscious of their health (87). HEI scores truly reflect diet quality as most nutritional biomarkers increase as HEI scores increase.

Chapter 3.0 Theoretical Framework

The Health Belief Model (HBM) was developed to help explain compliance issues with preventative health programs and will be used to help describe the motivating factors of patients who undergo bariatric surgery and the behaviours often seen post surgery (88). HBM contains four key constructs:

- *Perceived Susceptibility* of developing a certain health condition (88-90). In terms of obesity, it could be the perceived risk involved in developing obesity related health conditions (90).
- *Perceived Severity* of developing a certain condition or leaving it untreated. For example, this could be the attitude toward the potential health consequences of obesity such as developing obesity related medical conditions (88-90). The perceived susceptibility and severity is the perceived threat (89).
- *Perceived Benefits* that could result from taking action in terms of preventing or treating an illness (88-90). For example, weight loss surgery could lead to an improvement in diabetes management and related complications.
- *Perceived Barriers* or difficulties that could result from undertaking a health behaviour change (88-90). For example, attending regular follow-up appointments after bariatric surgery and maintaining lifestyle changes could be a potential barrier to undergoing surgery (89).

Cues to action which lead to readiness to change are another aspect of the HBM. Environmental factors such as having a family member suffer the complications of a

disease caused by obesity may motivate a person to lose weight. Also, physical factors such as painful joints may be a cue for an individual to take action to change behaviours in order to lose weight (88-90).

Self-efficacy is one's belief that he/she has the ability and self-confidence to make positive behaviour changes. Self-efficacy is the most important determinant of nutrition behaviour especially relating to food intake and purchases. Higher self-efficacy promotes more positive and fewer negative expectations about the consequences of healthier food choices. Individuals with higher self-efficacy in their ability to make healthy food choices have lower levels of fat intake and higher amounts of fruit, vegetable, and fiber intake (91). Once individuals recognize perceived threats to their health, self-efficacy is needed to overcome the perceived barriers in order to change behaviours. Individuals with higher levels of self-efficacy are more likely to successfully change behaviours (90).

Perceived threats are the main motivating factors for individuals to change behaviours (89). Since the primary motivation for individuals to pursue bariatric surgery is for medical/health reasons (63), it can be assumed that perceived threats will be the consequences of obesity on overall health. The perceived benefits of the surgery will have to be greater than the perceived barriers. Possible perceived benefits for bariatric surgery may be improvements in overall health once weight loss is achieved. Potential perceived barriers could be surgical complications or working at maintaining weight loss after surgery and self-efficacy will need to be present in order to overcome the perceived barriers.

Patients may view the components of the HBM differently after surgery. As mentioned earlier, as time after surgery increases, quality of life decreases and energy intake and weight often increase (12,13, 61). In terms of the HBM, the perceived threat of health related consequences of obesity several years after surgery may decrease and individuals may resort back to pre surgery behaviours which may lead to weight gain and decreased quality of life. Self-efficacy may decrease over time making it more difficult to see perceived benefits and overcome perceived barriers to change. It is anticipated that individuals who are recently post surgery (1-2 years) would have a greater perceived threat of obesity related health consequences compared to those who are several years post surgery. This is because individuals who are within a shorter time frame after surgery would likely remember the impact of obesity on their health before surgery as well as remember the cues to action which helped motivate behaviour change. This may lead to continued motivation to work at diet and lifestyle changes after surgery to maintain a healthy weight. Self-efficacy will likely remain high as weight loss may help maintain self-confidence and motivation. Over time, motivation may decrease, putting patients at risk for relapsing into behaviours which may lead to weight gain.

Chapter 4.0 Methodology

4.1 Research Design

This research study was a survey design and involved patients one year and greater after LSG. Four day food records and HEI scores were used to measure nutritional intake and diet quality and a BQL questionnaire was administered to collect information on quality of life. A retrospective chart review was used to collect information on laboratory parameters, patient characteristics, and height and weight.

4.2 Ethical Considerations

The study received ethical approval from Mount Saint Vincent University and Capital Health (Appendix B). Minor changes were required by Capital Health before full approval was obtained. It was later decided to send follow-up letters to patients to remind them to participate in the study and these were mailed once ethical approval was received from both institutions. Although informed consent was not necessary for this study, participants were giving their implied consent by taking part in the research. Participants were kept anonymous at all times throughout the research process. Research data was stored in a locked filing cabinet and electronic data was stored in encrypted files.

4.3 Subject Selection

Patients followed by the QEII Health Sciences Center weight loss surgery program, the single centre in Atlantic Canada specializing in LSG who had their LSG surgery between December 2008 and March 2010 were invited to participate in the study. The multi-disciplinary weight loss surgery team was formed in December 2008. The time frame specified was chosen as it takes several weeks after surgery to advance

to a regular diet and it can also take several months for nutrient deficiencies to develop. Recruiting patients who were ≥ 1 year post operatively at the time of data collection may be reflective of potential nutritional consequences resulting from the surgery. Also, this time frame may have allowed for changes in quality of life after surgery to take affect.

Inclusion Criteria:

- Patients must be able to read and write English

Exclusion Criteria:

- Major post operative complications
- Patients not attending clinic follow-up appointments
- Patients who were not getting routine blood work
- Patients who did not complete both the food record and BQL questionnaire

Weight Loss Surgery Program at the QEII Health Sciences Centre:

Patients are referred to the Weight Loss Surgery Program at the QEII by their family doctor. Patients attend a group pre-surgery clinic appointment where they learn about the LSG and the importance of lifestyle changes. If the patient feels they are ready to make the necessary changes and if members on the weight loss surgery team feel they may be an appropriate candidate, patients proceed onward to be assessed individually by the professionals on the team. During the assessment process patients are further assessed for candidacy, receive additional education about the surgery and undergo surgery if appropriate. Post surgery follow-up occurs one month, three months, six months, 12 months and then yearly for five years. Table 4 lists the

information collected and monitored for each patient during initial assessment and then during post surgery follow-up.

Table 4 - Information Collected and Monitored by the Weight Loss Surgery Team

Information Monitored			
Total Cholesterol	AC glucose	Gamma GT	FT4
HDL Cholesterol	Hemaglobin A1C	Urea	Vitamin D
LDL Cholesterol	ALT	Creatinine	Calcium
Triglyceride	AST	Albumin	Vitamin B ₁₂
Triglyceride/HDL ratio	LD	TSH	Folate
Hemaglobin	Ferritin	Thiamine	Blood Pressure
Weight	Height	BMI	C-reactive protein

Patients are asked to keep a daily food record which is reviewed by the dietitian at each appointment. Often patients record their food intake in a personal journal resulting in the information not being included in the medical record. Patients are required to have blood work done before each appointment and the results are reviewed by the dietitian and nurse practitioner. Information from clinic appointments and hospital admissions is stored in an electronic health record as well as in a paper chart. The paper charts are available from the nurse practitioner.

4.4 Recruitment Procedure

Approximately 72 patients were eligible to participate. Patients who had surgeries between the specified dates and who fit the inclusion and exclusion criteria were identified by the weight loss surgery team's dietitian and nurse practitioner. The dietitian or nurse practitioner provided each attending physician's administrative

assistant a list of names of patients who were selected to take part and the researcher provided them with a list of subject numbers to assign to each patient that was recruited. Subjects were recruited by sending a letter in the mail from each patient's attending physician inviting them to participate (Appendix C). The letter introduced the researcher, clearly outlined the purpose of the research, and explained that if the patient chose to participate they were giving their implied consent and were also allowing the researcher to complete a retrospective chart review. Included with the letter, was a BQL questionnaire (Appendix A) and blank four day food records (Appendix D) (each containing a subject number) to be completed if the patient chose to participate. The researcher placed subject numbers on the food records and BQL questionnaire and placed them along with the physician letter in an envelope. Each patient's attending physician's administrative assistant placed names and addresses on each envelope that corresponded with the subject numbers on the food records/questionnaire inside the envelope. An empty stamped envelope with the attending physician's mailing address was also included for return of the completed food records and questionnaire.

A follow-up letter (Appendix E) was sent to patients about six weeks after the initial package was mailed to remind patients to participate in the study if they were interested. The researcher placed the letters in envelopes and each attending physician's administrative assistant placed address labels on the envelopes and placed them in the mail. This procedure ensured that the researcher did not know participants prior to the provision of implied consent.

4.5 Data Collection

Data was collected between June 2011 and November 2011.

4.5.1 BQL Questionnaire

The BQL questionnaire (Appendix A) contained instructions on how to complete it. Questions regarding the use of vitamin and herbal supplements required to assess adequacy of intake were added to the original version of the questionnaire.

4.5.2 Four Day Food Record

The four day food record (Appendix D) contained instructions on how to complete a detailed record in addition to information on how to record serving sizes. An internet address to a narrated slide show on how to record food intake accurately was provided. The slide show was posted on the Capital Health internet website under the Weight Loss Surgery Program. Subjects were asked to record all food and beverages consumed each day along with the time of when it is consumed. There was space on the top of each page of the food record for subjects to record the date. Subjects were asked to include one weekend day in the record as previous research shows that nutritional intake on weekend days is often different than on weekdays (77).

4.5.3 Retrospective Chart Review

The retrospective chart review was performed to collect information on subject characteristics, weights, and laboratory parameters. The electronic health record at Capital Health is called Horizon Patient Folder (HPF) and it contains scanned documents from previous hospital admissions and clinic appointments. The documents are in order starting with the most recent documents at the beginning of the file. Medical records were obtained on HPF by entering a patient's medical record number. The medical record number was obtained through the subject number located on the returned questionnaires and food records. When the food records/questionnaires were

returned to each attending physician’s administrative assistant, he/she located the medical record number that corresponded to the name. Each participant’s name was identified through the subject number. The attending physician’s administrative assistant gave the returned food records and questionnaires to the researcher along with a list of medical record numbers that corresponded to the subject numbers on the returned items.

Some of the information was initially collected by reviewing dictated letters on HPF from previous clinic visits which contained information on blood work results, weight, and overall progress. The information on HPF was often incomplete so paper charts located in the nurse practitioner’s office were reviewed for each patient to collect necessary study data.

Most recent laboratory values were collected as shown below.

Table 5 - Lab Values, Normal Ranges, and Rationale for Measuring

Laboratory value	Normal Range*	Rationale
Albumin	35-50 g/L	Marker of overall nutritional status over the previous 21 days (92). Indicator of whether a patient is meeting their nutritional needs.
Vitamin D	>75 nmol/L	Deficiency is often seen in morbid obesity (36) and in post bariatric surgery (42,44).
Vitamin B ₁₂	156-672 pmol/L	Deficiency is often seen in morbid obesity and in post bariatric surgery. Fundus (containing parietal cells) is removed during LSG which is needed to absorb vitamin B ₁₂ (40).
Folate	≥12 nmol/L	Deficiency is often seen in morbid obesity (42,43) and in post bariatric surgery (36,40).
Hemoglobin	120-160 g/L	Used along with ferritin to identify iron

		deficiency anemia. Low levels indicate anemia (93). Post bariatric surgery patients are at risk for iron deficiency anemia (36,40).
Ferritin	12-100 ng/mL	Used along with hemoglobin to identify iron deficiency anemia. Low levels indicate iron deficiency (93). Post bariatric surgery patients are at risk for iron deficiency anemia (36,40).
Vitamin B1	7-44 nmol/L	Requested to record from the weight loss surgery team at the QEII as gastric bypass patients are deficient in this vitamin and it would be interesting to determine if LSG patients develop deficiency.
C- reactive Protein	0-8.0 mg/L	Measure of inflammation. Value is needed to interpret albumin as albumin is a negative acute phase reactant (92).
*Based on Capital Health's laboratory reporting system		

The reference ranges for the laboratory values collected varied for different facilities outside of Capital Health. The references ranges were recorded along with each laboratory value.

The following information was collected from the retrospective chart review:

Weights: Initial weight before surgery and most recent weight

Height: Most recent record on file

BMI: Most recent record on file or calculated using height and most recent weight

Percentage weight loss: Calculated by the number kilograms lost divided by initial weight in kilograms multiplied by 100%.

Date of Surgery: Collected to measure the amount of time that had passed since subjects had their surgery.

Season vitamin D measured: Assess known seasonal variation in vitamin D nutritional status.

Socio demographic variables included age, gender, employment status, and marital status were collected to determine if there would be a relationship between subject characteristics and study results. The data were recorded on a Data Collection Tool (Appendix F).

Information on patient characteristics such as age and gender was available on the top of each page on HPF or in the paper chart. Information on employment and marital status was available from the individual assessment prior to surgery. Data on initial weight was also found in the initial assessment notes. The date of surgery was found in a variety of places on HPF such as notes from the hospital admission for the surgery or under clinic follow-up letters. It was also available in the paper chart in clinic follow-up letters.

4.6 Data Analysis

4.6.1 Four Day Food Record

Food records were reviewed carefully paying close attention to overall themes that emerged and personal messages written in by participants. The number of meals and snacks consumed for each participant were recorded. A snack was defined as less than 150 calories and meals were considered to be more than 150 calories and were a minimum of 1.5 hours apart.

All of the codes in The Food Processor, ESHA (Elizabeth Stewart Hands and Associates) Research, Salem Oregon, Version 10.6.0 were reviewed and a list was formulated. Correct codes were placed next to the corresponding food item in each record. The codes and quantities for each food item were entered into The Food Processor to obtain nutrient analysis printouts for each day of intake for each participant. If quantities were not listed in the food record, they were estimated based on Eating Well with Canada's Food Guide and on information from the QEII Weight Loss Surgery dietitian.

Macronutrient distribution was calculated by dividing the overall average energy intake from each macronutrient by total energy intake, multiplied by 100%. Estimated energy requirement (EER) for a sedentary lifestyle was calculated using the Institute of Medicine's equation for BMI greater than 25 kg/m² (70).

Male EER = 1085.6-10.08* age (years) + 1*(13.7* weight (kg) + 416* height (m))

Female EER = 447.6-7.95* age (years) + 1*(11.4* weight (kg) + 619* height (m))

Ratio of actual energy intake to EER was calculated to assess under/over reporting.

Expected weight loss was calculated to determine if it differed from actual weight loss which may predict underreporting. The caloric deficit to equal a weight loss of 1kg per week was estimated at 700 calories per day. The following calculations were carried out:

- This difference between EER and actual energy intake was divided by 700 calories per day and multiplied by 48 weeks (average length of time between surgery and most recent weight) to give the expected weight loss in kilograms.
- The expected weight loss was subtracted from the pre-surgery weight to give the expected post surgery weight.
- Expected percentage weight loss=

$$\frac{(\text{pre-surgery weight}) - (\text{expected post surgery weight})}{(\text{pre-surgery weight})} \times 100\%$$

4.6.2 Measuring Dietary Adequacy

Estimated Average Requirement (EAR) was used as the reference standard to estimate an individual's nutrient requirement. Micronutrient intakes for each participant were obtained from the nutrient analysis printouts. Micronutrient intake and the EAR were used to calculate risk of micronutrient inadequacy/adequacy for participants.

The following calculations were carried out (78).

- The standard error (SE) and n at the population level from the Canadian Community Health Survey (CCHS) was used to calculate standard deviation (SD).

$$SE = SD / \text{square root of } n$$

$$SD = SE * \text{square root of } n$$

- Variance of daily intake was determined by squaring of the SD
- The square of the SD was divided by number of days of observed intake.

- This was added to the square of the coefficient of variation (CV). CV = 10% of the EAR except, 15% for niacin.
- The square root was then taken to determine SD_D for distribution.
- Difference (D) between mean intake and EAR/SD_D distribution = z score. The table below was used to determine the probability of risk of adequate/inadequate intake.

Table 6- Criteria to Predict Probability of Correct Conclusion of Adequate/Inadequate Micronutrient Intake

Criterion	Conclusion	Probability of correct conclusion
$D/SD_D > 2.00$	Usual intake is adequate	0.98
$D/SD_D > 1.65$	Usual intake is adequate	0.95
$D/SD_D > 1.50$	Usual intake is adequate	0.93
$D/SD_D > 1.00$	Usual intake is adequate	0.85
$D/SD_D > 0.50$	Usual intake is adequate	0.70
$D/SD_D > 0.00$	Usual intake is adequate (inadequate)	0.50
$D/SD_D < -0.50$	Usual intake is inadequate	0.70
$D/SD_D < -1.00$	Usual intake is inadequate	0.85
$D/SD_D < -1.50$	Usual intake is inadequate	0.93
$D/SD_D < -1.65$	Usual intake is inadequate	0.95
$D/SD_D < -2.00$	Usual intake is inadequate	0.98

To calculate the percentage of participants with risk of inadequate intake for each micronutrient, the number of participants with a probability of inadequacy was divided by *n*. To calculate the percentage of risk of inadequate micronutrient intake for each

participant, the overall number of inadequate micronutrient intakes for each subject was divided by 12 (the number of micronutrients measured).

4.6.3 Healthy Eating Index

Food records were reviewed to calculate HEI scores for each participant. The number of servings consumed by participants for the first seven food categories (Table 3) in the HEI adequacy component was estimated based on food guide serving sizes from Eating Well with Canada's Food Guide (94). The number of grams of saturated fat for the saturated fat food category in the adequacy component was obtained from the nutrient analysis printout. Percentage of total energy intake from saturated fat and sodium intakes for the moderation component was taken from the nutrient analysis printout. The amount of calories from "other food" for the other food category in the moderation component was obtained from looking up the nutritional information of these foods in the nutrient analysis program. The calories from other foods consumed were divided by the total amount of energy consumed to calculate percentage of calories from other food.

Scores were calculated for the two components of the HEI scoring system.

Adequacy Component:

- Density score was calculated for each food category as per 2005 HEI syntax (95).

The total number of servings is the servings of food consumed from each adequacy food category.

Density Score=Total number servings/total calories

- A score was assigned proportionately according to the Canadian adaptation scoring criteria based on age and gender (Table 3).

Moderation Component:

- The percentage of total energy intake for saturated fats and other foods was assigned proportionately based on Canadian adaptation scoring criteria (Table 3).
- A score for sodium was assigned proportionately based on comparing intake to adequate intake and tolerable upper limits.

HEI scores were calculated for each participant's days of intake by summing the scores from the food categories in the adequacy and moderation components. Overall scores were calculated for the adequacy and moderation components for comparison purposes.

Some of the HEI food categories were the same as the four food groups in Eating Well with Canada's Food Guide (94). The HEI data were used to calculate the consumption of servings from the food groups.

4.6.4 Laboratory Data

Laboratory values were categorized into normal, above normal, or deficient based on the normal ranges given by the laboratory.

4.6.5 BQL Questionnaire

The majority of the questions in the BQL questionnaire were scored based on the assigned scoring criteria. An additional question on vitamin supplements was added to the questionnaire for convenience purposes but was not assigned a score because it is not related to quality of life. The BQL questionnaire contained some scoring errors. Questions seven through nine in part two of the questionnaire were reverse scored so that a negative attitude would not be associated with higher scores and better quality of life (Appendix G). This was also done in a previous study that used the questionnaire (68).

Various combinations of questions were run through reliability analysis on SPSS and a Cronbach's Alpha was calculated to measure internal consistency. Question 11 a-c in part two was removed due to the impact it had on lowering Chronbach's Alpha. The last physical condition/symptom listed in question one in part one was removed as no participants reported it. After removing the questions, the Cronbach's Alpha was .692 which is very close to the internal consistency of the original version (69). BQL scores were standardized on a 0 to 100 scale with higher scores indicating better quality of life.

4.6.6 Statistical Analysis

Data were entered into Microsoft Office Excel 2007 (version 12.0.6425.1000, Microsoft Office Corporation, USA) or in SPSS (version 18, International Business Machines (IBM), Armonk, NY, USA). Socio demographic, dietary, laboratory values, BQL questionnaire scores, and diet quality scores were treated as continuous variables or were dichotomized into groups greater than and equal to the mean or less than the

mean or into age groups of <50 years and \geq 50 years and treated as categorical variables. Data were summarized using mean, standard deviation (SD), percentages, and ranges and were presented in tables and figures. Pearson Correlation analysis was used to measure associations between continuous variables. Level of significance for a two-tailed Pearson Correlation analysis at alpha of .05 for n=19 participants is 0.456. Two tailed t-tests (Levene's Test for Equality of Variances) were carried out in SPSS to determine significant differences between age group and continuous variables. Chi-squared test for independence was used to determine differences between observed and expected frequencies of categorical variables. All statistical significant results are defined as $p < .05$.

4.6.7 Subgroup

A small group of participants who completed the BQL questionnaire but did not complete the food record were analyzed separately. Descriptive statistics were used to summarize percentage weight loss, pre and post surgery BMI, age, overall BQL scores and components of the BQL questionnaire.

Chapter 5.0 Results

Seventy-two (72) patients were invited to take part in the study of which 22 completed the BQL questionnaire and 19 completed the food record giving response rates of 31% and 26% respectively. Eighteen (18) participants completed a four day food record and one participant completed a three day food record. Some categories of the demographic variables cannot be reported ($n < 5$) in keeping with Statistics Canada (96) confidentiality requirements.

The subgroup ($n=3$) of participants who completed the BQL questionnaire but did not complete the food record had similar characteristics as the larger group and means did not vary greatly as a result of exclusion. For example, the BQL scores for those who completed the BQL questionnaire ($n=3$) were the same as those who completed the BQL questionnaire and food record ($n=19$).

There is a discrepancy in the amount of time between surgery and weight/laboratory measurements, and between surgery and completion of food records/BQL questionnaires. The average length of time between date of surgery and most recent weight/laboratory values was about one year. The average length of time between surgery and collection of food records/BQL questionnaires data was 22 months. This is because at the time of data collection, most participants were within a couple of months of being due for their yearly clinic follow-up appointment where updated weights and laboratory measurements would have been obtained.

5.1 Demographic and Weight Distribution

The majority of participants were female, employed, married, and 50 years and older. Mean age was 48.2 +/- 8.6 years and the mean length of time post surgery was 22 months with an average percentage weight loss of 26.1 +/- 10.6% at 13 months after surgery. Participants who weighted more prior to surgery lost more weight after surgery ($r=0.482$, $n=19$, $p<.05$). Those <50 years had higher pre-surgery BMI and lost more weight post surgery when compared to the ≥ 50 age group.

Table 7 - Demographics, BMI, and Percentage Weight Loss by Age Category 13 months after LSG

Age Category (<i>n</i>)	Age (years)	Married	*Pre surgery BMI (kg/m ²)	*Post surgery BMI (kg/m ²)	*Percentage weight loss
< 50 yrs (9)	Range:35-49 *41.2 +/- 5.6 (47%)	56%	48.7 +/- 9.6	31.6 +/- 3.8+	33.6 +/- 10.8+
≥ 50 yrs (10)	Range :50-67 *54.5 +/- 5.3 (53%)	60%	46.7 +/- 6.6	37.5 +/- 7.1+	19.3 +/- 7.8+

*Expressed at mean +/- SD

+Statistical significance ($p<.05$)

Although unmarried participants lost 6% more weight (24.3 % versus 30.4%), this difference was not statistically different.

5.2 Laboratory Data Distribution

The average length of time between surgery and most recent blood work was 11 months. Of all the nutrients assessed for adequacy, only Vitamin B₁₂ was found to be deficient. Two participants (10.5%) had vitamin B₁₂ deficiency and they were evenly

distributed among both age groups. Both participants with the deficiency were taking a multivitamin, and one participant was also taking a vitamin B₁₂ supplement. Vitamin B₁₂ levels were negatively skewed showing most intakes to the lower to mid range of normal (156-672 pmol/L) (Figure 2).

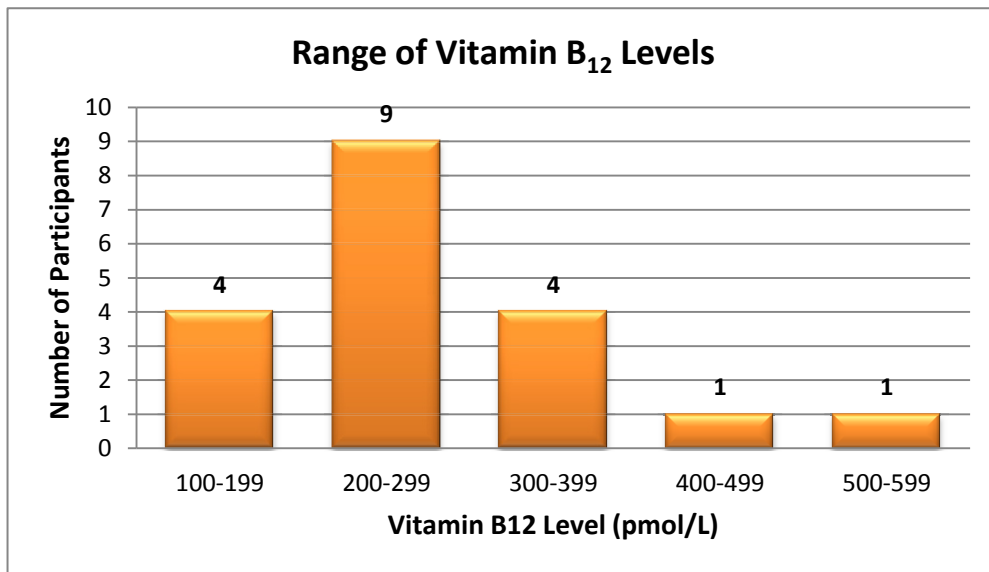


Figure 2 - Range of Vitamin B₁₂ levels 11 months after LSG

Many participants had suboptimal vitamin D levels. One participant had insufficient vitamin D levels (<40 nmol/L) and eight participants (42%) had levels between insufficient and desirable (>40nmol/L but <75 nmol/L) as per criteria provided by the laboratory (97) and were divided evenly among the two age groups. No participants had levels that would be considered deficient and about three quarters of participants that had below desirable levels were taking a multivitamin/mineral supplement and a vitamin D supplement. The range of vitamin D levels was fairly normally distributed (Figure 3).

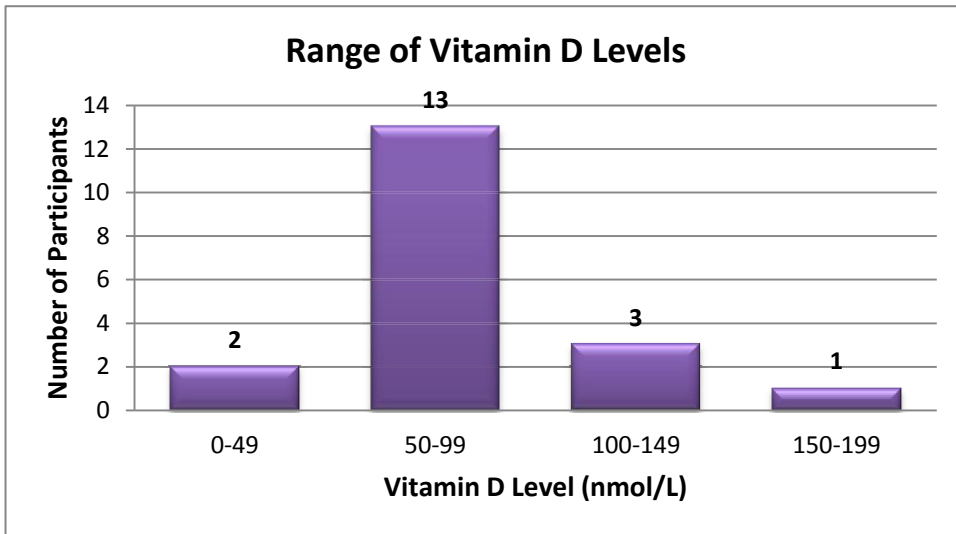


Figure 3 - Range of Vitamin D levels 11 months after LSG

Vitamin B₁ and albumin levels were normal for all participants. One participant had an above normal CRP level and another had an above normal folate level and were taking a folic acid supplement. Three participants (15.7%) had below normal ferritin levels and two of them were in the <50 age group. Two participants had below normal haemoglobin levels and one of them also had a below normal ferritin level. One participant had below normal levels/deficiency in both ferritin and vitamin B₁₂. Some participants had missing lab values for certain nutrients that were measured making it possible that those with a missing value may have had a deficiency.

Table 8 - Normal ranges, Mean+/- SD of Laboratory Tests by Age Category 11 months after LSG

Laboratory Test	Normal Range	<50 Years (n)	≥50 years (n)
Folate	>6.25 nmol/l	27.2+/-10.2 (8)	32.5+/-15.2 (8)
Vitamin B12	156-672 pmol/L	256.0+/-59.0 (9)	314.0+/-125.6 (10)
Vitamin B1	7-44 nmol/L	38.2+/-13.2 (7)	40.4+/-15.5 (7)
Vitamin D	>70 nmol/L Desirable <40 nmol/L Insufficient <25 nmol/L Deficient	77.8+/-13.3 (9)	82.7+/-35.3 (10)
Albumin	35-50 g/L	39.3+/-3.0 (9)	41.5+/-3.8 (10)
Ferritin	10-291 ug/L	48.6+/-57.2 (9)	107.2+/-136.4 (9)
Hemoglobin	120-160g/L	126.6+/-12.6 (9)	139.0+/-16.3 (10)
C-Reactive Protein	<10mg/L	3.8+/-3.2 (9)	4.8+/-4.6 (10)

5.3 BQL Questionnaire

5.3.1 BQL Scores

The amount of time surgery between surgery and BQL questionnaire administration was 22 months. The BQL questionnaire scores ranged from 51 to 95.2 with a mean of 78.1+/-14.0 out of 100. The distribution of BQL scores was binomial with the 60-69 and 80-89 ranges containing the most participants compared to the other three ranges (Figure 4).

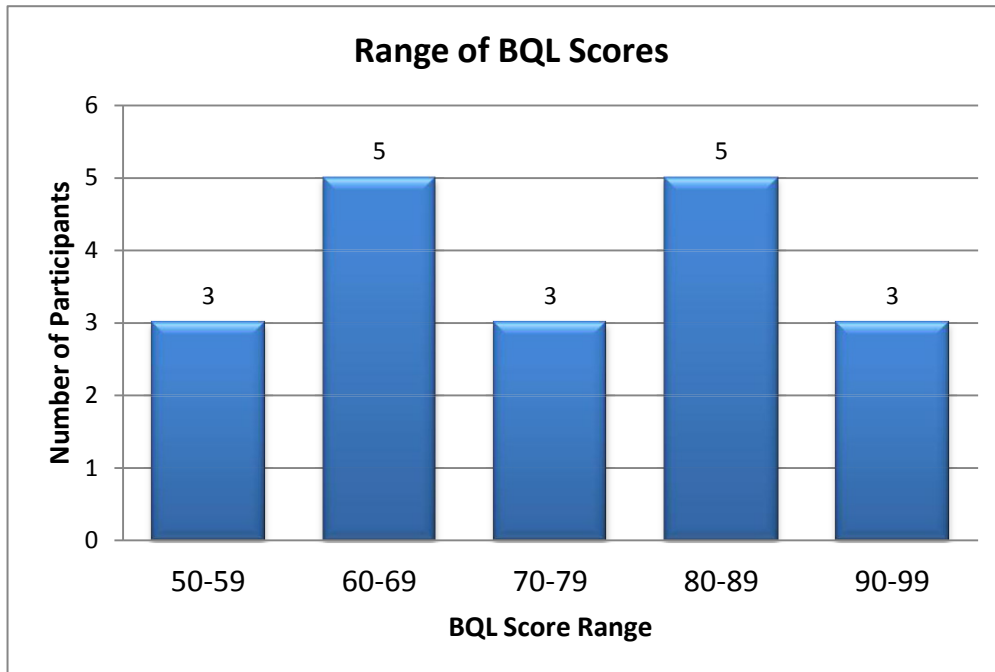


Figure 4 - Range of BQL Scores 22 months after LSG

Post-surgery BMI was negatively correlated with the BQL score ($r=-0.641$, $n=19$, $p<.05$) while percentage weight loss was positively correlated with the BQL score ($r=0.476$, $n=19$, $p<.05$). Participants aged <50 had higher BQL scores, were on less medications, and had fewer physical symptoms/conditions compared to the ≥ 50 age category. There was no association between energy intake and BQL score.

Table 9- Overall BQL Score and Components of BQL Questionnaire by Age Category 22 months after LSG

Age Category	*BQL Score (Range)	*Raw Attitude Score	*Number of Physical symptoms/conditions	*Number of Medications
<50 years	82.3+/-9.7 (62.5-86.5)	52+/-7.3	2.3 +/-2.18	0.7 +/- .71
≥ 50 years	74.2+/-16.6 (51-94.2)	51.7+/-5.4	3.6 +/-2.6	1.4 +/-1.7

*Expressed as mean +/- SD

5.3.2 Medication Intake

The ≥ 50 age group took more medication than the < 50 group. Most participants (57.9%) took at least one medication on a regular basis. The majority of individuals were taking one medication (36.8%) and few (10.5%) were taking three or four medications. Anti-depressants, anti-hypertensives, and pain killers were taken most frequently. Appetite suppressants and diuretics were taken less often (Figure 5).

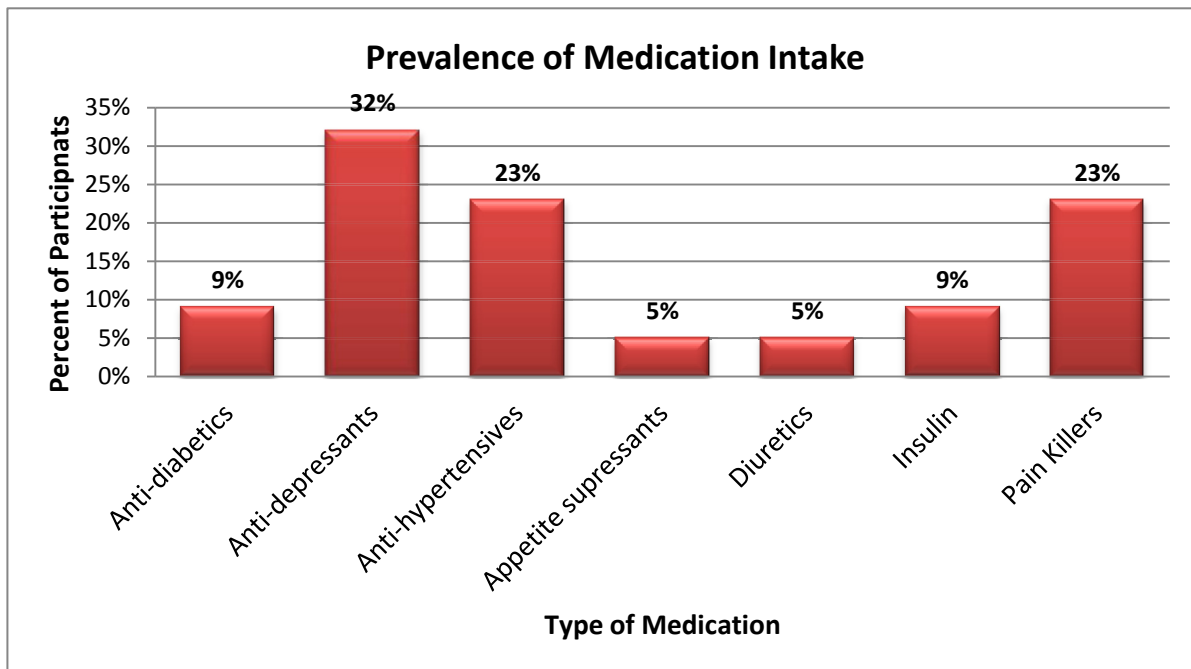


Figure 5 - Prevalence of Medication Intake 22 months after LSG

5.3.3 Physical Symptoms/Medical Conditions

Eighty-four percent (84%) of participants reported physical symptoms/medical conditions. Forty-two percent (42%) reported two to three symptoms/conditions and fewer (15.8%) reported five to seven symptoms/conditions. Participants with more physical symptoms were older ($r=0.499$, $n=19$, $p<.05$) and there was no association

between the number of physical symptoms and weight loss. One third of participants self identified as being diabetic and 18% of participants reported taking medications to manage diabetes (Figure 5). About a quarter of participants identified themselves as having hypertension and the same number reported taking antihypertensive drugs.

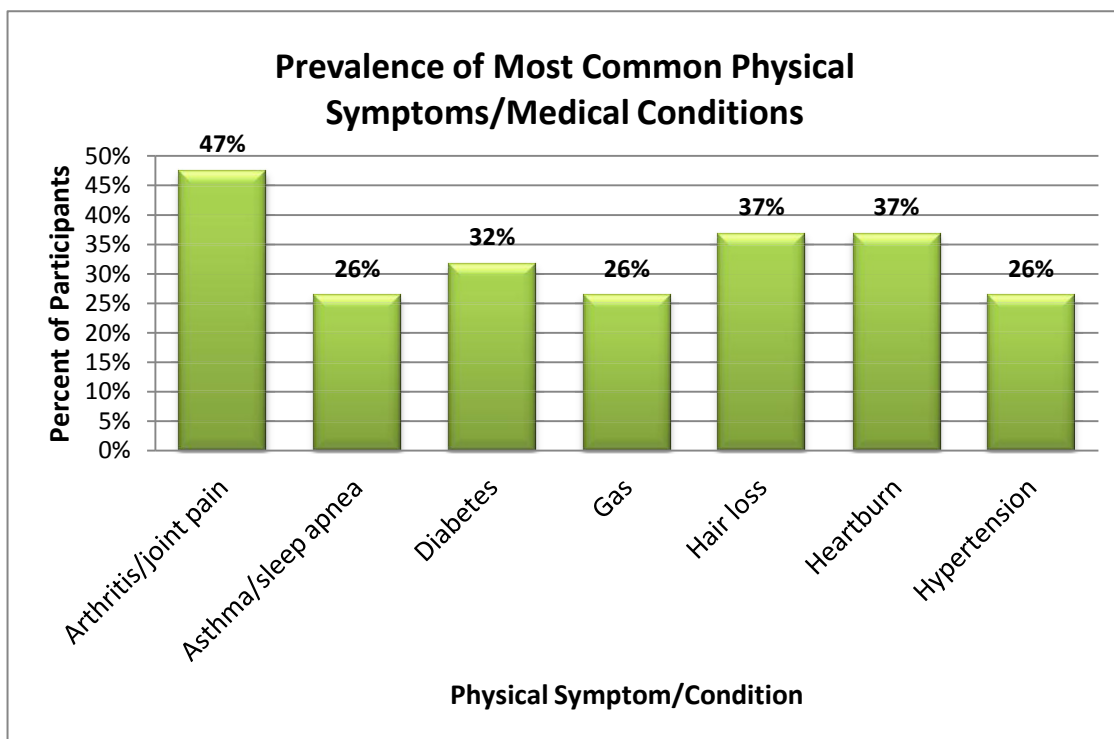


Figure 6 - Prevalence of Physical Symptoms/Medical Conditions 22 months after LSG

5.3.4 Attitude

The majority of participants (84%) rated their quality of life as “good” to “very good” (Table 10). Consistent with this appraisal (84%) rated their satisfaction with life to be “true” to “absolutely right” and about three quarters of participants “agree” to feeling self-confident. There was no association between attitude score and weight loss.

Table 10 - Responses to the Attitude Component of the BQL Questionnaire

I like my weight.				
<input type="checkbox"/> (0%) Absolutely wrong	<input type="checkbox"/> (10.5%) Wrong	<input type="checkbox"/> (52.6%) Half/half	<input type="checkbox"/> (26.3%) True	<input type="checkbox"/> (10.5%) Absolutely right
I can accept my weight.				
<input type="checkbox"/> (0%) Absolutely wrong	<input type="checkbox"/> (0%) Wrong	<input type="checkbox"/> (26.3%) Half/half	<input type="checkbox"/> (47.4%) True	<input type="checkbox"/> (26.3%) Absolutely right
How is your actual quality of life?				
<input type="checkbox"/> (0%) Very bad	<input type="checkbox"/> (0%) Bad	<input type="checkbox"/> (15.8%) Ok	<input type="checkbox"/> (26.3%) Good	<input type="checkbox"/> (57.9%) Very good
I exercise regularly.				
<input type="checkbox"/> (0%) Absolutely wrong	<input type="checkbox"/> (0%) Wrong	<input type="checkbox"/> (26.3%) Half/half	<input type="checkbox"/> (21.1%) True	<input type="checkbox"/> (52.6%) Absolutely right
I am participating in social activities (movies, etc).				
<input type="checkbox"/> (0%) Absolutely wrong	<input type="checkbox"/> (5.3%) Wrong	<input type="checkbox"/> (5.3%) Half/half	<input type="checkbox"/> (15.8%) True	<input type="checkbox"/> (73.7%) Absolutely right
I often meet friends or family.				
<input type="checkbox"/> (0%) Absolutely wrong	<input type="checkbox"/> (0%) Wrong	<input type="checkbox"/> (21.1%) Half/half	<input type="checkbox"/> (26.3%) True	<input type="checkbox"/> (52.6%) Absolutely right
I feel excluded from social life.				
<input type="checkbox"/> (68.4%) Absolutely wrong	<input type="checkbox"/> (21.1%) Wrong	<input type="checkbox"/> (5.3%) Half/half	<input type="checkbox"/> (0%) True	<input type="checkbox"/> (5.3%) Absolutely right
I feel under pressure because of my weight				
<input type="checkbox"/> (31.6%) Absolutely wrong	<input type="checkbox"/> (36.8%) Wrong	<input type="checkbox"/> (21.1%) Half/half	<input type="checkbox"/> (10.5%) True	<input type="checkbox"/> (0%) Absolutely right
Sometimes, I feel depressed.				
<input type="checkbox"/> (31.6%) Absolutely wrong	<input type="checkbox"/> (31.6%) Wrong	<input type="checkbox"/> (15.8%) Half/half	<input type="checkbox"/> (21.1%) True	<input type="checkbox"/> (0%) Absolutely right
All in all, I feel satisfied in my life.				
<input type="checkbox"/> (0%) Absolutely wrong	<input type="checkbox"/> (0%) Wrong	<input type="checkbox"/> (15.8%) Half/half	<input type="checkbox"/> (42.1%) True	<input type="checkbox"/> (42.1%) Absolutely right

I feel self-confident.				
□(0%)	□(0%)	□(26.3%)	□(26.3%)	□(47.4%)
Absolutely wrong	Wrong	Half/half	True	Absolutely right

5.4 Vitamin Supplement Intake

Mean daily supplement intakes were 2.7+/-1.3 and 2.9+/-1.9 for the <50 and ≥50 age groups respectively 22 months after surgery. Almost all participants (95%) indicated that they took a vitamin/mineral supplement regularly. The number of supplements consumed ranged from zero to seven. More than half (53%) of participants took two or three supplements. The most common “other supplements” taken were herbal sleep aids and omega three. The majority of participants took a multivitamin/mineral supplement, vitamin D, and calcium (Figure 7).

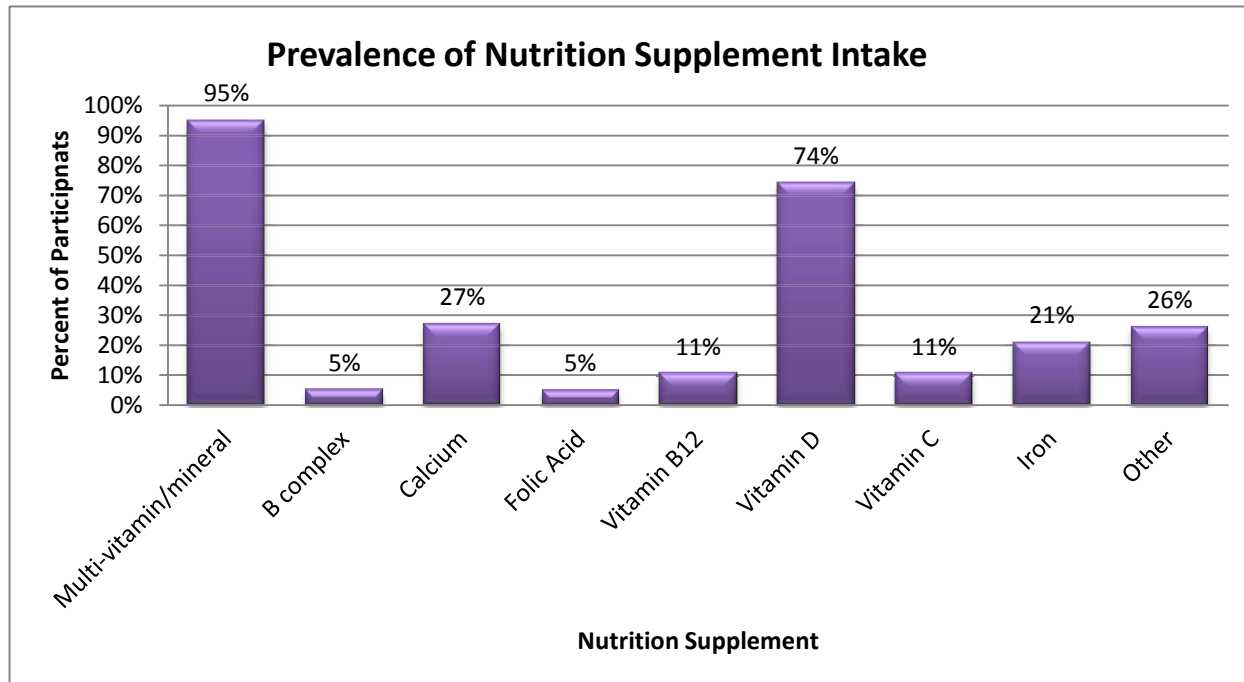


Figure 7- Prevalence of reported Nutrition Supplement Intake 22 months after LSG

5.5 Healthy Eating Index

The overall mean HEI score was 60.4 +/-8.8 with a range of 37.5-69.9 out of a maximum score of 100 at 22 months after surgery. The mean score for the adequacy and moderation components were 30.2 and 31.1 out of maximum scores of 60 and 40 respectively. The HEI scores improved as energy intake decreased ($r = -0.564$, $n=19$, $p<.05$) (Table 11).

Table 11- Mean Scores for HEI Categories by Age Group 22 months after LSG

Food Category	<50 years*	≥50 years*
<i>Adequacy Component</i>		
Vegetable and Fruit	3.2 +/-1.0	3.2+/-1.3
Green and orange vegetables	1.3+/-0.9	1.9+/-1.2
Whole fruit	2.4+/-1.0	2.3+/-1.3
Grain	.7+/-0.5	1.2+/-0.4
Whole grain	.7+/-1.1	1.1+/-0.8
Milk and Alternatives	6.2+/-1.8	5.1+/-2.1
Meat and Alternatives	6.7+/-1.5	6.4+/-1.1
Unsaturated Fat (g)	2.3+/-0.7	3.3+/-1.7
<i>Moderation Component</i>		
Saturated fat (%)	6.2+/-2.6	4.7+/-2.3
Sodium (mg)	9.3+/-1.4	8.1+/-2.2
Other Food (%) 1992 version of food guide	17.8+/-3.3	16.5+/-3.9

*Expressed as mean +/- SD

The majority of points were scored in the moderation component, particularly in the percentage of calories from “other food” category for both age groups. The <50 age

group had higher scores in the moderation component and overall compared to the ≥ 50 age group.

Table 12 - Scores for the Components of the HEI and overall HEI Score 22 months after LSG

Age Category	*Adequacy Component Score	*Moderation Component Score	*Overall HEI Score
<50 years	29.7 +/- 3.4	33.3 +/-4.2	61.2+/-6.6
≥ 50 years	30.5+/-5.6	29.9 +/-6.6	59.7+/-10.7

*Expressed as mean +/-SD

5.6 Four Day Food Record

Energy intake ranged from 856-2060 kilocalories per day with a mean energy intake of 1256+/- 384.5 kilocalories per day. Protein intake ranged from 47 to 115 g per day with a mean intake of 77.3 +/-17.5g per day. Protein intake increased as energy intake increased ($r=0.682$, $n=19$, $p<0.05$). Participants with higher energy intakes were more likely to have a greater number of physical symptoms/medical conditions ($p<0.05$). The ratio between energy intake and EER ranged from 0.36 to 0.92 with a mean of 0.57+/-0.17. Mean Predicted percentage weight loss was 65+/-26% for the <50 age group, 58+/-25% for the ≥ 50 age group, and 53+/-23% overall.

Participants in the <50 age group consumed fewer calories, consumed less percentage of total calories from fat and had similar protein, meal, and snack intake compared participants in the ≥ 50 age category. In terms of servings from the various food groups from “Eating Well with Canada’s Food Guide”, the <50 age group consumed less servings of grains and a greater number of servings from milk and alternatives compared to the ≥ 50 age group (Table 13). Consumption of servings from

the vegetables and fruit and meat and alternatives food groups were similar between the two age groups. Mean ratios of energy/EER were identical between the two age groups and underreporting of energy intake was about 43%.

Table 13- Energy, Macronutrient, Meal and Snack intake, and Food Guide Serving Consumption by Age Category

	<50 years	≥50 years
Energy (kcal)	1169.5 +/-281.8	1334.3 +/-459.2
EER	2087.6+/-210.6	2328.8+/-335.5
Energy/EER	.57+/.19	.57+/- .17
Protein (g)	75.8 +/-15.3	78.7+/-20.0
Meals	2.6 +/-1.5	2.0 +/- .80
Snacks	3.1 +/- .45	3.2+/- .27
Protein (% of Kcal)	26.4 +/-5.0	24.9+/-5.9
Carbohydrate (%of kcal)	45.0+/-9.0	39.8+/-8.1
Fat (% of Kcal)	29.0+/-7.4	36.6+/- .98
Food Guide Servings		
Fruit and Vegetable	3.7 +/-1.2	3.5+/-1.6
Grain	1.4+/- .9	2.4+/- .9
Milk and Alternatives	2.3+/-1.13	1.9+/- .05
Meat and Alternatives	2.4+/- .4	2.6+/- .6

There is a large degree of variation in micronutrient intakes. Participants consumed less vitamin D and iron compared to the EAR and a greater amount of niacin, vitamin B₆ and vitamin B₁₂ compared to the EAR (Table 14).

Table 14 – Mean Micronutrient Intake Compared to the EAR 22 months after LSG

Micronutrient	Mean Intake+/-SD	*EAR
Vitamin C (mg)	63.4+/-37.2	60-75
Vitamin A (IU)	6926.3+/-3923.6	2083
Calcium (mg)	886.8+/-366.0	800-1000
Folic Acid (mcg)	227.9+/-126.2	320
Iron (mg)	10.3+/-8.0	5-8.1
Niacin (mg)	19.5+/-7.5	11-12
Riboflavin (mg)	1.17+/-0.47	0.9-1.1
Vitamin B ₆ (mg)	2.4+/-4.4	1.1-1.4
Vitamin B ₁₂ (mcg)	4.77+/-4.5	2.0
Vitamin D (IU)	113.6+/-82.8	400
Zinc (mg)	6.1+/-2.2	3.8-9.4

*According to age and gender

Participants with risk of inadequate intake of micronutrients ranged from one to ten out of a possible 12 micronutrients analyzed. Eight participants (42%) had risk of inadequate intakes of between three and five micronutrients and nine participants (47%) had risk of inadequate intakes of between seven and ten micronutrients. Participants with lower energy and protein intakes were more likely to be at a lower risk of inadequate intakes ($p < .05$). The percentage of participants with risk of inadequate intakes of various micronutrients is described in Figure 8. Vitamin D had the highest probabilities of inadequacy with almost 80% of participants with a 0.70 to 0.85 probability of inadequacy using z-scores.

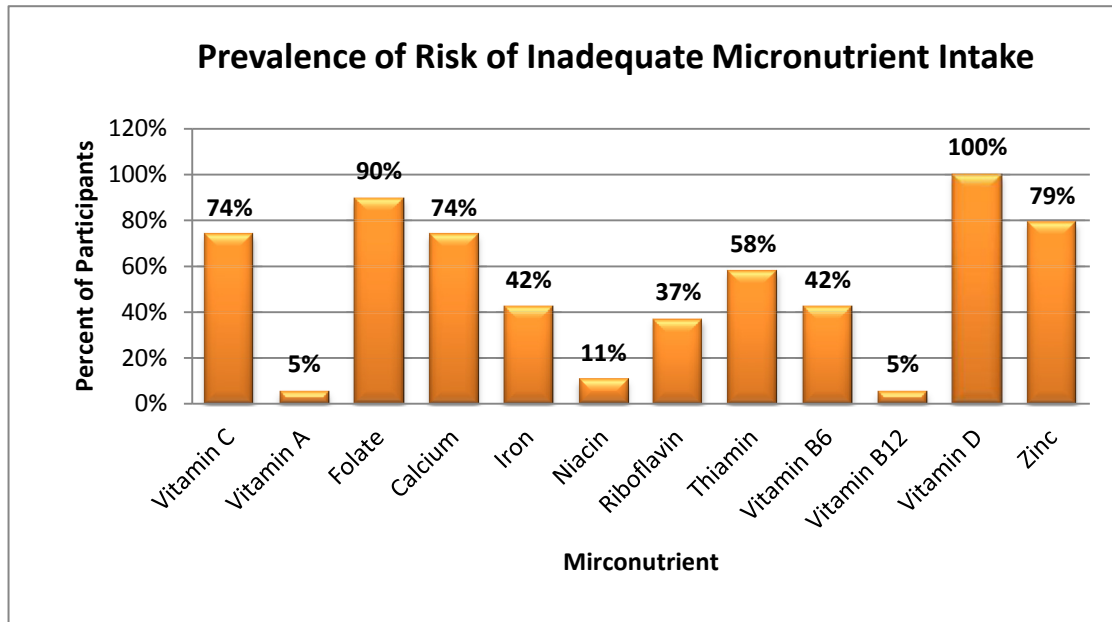


Figure 8 - Prevalence of Risk of Inadequate Micronutrient Intake 22 months after LSG

A greater number of participants in the <50 age category had risk of inadequate vitamin C, calcium, iron, riboflavin, vitamin B6, and zinc intake compared to the ≥ 50 age group. The number of participants with risk of inadequate intakes of folic acid and vitamin D were similar between the two groups and the ≥ 50 group had a greater number of participants at risk of inadequate vitamin B₁₂ intakes compared to the <50 age category. There was a significant relationship between age category and risk of inadequate iron intakes. Participants in the <50 age category were more likely to be at risk of inadequate iron intake ($p < .05$).

Table 15 - Prevalence of Risk of Inadequate Micronutrient intake by Age Category and Chi Square Analysis between Age and Adequacy/Inadequacy of intake

Micronutrient	<50 Years	≥50 Years	Degrees of Freedom	Chi Square (p-value)
Vitamin C	77%	70%	1	.7
Vitamin A	11%	0%	1	.4
Calcium	56%	80%	1	.09
Folic Acid	89%	90%	1	.9
Iron	67%	20%	1	.04+
Niacin	11%	10%	1	.9
Riboflavin	44%	30%	1	.5
Vitamin B6	44%	40%	1	.9
Vitamin B ₁₂	0%	10%	1	.5
Vitamin D	100%	100%	1	_____
Zinc	100%	60%	1	.1

+ statistical significance ($p < .05$)

In terms of supplement use and nutrient intake, two participants taking an iron supplement had a probability of adequate iron intakes. One participant taking a folic acid supplement had a probability of adequate dietary folate intake. All individuals (n=6) taking a calcium supplement had a risk of inadequate calcium intake.

Chapter 6.0 Discussion

6.1 Introduction

Obesity is a major health issue in Canada. One quarter of Canadians are considered obese (1) and in Nova Scotia 30% of women and 20% of men are obese (2). Bariatric surgery has been shown to be the only effective long term treatment for morbid obesity (16). Several reports indicate that the LSG is an effective weight loss surgical procedure without the surgical and nutritional complications associated with other types of weight loss procedures (8,30). Nutritional status and quality of life after LSG has not been extensively investigated and this is the first study to examine both nutritional intake and quality of life together. In addition, this was unique in the number of tools used to measure nutritional status and the use of the BQL questionnaire to measure quality of life in the LSG population.

The Health Belief Model (HBM) can be used to help explain motivating factors of participants who undergo weight loss surgery and behaviours seen post operatively (88). Patients may be motivated by the potential threat of obesity to overall health (89) which will be reduced through surgery. Self-efficacy is needed to overcome perceived barriers of undergoing surgery and to live a healthy lifestyle after surgery. Self-efficacy plays a role in long term health behaviour changes (91) and degree of self efficacy may impact long term outcomes of weight loss surgery which may influence quality of life.

6.1.1 Response Rate

Participant response rate was within acceptable range although lower than other self-administered, mailed surveys reported in the literature (98). There are no studies

that used these tools together in a weight loss surgery population. Typically the response rate for food records and QOL questionnaires range from 42% (99) to 59% (100) respectively. The response rate of this study appears reasonable considering the amount of time that participants were asked to invest in the study and the type of information that was gathered.

6.2 Demographics and Weight

Participants were dichotomized into two age groups: <50 years and \geq 50 years. This was due to several reasons: dividing participants amongst other demographic groups caused an uneven distribution of individuals which created one small group with a size that did not comply with Statistics Canada confidentiality requirements ($n < 5$) (96); the age groups likely reflected pre and post menopausal status; and age groups were similar to the cut-offs for the EAR of micronutrients (19-50 and >50 years) (41).

Similar to other studies, more women compared to men had a LSG. (8,10,12,13,36,53,54,68). This is related to several factors: there are more obese women compared to men (2); women are more impacted by obesity and dissatisfaction with appearance compared to men (64); and women may have a greater insight on the direct consequences of the health impacts from their weight and may have greater perceived threats from obesity on their health and greater perceived benefits from undergoing weight loss surgery compared to men.

The majority of participants failed to meet the criteria for satisfactory weight loss following LSG (\geq 50% excess body weight in one year) (8,10,36). Previous reports indicate a weight loss of 49 and 63% (8,10) at one year follow-up compared to 26% for

this sample. Individuals with a pre-surgery BMI < 50 lose significantly more weight than those with a pre-surgery BMI ≥ 50 (8). The mean pre-surgery BMI for both age categories was <50 so it would be expected that participants in the sample would have lost more weight.

The lower than expected percentage weight loss could be related to age and energy intake. Participants in the <50 age group had higher percentage weight loss and had lower energy intakes after surgery than those in the ≥ 50 age category. The mean age of participants in this study was older at 48 years old compared to 40 and 43 years in previous studies (8,10) showing greater weight loss. As age increases lean body mass decreases leading to increase in BMI (60). Participants on the >50 age group lost less weight likely due to age related body composition changes which may decrease metabolism and slow weight loss.

6.3 Four Day Food Record

6.3.1 Energy and Macronutrient Intake

There was a drastic reduction in energy intakes post surgery. The mean energy intake in the present study was 1256 \pm 385 kilocalories 22 months after surgery compared to reports from Andreu et al of 1418 \pm 42 kilocalories (56) less than 12 months after gastric bypass or LSG using a three day food record for data collection. Reported food intake increases >1 year after surgery leading to increased intakes of healthy, high sugar, and high fat foods (59). It is anticipated that as time since surgery increases, energy intakes increase as perceived threats from obesity decrease, causing individuals to go back to pre-surgery eating behaviours. It seems that energy intakes

should have been higher in the present study as food intake was recorded at a greater length of time after surgery compared to the study by Andreu et al (56).

Protein intakes appear to be less reduced after surgery compared to energy intakes. Protein intakes were more variable and higher compared to the literature. Protein intake was 77.3+/- 17.5g compared to 71.3+/-2.3g per day in a previous report (56) and fit within the 60-80g of protein per day recommended by the Weight Loss Surgery program at the QEII (40).

Meal and snack intake was similar to the gastric bypass population two years after surgery (62). Both procedures drastically reduce the volume of the stomach, creating the need to consume small frequent meals and snacks throughout the day due to early satiety (30,34,54).

Macronutrient distribution differed from the Canadian population. Percentage of calories from fat were slightly less for the <50 age group and greater for the ≥ 50 age group compared to the Canadian population. Percentage of calories from protein was higher and percentage calories from carbohydrate was lower compared to Canadians (101). The higher intakes of protein likely contributed to the lower intakes of carbohydrates.

Macronutrient distribution of the <50 age group fell within the Acceptable Macronutrient Distribution Ranges (41). The ≥ 50 age group had slightly above normal percentage of energy from fat and below normal percentage of energy from carbohydrate which may have contributed to the higher energy intake compared to the

<50 age group. Fat is a concentrated form of energy and supplies more than twice as many kilocalories per gram compared to carbohydrate (41).

Similar to the Canadian population, participants had an inadequate intake from the vegetables and fruit food group and an adequate intake from the meat and alternatives food group. Participants had a higher number of servings from the milk and alternatives food group and a lower number of servings from the grain products food group compared to the Canadian population (101). Participants met their protein needs but diet appears to be lacking in B vitamins, antioxidants, vitamin C, fiber, and complex carbohydrates provided from vegetables and fruit and grain products (102).

The low consumption of fruit and vegetables and grains could be related to perceived barriers of consuming these types of foods. Possible perceived barriers could be the cost of purchasing these foods or the time involved to prepare them. There is likely a very low perceived susceptibility of developing nutrient deficiencies and health consequences from lack of consumption. It seems that weight loss surgery individuals likely understood the perceived benefits from undergoing weight loss surgery but may not understand the perceived threats of nutrient deficiencies after surgery.

6.3.2 Underreporting of Dietary Intake

The degree of underreporting of nutritional intake in the study is unclear. The ratio of energy intake to EER indicated a large degree of underreporting of energy intake at 43% compared to 10% in the general Canadian population (70). A study using seven day food records have found underreporting to be 16% using estimated energy expenditure to calculate degree of underreporting (73). It would be expected that LSG

patients would have lower energy intakes compared to the calculated EER as they are intentionally trying to lose weight making it appear that they are underreporting to a greater extent than is true.

The predicted weight loss based on actual energy intake was twice as high as the actual weight loss for the <50 age group and almost three times higher in the ≥ 50 age group. Based on these predictions, participants should have lost more weight indicating the likelihood that many have underreported. It appears that participants ≥ 50 underreported to a greater extent than those <50 which could be a contributing factor to a lower percentage weight loss present in the older age group.

Bariatric surgery patients may be more likely to underreport compared to the general population as underreporting of dietary intake increases with BMI (73,76). The average amount of calories and protein consumed was almost identical to the recommendations suggested by the QEII Weight Loss Surgery Program of up to 1200 calories and 60-80g of protein (39,40) daily for women indicating that the participants may have been intentionally reporting intake to meet the program's recommendations. Participants may have underreported by decreasing their energy intake during the days of keeping the food record or by misreporting their intakes (75) to show a lower intake of calories.

It is unknown whether using other forms of collecting data for dietary assessment such as the food frequency questionnaire decreases underreporting. Energy intakes in food frequency questionnaires are 10% higher for women and remain the same for men in comparison to a seven day food record (103). There could be less room for reporting

bias with food frequency questions compared to food records. In contrast to these findings, it has also been found that there is less underreporting with food records compared to food frequency questionnaires (71). For the purposes of the study, food records were chosen as they provide information on present nutritional intake (104, 105) and give more precise information on nutrient intake especially in terms of day to day variation which may be more useful when assessing for nutrient adequacy (104).

6.3.4 Micronutrient Nutritional Status

Several participants had risk of dietary inadequacy of several micronutrients. This is not a reflective deficiency as it is an estimate of risk and true requirement is not known (78). Food intolerances specifically to red meat, bread, pasta, and rice (52, 54) after LSG and underreporting of food intake may be contributing factors to the appearance of risk for dietary inadequacy. The risk of inadequacy for several micronutrients appear to be related to the number of food guide servings consumed by participants.

Low consumption of fruits and vegetables may have contributed to high risk of inadequate vitamin C intake. Participants consumed at least half the recommended number of food guide servings of vegetables and fruit per day according to age and gender (95) which is the main dietary source for vitamin C (102).

Very few participants were at risk of inadequate vitamin A intake. This is surprising considering the lack of vegetables and fruit that were consumed by participants. Vitamin A is a highly variable micronutrient and often requires months or

years of food intake records to evaluate it (78). Perhaps the fruits and vegetables that were consumed were rich sources of carotenoid and were not as high in vitamin C.

Risk of inadequate calcium intake was related to age. The <50 age group had fewer participants at risk for inadequate calcium intake compared to the older group. The EAR for calcium is higher for individuals >50 years compared to \leq 50 years (41) making it more difficult for the older age group to meet nutritional needs through diet.

All participants were at high risk for inadequate Vitamin D intake and this could be because most individuals did not consume milk which is a significant dietary source of vitamin D (102). Only about half of participants with inadequate calcium intakes were taking a calcium supplement and about three quarters of participants were taking a vitamin D supplement meaning that some individuals not taking supplements are at increased risk for osteoporosis.

Risk of inadequate zinc intake could be related to lack of consumption of red meat. The richest sources of zinc are found in red meat and few participants consumed red meat (48) which could be related to food intolerance (52). Zinc status after LSG has not been well studied with one report which shows 34.8% of patients have zinc deficiency 24 months after weight loss surgery (48).

Low consumption of grain products may have contributed to risk of inadequate intake of B vitamins. A fewer number of participants in the \geq 50 age category had risk of inadequate intakes of B vitamins compared to those in the <50 age group. Participants in the \geq 50 age group consumed more grain products which are rich sources for B vitamins (102).

Vitamin B₁₂ was the B vitamin with the lowest number of participants at risk of inadequate intakes. Participants consumed a number of foods from animal sources through dairy and meat alternatives which may have helped most individuals meet their needs through diet (102).

Iron was the only micronutrient with statically significant results in relation to younger age (<50 years) and risk of inadequate intake. Fewer participants in the ≥ 50 age category were at risk for inadequate iron intakes compared to the <50 age group. The estimated average requirement for iron is lower for women >50 making it easier for them to meet their iron needs (41).

The number of participants at risk of inadequate iron intakes was surprising considering that many consumed adequate food guide servings of meat and alternatives. This could be explained by several factors. First, many participants received their servings of meat and alternatives from non-meat sources such as nuts and seeds and nut butters which are not as rich in iron as meat. Second, participants had very low intakes of grains which contain iron. Finally, participants were at risk for inadequate intakes of vitamin C which enhances iron absorption (106).

There were a number of participants who had risk of inadequate micronutrient intakes but did not show a deficiency through blood work. This could be because an individual's true micronutrient requirement is unknown, therefore intake may not reflect deficiency (78). Also, the majority of participants in this study were taking a multivitamin/mineral supplement. This may have minimized the occurrence of nutritional deficiencies for nutrients such as folate and vitamin B1.

Vitamin B₁₂ was the only nutrient deficiency identified through blood work. The literature available indicates that deficiencies in zinc, vitamin D, folate, iron, vitamin B₁₂ and hypoalbuminaemia occur one year after LSG and are often present pre surgery (37). The QEII Weight Loss Surgery Program does not measure zinc and iron levels. As a result, participants did not have laboratory values for zinc and iron. This means these individuals may have had a deficiency that was not captured.

Several factors can explain the appearance of vitamin B₁₂ deficiency despite supplementation and low risk of inadequate dietary intake compared to other micronutrients examined. One participant with vitamin B₁₂ deficiency was taking a vitamin B₁₂ supplement. Perhaps the weight loss surgery team notified the participant to take vitamin B₁₂ supplement and the blood work may not have been reflective of vitamin B₁₂ status since the participant had started supplementation. Most of the laboratory data was almost a year old at the time of data collection as most patients were almost due for their yearly blood work through the weight loss surgery clinic. The cause for the vitamin B₁₂ deficiency could have been pre-operative vitamin B₁₂ deficiency or lack of intrinsic factor to absorb sufficient amounts due to anatomical changes as a result of surgery (40). Although vitamin B₁₂ was the micronutrient having the fewest number of participants at risk of inadequate intake, more than half of participants had a 50% probability of having an adequate intake. Lack of intrinsic factor (40) and low probability of adequate intake may indicate that participants are at risk for vitamin B₁₂ deficiency.

It seems unusual that no participants had a vitamin D deficiency. It is a well documented deficiency in the obese population before bariatric surgery (37,44,51) but has not been well documented after LSG as post-operative vitamin D status has not been well studied. Pre-operative vitamin D status is related to post operative status (37) and participants may have had acceptable pre-operative vitamin D levels and better absorption compared to individuals in other studies. Vitamin D absorption decreases with increasing adipose tissue. Participants in the study had lower post-surgery BMI compared to another study demonstrating vitamin D deficiency in individuals post LSG (37) and participants may have been able to better absorb vitamin D due to decreased adipose tissue.

Many participants (37%) had vitamin D levels below the typical levels (<67nmol/L) for most Canadians (107). Many may have already been taking a vitamin D supplement as the weight loss surgery clinic may have notified them that levels were not desirable and follow-up blood work after implementation of the supplement was not available. It appears LSG individuals are at risk for deficiency given lack of vitamin D intake through diet and sub-optimal vitamin D blood levels.

Although many participants were at risk for inadequate iron intake, almost all had normal haemoglobin levels. It is likely that low haemoglobin was caused by iron deficiency anemia but this cannot be proven as iron was not measured. It is suspected that one participant may have had an iron deficiency due low haemoglobin and ferritin levels. Since ferritin stores iron, it would be expected that iron levels may be low (93) if ferritin is low. Interestingly, this participant had a 98% probability of having adequate

iron intakes through diet. Perhaps they were aware of the iron deficiency and were purposely making adjustments in diet to account for it.

Protein calorie malnutrition was not apparent amongst this sample of LSG patients. Albumin levels were normal for all participants and the prevalence of reported below normal albumin in the literature is low at 4% (36). Many participants had adequate protein intakes and the LSG does not cause nutrient malabsorption like other weight loss surgeries (8,30,31). This may have minimized the likelihood of poor nutritional status and low albumin levels. The elevated CRP levels present in few participants did not seem to affect albumin levels. This is surprising since albumin is a negative acute phase reactant and often decreases in inflammatory states (93) such as when CRP is elevated. CRP levels after weight loss surgery have not been documented in the literature when assessing albumin. It is possible that albumin levels may have been much lower prior to surgery due to elevated CRP from the inflammatory effects of obesity (46).

6.5 Healthy Eating Index

HEI scores were similar to the rest of the Canadian population (84) and are considered “needs improvement” according to the HEI grading scale (Table 2). So far, there are no studies measuring HEI scores in the weight loss surgery population. The majority of points scored in the HEI were in the percent other food and percent saturated fat categories indicating that participants had very little reported intakes of these foods.

One reason for this result could be underreporting. Individuals who underreport have low intakes of sweets and fried foods (71,76). In particular, overweight women are ashamed of intakes of sweets and snack foods and underreport or eat fewer sweets (75). Another explanation for this result could be that participants were intentionally avoiding other foods and foods high in saturated fat in order to lose weight.

Participants scored well in the high protein milk and alternatives and meat and alternatives categories. Weight loss surgery programs put an emphasis on adequate protein intake in order to preserve muscle mass (56). Participants with lower energy intakes, were more likely to have a fewer number of risk of inadequate micronutrient intakes and a decreasing energy intake was associated with increasing HEI scores. This indicates that participants with higher energy intakes were more likely to have poorer diet quality and have a higher risk of inadequate micronutrient intakes. HEI scores increase with increasing intake of vegetable and fruit, unsaturated fats and grain products (84).

6.6 BQL Questionnaire

The BQL questionnaire measures a variety of factors pertaining to quality of life such as physical symptoms/medical conditions and attitude. It is very fortunate that the authors of the questionnaire allowed the questionnaire to be included in their publication to be used in other studies (69).

It is difficult to compare BQL scores to the literature as this is the only known study that has removed questions from the original BQL questionnaire in order to improve internal consistency. The BQL scores seemed fairly high, indicating that

participants were likely satisfied with their quality of life. Percentage weight loss was positively associated with BQL score. These findings are consistent with previous reports showing that quality of life is dependent on weight loss (11,14).

There was no association between energy intake and BQL score. This is surprising as those who consume higher amounts of energy would be more likely to lose less weight and therefore have lower BQL scores. Energy intake is dependent upon the accuracy of reporting and underreporting may have led to inconsistencies between intake and BQL scores.

The majority of points scored on the BQL questionnaire come from the attitude portion. There are a number of attitude questions focusing on weight and self confidence. Since the overall BQL scores seemed high, it seems likely that participants are satisfied with their weight loss and level of self confidence.

Attitude score may be an important factor in predicting outcomes after weight loss surgery as self efficacy is a determinant of nutrition behaviour (91). It would be expected that participants had a high level of self-efficacy given the high BQL scores. Quality of life decreases as time since surgery increases (14) and this may due to a decrease in self efficacy over time. The perceived threat of the health related consequences of obesity after surgery may decrease over time and individuals may start to go back to pre-surgery behaviours which may lead to weight gain and a decreased quality of life. Self-efficacy may decrease over time making it challenging for individuals to remain motivated to make positive behaviour changes. It appears that attitude impacts quality of life and research is needed to determine the impact weight

loss has on self-efficacy in the weight loss surgery population. Study participants were likely motivated to continue with positive behaviour changes as the mean length of time after surgery was less than two years and many likely remembered the cues to action for undergoing the surgery.

Few points can be scored on the BQL questionnaire in relation to physical symptoms/ medical conditions. This could be a bias of the BQL questionnaire as it may not accurately capture the quality of life of those who may be greatly impacted by their physical symptoms/medical conditions. Increased age was associated with increased physical symptoms and decreased BQL scores. The most common reported physical symptom/condition was arthritis/joint pain which increases with age and is associated with limitations in activity (108) which would likely impact quality of life.

Participants were taking a number of medications related to specific self reported medical conditions. Weight loss after bariatric surgery has been shown to be effective at reducing the use of medication to manage chronic diseases (36). The self identified chronic diseases were similar to what would be seen in a typical obese population (1,2,4).

Weight loss surgery candidates have higher levels of stress, anxiety, and depression compared to normal weight individuals (5). This could be related to the higher prevalence of antidepressant intake compared to the other types of medications. The incidence of chronic conditions and/or medication intake before and after surgery was not measured but it is assumed that it may have decreased after surgery in association with weight loss which has been shown in other studies (8,36).

6.7 Vitamin Supplement Intake

It is difficult to compare supplement intake to the literature as no studies have measured vitamin supplement intake when measuring nutritional status in the bariatric surgery population. The QEII Weight Loss Surgery Program strongly encourages intake of a multivitamin/mineral supplements which explains the high prevalence of reported intake. Previous studies report compliance rates with supplement intake to be low at 33% (31). It is predicted that supplement use may decline over time as the perceived threats of surgery on nutritional health decreases over time leading to less compliance. The dose and frequency of supplement intake is unknown. It seems that in this study participants must have been fairly compliant with taking multivitamin/mineral supplements due to the low incidence of vitamin deficiency.

Chapter 7.0 Study Limitations

The study was limited by sample size and data collection tools. The small sample size was related to the small study population and response rate. The weight loss surgery program at the QEII Health Sciences Centre, which is the single centre in Atlantic Canada specializing in weight loss surgery, was still in its infancy stage at the time of recruitment making for a small pool of subjects to recruit from.

The response rate was affected by a postal strike which occurred within two to three days of mailing the initial packages inviting patients to participate in the research. To minimize the impact of this, a follow-up letter was mailed out after the postal strike to remind participants to complete the BQL questionnaire and food records. Some participants did not receive the initial package, contacted the researcher, and an additional one was mailed. The postal strike likely had the most impact on the response rate.

The four day food record was limited by underreporting. A narrated slideshow on estimating portion sizes was placed on the weight loss surgery website and participants were asked to view it prior to recording their intake. Unfortunately, the Capital Health website changed the day after it was posted and the link was lost. Information Technology services was contacted and the link to the slideshow was resorted within a few days. It is unknown how many participants viewed the slideshow prior to completing the food record.

Portion sizes and reporting calorie dense foods was a challenge with the four day food records. In some food records there were sections where portion sizes were not recorded. Portions were estimated based on servings from Eating Well with Canada's Food Guide and from information discussed with the weight loss surgery dietitian about typical portion sizes that are consumed by the population. Participants may have underreported high calorie foods. This was evident by the points scored in the HEI for percentage of calories from other foods consumed. Energy and protein intakes were identical to the weight loss surgery program's recommendations to patients indicating that participants may have purposely responded in a certain way to meet the suggested guidelines. Underreporting was considered throughout the interpretation of results and discussion.

The four day food record may not have been reflective of typical intake. Food records represent a small snapshot of intake over the duration of measurement. Often several days of intake are needed to obtain an accurate representation of typical intake. However, it is an acceptable tool to measure dietary intake especially when combined with other forms of nutritional assessment (78) such as supplement use and examining nutritional laboratory parameters.

The nutrient analysis program used to analyze the four day food records may have contributed to errors in the nutrient data. There were some foods that were not in the nutrient analysis program and there were discrepancies between brand names of foods consumed and those listed in the program leading to some inaccuracies in the

nutrient information. Food codes were selected ahead of time to ensure consistency of food codes used.

Quality of life measurement was limited by the BQL questionnaire. The BQL questionnaire is biased in the sense that the scores are highly dependent on satisfaction with weight and self confidence and does not reflect quality of life in those who are highly impacted by physical symptoms/medical conditions.

A final study limitation is the motivating factors behind participation. It is likely that participants who were satisfied with their LSG outcomes would be more likely to participate. Participants may have felt inclined to respond positively to the BQL questionnaire especially to questions pertaining to weight since the purpose of the LSG was to aid with weight loss.

Chapter 8.0 Recommendations and Conclusions

8.1 Recommendations for Future Research

The key recommendation resulting from this study is the need for more long term studies on nutritional status and quality of life after LSG. Nutritional status should be measured over the long term and more research is needed on effective tools to measure nutritional status in the LSG population.

Since there is no one tool to measure nutritional status, it is suggested that future studies combine the use of a number of tools. Previous studies which have measured nutritional status after LSG used only one tool which does not provide enough information for proper nutritional assessment (78). To the author's knowledge, this study is the only one at this time, which has used a number of different tools to measure nutritional status.

More research is needed on the factors that impact weight gain over time so that they can be addressed early on after LSG before weight gain starts to occur. According to the HBM, self-efficacy is a determinate of nutrition behaviour (91). Those with higher levels of self efficacy may have slower rates of weight re-gain after surgery. Perhaps continued support and follow-up through weight loss surgery programs may help keep levels of self-efficacy high. Collecting information on physical activity levels would be beneficial in determining if this impacts weight regain.

Quality of life has been studied more extensively compared to nutritional status. However, many studies have used tools that are not specific to the weight loss surgery population and may therefore not truly represent the quality of life in the LSG

population. The BQL questionnaire is one tool that may one day be more widely used for this purpose.

8.2 Recommendations for Dietetic Practice

Future research on the topic may help to develop guidelines on the nutritional management of patients after LSG to standardize practice among nutrition professionals. The most important areas for nutrition professionals to focus on is continued follow-up and support to LSG patients to monitor nutritional status and weight gain. A multidisciplinary team is important to ensure that all of the needs of patients are met. This may lead to more successful outcomes and cost savings to the healthcare system.

Until more research is available, it is recommended that nutrition professionals continue to encourage patients to take a multi-vitamin/mineral supplement before and after surgery to prevent deficiency. Although an emphasis is often put on protein intake, it is important for nutritional professionals to ensure patients have a high diet quality by providing education on the importance of consuming nutrients from a variety of food groups to ensure nutritional adequacy of diet.

It is recommended that nutritional laboratory parameters be measured before weight loss surgery so that nutritional deficiencies can be corrected ahead of time to ensure optimal outcomes post surgery. It is suggested that zinc levels be included with routine blood work as there is a fairly high incidence of zinc deficiency after weight loss surgery, including LSG (48). All nutritional related laboratory parameters should be monitored routinely especially vitamin B₁₂ and vitamin D as patients seem to be at increased risk for these deficiencies.

Nutrition professionals should keep in mind the quality of life aspects after weight loss surgery. Weight gain is associated with a decrease in quality of life (14) which may lead to a decrease in self-efficacy, further impacting nutritional behaviours.

8.3 Conclusions

It appears that individuals are at increased nutrition risk according to dietary intake 22 months after weight loss surgery but have acceptable quality of life. There are no objective measurements to show nutritional risk but it is evident by the number of participants at risk of inadequate dietary micronutrient intakes which may over time lead to deficiency. It must also be considered that dietary intake was recorded almost a year after the blood work was measured indicating that the blood work may not have been a reflection of current dietary intake. High prevalence of reported multivitamin/mineral supplement use may have prevented the appearance of nutrient deficiencies. The results and conclusions of this study indicate the need for more large scale studies to explore this topic further.

References

1. World Health Organization: Obesity and Overweight; 2006 [cited 2010 Sept 4]. Available from: <http://www.who.int/mediacentre/factsheets/fs311/en/index>.
2. Tjepkema M. Nutrition: Findings from the Canadian Community Health Survey - Adult Obesity in Canada: Measured Height and Weight. Statistics Canada catalogue number 82-620-MWE [cited 2010 Nov 10]. Available from: <http://www.statcan.gc.ca/pub/82-620-m/2005001/pdf/4224906-eng.pdf>
3. Katzmarzyk PT, Janssen I. The economic costs associated with physical inactivity and obesity in Canada: an update. *Can. J. Appl. Physiol.* 2004;29(1):90-115.
4. Health Canada. Canadian Guidelines for Body Weight Classification in Adults – Quick Reference Tool for Adults; 2003 [cited 2010 Sept 4]. Available from: http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/nutrition/cg_quick_ref_ldc_rapide_ref-eng.pdf
5. Abiles V, Rodriguez-Ruiz S, Abiles J, Mellado C, Garcia A, Perez de la Cruz A, et al. Psychological characteristics of morbidly obese candidates for bariatric surgery. *Obes Surg.* 2010;20:161-167.
6. Jokovic A, Froot J, Leeb K. Bariatric surgery in Canada. *Healthcare Policy.* 2006;1(2):64-70 [cited 2010 Aug 28]. Available from: <http://www.ncbi.nlm.gov/pmc/articles/DMC2585330/pdf/policy-01-64.pdf>
7. Snyder-Marlow G, Taylor D, Lenhard J.M. Nutrition care for patients undergoing laparoscopic sleeve gastrectomy for weight Loss. *J Am Diet Assoc.* 2010;110:600-607.
8. Sasmour T, Hill AG, Singh P, Ranasinghe A, Babor R, Rahman, H. Laparoscopic sleeve gastrectomy as a single-stage bariatric procedure. *Obes Surg.* 2010;20:271-275.
9. Lakdawaia MA, Bhasker A, Mulchandani D, Goel S, Jain S. Comparison between the results of laparoscopic sleeve gastrectomy and laparoscopic roux-en-y gastric bypass in the Indian population: a retrospective 1 year study. *Obes Surg.* 2010;20:1-6.

10. Fuks D, Verhaeghe P, Brehant O, Sabbagh C., Dumont F, Riboulot M, et al. Results of laparoscopic sleeve gastrectomy: a prospective study in 135 patients with morbid obesity. *Surgery*. 2009;145(1):106-13.
11. Mohos E, Schmaldienst E, Prager M. Quality of life parameters, weight change and improvement of co-morbidities after laparoscopic and roux Y gastric bypass and laparoscopic gastric sleeve resection – comparative study. *Obes Surg*. 2010;Jul 14 [cited 2010 Sept 4]. Available online from <http://www.springerlink.com/content/p3u40732u020q457/>
12. Arcila D, Velazquez D, Gamino R, Sierra M, Salin-Pascual R, Gonzalez-Barranco J, Et al. Quality of life in bariatric surgery. *Obes Surg*. 2002;12:661-665.
13. Canetti L, Berry EM, Elizur Y. Psychosocial predictors of weight loss and psychological adjustment following bariatric surgery and a weight-loss program: the medicating role of emotional eating. *Int J Eat Disord*. 2009;42:109-117.
14. Karlsson J, Taft C, Ryden A, Sjostrom L, Sullivan, M. Ten-year trends in health-related quality of life after surgical and conventional treatment for severe obesity: the SOS intervention study. *Int J Obes*. 2007;31:1248-1261.
15. de Man Lapidoth, Ghaderi A, Norring, C. A comparison of eating disorders among patients receiving surgical vs non-surgical weight-loss treatments. *Obes Surg*. 2008;18:715-720.
16. Kruseman M, Leimgruber A, Zumbach F, Golay A. Dietary, weight, and psychological changes among patients with obesity, 8 years after gastric bypass. *J Am Diet Assoc*. 2010;110:527-534.
17. Lau DCW, Douketis JD, Morrison KM, Hramiak IM, Sharma AM, Ur E. 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children [summary]. *CMAJ*. 2007;176(8):S1-13.
18. Grave RD, Melchionda N, Calugi S, Centis E, Tufano A, Fatati G, et al. Continuous care in the treatment of obesity: an observational multicentre study. *Journal of Internal Medicine*. 2005;258:265-273.

19. Bay HE. Current and investigational antiobesity agents and obesity therapeutic treatment targets. *Obes Res.* 2004;12:1197-1211.
20. Bray GA, Tartaglia LA. Medicinal strategies in the treatment of obesity. *Nature.* 2000;404(6):672-677.
21. Laddu D, Dow C, Hingle M, Thomson C, Going, S. A review of evidence-based strategies to treat obesity in adults. *Nutrition in Clinical Practice.* 2011;26(5):512-525.
22. Muller MK, Wenger C, Schiesser M, Clavien PA, Weber M. Quality of life after bariatric surgery – a comparative study of laparoscopic banding vs. bypass. *Obes Surg.* 2008;18:1551-1557.
23. Grandy SM, Barondess JA, Bellegie NJ, Fromm H, Greenway F, Halsted CH. Gastrointestinal Surgery for Severe Obesity. NIH Consens Statement Online 1991 Mar 25-27 [cited 2010 Sept 24];9(1):1-20. Available from <http://consensus.nih.gov/1991/1991GISurgeryObesity084html.htm>
24. Capital Health. Sleeve Gastrectomy Weight Loss Surgery – General Information;2010 [cited 2010 Sept 24]. Available from <http://www.cdha.nshealth.ca/default.aspx?page=DocumentRender&doc.Id=7296>
25. Salameh J R. Bariatric surgery past and present. *Am J Med Sci.* 2006;331(4):194-200.
26. Iannelli A, Dainese R, Piche T, Facchiano E, Gugenheim J. Laparoscopic sleeve gastrectomy for morbid obesity. *World J Gastroenterol.* 2008;14(6):821-827.
27. Wong SKH, Kong APS, Mui WLM, So WY, Tsung BYS, Yau PYP, et al. Laparoscopic bariatric surgery: a five-year review. *Hong Kong Med J.* 2009;15:100-9.
28. Warde-Kamar J, Rogers M, Flancbaum L, Laferrere B. Calorie intake and meal patterns up to 4 years after roux-en-y gastric bypass. *Obes Surg.* 2004;14:1070-1079.

29. Wong SK, So WY, You PYP, Chan AKL, Lee S, Chan PN, et al. Laparoscopic adjustable gastric banding for the treatment of morbidly obese patients: early outcome in a Chinese cohort. *Hong Kong Med J.* 2005;11:20-9.
30. Thomas S, Schauer P. Bariatric surgery and the gut hormone response. *Nutr Clin Pract.* 2010;25(2):175-182.
31. Gasteyger C, Suter M, Gaillard RC, Giusti V. Nutritional deficiencies after roux-en-y gastric bypass for morbid obesity often cannot be prevented by standard multivitamin supplementation. *Am J Clin Nutr.* 2008;87:1128-33.
32. Maggard MA, Shugarman LR, Suttorp M, Maglione M, Sugarman HJ, Livingston EH, et al. Meta-analysis: surgical treatment of obesity.
33. Regan JP, Inabnet WB, Gagner M, Pomp A. Early experience with two-stage laparoscopic roux-en-y gastric bypass as an alternative in the super-super obese patient. *Obes Surg.* 2003;13:861-864.
34. Langer FB, Reza Hoda MA, Bohdjalian A, Felberbauer FX, Zacherl J, Wenzl E, et al. Sleeve gastrectomy and gastric banding: effects on plasma ghrelin levels. *Obes Surg.* 2005;15:1024-1029.
35. Eastern Obesity Clinic [cited 2010 Nov 14]. Available from <http://www.easternobesityclinic.com.au/sleeve-gastrectomy.html>
36. Fezzi M, Kolotkin RL, Nedelcu M, Jaussent A, Schaub R, et al. Improvement in Quality of life after laparoscopic sleeve gastrectomy. *Obes Surg.* 2011;21:1161-1167.
37. Gehrler S, Kern B, Peters T, Christoffel-Courtin C, Peterli, T. Fewer nutrient deficiencies after laparoscopic sleeve gastrectomy than after laparoscopic roux-y-gastric bypass (LRYGB) – a prospective study. *Obes Surg.* 2010;20:447-453.
38. Capital Health. Sleeve Gastrectomy Weight Loss Surgery – Pre Surgery Diet ;2010 [cited 2010 Sept 24]. Available from <http://www.cdha.nshealth.ca/default.aspx?page=DocumentRender&doc.Id=7299>
39. Capital Health. Capital Health. Sleeve Gastrectomy Weight Loss Surgery – Diet Stages 1 Through 3 ;2010 [cited 2010 Sept 24]. Available from <http://www.cdha.nshealth.ca/default.aspx?page=DocumentRender&doc.Id=7294>

40. Capital Health. Capital Health. Sleeve Gastrectomy Weight Loss Surgery –Diet Stages 4-5 ;2010 [cited 2010 Sept 24]. Available from <http://www.cdha.nshealth.ca/default.aspx?page=DocumentRender&doc.Id=7294>
41. Health Canada. Dietary Reference Intakes Tables [cited 2011Dec 10]. Available from <http://www.hc-sc.gc.ca/fn-an/nutrition/reference/table/index-eng.php>
42. Hakeam HA, O`Regan PJ, Salem AM, Bamehriz FY, Eldali AM. Impact of laparoscopic sleeve gastrectomy on iron indices: 1 year follow-up. *Obes Surg.* 2009;19:1491-1496.
43. Ernst B, Thurnheer M, Schnid SM, Schultes B. Evidence for the necessity to systematically assess micronutrient status prior to bariatric surgery. *Obes Surg.* 2009;19:66-73.
44. Schweiger C, Weiss R, Berry E, Keider A. Nutrition deficiencies in bariatric surgery candidates. *Obes Surg.* 2010;20:193-197
45. Goldner WS, Stoner JA, Thompson J, Taylor K, Erickson J, et al. Prevalence of vitamin D insufficiency and deficiency in morbidly obese patients: a comparison with non-obese controls. *Obes Surg.* 2008;18:145-150.
46. Ausk KJ, Ioannou GN. Is obesity associated with anemia of chronic diseases? A population-based study. *Obesity.* 2008;16:2356-2361.
47. Munoz M, Botella-Romero F, Gomez-Ramirez S, Campos A, Garcia-Erce JA. Iron deficiency and anemia in bariatric surgical patients: causes, diagnosis and proper management. *Nutr Hosp.* 2009;24:640-654.
48. Doley, J. Pressure Ulcers. *Nutr Clin Pract.* 2010;25(1):50-60.
49. Salle A, Demarsy D, Poirier AL, Lelievre B, Topart P, et al. Zinc deficiency: A frequent and underestimated complication after bariatric surgery. *Obes Surg.* 2010;20:1660-1670.
50. Health Canada. Canadian Community Health Survey Cycle 2.2 (Nutrition 2004). Nutrient Intakes from Food. Provincial, Regional and National Summary Tables volume 2 [cited 12 Nov 2011]. Available from <http://equinox.uwo.ca/Docfiles/cchs/c2.2/NutrientIntakes/English%20Files/Englis>

h%20Summary%20Data%20Tables%20by%20Nutrient/Nutrient%20Intakes%20from%20Food%20-%20Volume%201.pdf

51. Wortsman J, Matsuoka LY, Chen TC, Lu Z, Holick MF. Decreased bioavailability of vitamin D in obesity. *Am J Clin Nutr.* 2000;72:690-3.
52. Schweiger C, Weiss R, Keider A. Effect of different bariatric surgery operations on food intolerance and quality of eating. *Obes Surg.* 2010;Aug 1 [cited 2010 Sept 4]. Available from <http://www.springerlink.com/content/46255104782k1723/>
53. Brunault P, Jacobi D, Leger J, Bourbao-Tournois C, Hutten N, et al. Observations regarding 'quality of life' and 'comfort with food' after bariatric surgery: comparison between laparoscopic adjustable gastric banding and sleeve gastrectomy. *Obes Surg.* 2011;21:1225-1231.
54. D'hondt M, Vanneste S, Pottel H, Devriendt D, Van Rooy F, et al. Laparoscopic sleeve gastrectomy as a single stage procedure for the treatment of morbid obesity and the resulting quality of life, resolution of comorbidities, food tolerance, and 6-year weight loss. *Surg Endosc.* 2011;25:2498-2504.
55. Carrasco F, Papapietro K, Csendes A, Salazar G, Echenique C, Lisboa C, et al. Changes in resting energy expenditure and body composition changes after weight loss following roux-en-y gastric bypass. *Obes Surg.* 2007;17:608-616.
56. Andreu A, Moize V, Rodriguez L, Flores L, Vidal J. Protein intake, body composition, and protein status following bariatric surgery. *Obes Surg.* 2010;20:1509-1515.
57. Carey DG, Pliego GJ, Raymond RL, Skau KB. Body composition and metabolic changes following bariatric surgery: effects on fat mass, lean mass, and basal metabolic rate. *Obes Surg.* 2006;16:469-477.
58. Sarela A, Dexter SPL, O'Kane M, Menon A, McMahon MJ. Long-term follow-up after laparoscopic sleeve gastrectomy 8-9 year results. *Surg Obes Relat Dis.* 7;2011:20:1-6.
59. Kafri MA, Valfer R, Nativ O, Shiloni E, Hazzan D. Health Behavior, food tolerance, and satisfaction after laparoscopic sleeve gastrectomy. *Surg Obes Relat Dis.* 7;2011:82-88

60. Siervo M, Stephan BCM, Nasti G, Colantuoni A. Aging, adiposity indexes and low muscle mass in a clinical sample of obese women. *Obesity Research in Clinical Practice*. 2011;6(1):e63-e70.
61. Odom J, Zalesin KC, Washington TL, Miller WM, Hakmeh B, Zaremba DL, et al. Behavioral predictors of weight regain after bariatric surgery. *Obes Surg*. 2010;20:349-356.
62. Silver HJ, Torquati A, Jensen GL, Richards WO. Weight, dietary and physical activity behaviors two years after gastric bypass. *Obes Surg*. 2006;16:859-864.
63. Munoz, DJ, Lal M, Chen EY, Mansour M, Fischer S, Roehrig M. Why patients seek bariatric surgery: a qualitative and quantitative analysis of patient motivation. *Obes Surg*. 2007;17:1487-1491.
64. Duval K, Marceau P, Lescelleur O, Hould FS, Marceau S, Biron S, et al. Health related quality of life in morbid obesity. *Obes Surg*. 2006;16:574-579.
65. World Health Organization: Health Promotion Glossary;1998 [cited 2011 Jan 1]. Available from http://www.who.int/hpr/NPH/docs/hp_glossary_en.pdf.
66. Dziurawicz-Kozłowska A, Lisik W, Wierzbicki Z, Kosieradzki M. Health-related quality of life after the surgical treatment of obesity. *J Physiol Pharmacol*. 2005;56(Supp 6):127-134.
67. Sutton D, Raines DA. Health-related quality of life following a surgical weight loss intervention. *Applied Nursing Research*. 2010;23:52-56.
68. Alley JB, Fenton SJ, Harnisch MC, Tapper DN, Pfluke JM, et al. Quality of life after sleeve gastrectomy and adjustable gastric banding. *Surg Obes Relat Dis*. 8;2012:31-40.
69. Weiner S, Sauerland S, Fein M, Blanco R, Pomhoff I, Weiner RA. The bariatric quality of life(BQL) index: a measure of well-being in obesity surgery patients. *Obes Surg*. 2005;15:538-545.
70. Garriguet D. Under-reporting of energy intake in the Canadian community health survey. *Statistics Canada – Health Reports*. 2008;19(4):1-9.
71. Scagliusi FB, Ferriolli E, Pfrimer K, Laureano C, Cunha CSF, Gualano B. Underreporting of energy intake of Brazilian women varies according to dietary

assessment: a cross-sectional study using doubly labelled water. J Am Diet Assoc. 2008;108:2031-2040.

72. Poslusna K, Ruprich J, de Vries JHM, Jakubikova M, van't Veer P, Misreporting of energy and micronutrient intake estimated by food records and 24 hour recalls, control and adjustment methods in practice. Br J Nutr. 2009;101(s2):s73-s85.
73. Hoidrup S, Andreasen AH, Osler M, Pedersen AN, Jorgensen LM, Jorgensen T, et al. Assessment of habitual energy and macronutrient intake in adults: comparison of a seven day food record with a dietary history interview. Eur J Clin Nutr. 2002;56:105-113.
74. Lara JJ, Scott JA, Lean MEJ. Intentional mis-reporting of food consumption and its relationship with body mass index and psychological scores in women. J Hum Nutr Dietet. 2004;17:209-218.
75. Scagliusi FB, Polacow VO, Artioli GG, Benatti FB, Lancha AH. Selective underreporting of energy intake in women: magnitude, determinants, and effect of training. J Am Diet Assoc. 2003;103:1306-1313.
76. Bailey RL, Mitchell DC, Miller C, Smiciklas-Wright H. Assessing the effect of underreporting energy intake on dietary patterns and weight status. J Am Diet Assoc. 2007;107:64-71.
77. Whybrow S, Horgan G, Stubbs RJ. Low-energy reporting and duration of recording period. Eur J Clin Nutr. 2008;62:1148-1150.
78. Dietary Reference Intakes: Application in Dietary Assessment (2000). National Academy of Sciences. National Academy Press Washington, DC [cited 2010 Oct 24]. Available from <http://www.nap.edu/catalog/9956.html>.
79. Guenther PM, Reedy J, Krebs-Smith SM. Development of the healthy eating index-2005. J Am Diet Assoc. 2008;108:1896-1901.
80. US Department of Agriculture Center for Nutrition Policy and Promotion. Healthy Eating Index; 2009 [cited 2010 Oct 24]. Available from <http://www.cnpp.usda.gov/healthyeatingindex.htm>
81. Guenther PM, Reedy J, Krebs-Smith SM, Reeve BB, Bosiotis PP. Development and Evaluation of the Healthy Eating Index-2005. US Department of Agriculture; 2007[cited 2010 Oct 24]. Available from <http://www.cnpp.usda.gov/Publications/HEI/HEI-2005/HEI-2005TechnicalReport.pdf>

82. US Department of Agriculture Center for Nutrition Policy and Promotion. Healthy Eating Index;1995 [cited 2010 Oct 24]. Available from <http://www.cnpp.usda.gov/publications/hei/HEI89-90report.pdf>
83. Guenther PM, Reedy J, Krebs-Smith SM, Reeve BB. Evaluation of the healthy eating index-2005. *J Am Diet Assoc.* 2008;108:1854-1864.
84. Garriguet, D. Diet Quality in Canada. *Statistics Canada – Health Reports.* 2009;20(3):1-12.
85. Guo X, Warden BA, Paeratakul S, Bray GA. Healthy eating index and obesity. *Eur J Clin Nutr.* 2004;58:1580-1586.
86. Tande DL, Magel R, Strand BN. Healthy eating index and abdominal obesity. *Public Health Nutr.* 2009;13(2):208-214.
87. Weinstein SJ, Vogt TM, Gerrior SA. Healthy eating index scores are associated with blood nutrient concentrations in the third national health and nutrition examination survey. *J Am Diet Assoc.* 2004;104:576-584.
88. Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education – Theory, Research, and Practice* (3rd ed). 2003 San Francisco Jossey-Bass.
89. Armstrong SN, Anderson M, Le E, Nguyen LH. Application of the health belief model to bariatric surgery. *Gastroenterology Nursing.* 2009;32(3):171-178.
90. Baranowski T, Cullen KW, Nicklas T, Thompson D, Baranowski J. Are current health behavioural change models helpful in guiding prevention of weight gain efforts? *Obesity.* 2003;11:23S-43S.
91. Anderson ES, Winett RA, Wojcik JR. Self-regulation, outcome expectations, and social support: social cognitive theory and nutrition behavior. *Ann Behav Med.* 2007;34(3):304-312.
92. E-medicine. Hypoalbuminemia [cited 2010 Nov 12]. Available from <http://emedicine.medscape.com/article/166724-overview>
93. Carpenter DO, Ambrose M, Smith J, Tscheschlog BA. *Clinical Laboratory Tests – Values and Implications* (3rd ed). 2001 USA Springhouse.
94. Health Canada. Canada's Food Guide [cited 2011 Feb 20]. Available from <http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/order-commander/index-eng.php#1>

95. US Department of Agriculture Center for Nutrition Policy and Promotion. Healthy Eating Index [cited 2011 Nov 11]. Available from http://www.cnpp.usda.gov/Publications/HEI/HEI-2005/HEI2005_NHANES0102_PopulationScore.txt
96. Statistics Canada. Confidentiality, privacy and security [cited 2012 Mar 3]. Available from <http://www.statcan.gc.ca/edu/power-pouvoir/ch7/5214810-eng.htm#a6>
97. Hospitals In-Common Laboratory Inc. Toronto, Ontario Canada.
98. Ash DA, Jedrzejewski MK, Christakis NA. Response rates to mail surveys published in medical journals. *Journal of Clinical Epidemiology*. 1997;50(10):1129-1136.
99. McNaughton SA, Mishra GD, Bramwell G, Paul AA, Wadsworth MEJ. Comparability of dietary assessment methods: results from the 1946 British Birth Cohort. *European Journal of Clinical Nutrition*. 2005;59:341-352.
100. Batsis, JA, Lopez-Jimenez F, Collazo-Clavell ML, Clark MM, Somers VK, et al. Quality of Life after bariatric surgery: A population based cohort study. *The American Journal of Medicine*. 2009;122(11):1055.e1-1055.e10.
101. Garriguet, D. Canadian's Eating Habits. *Statistics Canada – Health Reports*. May 2007;18(2):17-32.
102. Health Canada. Eating Well with Canada's Food Guide – A Resource for Educators and Communicators [cited 2012 Mar 3]. Available from <http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/educ-comm/resource-ressource-eng.php>
103. Brunner E, Stallone D, Juneja M, Bingham S, Marmont M. Dietary assessment in the Whitehall II: comparison of the 7 d diet diary and food-frequency questionnaire and validity against biomarkers. *British Journal of Nutrition*. 2001;86:405-414.
104. Rutishauser IHE. Dietary Intake Measures. *Public Health Nutrition*. 2005;8(7A):1100-1107.
105. Hernandez-Avila M, Romieu I, Parra S, Hernandez-Avila J, Madrigal H, et al. Validity and reproducibility of a food frequency questionnaire to assess dietary intake of women living in Mexico City. *Salud Publica de Mexico*. 1998;39(40):133-140.

106. Health Canada. Prenatal Nutrition Guidelines for Health Professionals – Iron Contributes to a Healthy Pregnancy [cited 2012 Mar 3]. Available from <http://www.hc-sc.gc.ca/fn-an/pubs/nutrition/iron-fer-eng.php>
107. Statistics Canada. Canadian Health Measures Survey: Cycle 1 Data Tables 2007-2009 [cited 2012 Feb 20]. Available from <http://www.statcan.gc.ca/bsolc/olc-cel/olc-cel?catno=82-623-X&lang=eng>
108. Hootman JM, Helmick CG. Projections of US Prevalence of Arthritis and Associated Activity Limitations. *Arthritis and Rheumatism*. 2006;54(1):226-229.

Quality of Life Questionnaire

Instructions:

Quality of life after weight loss surgery is an important part of your health. This questionnaire measures perception of quality of life. Respond to each question with how you feel - there are no right or wrong answers. For each question check the box that best fits your answer. Please add details in the spaces marked “**Other**” to give more information if needed. This questionnaire will take about 5 minutes to complete. When finished please place in the extra envelope provided along with the completed food records and place in the mail. Please complete and mail it within 30 days of receiving it.

Part 1

1. Do you suffer from:

- | | | |
|--|------------------------------|-----------------------------|
| • Vomiting | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Sour belching | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Heartburn | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Nausea | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Diarrhea | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Flatulence (gas) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Foul-odor feces | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Bladder problems/urinary incontinence | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Hair loss | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Gallstones (or gallbladder removed) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Diabetes | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • High blood pressure/hypertension (also if treated) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Asthma/sleep apnea | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Arthritis/joint pain | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| • Gout | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Others: _____

2. Do you take medication regularly?

Yes

No

If yes, what kind of medication do you take?

- Anti-diabetics (diabetes pills)
- Insulin
- Antihypertensives (high blood pressure pills)
- Antidepressants
- Appetite suppressants (pills to lower appetite)
- Diuretics (fluid pills)
- Pain killers

Other: _____

3. Do you take vitamin/mineral supplements regularly?

Yes

No

If yes, what kind of vitamin/mineral supplements do you take?

- Multivitamin/mineral supplement
- B complex
- Iron
- Vitamin D
- Vitamin B12
- Vitamin C
- Vitamin E
- Folic Acid
- Calcium

Herbal Supplements: _____

Part 2

1. I like my weight.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

2. I can accept my weight.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

3. How is your actual quality of life?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Very bad	Bad	Ok	Good	Very good

4. I exercise regularly.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

5. I am participating in social activities (movies, etc).

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

6. I often meet friends or family.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

7. I feel excluded from social life.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

8. I feel under pressure because of my weight.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

9. Sometimes, I feel depressed.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

10. All in all, I feel satisfied in my life.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

11. I feel restricted because of my weight.

a). At Home

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely right	Wrong	Half/half	True	Absolutely wrong

B). At Work

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely right	Wrong	Half/half	True	Absolutely wrong

C). Privately

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely right	Wrong	Half/half	True	Absolutely wrong

12. I feel self-confident.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absolutely wrong	Wrong	Half/half	True	Absolutely right

Appendix B



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University Research Ethics Board

UNIVERSITY RESEARCH ETHICS BOARD

Certificate of Research Ethics Clearance


Title of project: *Nutritional Intake and Quality of Life after Laparoscopic Sleeve Gastrectomy*

Researcher(s): Jennifer Bowser
Supervisor (if applicable): Theresa Glanville
Co-Investigators: n/a

File #: 2010-079

The University Research Ethics Board (UREB) has reviewed the above named proposal and confirms that it respects the *Tri-Council Policy Statement* as outlined in the *MSVU Policies and Procedures: Ethics Review of Research Involving Humans* regarding the ethics of research involving human participants.

This certificate of ethics clearance is valid one year from the date of issue. Renewals are available for up to two years in addition to the initial year and are contingent upon an annual submission to the UREB of a written request for renewal accompanied by a satisfactory annual ethics report thirty days prior to the expiry date as listed below. A final report is required within 30 days of expiry. Researchers are reminded that any changes to approved protocol must be reviewed and approved by the UREB prior to their implementation.


Dr. Michelle Eskritt, Chair
University Research Ethics Board (UREB)

April 21, 2011
Effective Date

[Expires: April 20, 2012]



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University Research Ethics Board

UNIVERSITY RESEARCH ETHICS BOARD

Certificate of Research Ethics Clearance [Change to Protocol]

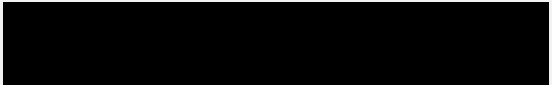
Title of project: *Nutritional Intake and Quality of Life after Laparoscopic Sleeve Gastrectomy*

Principal Researcher(s): Jennifer Bowser
Supervisor(s): Theresa Glanville
Co-Investigator(s): n/a

File #: 2010-079

The University Research Ethics Board (UREB) has reviewed a change to protocol request for the above named proposal and confirms that it respects the *Tri-Council Policy Statement* and *MSVU Policies and Procedures: Ethics Review of Research Involving Humans* regarding the ethics of research involving human participants.

This approval to a change to protocol is effective from the date of this issuance and does not affect the original expiry date that shall remain unchanged. Renewals are available for up to two additional years and are contingent upon submission to the UREB of a written request for renewal accompanied by a satisfactory annual ethics report thirty days prior to the expiry date as listed below. A final report is required within 30 days of expiry. Researchers are reminded that any changes to approved protocol must be reviewed and approved by the UREB prior to their implementation.



Dr. Michelle Eskritt, Chair
University Research Ethics Board (UREB)

June 13, 2011
Effective Date

[Expires: April 20, 2012]



Capital Health

Capital Health Research Ethics Board
Centre for Clinical Research, Room 118
5790 University Avenue
Halifax, Nova Scotia, Canada B3H 1V7
Phone: 473-6436 Fax: 473-5620

March 30, 2011

Ms. Jennifer Bowser
Food and Nutrition Services
Room 1-002, Centennial Building

Dear Ms. Bowser:

*Delegated Review
Full Approval Letter
(March 30, 2011 – March 30, 2012)*

RE: Nutritional Intake and Quality of Life after Laparoscopic Sleeve Gastroectomy.

REB FILE #: CDHA-RS/2011-294

Thank you for your response (received March 30, 2011) regarding your proposed study.

Documents Received	Version Number	Date
Cover Letter	n/a	March 25, 2011
Ethics Approval Submission Form	n/a	March 25, 2011
Physician Letter	Version 2	March 14, 2011
Quality of Life Questionnaire	Version 1	Nov 18, 2010
Quality of Life Questionnaire – Scoring Scheme	Version 1	Nov 20, 2010
Four Day Food Record	Version 1	Nov 12, 2010
Appendix C – Components of Canadian Adaptation of healthy Eating Index, Range of Scores and Scoring Criteria	Version 1	Oct 25, 2010
Appendix E – Data Collection Tool	Version 1	Nov 25, 2010

I have reviewed these documents on behalf of the Research Ethics Board (REB) and note that all requested changes have been incorporated.

I am now pleased to confirm the Board's full approval for this research study, effective today. This includes approval / favourable opinion for the following study documents:

Documents	Version Number	Date
Researcher's Checklist for Submissions	n/a	Feb 10, 2011
Letter of Support from the Principal Investigator's Dept/Div/Support/Program: E. Jane Pryor	n/a	Dec 15, 2010
Letter of Support from the Site Investigator's Dept/Div/Support/Program: Dr. David Kirkpatrick	n/a	Feb 18, 2011
Letter of Support from Collaborating CDHA Dept/Div/Support/Program: Dr. James Ellsmere	n/a	Jan 17, 2011
Ethics Approval Submission Form	n/a	March 25, 2011

Physician Letter	Version 2	March 14, 2011
Quality of Life Questionnaire	Version 1	Nov 18, 2010
Quality of Life Questionnaire – Scoring Scheme	Version 1	Nov 20, 2010
Four Day Food Record	Version 1	Nov 12, 2010
Appendix C – Components of Canadian Adaptation of healthy Eating Index, Range of Scores and Scoring Criteria	Version 1	Oct 25, 2010
Appendix E – Data Collection Tool	Version 1	Nov 25, 2010
Research Protocol	Version 1	Feb 4, 2011
Principal Investigator’s Current CV: Jennifer Bowser	n/a	Feb 10, 2011

Continuing Review

1. **The Board’s approval for this study will expire one year from the date of this letter (March 30, 2012).** To ensure continuing approval, submit a Request for Annual Approval to the Board 2-4 weeks prior to this date. If approval is not renewed prior to the anniversary date, the Board will close your file and you must cease all study activities immediately. To reactivate a study, you must submit a new Initial Submission (together with the usual fee) to the REB and await notice of reapproval.
2. Please be sure to notify the Board of any:
 - Proposed changes to the initial submission (i.e., new or amended study documents),
 - Additional information to be provided to study participants,
 - Material designed for advertisement or publication with a view to attracting participants,
 - Serious adverse events experienced by local participants,
 - Unanticipated problems involving risks to participants or others,
 - Sponsor-provided safety information,
 - Additional compensation available to participants,
 - Upcoming audits / inspections by a sponsor or regulatory authority,
 - Closure of the study (within 90 days of the event).
3. Approved studies may be subject to internal audit. Should your research be selected for audit, the Board will advise you and indicate any other requests at that time.

Important Instructions and Reminders

1. Submit all correspondence to Joan Morrison, Ethics Coordinator at the address listed at the top of this letter (do not send your response to the REB Chair or Co-Chair).
2. Be sure to reference the Board’s assigned file number, CDHA-RS/2011-294, on all communications.-
3. Highlight all changes on revised documents, and remember to update version numbers and/or dates.
4. If you plan to advertise in the newspaper. Print and electronic advertisements are to be submitted to the Audio Visual Department for placement in the appropriate Capital Health template. Complete a Request for Graphic Services form (Form CD 0019, available on the Intranet) and fax to Audio Visual Services together with the REB approved advertising materials and confirmation of REB approval.

Best wishes for a successful study.

Yours very truly,



Co-Chair, Research Ethics Board
/jm

Protocols, Informed Consent Forms, Research Team Contact Pages: Amendment Form

Use this form to submit new or amended study protocols, informed consent forms / addendums and research team contact pages after the study has received full approval by the REB. Prior to study approval, these documents are to be included with the initial submission or with a cover letter.

To be completed by Research Ethics Office	Date Received:	May 13, 2011
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Research Study			
REB File No.	CDHA-RS/2011-294	Protocol Identifier <i>(if applicable)</i>	
Title of Protocol	Nutritional Intake and Quality of Life after Laparoscopic Sleeve Gastrectomy		

Principal Investigator (PI)	
Name	Jennifer Bowser

Site Investigator (SI) <input type="checkbox"/> Not applicable <i>(clinical trial and/or PI has a CH appointment)</i>			
Name	Dr. James Ellsmere		
Mailing Address	Department of Surgery 1276 South Park Street [REDACTED] Halifax NS B3H 2Y9		
Phone No.	[REDACTED]	Fax No.	[REDACTED]
Email Address	[REDACTED]		

Contact Person for this Research Study <i>(person to whom correspondence should be sent)</i>			
Name	Jennifer Bowser		
Mailing Address	Food and Nutrition Services 1276 South Park Street 1-002 Centennial Building - VG Site Halifax NS B3H 2Y9		
Phone No.	[REDACTED]	Fax No.	[REDACTED]
Email Address	[REDACTED]		

Important instructions and reminders:

- Incomplete submissions/documents will not be processed and will be returned to sender.
- Mailing address must be detailed enough to enable successful delivery of return correspondence. Specify dept./division/program/service, institution, building, and room no. as well as any other required information.
- Print this form as a single-sided document.
- Submit one copy of each document with this form.
- Be sure to highlight all changes on amended documents. 'Track changes' versions will not be accepted.
- Distribute the attached documents to all affected parties (e.g., subinvestigators, research staff, service departments, study participants) after this form has been signed by the REB Co-chair.

Informed consent forms and research team contact pages:

- Remember to add / update version numbers and dates. All dates should be written as yyyy/mm/dd.
- Place the REB's file number in the lower left-hand corner of each page.
- The research team contact page is an optional tool designed to assist participants to contact relevant members of the study team. While the team contact page may be referenced on the cover page of the consent form, they are separate documents and can be modified independently.

Note: If the study is subject to Office for Human Research Protections (OHRP) regulations and/or the sponsor requires full Board review of study amendments, contact the REB manager to obtain the appropriate submission form.

Section A: Attached Documents

A1. Study Protocols, Informed Consent Forms, Research Team Contact Pages

Item No.	Document Type (e.g., amended protocol, protocol amendment, summary of changes, main consent form, consent form addendum, team contact page)	Version No.	Version Date
1	Research Protocol (with highlighted changes)	2	2011/05/09
2	Physician follow-up letter	1	2011/05/02
3			
4			
5			
6			
7			
8			

A2. Letter of No Objection (NOL) from Health Canada N/A - Complete Section A3
Note: If an NOL is required, DO NOT submit this form unless it is attached!

Letter from Health Canada		Corresponding Study Protocol	
Date of Letter	Control No.	Version No.	Version Date

A3. Reason why a Letter of No Objection is <u>not</u> attached: <input type="checkbox"/> Not applicable, NOL is attached		
<input checked="" type="checkbox"/> Non-interventional study (not a clinical trial)	<input type="checkbox"/> Study protocol has not changed	<input type="checkbox"/> Protocol changes do not affect the quality / safety of the investigational product(s) and do not alter the risk to participants
<input type="checkbox"/> Test article(s) is not a drug or natural health product	<input type="checkbox"/> Phase IV clinical trial	<input type="checkbox"/> Other (describe):

Section B: Changes from Previously Approved Versions

B1. Study Protocols and Amendments <input type="checkbox"/> Not applicable
--

Item No. (as per Section A1)	Summarize and justify changes, with reference to appropriate page / section numbers. Pay particular attention to changes affecting: <ul style="list-style-type: none"> • Level of risk, discomfort, or inconvenience to study participants, • Eligibility criteria, • Number of study participants at this site and/or globally.
1	Please see page 14 of the Research Protocol (version 2) to see changes. The following sentence was added to address possible low participation rates: "However, if participation rates are lower than expected a follow-up letter from each patient's attending Physician will be mailed out to remind subjects to complete the BQL questionnaire and Food Records if they are planning on participating in the study."
2	Please see attached Physician letter

- a) Has this amendment(s) already been implemented to eliminate an immediate hazard to study participants? (ICH GCP 4.5.2) Yes No
- b) How will current participants be informed of any changes / information that may affect them?
Participants must be informed in a timely manner if new information becomes available that may affect their willingness to continue in the study.
- N/A

B2. Informed Consent Forms and Addendums <input checked="" type="checkbox"/> Not applicable

Item No. (as per Section A1)	Describe and justify all changes, with reference to appropriate page / section numbers:

Item No. (as per Section A1)	Who will be asked to sign these consent forms / addendums? (e.g., new participants, current participants, a particular subset of participants who are impacted by the study changes)

B3. Research Team Contact Page Not applicable

Item No. (as per Section A1)	Describe and justify all changes, with reference to appropriate page numbers (as applicable):	
	<input type="checkbox"/> N/A (new)	

Section C: Financial Impact

Will these amendments / modifications directly impact your current departmental service agreements or the study budget? Yes No

If unsure, contact the Office of Contract / Grant Facilitation & Support at 473-6682.

Signature Page
 Protocols, Informed Consent Forms,
 Research Team Contact Pages: Amendment Form

Research Study		
REB File No.	CDHA-RS/2011-294	Protocol Identifier <i>(if applicable)</i>

Principal Investigator's Signature

Signature:  Date: 2011 | 05 | 12
 (yyyy/mm/dd)

Research Ethics Board Use Only


The Capital Health REB approves the use of the study documents described in this Amendment Form.

Is referral to the REB Executive Committee recommended? Yes No

Signature:  Date: 11.05.15
 (Chair/Co-Chair, REB) (yyyy/mm/dd)

Print Name: 
 (Chair/Co-Chair, REB)

Attestation: The REB carries out its functions in a manner consistent with good clinical practices.

<i>Processed by:</i>	<i>Date Processed (yyyy/mm/dd)</i>
	<u>2011-May-16</u>

Appendix C

Nutritional Intake and Quality of Life After Laparoscopic Sleeve Gastrectomy

You are being invited to take part in a research study on laparoscopic sleeve gastrectomy surgery. The laparoscopic sleeve gastrectomy is the weight loss surgery procedure that you underwent at the QEII Health Sciences Centre. You may know it as the gastric sleeve or the vertical sleeve gastrectomy.

The research study is called *Nutritional Intake and Quality of Life After Laparoscopic Sleeve Gastrectomy (LSG)*. This study is being carried out in collaboration with Capital Health's Weight Loss Surgery Program and Mount Saint Vincent University. The Study has been reviewed and approved by the Weight Loss Surgery Program.

The study is designed to answer three questions:

- What is the nutritional intake of patients one year or more after surgery?
- Is nutritional intake optimal for health?
- How does quality of life affect nutritional intake and weight loss?

Information gained from the study will help give healthcare professionals insight on:

- any nutritional problems that may occur after weight loss surgery;
- quality of life experienced after surgery.

This information will help healthcare professionals better meet the needs of patients after weight loss surgery. There will be no direct benefit to you.

Who is conducting the Study?

Jennifer Bowser is the Principle Investigator for the study. She is a Clinical Dietitian at the QEII Health Sciences Centre. She is also a student in the Master of Science, Applied Human Nutrition program at Mount Saint Vincent University. The proposed research is being done as part of her thesis.

Why am I being asked to join this study?

You are being asked to join the study because you are a patient of the Weight Loss Surgery Program at the QEII Health Sciences Centre and you had LSG surgery between December 2008 and March 2010.

What does this study involve?

Should you choose to participate, you will be asked to:

- record your food and beverage intake in as much detail as possible for four days in the booklet provided with this package; and
- complete the Quality of Life Questionnaire included in this package.

The food record will take about 20 minutes to complete each day. The Quality of Life Questionnaire will take about 10 minutes to complete. You may find the questionnaire you receive upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer the questions you find too distressing. A stamped, addressed envelope is being provided for you to return your completed food record and questionnaire to the QEII Health Sciences Centre.

If you choose to participate, the Principal Investigator will also review your medical record to collect the following information: age, gender, employment status, marital status, height, pre-surgery weight, recent weight, and surgery date. A number of blood work values will also be collected from the medical record, including folate, vitamin B12, vitamin D, vitamin B1, ferritin, hemoglobin, albumin, C-reactive protein, and season of the year the blood sample was drawn.

What about my right to privacy?

Personal information, such as your name or other identifying information **will not be disclosed** to anyone. A subject number is included on the four day food record form and the Quality of Life questionnaire. This number has been assigned by the clinic and corresponds to your name and medical record number which is needed to review your medical record. Only after the completed food records and Quality of Life Questionnaire are received, the principle Investigator will be given information to link you to your medical record and identify you by name.

The information collected by the Principal Investigator will only be used for the purpose of the research study. Your personal information will not be disclosed by the Principal Investigator and will not be shared or published in any reports. Discussion related to the study participants will be as a group and individual participants **will not** be singled out in the study's findings.

Do I need to fill out a consent form if I chose to participate?

If you chose to take part in the study you will not need to complete a consent form. You are consenting to take part in the research study if you complete the food record and the Quality of Life Questionnaire and return them in the mail. If you decide not to take part in the study, this will have no impact on future treatment you may expect to receive from the Weight Loss Surgery Program.

Returning the completed food record and Quality of Life Questionnaire also means you are giving the Principle Investigator permission to review your medical record to collect the information needed for the study. If you return the completed food record and Quality of Life

Questionnaire and later decide to withdraw from the study, you can do so without penalty by contacting the Principle Investigator.

What are my rights?

If you have questions about your rights as a research participant, you can contact the QEII Health Sciences Centre Patient Representative at 902-473-2133.

What about questions during or after the study?

If you have any questions about the study or would like to receive a copy of the study results, please contact the Principle Investigator:

Jennifer Bowser, Clinical Dietitian
QEII Health Sciences Centre
Room 1-002 Centennial Building
1276 South Park Street,
Halifax, Nova Scotia, B3H 2Y9
[REDACTED]

Thank you for your consideration in taking part in this research study.

Dr J Ellsmere
Weight Loss Surgeon

Dr D Klassen
Weight Loss Surgeon

March 2011

Appendix D

Four Day Food Record

Subject #

Instructions

- Fill in the date at the top of each page
- Record all food and beverages consumed each day
- Record the time when the foods/beverages are consumed
- Record the amount consumed
- Include at least one weekend day in the record
- Include as much detail as possible
- Please visit the Capital Health Weight Loss Management Program website for a narrated slide show on how to keep a detailed food record:
<http://www.cdha.nshealth.ca/default.aspx?page=SubPage¢erContent.Id.0=73341&category.Categories.1=112>

Date: _____

Date: _____

Time	Foods and Beverages Consumed

Time	Foods and Beverages Consumed

Date: _____

Time	Foods and Beverages Consumed

Date: _____

Time	Foods and Beverages Consumed

Appendix E

Nutritional Intake and Quality of Life After Laparoscopic Sleeve Gastrectomy

You have been sent an invitation to take part in a research study on laparoscopic sleeve gastrectomy surgery. The laparoscopic sleeve gastrectomy is the weight loss surgery procedure that you underwent at the QEII Health Sciences Centre. You may know it as the gastric sleeve or the vertical sleeve gastrectomy.

This is a follow-up letter to remind you to complete the Quality of Life Questionnaire and Four Day Food Record within the next two weeks if you are choosing to participate in the research study. Remember to place the completed Questionnaire and Food Record in the envelope provided and place in the mail. If you have already done so, thank you for your participation.

If you have any questions about the study or would like to receive a copy of the study results, please contact the Principle Investigator:

Jennifer Bowser, Clinical Dietitian
QEII Health Sciences Centre
Room 1-002 Centennial Building
1276 South Park Street,
Halifax, Nova Scotia, B3H 2Y9
[REDACTED]

Thank you for your consideration in taking part in this research study.

Dr J Ellsmere
Weight Loss Surgeon

Dr D Klassen
Weight Loss Surgeon

May 2011

Appendix F

Data Collection Tool

Subject #							
Age							
Gender (M/F)							
Employed (Y/N)							
Married (Y/N)							
Date of Surgery (yy/mm/dd)							
Height (cm)							
Pre surgery weight (kg)							
Weight (kg)							
% weight loss							
BMI (kg/m²)							
Albumin							
C-reactive protein							
Ferritin							
Hemoglobin							
Folate							
Vitamin B12							
Vitamin D							
Season Vitamin D was measured							
Vitamin B1							

Appendix G

Quality of Life Questionnaire

Scoring Scheme

Part 1

1. Do you suffer from:

- | | | |
|--|--------------------------------|---------------------------------|
| • Vomiting | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Sour belching | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Heartburn | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Nausea | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Diarrhea | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Flatulence (gassing) | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Foul-odor feces | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Bladder problems/urinary incontinence | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Hair loss | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Gallstones (or gallbladder removed) | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Diabetes | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • High blood pressure/hypertension (also if treated) | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Asthma/sleep apnea | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Arthritis/joint pain | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |
| • Gout | Yes <input type="checkbox"/> 0 | No <input type="checkbox"/> 0.5 |

Others: _____

2. Do you take any medication regularly?

Yes 0 No 0.5

If yes, what kind of medication do you take?

- Anti-diabetics (diabetes pills)
- Insulin
- Antihypertensives (high blood pressure pills)
- Antidepressants
- Appetite suppressants (pills to lower appetite)
- Diuretics (fluid pills)
- Pain killers

Other: _____

2. Do you take vitamin/mineral supplements regularly?

Yes No

If yes, what kind of vitamin/mineral supplements do you take?

- Multivitamin/mineral supplement
- B complex
- Iron
- Vitamin D
- Vitamin B12
- Vitamin C
- Vitamin E
- Folic Acid
- Calcium

Herbal Supplements: _____

Part 2

1. I like my weight.

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

2. I can accept my weight.

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

3. How is your actual quality of life?

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Very bad	Bad	Ok	Good	Very good

4. I exercise regularly.

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

5. I am participating in social activities (movies, etc).

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

6. I often meet friends or family.

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

7. I feel excluded from social life.

<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Absolutely wrong	Wrong	Half/half	True	Absolutely right

8. I feel under pressure because of my weight.

<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Absolutely wrong	Wrong	Half/half	True	Absolutely right

9. Sometimes, I feel depressed.

<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Absolutely wrong	Wrong	Half/half	True	Absolutely right

10. All in all, I feel satisfied in my life.

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

11. I feel restricted because of my weight.

a). At Home

<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Absolutely right	Wrong	Half/half	True	Absolutely wrong

B). At Work

<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Absolutely right	Wrong	Half/half	True	Absolutely wrong

C). Privately

<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Absolutely right	Wrong	Half/half	True	Absolutely wrong

12. I feel self-confident.

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Absolutely wrong	Wrong	Half/half	True	Absolutely right

