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FLORIDA INTERNATIONAL UNIVERSITY

Miami, Florida

IMPACT OF A COMPREHENSIVE NUTRITION AND LIFESTYLE EDUCATION INTERVENTION ON BODY WEIGHT AND HEALTH-RELATED OUTCOMES IN MORBIDLY-OBESE HISPANIC-AMERICANS FOLLOWING LAPAROSCOPIC ROUX-EN-Y GASTRIC BYPASS

A dissertation submitted in partial fulfillment of the

requirements for the degree of

DOCTOR OF PHILOSOPHY

in

DIETETICS AND NUTRITION

by

Monica Petasne Nijamkin

2010

To: Interim Dean Michele Ciccazzo
R. Stempel College of Public Health and Social Work

This dissertation, written by Monica Petasne Nijamkin, and entitled Impact of a Comprehensive Nutrition and Lifestyle Education Intervention on Body Weight and Health-Related Outcomes in Morbidly-Obese Hispanic-Americans Following Laparoscopic Roux-en-Y Gastric Bypass, having been approved in respect to style and intellectual content, is referred to you for judgment.

We have read this dissertation and recommend that it be approved.

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Date of Defense: October 1, 2010

The dissertation of Monica Petasne Nijamkin is approved.

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Florida International University, 2010

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DEDICATION

I dedicate this dissertation to my husband and children. Without their patience, understanding, support, and most of all love, the completion of this work would not have been possible.

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I wish to extend my sincere gratitude to all of the members of my committee for their support and guidance:

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ABSTRACT OF THE DISSERTATION

IMPACT OF A COMPREHENSIVE NUTRITION AND LIFESTYLE EDUCATION INTERVENTION ON BODY WEIGHT AND HEALTH-RELATED OUTCOMES IN MORBIDLY-OBESE HISPANIC-AMERICANS FOLLOWING LAPAROSCOPIC ROUX-EN-Y GASTRIC BYPASS

by

Monica Petasne Nijamkin

Florida International University, 2010

Miami, Florida

Professor Adriana Campa, Major Professor

As morbid obesity increasingly affects Hispanic-Americans, the incidence of Roux-en-Y gastric bypass procedures (RYGB) among this population rises. Prospective research on the impact of postoperative educational interventions focused on Hispanic-Americans is needed to prevent premature weight loss plateau, weight regain, nutritional deficiencies, and relapse of obesity-related comorbidities.

This randomized-controlled study evaluated the impact of a comprehensive nutrition and lifestyle education intervention (6 biweekly postoperative sessions that incorporated motivational strategies for behavioral change) as compared to a non-comprehensive approach (printed guidelines for healthy lifestyle). The variables to consider are body weight, obesity-related comorbidities (depression, diabetes, dyslipidemia, and others), nutrient status, physical activity, and eating habits in 144 morbidly-obese adult Hispanic-Americans 6 to 12 months following RYGB.

Patients were randomly assigned to either the comprehensive intervention (n=72) or the comparison group (n=72). Participants (mean age 44.5 ± 13.5 years) were mainly Cuban-born females (83.3%). Intervention sessions attendance was 64%. At 12 months, both groups lost weight significantly, but those in the comprehensive intervention experienced greater excess weight loss than those in the comparison group (80% vs. 64% from preoperative excess weight, $P<.001$). Intervention participants were significantly more involved in physical activity (+ 14 min/week vs. – 4 min/week), had decreased depression, joint illness, and required less medication for comorbidities than comparison participants. Additionally, those in the comprehensive intervention had sustained supplement intake experiencing less folate deficiency ($P=.014$).

The non-comprehensive intervention group significantly decreased their protein and supplement intake compared to the intervention group. Patients in the comprehensive intervention had significantly better eating habits reflected by fewer episodes of dumping syndrome, constipation, and night eating, than those in the comparison group who reported greater eating in response to negative emotions ($P=.003$). These findings support the importance of a comprehensive educational approach to achieve more effective weight reduction and health-related outcomes to prevent relapse of obesity-related comorbidities and nutritional deficiencies in Hispanic-Americans 6 to 12 months following RYGB.

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CHAPTER I. INTRODUCTION

The accelerated spread of morbid obesity[1–3] combined with lack of appropriately effective dietary and pharmacologic interventions[4,5] has led to increased demand for a non-conventional treatment of obesity known as bariatric surgery.[6,7] Morbid or severe obesity, characterized by a body mass index (BMI) equal or greater than 40 kg/m^2 or being 100 pounds overweight is associated with a substantial negative effect on longevity[8] and an increased risk for obesity-related comorbidities. Comorbidities include cardiovascular diseases, type 2 diabetes mellitus, and cancer that account for the most common causes of death in the United States[9] and more than 70 percent of the trillion dollars spent on healthcare each year.[10,11]

Obesity (BMI $\geq$ 30 kg/m^2) increasingly affects minorities in the United States.[1,12] The most recent National Health and Nutrition Examination Survey data (NHANES 2007-2008) has shown that the prevalence of obesity for Hispanic-Americans exceeds 38%.[1] The prevalence of morbid or severe obesity ranged from 3.8 % (95% CI, 2.1-5.6) and 7% (95% CI, 5.7- 8.4) for Hispanic-American adult men and women respectively.[12]

Laparoscopic Roux-en-Y gastric bypass surgery (RYGB) has become the gold standard and most successful treatment of morbid obesity in the United States reducing weight significantly and resolving or improving most obesity-related comorbid conditions, such as diabetes, hyperlipidemia, and hypertension.[13–19] However, some patients may experience premature weight loss plateau or weight regain, which mitigate the improvement of obesity-related comorbidities if patients fail to comply with healthy eating habits and regular physical activity.[20,21] The extensive surgically induced

anatomical changes of the gastrointestinal tract may lead to nutritional deficiencies in those unable to comply with strict adherence to vitamin and mineral supplementation.[22–25]

The increasing demand for RYGB procedures requires thorough patient education and motivation for dealing with difficulties encountered after surgery.[26] Studies have indicated that comprehensive approaches that incorporate behavioral change strategies and motivational interviewing have shown promise as effective interventions in medical settings.[27,28] However, insufficient evidence exists in the field of bariatric surgery to determine the effectiveness of a comprehensive nutrition and lifestyle education program to promote healthful eating behaviors and increased physical activity, to prevent premature weight loss plateau, weight regain, nutritional deficiencies, and relapse of obesity-related comorbidities, in Hispanic-American adults before the first year following RYGB surgery.

Therefore, this research study was implemented to evaluate the effect of a comprehensive nutrition and lifestyle education intervention that incorporated behavioral change strategies and motivation for nutrition counseling on weight loss in morbidly-obese Hispanic-Americans 6 to 12 months following RYGB surgery. This type of counseling also covered issues on some obesity-related comorbid conditions (hypertension, diabetes, dyslipidemia, sleep apnea, and others), nutritional status (total proteins, albumin, iron, vitamin B12, folate, and calcium), eating habits, and physical activity patterns that were critical for the success of the bariatric intervention and for the long-term well-being of the patients.

Aims and Hypotheses

The primary aim of this study was to implement and evaluate 2 types of interventions: (1) a comprehensive nutritional and lifestyle education intervention (6 postoperative educational sessions that incorporated behavior modification strategies and motivation to nutrition counseling) in comparison to (2) a non-comprehensive minimal approach (printed guidelines on healthy eating and physical activity recommendations) in morbidly-obese Hispanic-American adults. The interventions were initiated 6 months following laparoscopic Roux-en-Y gastric bypass surgery because at that time the surgically-induced rapid weight loss may start to naturally decline. Patients start to consume the highest calorie-intake diet since surgery and are prone to weight regain if they fail to comply with healthy lifestyle changes. [29]

The outcome measures were body weight changes, improvement of some obesity-related comorbid conditions (hypertension, diabetes, dyslipidemia, and others), micro and macronutrient status (total proteins, albumin, iron, vitamin B 12, and folate), physical activity, and eating habits in morbidly- obese Hispanic-American adults.

Primary or Main Hypothesis

Hypothesis 1: Patients who receive a comprehensive nutrition and lifestyle education intervention will experience greater weight loss from total baseline weight, greater excess body weight loss from total baseline excess weight, and greater decrease in BMI without weight loss plateau or weight regain during the period from 6 to 12 months following surgery than those patients in the comparison group who will be provided with printed guidelines for healthy eating and physical activity recommendations at the first assessment visit [29] (Appendix 1).

Secondary Hypotheses

Hypothesis 2: Patients in the comprehensive nutrition and lifestyle education group will experience greater improvement of their obesity-related health conditions than those in the comparison group, as measured by improved glycemic control, improved depression, and decreased need of medications for obesity-related comorbidities.

Hypothesis 3: Patients who receive comprehensive nutrition and lifestyle education will report fewer negative nutritional outcomes such as less micro and macronutrient deficiencies than those in the comparison group, as measured by complete cell blood count (CBC) and higher plasma levels of micronutrients (iron, vitamin B1, vitamin B12, and folate).

Hypothesis 4: Patients receiving comprehensive nutrition and lifestyle education will be more actively involved in physical activity than those in the comparison group as measured by greater weekly exercise frequency and intensity.

Hypothesis 5: Patients in the comprehensive nutrition and lifestyle education will have better eating habits reflected by fewer episodes of dumping syndrome and binge eating than those in the comparison group.

CHAPTER II. LITERATURE REVIEW

Bariatric Surgery

From the Greek words *Baros* meaning weight and *Iatrikos* meaning the art of healing, bariatric surgery is a rapidly evolving branch of the surgical science.[14,30] It aims to induce major weight loss in those whose obesity places them at risk of severe comorbidities. The National Institute of Health (NIH) established consensus guidelines in 1991, suggesting that the surgical treatment of obesity should be reserved for patients whose BMI exceeds 40 kg/m^2 and those with BMI 35 kg/m^2 or greater along with more than one high-risk obesity co-morbid conditions, if they have been unable to achieve or maintain weight loss with conventional therapy, have acceptable operative risks, and are able to comply with long-term treatment and follow-up.[31]

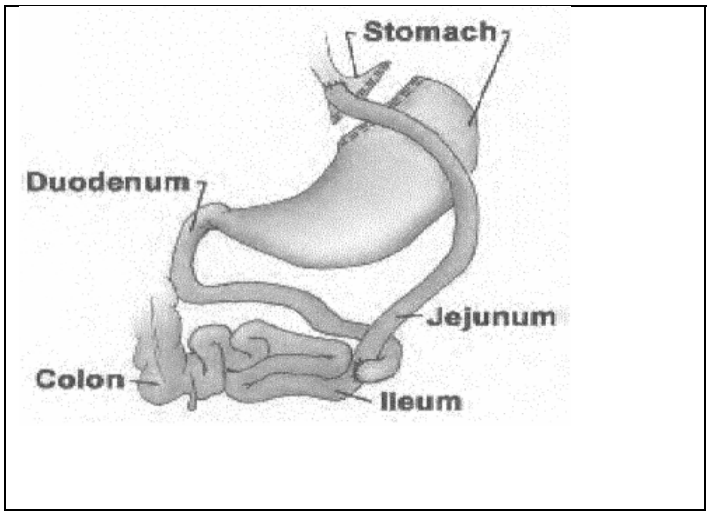
Weight loss surgical procedures can be broadly classified into two categories: restrictive and malabsorptive. Restrictive procedures work by reducing the gastric volume and inducing early satiety by creating a small gastric pouch and gastric outlet.[7,32,33] Adjustable gastric banding (the gold-standard procedure for losing weight in Europe and Australia), vertical banded gastroplasty, and sleep gastrectomy are purely restrictive surgical techniques.[7,32,33] Malabsorptive procedures combine gastric restriction with reduced calorie and nutrient absorption. This double restriction produces faster weight loss than simple restrictive techniques. Biliopancreatic diversion, duodenal switch, jejunoileal bypass, and Roux-en-Y gastric bypass are malabsorptive procedures.[34]

From 1998 to 2004, the total number of bariatric surgery procedures in the United States increased nine-fold, from approximately 13,300 to more than 121,000 surgeries, incrementing the total national inpatient hospital costs by more than eight times. The fastest increase in bariatric surgeries occurred among the population of adults aged 55 to 64, representing a twenty-fold increase. Women accounted for 82% of all bariatric surgeries in 2004.[35] The number of bariatric surgeries for Medicare, Medicaid, and other payers increased 8.2, 7.0, and 8.8 times, respectively.[35,36]

Laparoscopic Roux-en-Y Gastric Bypass Surgery

The laparoscopic Roux-en-Y gastric bypass surgery (Figure 1) is the gold standard and most common surgical procedure for weight loss in the United States.[7,32,33,34]

Figure 1: Roux-en-Y Gastric Bypass Surgery Procedure[a]



[a] The stomach is divided by a double row of staples but not removed

The Roux-en-Y gastric bypass surgery (RYGB) consists of the creation of a small gastric pouch with a measured capacity of less than 50 ml. The rest of the stomach is not removed but is completely shut by a double row of staples. A tiny stomach outlet slows

the speed of food that leaves the stomach. The small intestine is then divided just beyond the duodenum (first part of the small intestine) and the jejunum (middle part of the small intestine) is connected directly to the stomach pouch, bypassing the duodenum, which is the main area of calorie and nutrient absorption. The other end is sewn shut creating a Y shape that gives the technique its name. [7]

Weight Loss and Obesity-Related Comorbidities Following Bariatric Surgery

There is convincing evidence and wide consensus in the scientific literature about the positive impact of bariatric surgery not only on weight loss, but also on obesity-related comorbidities, such as diabetes, hyperlipidemia, sleep apnea, hypertension, depression, gastroesophageal reflux disease, and depression, as well as quality of life. [14–19,36–38] Weight loss following bariatric surgery ranges from approximately 47.5% to 70% depending on the surgical procedure used. The mean changes in weight loss are more favorable among the subjects treated by malabsorptive procedures, such as RYGB than among those treated by other procedures. [15,16,36,39,40] A recent publication reported a mean percent of excess body weight loss of 47.2 ± 18.2% after one year following RYGB. [41] Some variation in weight loss between different racial groups undergoing RYGB procedures has been reported. Caucasians lost more weight than African Americans, a difference that was explained in this case by metabolic differences between the groups, and not by postoperative dietary habits. [40]

Preliminary data obtained by the investigator (see preliminary data) showed that the mean weight lost at 6 months after RYGB surgery was 32.6 ± 6.1% of the initial body

weight. There were no significant differences in the mean weight loss over time between genders and different ethnic groups.

There is limited research comparing bariatric surgery with medical management of obesity beyond few randomized-controlled trials and cohort studies, all of which were considered to be at risk for design bias.[18,30,33] Studies suggested that the typical weight loss with various bariatric procedures was between 20 to 50 kg (44 to 110 lb) which compared favorably to a modest weight gain in medically treated patients.[18,30,33] More recently, the literature has shown that compared with conventional treatment, surgery resulted in greater long-term weight loss (21 kg body weight loss at 8 years versus weight gain), with improvements in quality of life and obesity-related comorbidities.[20,21]

A significant long-term prospective study carried out in patients following RYGB surgery has showed that weight loss at 10 years ranged from 14% to 25% among subjects who had undergone bariatric surgery as compared with only 2% among matched control subjects.[42] A meta-analysis confirmed that bariatric surgery is highly effective in weight reduction in morbidly obese patients (up to 60% of the excess body weight loss), along with resolution of preoperative diabetes in more than 75% of cases. Malabsorptive techniques, such as RYGB, appeared to be more effective on both outcomes than restrictive techniques.[43] No correlation was found between the stomach pouch size and short-term weight loss following RYGB surgery when the proximal gastric pouch area was estimated by routine upper gastrointestinal contrast studies multiplying the maximal transverse by the longitudinal diameters.[44]

Despite the significant weight loss of approximately 40% of the body weight at one year and dramatic improvement in obesity-related comorbidities following RYGB, some patients appear to experience suboptimal weight loss mitigating the improvement of comorbidities.[20,21,46] The reasons for suboptimal weight loss are not well understood, but the suboptimal weight loss is often ascribed to the patients' preoperative psychological characteristics or eating behaviors, as well as poor compliance with postoperative dietary and exercise recommendations.[46] Some patients may experience premature (< one year following surgery) weight loss plateau or weight regain due to anatomical or medical problems, such as pouch or anastomotic dilatation or gastric fistula due to staple line breakdown; hypothyroidism, kidney, adrenal, and heart disease, as well as pregnancy and new medications may contribute to this distortion. However, behavioral problems are the most frequent reasons for weight regain. These problems, reflect patients' failure to adhere to healthy eating habits and regular physical activity, and their return to old, unhealthy habits. Noncompliance with behavioral recommendations is prevalent following bariatric surgery, with lack of exercise being the most likely area of noncompliance.[47,48]

Research studies have shown that type 2 diabetes was completely resolved in 76.8% and resolved or improved in 86% of morbidly- obese patients who had undergone bariatric surgery.[14–17,36] Recent experimental studies pointed toward the anatomical changes of the gastrointestinal tract as the main mediator of the surgical control of diabetes, raising the provocative question whether type 2 diabetes might be an operable intestinal disease.[49]

Clinical trials showed a variable effect of weight loss on lipid profile. The degree of improvement in serum triglyceride and cholesterol concentrations was related to the amount of weight lost and weight regain leading to relapse in serum lipid levels. The greatest improvement in serum lipid concentrations tended to occur in the first two months of weight loss. A sustained weight loss of 5% was sufficient to maintain the reduction in serum triglyceride concentrations; whereas serum total cholesterol and LDL-cholesterol levels reverted toward baseline unless a 10% weight loss was maintained. [50,51]

According to the literature, hypertension was completely resolved in 61.7% of patients (95% CI, 55.6%-67.8%) and was resolved or improved in 78.5% of patients following bariatric surgery. [36] Several publications have shown decreased rates of hypertensive disorders, such as pre-eclampia and gestational hypertension, in women who delivered after bariatric surgery. [52,53]

Not all patients who undergo RYGB with an initial BMI > 50 Kg/m^2 achieve a BMI < 35 Kg/m^2 postoperatively; however, those patients can experience significant improvements in their obesity-related comorbidities. The rate of diabetes, hypertension, dyslipidemia, and gastroesophageal reflux disease (GERD) was completely resolved in 73.8%, 62.3%, 38.9%, and 87.8% of those super-obese patients. [45]

Metabolic and Nutritional Status Following Bariatric Surgery

The extensive surgically induced anatomical changes of the gastrointestinal tract may lead to some metabolic and nutritional complications in those unable to comply with nutritional recommendations. Metabolic consequences of bariatric surgery may include

vomiting, dumping syndrome, dehydration, nutritional deficiencies, and symptomatic cholelithiasis.[54–58]

Persistent vomiting may occur due to overeating in a patient with a smaller gastric pouch, however this symptom is less observed after malabsorptive procedures such as RYGB than after pure restrictive procedures. Pain medication, vitamin supplements, and dehydration are other reasons of nausea and vomiting following surgery.[59]

Dehydration is a very common phenomenon because it is extremely difficult for patients to hold much fluid in a tiny gastric pouch or drink enough water separately from meals. In order to prevent dehydration, it is recommended that patients sip water constantly to meet their daily requirements.[54]

Dumping syndrome, characterized by uncomfortable feelings of weakness, restlessness, headache, nausea, vomiting, palpitations, sweating, diarrhea, tachycardia, salivation, dizziness, and in severe cases syncope and shock, is a frequent complication after RYGB in those unable to comply with dietary recommendations and may result after eating a high-glucose meal.[54,57] The severity of this syndrome is proportional to the rate of gastric emptying, which is normally controlled by the fundic and antropyloric tone and by duodenal feedback, all mechanisms that are distorted following gastric surgery.[60] Dumping syndrome is a consequence of poor adherence to permissible food in the postoperative period and by osmotic overload into the small intestine after bypassing the stomach.[60,61] The syndrome is self-limited, usually declining after two hours. In order to prevent this syndrome, patients must avoid the consumption of high-glycemic carbohydrates.[61]

Studies have showed that rapid weight loss may increase the risk of postoperative cholesterol gallstone formation independently of the type of procedure performed. [62,63,64] Gallstones may develop within 6 months after RYGB surgery in approximately 19% to 36% of patients. [65,66] Prophylactic treatment with ursodeoxycholic acid for 6 months following surgery can reduce the incidence of postoperative new gallstone formation from 32% to 2%. [66]

The medical literature shows that RYGB surgery is associated with increase in urinary oxalate excretion and decrease urinary citrate excretion that predispose patients to develop renal stones of calcium oxalate. [67–69] The etiology of the hyperoxaluria is not known, but may be related to subtle and apparently subclinical fat malabsorption. [68]

Nutritional deficiencies following RYGB surgery are a growing concern. [26,54–59,71–78,84,93–113] Shortage of nutrients may happen due to loss of intrinsic factor (a glycoprotein produced by the parietal cells of the stomach needed for the absorption of vitamin B12 in the terminal ileum), decreased acid secretion of the stomach, reduced small intestinal absorption, and increased intolerance for some dairy and meat products. [26,54–58] However, research has shown that morbidly-obese people have nutritional deficiencies not only after, but also before bariatric surgery that may be explained by poor nutritional habits of this population. [24,58,70–73] Protein malnutrition may develop after RYGB due to restricted energy intake, decreased absorption, and excess loss of lean tissue. Although energy and protein intake increased significantly over one-year period following RYGB, protein intake remained insufficient and was related to protein intolerance. [21,74–76] The recommended dietary allowance for proteins is 0.8

g/kg/day and the daily value (DV) based on a 2000 calorie diet is 50 g per day.[77] However, protein intake and recommendations for RYGB patients are generally higher than the recommended for other adults due to increased needs based on rapid weight loss and a degree of protein malabsorption.[76] Common dietary protein recommendations for this population of Roux-en-Y gastric bypass surgery patients, is 60 to 105 g or 20% to 30% of a 1,200-calorie diet.[78] Protein in excess of these recommendations provides no benefit, and may worsen existing renal problems[79] accelerating bone loss due to increased calcium excretion.[80,81]

After the first postoperative months, the risk of anemia due to iron and vitamin B12 deficiency may increase, along with folate, calcium, fat-soluble vitamins (A, D, E, and K) and other micronutrients deficiencies.[24,54–58,82–84] Severe and irreparable complications can result if those problems are left undiagnosed. Vitamin B12 and iron are the most common deficiencies encountered among RYGB patients, having an incidence rate of greater than 50%.[24,54,57,82,84,86] The incidence rate of all types of anemia and folate deficiency has been reported to be as high as 74% and 38% respectively.[82,84,86]

The pathogenesis of iron deficiency is multifactorial.[87] Absorption of dietary iron requires the reduction of ferric iron in food to the ferrous state, a process that occurs in the stomach, which is facilitated by hydrochloric acid.[84,88] Gastric acid secretion from the proximal gastric pouch might be absent following RYGB and achlorhydria may develop.[84,88] In addition, the intake of iron-rich foods declines substantially after bariatric surgery, mainly due to a low tolerance of meat, which can result in iron deficiency (microcytic hypochromic) anemia.[84,88] It is recommended that routine laboratory work,

such as complete blood cell count, serum iron, transferrin, and ferritin be performed and monitored twice a year.[84,88]

The absorption of vitamin B12 starts in the stomach, where both pepsin and hydrochloric acid cleave it from food (primarily from meat), and continues in the small intestine where it binds to intrinsic factor and then it is absorbed into the bloodstream. Pathogenesis of vitamin B12 deficiency involves inadequate secretion of intrinsic factor, achlorhydria that prevents cleavage of vitamin B12 from food, and decreased consumption from diet due to intolerance to meat and dairy products.[89,90] Significant deficiency of vitamin B12 might lead to megaloblastic anemia, thrombocytopenia, leucopenia, and glossitis, all reversible with replacement therapy.[84,89]

Folate absorption is facilitated by hydrochloric acid and occurs in the first portion of the small intestine.[89] Vitamin B12 acts as coenzyme removing a methyl group to activate the folate coenzyme, thus vitamin B12 deficiency may result in subsequent folate deficiency.[89] However, decreased folate consumption from food might be the predominant cause of deficiency.[84,91] Folate deficiency can appear as megaloblastic anemia, thrombocytopenia, leucopenia, or glossitis.[89] Folate deficiency is not widely seen in RYGB patients due to the abundance of foods fortified with folic acid.[84,91] A balanced multivitamin will also provide a good quality source of folate, easily well-absorbed in the jejunum.[89] However, it is beneficial to include serum folate levels among regular follow-up following RYGB surgery for reasons other than detecting a folate deficiency. Elevated folate levels and supplementation above the upper limit of 1000 mcg can mask a vitamin B12 deficiency.[92] In addition, elevated folate may indicate bacterial

overgrowth in the lumen of the small intestine or blind loop syndrome.[93] A deficiency in folic acid could result in elevated homocysteine levels.[94] Treatment with 1 to 5 mg of folate twice a day will correct deficiencies within 2 to 3 months.[95]

Active absorption of vitamin B1 or thiamine occurs principally in the proximal small intestine. Humans cannot synthesize thiamine and it is not stored in adequate amounts, thus daily intake is vital.[96,97] The restrictive dietary intake following RYGB may lead to a drastic reduction of not only vitamin B complex, but also fat-soluble vitamins.[96]

Several cases of Wernicke's encephalopathy, a syndrome characterized by eye movement disorders, gait ataxia, confusion, confabulation, and short-term memory loss due to vitamin B1 (thiamine) deficiency have been increasingly reported.[96–99] Neural tube defects in newborns due to maternal folate deficiency,[100] low serum levels of vitamin A, D, and E, and mild decrease of prothrombin time along with hemorrhages due to vitamin K deficiency are also shown after RYGB surgery.[23,25,26,57,58,100–102] Fat-soluble vitamin deficiency may occur after RYGB because bypassing the duodenum results in delayed mixing of dietary fat with pancreatic enzymes and bile salts, resulting in malabsorption.[23,25,26,57,58,100–102]

Vitamin A deficiency may develop years after RYGB, suspected by an unexplained decrease of visual acuity and history of intestinal surgery. Ophthalmologic complications may occur such as xerophthalmia (abnormal eye dryness and chronic conjunctivitis due to deficiency of tears), nyctalopia (night blindness), and total blindness.[100–103]

Vitamin D and calcium deficiencies are less probable because they are mainly absorbed in the jejunum and ileum; however, lower urinary calcium excretion and increased parathyroid hormone concentration have been increasingly reported years after RYGB, reflecting a negative calcium balance with secondary hyperparathyroidism.[83,104–106] These indicators may predict potential development of bone mineralization problems such as excessive bone resorption leading to decrease in bone mass, osteomalacia, and osteoporosis.[83,104–111]

Despite strong recommendations and emphasis about the need of lifelong multivitamins intake following RYGB, the adherence rate to both supplements and one-year postoperative diet counseling remain low.[25,26,111] In addition, the literature has reported an intake of most vitamins and minerals below 50% of the recommended dietary allowances.[25,26,84,111,112] There is lack of coordinated nutritional approach and official guidelines on chronic use of vitamin and mineral supplements in the field of bariatric medicine despite recent publications that are increasingly addressing these issues.[111–114]

Prevention of Negative Nutritional Outcomes Following Bariatric Surgery: Education

The increasing incidence of bariatric surgery procedures demands patients to be well educated to deal with the difficulties encountered after surgery. Education seems to be the key to achieve long-term success, preventing premature weight loss plateau and weight regain, nutritional deficiencies, and relapse of obesity-related comorbidities.[114]

Participation in support groups has become an essential element of the postoperative educational intervention for patients regarding weight loss, lifestyle changes, and the nutritional management process. Educational support groups seem to be

a significant method for maintaining weight loss especially following the first postoperative months, when the rate of weight loss may begin to naturally decline.[114,115,116] Helping patients achieve and maintain their healthy weight is a challenging task. Optimal education should involve lifestyle interventions that contain not only dietary counseling, but also physical activity and behavior modification strategies.[27,117] Evidence demonstrates that structured, intensive lifestyle programs involving counseling and participant education regarding reduced energy and fat intake, regular physical activity, and frequent participant contacts are necessary to produce long-term weight loss of as much as 5% to 7% of starting weight.[118] Little lifestyle changes, such as the reduction of energy intake by approximately 10 kcal or an extra walk of 2 to 3 minutes per day, are sufficient to stop the increase in obesity prevalence in the United States. However, in practice this proves hard to accomplish due to the obesogenic environment that does not encourage physical activity and low food consumption.[119]

Comprehensive Approaches

Several studies have shown that comprehensive approaches that include behavioral modification strategies were very useful when combined with diet and exercise.[120–122] For instance, adults who completed a comprehensive intervention that included a low-calorie diet, physical activity, and behavior modification strategies (stress management and social support) which were taught in group sessions, reported a reduction of 15% to 25% of their initial weight during 3 to 6 months of treatment, and a weight loss maintenance of 8% to 9% at one year after the intervention.[122]

The Diabetes Prevention Program, a large multicenter randomized controlled trial provided a good example of the efficacy of lifestyle modification interventions.[120] It included more than 3,000 overweight and obese adults (mean BMI 34±6.7) with impaired fasting glucose who were assigned to receive placebo, metformin (850 mg twice daily), or lifestyle modification. The lifestyle intervention was delivered primarily by Registered Dietitians and included 16 individual sessions over the first 24 weeks. Then, sessions were held at least once every two months for the remainder of the study. The lifestyle modification program induced a weight loss of 6.7 kg during the first year of treatment, compared with losses of 2.7 kg and 0.4 kg in the metformin and placebo groups respectively. The risk of developing diabetes among those who received lifestyle modification was 58% lower than those who received placebo and 31% lower than participants who received the medication.[120]

Several recent publications have demonstrated the efficacy of lifestyle modification interventions that can be implemented in the community or primary care settings to prevent diabetes morbidity, weight gain, and cardiometabolic disease risk.[123–127] Studies also showed that short-term weight and physical activity changes can be achieved with motivational interventions delivered either by nurses or non-health professionals, with relatively low usage of primary resources.[123,124]

Motivational Interviewing

Counseling sessions that incorporate principles of motivational interviewing on patient-centered behavioral-cognitive strategies have shown promise as an effective intervention in medical settings.[27,28] In behavioral weight loss programs, motivational

interviewing might increase patients' motivation toward behavior change complementing the achievement of skills.[128,129] Motivational interviewing is a non-judgmental and non-confrontational approach that aims to increase patients' awareness of the potential problems, risks, and consequences faced as a result of their "bad" behavior.[125]

A meta-analysis showed a significant effect of motivational interviewing for combined effect estimates on body mass index, total cholesterol levels, systolic blood pressure, and blood alcohol concentration.[27] Motivational interviewing is based on four main principles that therapists should exhibit: to manifest empathy, to support self-efficacy, to develop discrepancy, and to accept client reluctance to change.[129]

Behavior Therapy, Behavior Change Theories and Strategies

The aim of behavior therapy in weight loss is to change eating and physical activity behaviors over time on an individual or group basis.[131] Specific behavior strategies may include self-monitoring of eating and physical activity habits, stress management, stimulus control, self-rewards, cognitive restructuring, social support, problem solving, and others.[131,132,133] Behavior strategies are very effective in reinforcing changes in diet and physical activity in obese adults, producing weight loss in the range of 10% of baseline over four months to one year. The greatest amount of weight loss is usually observed after less than 12 months of an intervention.[134,135] Strong evidence has suggested that behavior therapy, when used in conjunction with other weight loss approaches, is more effective in reducing weight or delaying weight regain at one year follow-up.[136,137]

Which behavior intervention model is the best to apply on morbidly-obese patients following RYGB surgery, and how frequently and intense the intervention should be is not defined in the literature. In general, several strategies were used to modify patients' behavior, but, no single theory or combination of behavioral methods proved to be clearly superior.[131] According to Bartholomew, those who plan the program have the job of piecing together behavior theories rather than just testing a single theory, suggesting the need for a multitheory approach.[133]

The literature has shown that four health behavior change theories, Social Cognitive Theory, Transtheoretical Model, the Theory of Planned Behavior, and Self-determination Theory were the most frequently employed in weight control programs.[138]

Social Cognitive Theory (SCT) is the most frequent paradigm used in weight loss interventions.[139] This theory postulates a multifaceted causal structure, in which self-efficacy beliefs work together with goals, outcome expectations, and perceived environmental obstacles in the regulation of human motivation, behavior, and well-being.[140] Self-efficacy, one of the most analyzed psychosocial constructs in both nutrition and physical activity studies, represents the strongest predictor of weight change.[138] SCT has been successfully used as the underlying theory for behavior change in several nutritional areas and is still a dominant framework in the current practice.[138] This theory describes a dynamic, continuing process in which personal factors, environmental factors, and human behavior, exert influence upon each other.[140]

By influencing people's pattern of thinking, their feelings and actions will be modified.[141] Three main factors or major determinants affect the likelihood that a person

will change a health behavior: self efficacy, goals, and outcome expectancies. If individuals feel that they can exercise control over their health behavior, they will be motivated to act, persisting through difficult challenges.[133] Strategies to improve self-efficacy, the most important personal factor in behavior change, may include setting incremental goals, such as exercising for ten minutes every day, behavioral contracting with specific goals and rewards, and monitoring one's own behavior by record keeping and reinforcing good habits.[140] Cognitive processes, such as special emphasis on enjoyment and interest in physical activity, play a very important role in achievement long-term weight loss.[142]

The Transtheoretical Model (TTM) has been extensively used both in nutrition[145] and exercise settings;[144,145] however, methodological difficulties have restrained meta-analytical studies to put forward a precise conclusion about the effectiveness of the theory to predict behavior.[145] This model has been used to describe cessation of an addictive behavior and to predict uptake of health-promoting behaviors.[146] An important contribution of this model is the specific tailoring of educational efforts to enclose different methods for individuals in different stages of change: precontemplation (no intention to change behavior), contemplation (thinking about changing the problem in the next 6 months), preparation (planning to change behavior in a short term [one month] and are taking steps to be ready), action (people have recently changed the behavior), and maintenance (have performed the new behavior for more than 6 months).[146] People in the action or maintenance stages may lapse and recycle to earlier stages. In the last stages, people will need skills enhancement for problem solving about restructuring cues

and social support, anticipating and eluding obstacles, and modifying goals. They will also need to deal with barriers, understanding that setbacks are common and can be overcome, manage contingency by increasing the rewards for the positive behavior, and stimulus control by removing reminders or cues to engage in the unhealthy behavior.[146] In the maintenance stage, people should enhance coping skills, identifying high-risk situations, finding alternatives, selecting solutions, and coping with slips and relapses.[146]

The Theory of Planned Behavior (TPB) suggests that an individual's behavior is determined by the intentions to engage in that behavior and by the degree of confidence perceived by the person regarding his/her abilities to perform the behavior.[138] TPB can be applied in situations in which people are aware of the negative consequences of their behavior, for instance, when obese people become conscious that they are eating a high-fat diet[147] or not exercising enough.[148] Intention, the principal determinant of behavior according to this theory, is measured by three independent constructs: attitude, subjective norms, and perceived behavior control.[138] Perceived behavior is an equivalent construct to self-efficacy in SCT.[140] Attitude is defined as a disposition to respond favorably or unfavorably to an object, behavior, person, or event.[149,150] Subjective norms (perceived social expectations) are a function of beliefs that specific, important individuals or groups (social referents) approve or disapprove of performing the behavior, for instance, what my partner thinks or my mother thinks about my behavior.[151]

The Self-Determination approach is a motivation theory that emphasizes people's innate needs to evolve and to be integrated in a social scenario.[152] This theory has been used in nutrition, weight managing settings, and physical activity with optimal results.[142]

The Persuasion Communication Model (PCM) was adapted to public health education by including the SCT constructs of attitude, social influences, and self-efficacy.[153] In his original model, 6 stages were distinguished: exposure to the message, attention to the message, comprehension of the argument and conclusions, acceptance of the arguments, retention of the content, and attitude change.[153] Applying this model to all program communications is a basic method for change.[154] PCM can use intervention group recipients at different levels of awareness, comprehension, attitude, social support, or self-efficacy.[131]

The Health Belief Model is one of the first and most recognized theories in the field that has been used in a wide range of health-related contexts.[155,156] According to this theory an individual's decision to engage in a specific health action is determined by the perceptions of personal susceptibility and severity of a particular condition balanced against perceived benefits and barriers.[155,156] Perceived susceptibility is a person's subjective perception of the risk of contracting a particular disease or condition. Perceived severity is a person's feelings concerning the seriousness of getting a disease. Perceived benefit is a person's belief regarding the benefit of his/her actions. Perceived barrier is defined as the potential negative aspect of a particular health action.[155] Some of the above theories lack strong empirical basis and are not used in the most efficient way, in addition, they provide information about what needs to be changed to promote healthy behavior, but not about how changes can be induced in the clinical practice.[147]

Physical Activity and Eating Habits Following Bariatric Surgery

Regular participation in physical activity is significantly associated with a reduction in cardiovascular disease risk and an improvement in physical and psychological wellbeing.[157,159] Unfortunately, similar to the majority of adults in the United States,[159,160] obese people tend to adopt sedentary lifestyles.

Morbidly obese patients have inferior exercise capacity, cardiac efficiency, and compensatory hyperventilation at peak exercise, and poorer gas exchange at rest than physically active non-obese individuals.[161] After surgically-induced weight loss, most patients can markedly improve their exercise capacity being able to walk as early as the first weeks following surgery.[162,163] Compliance to exercise programs can significantly impact RYGB outcomes through losing more weight, gaining more muscle mass and burning larger amounts of fat.[162,163] Lack of exercise is the most likely area of noncompliance following obesity surgery.[48] There are several considerations to take into account regarding non-adherence to exercise regimens: the preoperative patient's weight limitations and previous lack of engagement in regular exercise activities.[163]

The literature has shown that bariatric surgery is an effective way to diminish abnormal eating behavior and improve quality of life; however, a significant minority of morbidly-obese patients did not respond positively and did not benefit psychologically from bariatric surgery.[165] Greater success appeared to occur in young females, who had a satisfactory marriage, high socio-economic status, reasonable expectations, and undisturbed eating behaviors before surgery.[166]

The eating status pattern should be part of a systematic profiling of morbidly-obese patients for postoperative nutrition education, in order to achieve the best comprehensive treatment regarding weight loss.[167] Even though bariatric surgery seems to generate changes in patients' relationship to food that might help them to re-establish a perception of control over eating behavior, patients should participate in postoperative counseling to reduce anxiety and increase compliance to restrain from the amount of food that can be eaten.[168,169] It is not only the consumption of banned foods, such as sweets or soft drinks, but rather a general hypercaloric eating behavior, as an expression of the patient's insufficient adherence that is associated with a poor weight loss following surgery.[170] According to the American Medical Association, successful weight management to improve overall health requires a lifelong commitment to promote lifestyle behaviors emphasizing sustainable and enjoyable eating practices, and daily physical activity.[171]

Conclusions of Significance

Evidence indicates that RYGB surgery is a successful way for reducing weight in morbidly-obese patients, leading to mitigation of most obesity-related comorbid conditions, such as hypertension, diabetes, dyslipidemia, sleep apnea, gastroesophageal reflux disease, depression, and others.[13–19] However, this surgical approach still carries the risk of developing serious metabolic and nutritional complications due to the extensive anatomical changes of the gastrointestinal tract boosted by failure to comply with lifelong vitamin and mineral supplementation.[54–58] Despite strong recommendations and emphasis about the need of lifelong multivitamins intake following RYGB, the

adherence rate to both supplements and one-year postoperative dietetic counseling remains low.[25,26,111] In addition, some patients are likely to experience weight loss plateau or weight regain if they fail to be actively involved in postoperative healthy lifestyle changes, such as regular physical activity and adherence to healthy eating habits.[20,21,47] Those facts suggest the need for patients' education beyond imparting dietetic counseling, to influence behavior and produce changes in knowledge, attitudes, and skills patients require for maintaining and improving their health over time.[114] Several strategies can be used by a health care professional to modify patient's behavior, no single method or combination of behavioral methods have proven to be clearly superior.[131] The purpose of a behavior therapy is to change eating and physical activity behaviors over time on an individual or group basis;[133] adding motivational interviewing to counseling sessions might increase the effectiveness of an intervention.[27,28]

This research study was designed to show how health-related changes can be induced by a well-implemented comprehensive nutritional and lifestyle education intervention. A combination of behavioral models as the theoretical framework for this study was used. The Social Cognitive Theory (SCT) was mainly applied because it integrates essential concepts and processes from the cognitive and behavioral model including the important constructs of self-efficacy, goals, and outcome expectation.[140] SCT has been successfully used as the basic theory for behavior change in nutritional areas and is still a dominant framework in the current practice of nutrition.[138] The investigator also applied some concepts of the Persuasion Communication Model (PCM)[153] because adopting this model to every educative program is an essential method

for change.[154] In addition, PCM can use intervention group recipients at different levels of awareness, comprehension, attitude, social support, or self-efficacy.[133] The investigator also applied the Transtheoretical Model because it has been successfully used both in nutrition and exercise settings, and it makes a valuable contribution to understanding and promoting behavior change.[143–145]

As obesity increasingly affects minorities in the United States,[1,12] this research study has responded to the need for a comprehensive education of Hispanic-Americans who have undergone RYGB surgery for losing weight. Those patients are at risk for premature weight loss plateau, weight regain, relapse of obesity-related comorbidities, and nutritional deficiencies if they fail to comply with postoperative healthy lifestyle changes. This research evaluated the effectiveness of a comprehensive nutrition and lifestyle education intervention that incorporated behavior modification strategies and motivation to diet counseling. This randomized-controlled trial aimed to promote weight loss by encouraging physical activity and healthy eating habits. In addition, the study attempted to improve some obesity-related conditions (depression, diabetes, dyslipidemia, and others) and patients' nutrient status (proteins, iron, vitamin B12, folate, calcium, and others). The intervention was implemented between 6 and 12 months after RYGB surgery in morbidly-obese adult Hispanic-Americans. Appendix 13 includes the evidence-based rating of some articles used in the literature review.

Preliminary Data

The investigator acquired experience in collection of data from medical records after conducting a retrospective, descriptive, archival study as part of a Dietetics and

Nutrition Master's degree research project. After Florida International University Institutional Review Board approval of the study, the database of all morbidly-obese patients who had bariatric surgery in 2005 at a South Florida center of bariatric surgery was analyzed. A sample of 59 patients was extracted according to the following inclusion criteria: undergone RYGB procedure and answered a survey sent to the patients at 6 months following surgery. Demographics, anthropometrics, and nutritional data, such as eating behaviors, quality of diet, obesity comorbidities, laboratory tests before and after surgery, and other information available in the patients' medical records were collected and analyzed. All patients received a preoperative evaluation that included a complete medical history, physical examination, laboratory tests, and determination of obesity comorbidities, as well as psychiatric and respiratory evaluations. Quality of diet and food habits was recorded by a Registered Dietitian at the preoperative assessment such as excessive energy, sugar, fat, and snacking. After surgery the dietitian made recommendations on changing the diet, adding nutritional supplements, and checking compliance with the recommendations at two weeks, at one, 2, 4, and 6 months, and at one year after surgery.

The sample included 59 morbidly-obese patients, 22 were men (37%) and 37 were women (63%). The mean age of the participants was 47.3±10.7 years. The majority (80%) was White, non-Hispanic, 12% were African-Americans, and 8% Hispanic-Americans. Most of them worked in office-administrative jobs and were married (58%).

Before surgery, 26 out of 59 (44%) reported practicing some form of exercise as a strategy to lose weight and 34% used weight loss medications. Of the participants, 15 out of 59 (25%) had attempted at least one diet before undergoing surgery while the rest

attempted from 2 to 7 different diets. The most popular diet (75%) was Weight Watchers, followed by Atkins diet (51%) and Slimfast diet (39%).Weight regain after dieting and taking medications was reported by nearly all of the patients (91.5%).

Mean age for onset of obesity was 15±12.9 years with no significant difference between genders. Age was not associated with weight loss at 6 months. Hispanic-Americans lost more weight at each assessment visit, but it was not significantly different from White, non-Hispanics or African-Americans.

The initial mean BMI was 46.8±6.8kg/m^2, which was reduced to 31.6±4.4 kg/m^2 at 6 months following RYGB. The mean weight was 303.2±60.5 at baseline and 204.7± 48.6 lbs at 6 months following surgery. Mean weight lost at 6 months was 98.5±29 lbs (32.6±6.1% of initial weight).

Table 1 shows the mean weight loss by gender following surgery. Statistical analysis showed that men were not significantly different from women in weight loss (in lbs) through time (*P*>.05).

Table 1: Mean Weight Loss by Gender Following Surgery Preliminary Data[a]

Time Since Surgery	Gender	n	Mean	SD	*P* value
Two weeks					.551
	Female	23	23.1	7.6	
	Male	8	23.7	12.2	
Two months					.378
	Female	16	52.8	15.4	
	Male	14	55.3	14.8	
Six months					.115
	Female	25	93.7	28.7	
	Male	12	108.6	28.6	

[a] Beginning number of females (n=37) males (n=22).

Bariatric surgery did not produce a constant weight loss during the 6 months following surgery; those who were more obese lost significantly more weight. Initial

BMI (r=.804, *P*< .001), and initial weight (r=0.742, *P*<.001) were directly and significantly correlated with weight loss at 6 months. In separate linear regression models, initial weight in lbs (*P*=.006) and BMI in Kg/m^2 (*P*<.001) were significant predictors of weight loss at 6 months after controlling for gender and exercise.

Table 2 shows the post-surgery obesity-related comorbidity progression up to 6 months following surgery.

Table 2: Post-Surgery Obesity-Related Comorbidity Progression Preliminary Data[a]

Comorbidity	Presurgical	6 months		
		Improved	Resolved	No change
Sleep apnea	44(75)	27(61)	11(25)	6(14)
Joint illness	42(72)	0(0)	11(26)	31(74)
Hypertension	37(63)	19(51)	7(19)	11(30)
Hypertriglyceridemia	31(52)	10(32)	7(22)	14(45)
Depression	28(47)	12(43)	5(18)	11(39)
Shortness of breath on exercise	26(44)	3(11)	6(23)	17(65)
Non-Insulin diabetes mellitus	26(44)	15(58)	11(42)	0(0)
Gastroesophageal-reflux disease	25(42)	9(36)	6(24)	10(40)
Hypercholesterolemia	17(29)	8(47)	4(23)	5(29)
Urinary incontinence	15(25)	7(47)	4(27)	4(27)
Low back pain	13(22)	0(0)	1(8)	12(93)
Asthma	8(14)	2(25)	2(25)	4(50)
Coronary artery disease	7(12)	0(0)	1(14)	6(86)
Insulin-Dependent diabetes mellitus	5(8)	4(80)	1(20)	0(0)
Cardiovascular disease	2(3)	0(0)	0(0)	2(100)

[a] Values are number of participants= n (%).

Sleep apnea was the most frequent medical condition associated with morbid obesity and cardiovascular diseases were the least frequent comorbidities. All patients with diabetes mellitus improved or resolved their diabetic symptoms with weight loss after surgery.

Pre-surgical comorbidities did not significantly increase the risk of post-surgical complications. There was no significant difference in mean weight loss at 6 months between those with complications (98.5±37 lbs, n=28) or without complications (98.5±22 lbs, n=31), *P*=.99. Table 3 shows the most frequent complications that occurred up to 90 days following RYGB surgery in the cohort studied (perioperative complications).

Table 3: Perioperative Complications Preliminary Data

Surgical Complications	n(%)
None	31(52)
Bleeding Anemia	11(19)
Dumping Syndrome	10(17)
Ulcer	3(5)
Gallstones	2(3)
Others	2(3)

Weight loss at 6 months was mainly predicted by initial weight, independent of gender and exercise. The mean weight lost at 6 month after surgery was 98.5± 29 lbs (32.6±6.1% of initial body weight). The mean BMI at 6 months after surgery was 31.6±4.4 kg/m^2. There were no significant differences in the mean weight loss over time between genders and different ethnic groups. The most frequent complication after surgery was bleeding anemia (19%). Surgical complications that occurred in approximately half of the patients were not significantly related to the pre-surgical

comorbidities. Post-surgical complications did not significantly affect weight loss at 6 months.

The main limitation of the preliminary study was that 6 months might not be enough time to assess the full consequences of the surgical procedure. The study was retrospective and archival, with weak dietary records. According to this preliminary study, it seems that RYGB surgery is a very effective way to lose weight, rapidly reversing or ameliorating some obesity comorbid conditions immediately after surgery. This non-conventional treatment of morbid obesity might keep patients motivated to adhere to healthy lifestyle choices, but the surgery itself may not make behavioral changes happen.

There is a need for effective nutrition and lifestyle education interventions in the field of bariatric surgery that may keep patients motivated over time to adhere to healthy lifestyle choices and to lifelong intake of multivitamin supplements. There is also a need for more prospective studies to evaluate the impact of culture-sensitive, comprehensive educational interventions on weight loss, prevention of nutritional deficiencies, and relapse of obesity-related comorbidities following RYGB surgery. Therefore, this randomized-controlled study was designed to expand the research knowledge on the characteristics associated with weight loss beyond the 6 months following RYGB surgery. In addition, it supports the feasibility of implementing a comprehensive nutrition and lifestyle educational intervention on Hispanic-American adults who have recently undergone obesity surgery.

CHAPTER III. RESEARCH DESIGN AND METHODOLOGY

Study Design and Overview

This research study entailed a randomized-controlled clinical trial to evaluate a comprehensive nutrition and lifestyle education intervention, based on bariatric dietetic recommendations reinforced by behavior modification strategies and motivation. It was designed to address premature weight loss plateau, weight regain, relapse of obesity-related comorbidities, and nutritional deficiencies. The goal was to implement a thorough educational intervention in a population of morbidly-obese adult Hispanic-Americans who have had RYGB surgery for losing weight. The intervention emphasized the idea that the surgery alone is not life-changing. Long-term postoperative lifestyle modification is needed to succeed.

The study assessed the effect of a comprehensive postoperative nutrition and lifestyle education intervention implemented every other week over 6 months in morbidly- obese adult Hispanic-Americans who were initiated in the educational intervention 6 months after RYGB surgery. Measures included weight reduction rate, improvement of hypertension, diabetes, hyperlipidemia, and other obesity-related comorbid conditions, nutritional status, such as proteins, iron, vitamin B12, and folate, eating habits, and physical activity.

Study Population and Sample Size Calculation

The study was conducted between the 1st of November 2008 and the 31st of March 2010. It was a prospective randomized-controlled clinical trial that comprised of 144 morbidly-obese Hispanic-Americans (BMI > 40 kg/m^2 or having associated obesity-related comorbid conditions such as hypertension, diabetes mellitus, dyslipidemia, sleep

apnea, cardiovascular disease, urinary incontinence, asthma, GERD, joint illness, or depression along with a BMI $\geq$ 35 kg/m^2). Participants were 18 years or older who have undergone a laparoscopic Roux-En-Y Gastric Bypass surgery 6 months earlier. The patients were recruited from a medical practice of bariatric surgery and were followed-up at the Laparoscopic Institute of South Florida, in Hialeah, Florida (Appendix 2).

The sample size of the population was estimated from the published literature based on similar research results as well as based on the preliminary study described earlier. Finally, the sample size was calculated based on the primary hypothesis, using the PASS 6.0 software two-sample t-test power analysis tables for clinical studies.[172] Assuming a power of 80%, a *P* value of 0.05, and a medium effect size of 0.5, a sample of 130 individuals (65 in the intervention group and 65 in the comparison group) would be required. However, the literature has shown that a dropout rate of 10 to 20 % is to be expected in a short-term clinical nutrition study of up to 6 months of intervention.[173,174] Other studies showed lower attrition rates in weight reduction programs, for instance, Jeffery and collaborators found only 6% attrition rate over 6 months of participation in a weight-loss intervention in which the central component was a biweekly worksite self-motivation program.[175] Based on the literature, it was estimated that a dropout rate of 10% was realistic, thus a total sample size of 144 individuals (72 in the intervention and 72 in the control group) was recruited to achieve 80% power to detect a medium effect size of 0.5 using a two-sided two sample *t* test with an alpha level of significance of .05.

Initial Screening and Recruitment

After the Florida International University Institutional Review Board approval, study participants were selected and recruited from the Laparoscopic Institute of South

Florida in Hialeah. The primary strategy for getting participants was placing flyers in the waiting room that invited eligible patients to participate in the study (Appendix 3). Each potential participant was fully informed by the investigator regarding the purpose and nature of the study, frequency of the intervention and assessment schedules, including the expectations of his/her efforts and extent of his/her participation. Risks and benefits associated with the study were also explained and each participant was provided with a document assuring confidentiality and the voluntary nature of the study. Those who agreed to participate were requested to sign the informed consent form. (Appendix 4) Only those who agreed to participate and met the inclusion criteria were included in the study.

As obesity in the United States occurs at higher rates in racial minority populations [1,176] and because the Laparoscopic Institute of South Florida is a bilingual (English-Spanish) institution, was expected to be found a higher representation of Hispanic-American participants. In order to overcome potential barriers to participation, individuals were asked about their preferred language for communication (English or Spanish). Incentives were provided in the form of frequent contact with the investigator (twice per month to deliver the intervention providing nutrition education, behavior-change strategies and motivation plus 2 assessment meetings at initial and final point times), either in Spanish or English according to participant's preference. Participants were not monetarily compensated for their time or transportation expenses. An average of 18 patients was enrolled each month and accrual was completed by the end of the ninth month after initiation of the recruitment obtaining the desired sample.

Inclusion and Exclusion Criteria

The criteria for eligibility were as follow:

1) Adult Hispanic-American patients aged 18 years and older of both genders.

2) Recent past medical history (6 months ± 6 weeks) of morbid obesity defined by a BMI $\geq$ 40 kg/m^2, or having associated obesity-related comorbidities (hypertension, diabetes mellitus, dyslipidemia, sleep apnea, urinary incontinence, asthma, gastroesophageal reflux disease, joint illness, or depression) along with a BMI $\geq$ 35 kg/m^2 determined by medical chart review.

3) Non-institutionalized patients.

4) Willingness to participate in a clinical trial beginning at 6 months after surgery, with a total of 6 biweekly contacts with the investigator for comprehensive nutrition and lifestyle education sessions, and two assessment meetings at 6 months following surgery (initial or baseline assessment) and at 12 months following surgery (final assessment).

5) English or Spanish proficiency.

6) Patients who have had at least 5 nutrition counseling sessions with a registered dietitian since surgery.

The exclusion criteria were as follow:

1) Participation in another clinical trial.

2) Non-ambulatory patients.

3) Pregnancy

4) Anatomical problems following surgery: pouch dilatation, anastomotic dilatation, or gastric fistula.

5) Medical problems following surgery: kidney, adrenal, or heart disease.

Randomization

A research identification number was assigned in a continuous order of appearance to each patient who consented to participate in the study. Natural positive integers were used starting from number 001 (first participant's research ID number) to 144 (last participant's research ID number). After obtaining informed consent participants were randomly assigned into one of 2 groups: intervention or control to create statistically equivalent groups. A computer randomizer was used by the investigator to perform randomization of one set of 72 unique numbers, ranging from 1 to 144 and sorted from the smallest to the largest.[177] This set of numbers represented the individuals' research identification numbers assigned to those in the intervention group. The rest of the numbers represented the individuals' research identification numbers assigned to those in the comparison group. Following randomization, all the study participants entered the initial or baseline assessment phase.

Study Phases: Initial and Final Assessments and Intervention

The study phases consisted of 2 assessment meetings with the investigator at 6 and 12 months following surgery (initial or baseline and final assessment respectively) and a nutrition and lifestyle intervention.

Initial or Baseline Assessment

The initial or baseline assessment visit for all participants took place at the sixth month compulsory visit to the bariatric surgeon following RYGB at the Laparoscopic Institute of South Florida. This phase included the collection of medical and nutritional information by a baseline assessment questionnaire, a physical activity questionnaire, a

24-hour dietary recall, an eating behavior questionnaire, and the Beck's Depression Inventory. The assessment lasted approximately 30 minutes.

Baseline assessment questionnaire (Appendix 5): The collection of medical data utilized a self-reported form-oriented assessment questionnaire previously used in the preliminary study and widely used as part of the medical records in bariatric surgery settings. Medical records self-reported data have been previously validated as being reasonably accurate for chronic conditions such as hypertension, diabetes, and dyslipidemia and for routine screening exams.[178] The baseline assessment questionnaire included the following information:

1) General information: Patient's research ID number, current date, date of surgery, and visit code (initial or final assessment visit).

2) Patient socio-demographic information: Socio-demographic information included age, gender, ethnicity, country of origin, marital status, family unit, current pregnancy if applicable, tobacco use, level of education, language proficiency, occupation, employment status, and type of health insurance used to pay for the surgery.

3) Anthropometric data: This information consisted of the main outcome of the study and included preoperative information, such as body weight, height, body mass index (BMI), ideal body weight (IBW), and excess body weight (EBW), obtained from patients' medical charts and corroborated by the investigator by calculating with patient's weight and height. Postoperative information comprised of body weight, BMI, body weight lost, excess body weight loss (EBW), and percentage of excess body weight loss (% EWL). This section included additional self-reported information regarding patient's body

weight history, such as age at onset of obesity, weight loss dieting programs attempted before surgery, and weight loss medications taken up to surgery.

4) Patient's medical history: Included medical information regarding preoperative obesity-related comorbid conditions and their postoperative progression. The information was self-reported and corroborated from patients' medical records. Criteria for obesity-related comorbid conditions were based on cutoff laboratory values, or the use of medications for the condition in question. Obesity-related comorbid conditions included: hypertension, diabetes mellitus, dyslipidemia (hypercholesterolemia and hypertriglyceridemia), sleep apnea, depression, asthma, joint illness, gastroesophageal reflux disease, urinary incontinence, and others.

5) Medications for obesity-related comorbidities and number of supplements taken were self-reported by participants.

6) Laboratory tests: Fasting blood tests were performed at 6 and 12 months following surgery to monitor changes of obesity-related comorbid conditions and micro and macronutrient status. Blood levels of glucose, hemoglobin A1c, lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides), complete blood count (CBC) including hemoglobin, urea nitrogen (BUN), creatinine, total proteins, albumin, iron, vitamin B12, and folate were obtained.

7) Complications: This segment of the assessment questionnaire documented the followings events: episodes of dumping syndrome, vomiting, diarrhea, constipation, and others. This information was self-reported and corroborated by medical records.

Physical activity questionnaire (Appendix 6): This section included a simple and easy to use questionnaire adopted for most bariatric surgery institutions to assess physical

activity. The structure of the questionnaire was based on both the Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) that has demonstrated to be a reliable and reasonably valid questionnaire for adult populations[179] and the physical activity updated recommendations for adults from the American College of Sports Medicine and the American Heart Association.[158] The physical activity questionnaire included information concerning type of exercise, frequency, and intensity in the past week.

Dietary recall (Appendix 7): The collection of nutritional data used three 24-hour dietary recalls at each assessment point. This method was validated for normal weight, overweight, and obese individuals showing a significant correlation between the energy intake and the estimated energy requirements (r=0.57, $P < .05$), and a significant inter-individual variation in accuracy of recall.[180] Accuracy of this dietary assessment instrument was evaluated in patients with eating disorders (bulimia) by comparing actual intake with reported intake in a 24-hour dietary recall interview with significant positive correlations between actual and recalled kilocalories, total grams, and grams of macronutrients consumed (proteins and carbohydrates).[181] The 24-hour recall was widely used for bariatric postoperative follow-up because bariatric patients have been found to be less motivated to cheat or underestimate their intakes than other populations.[182–184]

A multiple path method was applied by the investigator in order to limit the extent of underreporting of food intake.[180,185] Participants were asked to send to the investigator two additional 24-hour dietary recalls by mail or email immediately after the initial and final assessments as a way to improve the veracity of the information. Average data of

the three 24-hour recalls was analyzed using the Diet Analysis Plus software for Windows. Total daily calorie intake, percentage of total daily calories from protein, carbohydrates, and fat, total cholesterol, percentage of saturated, polyunsaturated and monounsaturated fat, total daily meals, micronutrient intake from food (iron, vitamin B1, vitamin B12, folate, and calcium), and adequacy of fluid and fiber intake were estimated.

Eating behavior questionnaire: (Appendix 6). The collection of eating behaviors utilized a simple, five-item self-administered questionnaire that assessed the eating habits to which respondents attributed their excess body weight. Based on the Weight and Lifestyle Inventory (WALI) questionnaire, a 24-item questionnaire that has demonstrated adequate internal consistency, [186] the eating behavior questionnaire is widely used in bariatric surgery settings and was found to have acceptable reliability in obese populations.[187]

Beck's Depression Inventory-II (Appendix 7): The Beck's Depression Inventory version II (BDI-II) is widely used as an assessment tool by healthcare professionals and researchers in a variety of settings, showing no over-sensitivity to daily variations in mood, and high internal consistency.[188] The BDI-II contains 21 questions, each answer being scored on a scale value of 0 to 3. Higher total scores indicate more severe depressive symptoms as follow: 0-13 minimal depression, 14-19 mild depression, 20-28 moderate depression, and 29-63 severe depression. Question 19 that refers to having lost or gain weight lately was counted as zero points. BDI-II was self-administered in English or Spanish according to the participant's language preference.

Final Assessment

All participants were re-assessed at 12 months following surgery. The final assessment included the same questionnaires applied in the initial assessment except for demographic information. Completing the final assessment questionnaires lasted approximately 30 minutes.

Intervention

Participants in the intervention group received a total of 6 nutrition and lifestyle education and behavioral-motivational sessions in groups of up to 12 participants in Spanish or English according to the participant's language preference. Sessions were conducted every other week by the investigator starting immediately after the initial or baseline assessment (at the seventh month following surgery). Each comprehensive educational session took place at the Laparoscopic Institute of South Florida and lasted approximately 90 minutes. The investigator presented the sessions in an educational lecture format. PowerPoint slides were utilized and participants were able to ask questions during the presentation. Group discussion was encouraged at the end of each session.

The decision to start the intervention 6 months post-surgery was based on several factors. After gastric bypass surgery patients experience various stages according to their individual diet progression; from a clear liquid-diet the day immediately after surgery to a low-fat, low-sugar solid diet approximately 8 weeks after surgery. However, it takes several more months to expand their diet choices to include a wide variety of foods.[29] At approximately 6 months following RYGB the surgically-induced rapid weight loss may start to naturally decline because patients start to consume the higher calorie-intake diet

since surgery. Bariatric patients may be prone to regain weight if they do not change their eating and lifestyle behavior.[46]

The literature supports the decision to conduct 6 intervention sessions. Even a single nutrition counseling session may be beneficial in improving short-term clinical outcomes especially in patients with chronic diseases, such as diabetes, hypertension, and dyslipidemia.[191] However, too few sessions might not be advantageous because they might lead to non-statistically significant differences in the outcome measures between the intervention and comparison groups. Furthermore, too many sessions might lead to higher level of non-compliance to the intervention sessions.

The purpose of the intervention was the promotion of dietary recommendations reinforced by practical behavioral modification strategies for dealing with emotional difficulties that might be encountered by the patients in the pursuit of healthy lifestyles. Participants in the comparison group did not receive the comprehensive nutrition and lifestyle education intervention but were provided printed guidelines for healthy eating and physical activity at the baseline encounter with the investigator (Appendix 1).

Both participants in the intervention and comparison group were free to decide receiving additional counseling by independent professionals, such as a Registered Dietitian, psychologist, or other professional counseling. This information was documented at both initial and final assessment questionnaires under the heading of "number of sessions and type of private counseling received in the previous 6 months."

The comprehensive nutrition and lifestyle program curriculum implemented by the investigator included both (1) nutrition and exercise education and (2) emotional support intervention (Appendix 10). Session 1 consisted of the nutrition education session

that included the daily meal planning guide and the maintenance diet. Session 2 discussed the importance of physical activity in the post-operative bariatric life. Sessions 3 to 6 consisted of the emotional support intervention including behavior change strategies, stress relief without food, self-talk, and relapse prevention.

The nutrition education session or session 1 was based on the American Dietetic Association and the United States Department of Agriculture nutrition education for wellness, because they provide sound science-based advice to promote health and reduce risk for chronic diseases through diet and physical activity.[118,190] According to the Bariatric Surgery Association, this nutrition intervention has been standardized for bariatric patients.[29] The daily calorie intake should be limited to 1000-1400 calories (the estimated calorie intake 6 to 12 months following RYGB) with the goal of providing adequate nutrition to preserve lean tissue and prevent nutritional deficiencies. The minimum intake of protein should be at least 60-70 grams per day, with an adequate intake of low glycemic carbohydrates and low saturated fat.[29] The nutrition segment of the intervention included dietetic recommendations for maintenance, identifying and avoiding unhealthful foods, stressing the need of lifelong vitamin and mineral supplements intake, giving tips to promote proper nutrition by controlling portion size, establishing new routine eating habits, and the use of a daily meal planning guide including a bariatric exchange list for weight management. Session 2 helped participants to begin a consistent exercise program and to identify why lifelong physical activity is important to keeping weight off after bariatric surgery. The emotional support intervention (sessions 3 to 6) was based on the book *The Emotional First Aid Kit: a Practical Guide to Life after Bariatric Surgery*[191] reproduced with permission from

Matrix Media Communication (Appendix 11). This intervention applied mainly the Social Cognitive Theory that embraces the construct of self-efficacy, the most analyzed psychosocial constructs in both nutrition and physical activity studies,[128,135] and is still a dominant framework in the current practice of nutrition.[135] Other concepts were emphasized such as self-empowering for change, stress relief without using food, increasing self-esteem, overcoming obstacles to establish a consistent exercise program, recognizing binge eating problems, and other motivational strategies using the Persuasion Communication Model[153] and the Transtheoretical Model[133,143,145] because the intervention group recipients might be at different levels of awareness, comprehension, attitude, social support, or self-efficacy.[133]

It was expected that the comprehensive nutrition education and lifestyle program (intervention group) would be superior to the non-comprehensive approach (comparison group) because the inclusion of support groups makes it easier and more efficient for patients' education regarding life after bariatric surgery.[114] In addition, the comprehensive approach was not limited to nutritional tips, dieting techniques, and exercise, but it also included behavioral and motivational strategies that enhance change and adherence to long-term healthy habits.[27,28,117] The selection of this particular intervention, described in detail in Appendix 10, was based on evidence-based practice. Behavior therapy, when used in conjunction with other weight loss approaches, such as nutrition counseling and motivation, is more successful in reducing weight or delaying weight regain.[40,118,120,121,123–127,135,136]

Before and after completion of each educational session, participants were asked to complete a brief multiple choice quiz in order to evaluate the knowledge acquired (Appendix 10). Following the 6 nutrition education sessions, participants in the intervention group were sent compliance reminders by emails and phone calls by the investigator. Participants had the opportunity to complete a missed session before the final assessment and were allowed to receive a missed session printed materials by mail or email only once.

Schedule of Events Monthly Post-Randomization

Table 4 shows the schedule of events including randomization, assessments, intervention sessions, and reminders.

Table 4: Schedule of Events

Month after surgery	6	7	8	9	10	11	12
Recruitment	x						
Assessments	Baseline						Final
Intervention sessions		1 and 2	3 and 4	5 and 6			
Reminder					x	x	

Pilot Study

After recruitment and informed consent, a pilot study of 12 adult Hispanic-American participants was conducted at the beginning of the study in order to test the instruments, compliance with educational sessions, and the knowledge acquired by the participants. All educational materials were presented by the investigator over the first 8 weeks after the recruitment. Participants completed a pre and post lecture quiz at each educational session (Appendix 10) except the last one and an evaluation satisfaction survey (Appendix 12) to evaluate knowledge gained and satisfaction.

Compliance with educational sessions by the pilot study participants was 68%. All the participants who attended the pilot study sessions answered that the lecture materials were helpful, not difficult to understand, and that they increased their understanding of the subject matter. Overall, the lectures were rated as excellent. In the pre-post lecture quizzes, the majority of the participants answered incorrectly to the questions before the initiation of the lecture and correctly after the completion of the lecture.

Some of the participants' testimonials regarding the intervention were as follow:
"Thank you very much, I feel I have learned a lot and the classes have been helpful."
"Excellent instructor, explains elaborately and brings support, which is very useful."
"She motivates and gives excellent tips to fight the hunger temptations."
"I liked the phrase: 'The doctor operated on your stomach, not on your mind.' This is right, if I do not make changes in my life, the surgery would have been useless."
"The course was very important, I do not understand why it is not included as part of the surgery. It needs to be implemented every year after surgery."
"Thank you very much for your clear explanations, motivation, and recommendations about how to change my lifestyle."
"Thank you for your effort to change our obese minds. You are right, if we do not change, all would of have been worthless."

Compliance

Study participants non-compliance involved failure to attend all of the nutrition intervention sessions. It was important to minimize attrition bias to maintain the external and internal validity of the study.[192]

Morbidly obese people who have decided to undergo bariatric surgery and have lost a significant amount of weight are considered a very motivated population, having the desire and willingness to engage in and comply with new activities that can help them to overcome difficulties in reaching their goals.[193] The sole fact of offering 6 free, comprehensive, and interesting nutrition and lifestyle educational sessions, in their chosen language could be an enticing strategy for the participants to remain engaged and prevent or decrease attrition. The researcher explained to the potential participants that they may expect benefits from participating in all the nutrition education sessions, for instance, the acquirement of some knowledge and skills about healthy food and lifestyle choices, and behavior change strategies needed to deal with the difficulties encountered following bariatric surgery. Benefits might also include the prevention of body weight regain and obesity-related comorbidities relapse.

Compliance is a complex phenomenon and special retention efforts were used in this study to decrease the attrition rate. These efforts included the development of a strong tracking system to continually contact participants in the intervention group through e-mails and telephone calls, especially immediately before each intervention session. Attendance to the educational sessions was recorded at each nutrition and lifestyle educational session, as part of the data analysis.

Outcomes

The outcome measures were determined by data collection at baseline or initial assessment at 6 months after undergoing surgery and at the final assessment 12 months following surgery. Assessments comprised monitoring of body weight and BMI, resolution of obesity-related comorbidities, nutritional deficiencies, physical activity, and

eating behaviors. The main outcome consisted of patients' success overtime to reduce or maintain their anthropometric measurements (body weight, BMI, excess weight loss, and percentage of excess weight loss) without premature weight plateau or weight regain. Several other variables were determined and used in the analyses, such as sociodemographic, avoidance of nutritional deficiencies, obesity-related comorbidities resolution, physical activity and eating habits-related variables.

According to the American Diabetes Association intensive lifestyle programs involving participant education and counseling, reduced dietary fat and energy intake, regular physical activity, and frequent participant contacts are necessary to produce long-term weight loss of up to 10% of starting weight at one year.[118] A greater weight loss in the intervention group than in the comparison group was expected at 12 months after surgery.

A research chart was kept for all study participants. The chart contained signed consent forms, progress notes, baseline and final assessment questionnaires, and the investigator reports of participants' attendance at each comprehensive nutrition and lifestyle education session.

Measurement of Variables

Medical and nutritional data was collected using a form-oriented database previously used in the pilot study, containing assessment questionnaires, physical activity questionnaires, 24-hour dietary recalls, Beck's depression inventories, and eating behavior questionnaires. Measurements of dietary habits were obtained from patients' medical and nutritional records.

1. Sociodemographic Variables

Sociodemographic data, collected by the assessment questionnaires, described the characteristics of the cohort. Demographic variables included age, gender, and ethnicity. Social variables included marital status, level of education and language proficiency, occupation, employment status, family unit, pregnancy (when applicable), and tobacco use.

Age: Was self-reported. Adults 18 years of age and older were included in the study.

Gender: Included the categories male and female.

Ethnicity: The sample included Hispanic-Americans defined as those Americans with origins in the Hispanic countries of Latin America or in Spain. Hispanic-Americans constitute 15.4% of the total United States population or 46.9 million people, forming the second largest ethnic group after non-Hispanic White Americans and the largest ethnic minority in the United States. [225]

Birth Country: Contained the countries where patients were born. This variable included the categories United States, Cuba, Puerto Rico, and other countries.

Marital status: Included the categories married, single, divorced, and widowed.

Education: Contained the number of years of school completed.

Language proficiency: Represented the most often spoken language at home. It included the categories Spanish or English only and Spanish and English both equally.

Occupation: Included the categories of: office or administrative, professional, educator, student, housewife, physical labor, or other.

Employment status: Documented whether the individual was currently working, disabled, or retired.

Family unit: Documented the number of children and members of the household.

Tobacco use: Documented whether the individual was currently smoking, never smoked, or was former smoker.

2. Anthropometric variables

This information comprised of the main outcomes of the study. To assess for changes from baseline to final assessments (6 to 12 months following surgery) anthropometric measurements were collected by a medical assistant and documented in patients' medical records. The variables included:

Body weight: Measured by a Seca 703 column scale, an extremely robust, precise, and stable scale, having a capacity of 550 pounds and a large but low platform. Weight was reported in lbs.

*Height: M*easured with the Seca 220 height rod fitted to the Seca 703 scale and was reported in inches.

Body mass index (BMI): Calculated by either equation:

BMI = Weight in Kilograms / Height squared in meters^2 or,

BMI = [Weight in Pounds/ (Height squared in inches)] x 703

BMI was expressed in kg/m² and categorized according to the National Institute of Health standards for Americans as: < 18.5= underweight, 18.5-24.9= normal weight, 25.0-29.9= overweight, 30.0-34.9= obesity class I, 35.0-39.9= obesity class II, > 40.0= obesity class III or extreme obesity.[194]

Ideal body weight (IBW): There are numerous formulas and published height-weight tables available to determine IBW, but there is not strong evidence comparing the validity of those formulas. Robinson's formula appeared to be a good equation for calculating

desirable healthy weights in men; however, no formula predicted a BMI of approximately 22 kg/m^2 in women.[195] Thus, IBW was calculated based on the midpoint of the medium frame range for gender and height of the Metropolitan Life Insurance Company tables of 1983.[196]

Excess body weight (EBW): Determined from the ideal body weight as the difference between the current weight and the ideal body weight.

Percentage of excess weight loss (% EWL): Defined as the difference between starting weight and current weight (weight loss) divided by baseline excess body weight. Excess weight was determined from the IBW based on the Metropolitan Life Insurance Company tables.[196]

Weight loss: Reported in pounds as the difference between starting weight and ending (or current) weight.

3. Medical Variables:

The database and data collection tools included information about obesity-related comorbid conditions over time. Those conditions included hypertension, diabetes (requiring and not requiring insulin), dyslipidemia (hypercholesterolemia and hypertriglyceridemia), sleep apnea, depression, asthma, joint illness, gastroesophageal reflux disease (GERD), urinary incontinence and others.

Hypertension: Overweight and obesity has showed a strong association with hypertension.[197,198] Systolic blood pressure has been determined to be a strong predictor of cardiovascular disease risk.[199,200] Hypertension was defined in this study as patients taking antihypertensive medications or a systolic blood pressure ≥ 140 mmHg or diastolic

blood pressure ≥ 90 mmHg.[194] Information regarding blood pressure was self-reported and corroborated in medical records.

Diabetes mellitus: Greater central adiposity seen in obese people is strongly associated with increased risk of diabetes mellitus.[201] Patients were considered as having diabetes if receiving oral antidiabetic medication, insulin treatment, having a fasting plasma glucose level of 126 mg per deciliter (7.0 mmol per liter) or greater, or having an elevated hemoglobin A1c (glycosylated hemoglobin) of ≥ 7%.[202] This information was self-reported and corroborated from patients' medical records.

Dyslipidemia: Direct correlation between lipid disorders and body weight has been shown in obesity research.[203] Obesity exerts a dose-response effect on blood lipids, specifically as increased VLDL, triglycerides, and cholesterol, and reduced HDL cholesterol. Dyslipidemia was diagnosed by blood lipid analysis (see laboratory tests). Hypercholesterolemia was diagnosed on the basis of elevated blood total cholesterol levels (200 mg per deciliter [5.2 mmol per liter] or greater), LDL-c ≥ 130 mg/dL, or HDL-c < 35 mg/dL or on the basis of taking medications to reduce cholesterol. Hypertriglyceridemia was diagnosed on elevated triglyceride levels in blood ≥150 mg per deciliter [1.7 mmol per liter] or taking medications to reduce triglycerides levels.[204]

Sleep apnea: Morbid obesity is associated with sleep apnea if excess fat in the neck compresses the airway. Obstructive sleep apnea is characterized by repetitive episodes of complete (apnea) or partial (hypopnea) upper airway obstruction occurring during sleep.[205] This disorder was diagnosed by polysomnography. Information was obtained from patients' self-reports and corroborated from medical records.

Depression: There is a strong association between obesity and depression.[206] Diagnosis of depression was done by a psychiatrist before surgery based on the *Diagnostic and Statistical Manual of Mental Disorders,*[207] which is the current reference used by mental health professionals and physicians to diagnose mental disorders. Information was obtained from patients' medical records. Assessments of depression at baseline and final point times included the Beck Depression Inventory-II (BDI-II), a 21-question multiple-choice self-administered instrument and one of the most widely used instruments for measuring the severity of depression.[188] BDI-II is widely used as an assessment tool by healthcare professionals and researchers in a variety of settings showing to have high one-week test-retest reliability (Pearson r =0.93), suggesting that it is not sensitive to daily variations in mood.[188]

Asthma or reactive respiratory disease: Several prospective studies have shown an association between body mass index and asthma.[208–211] Presence of asthma was determined by pulmonary evaluation and dependence on bronchodilators. This information was self-reported and corroborated from medical records.

Joint illness: Individuals who are overweight or obese have increased risk for the development of degenerative joint disease or osteoarthritis as well as joint pain.[212–215] This information was assessed by patient self-report, use of antiarthritic medication, and corroborated by medical records.

Gastroesophageal reflux disease (GERD): Some studies have shown that GERD is highly prevalent in patients who are morbidly obese and that a high body mass index is a risk factor for the development of GERD.[216–221] Diagnosis of GERD was done by

gastrointestinal evaluation and/or patient self-report of the use of medication for heartburn. Heartburn, the retrosternal sensation of burning or discomfort that usually occurs after eating when lying down or bending over is the most common symptom of GERD. [222] Information was corroborated by medical records.

Urinary incontinence: Obesity is a risk factor for urinary incontinence, a condition of involuntary loss of urine that is objectively demonstrable and is a social or hygienic problem. [223] Urinary incontinence was self-reported and corroborated by medical records.

Current pregnancy: Was applicable for women in their reproductive years (18 to menopause age) and was categorized as yes or no if currently pregnant or not respectively. Pregnant women were excluded from the study because they needed specialized nutritional care.

4. Laboratory Test Variables

Venipuncture was performed at 6 and 12 months after surgery on fasting participants to obtain blood samples from the antecubital vein to monitor relapse of some obesity-comorbid conditions. These conditions included diabetes (as measured by glucose, and hemoglobin A1c), dyslipidemia (measured by lipid profile), and status of some micro and macronutrients (measured by hemoglobin, BUN, creatinine, total proteins, albumin, iron, vitamin B12, and folate).

The biochemical markers included:

Fasting plasma glucose (FPG): Measured by immunoassay or high performance liquid chromatography. FPG was classified based on American Diabetes Association criteria [202] as follows: < 100 mg/dl = normal fasting plasma glucose; ≥ 100 mg/dl and < 126 mg/dl = Impaired Fasting Glucose (IFG); ≥ 126 mg/dl= diagnosis of diabetes.

Hemoglobin A1c: Gives information about the average blood glucose level during the past 3 months indicating how well diabetes has been controlled. It is useful to determine whether diabetes medications need to be adjusted. The American Diabetes Association recommends that persons with diabetes should have A1c level less than 7%. [202]

Lipid profile: According to the National Cholesterol Education Program Adult Treatment Panel III (NCEP, 2008) dyslipidemia is defined as any of the following measurements in blood: total cholesterol ≥ 200 mg/dl, LDL-C ≥ 130 mg/dl, HDL-C < 35 mg/dl, and Triglycerides ≥ 150 mg/dl.

Hemoglobin: Measured as part of a complete CBC count and reported in g/dl. It is one of the most routinely performed blood tests to check the presence of anemia, which is a common complication following RYGB surgery. [24,54–58,82–84] Normal hemoglobin level was considered 12.1 to 15.1 g/dl for women and 13.8 to 17.2 g/dl for men. [224]

BUN, creatinine, total proteins, and albumin: All of these metabolites can indirectly reflect protein nutritional status. [224] Blood urea nitrogen (BUN) normal range varies from 7-20 mg/dl (< 7 mmol/l). [224] Creatinine is the most commonly used indicator of renal function. [224] The typical creatinine reference range is 0.5 to 1 mg/dl (45-90 μmol/l for women and 0.7 to 1.2 mg/dl (60-110 μmol/dl) for men. [224] Total proteins and albumin reflect bioavailability of proteins and their concentration decline in the face of protein deficiency. [224]

Iron: Most common nutritional deficiency following RYGB surgery. [24,54,82] The normal range of Iron for men and women is 20 to 150 ng/ml deficiency. [224]

Vitamins: (*Vitamin B12 and folate)*: Measured quantitatively by radioisotopic assay of competitive binding at 6 and 12 months following RYGB to determine status and monitor effectiveness of treatment in case of deficiency. Normal blood levels for vitamin B12 and folic acid range from 200 to 900 pg/ml and from 3 to 16 ng/ml, respectively. [224]

5. Dietary Intake Variables

Twenty four-hour dietary recalls were analyzed using the Diet Analysis Plus software for Windows. [225] The average of 3 recalls was compared between the intervention and control groups at baseline and final assessments. The dietary intake variables and recommendations for RYGB patients included:

Total daily calorie intake: Recommended range of 1,000 to 1,400 calories per day as lifelong guidelines for weight maintenance to avoid stimulation of starvation mechanisms that can prevent weight loss. [55]

Total daily intake of proteins and proportion of total daily calories from protein: Recommended range of 60 to 105 g or 20 to 30% based on a 1,000- 1,400 calorie diet. [78]

Total daily intake of carbohydrates and proportion of total daily calories from carbohydrates: Recommended 45% carbohydrate intake would require a minimum intake of 113 g of carbohydrates. [78]

Total daily intake of fat and proportion of total daily calories from fat: The Institute of Medicine recommends a minimum of 27 to 47 g of fat per day or 25 to 35% fat. Due to the degree of malabsorption, the higher end of this range may be more beneficial for increased absorption of fat-soluble vitamins. [78]

Proportion of total daily calories from saturated, monounsaturated and polyunsaturated fat: American Heart Association recommends fats from sources of monounsaturated and polyunsaturated fatty acids (such as fish, avocado, nuts, and vegetable oil) and less than 10 percent of calories should come from saturated fat. [226]

Total daily cholesterol intake: American Heart Association recommends less than 300 g per day of cholesterol, keeping trans-fatty acid daily consumption as low as less than one % of total calories. [226]

Total daily meals: included the number of meal events per day.

Micronutrient intake from food: included the amount of iron, vitamin B1, vitamin B12, folate, and calcium from meals.

Micronutrient intake from supplements: included the amount of iron, vitamin B12, folate, and calcium from vitamin and mineral supplements taken. Adherence to vitamin and mineral supplements was recorded in the assessment questionnaire as name and dosage of supplements taken by the patient.

Fluid intake: Included all beverages consumed per day. Adequacy of fluid intake was estimated from 24-hour dietary recalls at initial and final assessments.

Fiber intake: Estimated from 24-hour dietary recalls at initial and final assessments. It was expressed in grams per day.

6. Eating Behavior Patterns

The collection of eating behavior habits utilized a simple five-item "yes/no" questionnaire, which assessed the eating patterns to which respondents attributed their excess body weight. This data included the following variables:

Eating in response to negative emotions: Included the following negative emotions: stress, anger, loneliness, anxiety, depression, boredom, and/or tiredness.

Eating in response to positive emotions: (affect and social cues): Included happiness with family and/or friends, socializing, celebrating, and business functions.

General overeating: Included binge eating episodes defined as the engagement in excessive unrestrained eating.

Eating large amount of food at night and/or avoiding breakfast: Defined as excessive eating after 10 P.M. and/or getting up from bed at night to eat, and/ or avoiding breakfast.

Eating not in response to hunger: Defined as the act of eating at a specific time of day or a specific kind of food, in response to environmental cues other than hunger.

7. Physical Activity Variables

This section included information obtained from the physical activity self-reported questionnaire that contained the following variables:

Type of exercise: Included walking or hiking, jogging or running, bicycling, tennis, racquetball, squash, dancing, weight lifting, football, rugby, basketball, netball, volleyball, softball, ping-pong, home exercise, gardening, raking, sweeping, and others.

Frequency of exercise: Included the number of days and average time in hours or minutes the participant reports exercising per week.

Intensity of exercise: Included the effort that the individual reported doing while exercising. It was expressed as moderate (activities such as brisk walking, gardening, slow cycling, dancing, doubles of tennis, or hard work around the house lasting at least 10 minutes) and vigorous (activities like jogging, running, fast cycling, aerobic classes,

swimming laps, singles tennis and racquetball) that make the individual sweat and feel out of breath, not including weight lifting lasting at least 20 minutes.

The time spent in each activity in hours per week was multiplied by its typical energy expenditure expressed in Metabolic Equivalent Task per hour (MET-hour) and then summed over all activities to yield a MET-hour score.[227] One MET, the energy expended by resting, is equivalent to 3.5 ml of oxygen uptake per kilogram of body weight per minute (one kcal/kg of body weight per hour). Vigorous activities are those requiring 6 MET-hour or more and moderate activities are those requiring 3 to 6 MET-hour.[228]

8. Other Variables

Additional information was obtained from baseline assessment questionnaires:

Weight history: Included the age of onset of obesity in years, number of weight loss dieting programs attempted before surgery (weight watchers, Atkins diet, slim fast, physicians weight loss, Richard Simmons, Jenny Craig, and others), and whether or not patients used weight loss medications before surgery.

Medications and supplements: Included whether or not patients were taking medications for obesity-related comorbidities and vitamin and mineral supplements.

Complications: Included complications following surgery including episodes of dumping syndrome, vomiting, diarrhea, constipation, and other complications that occurred from surgery to baseline assessment and from baseline to final assessments.

Private counseling: Included the number of sessions attended with an independent Registered Dietitian, a psychologist, and other healthcare professional from surgery to 6 months after surgery and between the initial and final assessments (6 to 12 months after surgery).

Adherence to intervention sessions (Compliance): Included the number of sessions attended by the intervention group participants to each educational session.

Data Management

The security and confidentiality of the data was of utmost concern. Appropriate data management and security procedures were established. The confidential nature of the data was maintained by using a unique patient information number (patient ID#). All questionnaires and report forms were identified by patient ID only.

During entry into the computer, data was verified, checked for inconsistencies and edited using the patient ID. All identifying information (signed consent form and locator form), was kept separate from the research charts in a locked cabinet in the office of the investigator. The locator information was accessible only to the investigator for purposes of follow-up. The confidentiality and security of the research data files in the computer was maintained by ensuring password protection on all computer accounts.

Because this study was a nutrition and lifestyle education intervention trial, no substantial risk to the subjects was expected. All participants were under standard medical care with their surgeon throughout the trial. The investigator's PhD Dissertation Committee acted as the Data and Safety Monitoring Board. The board reviewed the data at regular annual (12-month) intervals. The Data and Safety Monitoring Board members included Dr. Adriana Campa, (researcher's Major Professor), Professor Dr. Mariana Baum, (researcher's co-Major Professor), Dr. Susan Himburg, Dr. Paulette Johnson, all members of the investigator's PhD dissertation committee, and Dr. Robert Dollinger M.D. Data were derived from medical and nutritional histories, questionnaires, blood assays, and nutrition educational sessions reports. There were no adverse events during

the study. According to the established protocol, should there have been an adverse event not related to the intervention, was to notify quarterly the DSMB Dissertation Committee and the IRB Coordinator. In case that any relationship between the intervention and an adverse event was found, it needed to be reported within five days from the time the investigator received information of the event.

Data Analysis

With two treatment groups, comprehensive intervention and non-comprehensive or comparison, and 72 participants per group, this study had 80% power with a significance level of $\alpha = .05$ to detect a mean difference in weight change at 12 months between the intervention and comparison groups. All probability values were two-sided. Statistical analysis was performed using IBM SPSS software for Windows graduate version 18.

At baseline, descriptive statistics were used to summarize data for all variables of interest and reported as frequencies and percentages and mean values ± standard deviations. Analyses of differences between groups for demographic, anthropometrics, and preoperative comorbidities were performed using independent samples *t* tests for continuous data and chi-square tests for categorical data.

Changes in weight measures, depression scores, intake of medications, supplements and nutrients, visits to Registered Dietitian and other professionals, and physical activity time and energy expenditure (METs) from baseline (6 months) to 12 months following surgery, were compared using paired-samples *t* tests within each group and independent samples *t* tests between groups. Changes in obesity-related comorbidities, eating behaviors, complications, and other dichotomous data were tested

using McNemar's test within groups and Mann-Whitney *U* test or Wilcoxon rank sum between groups.

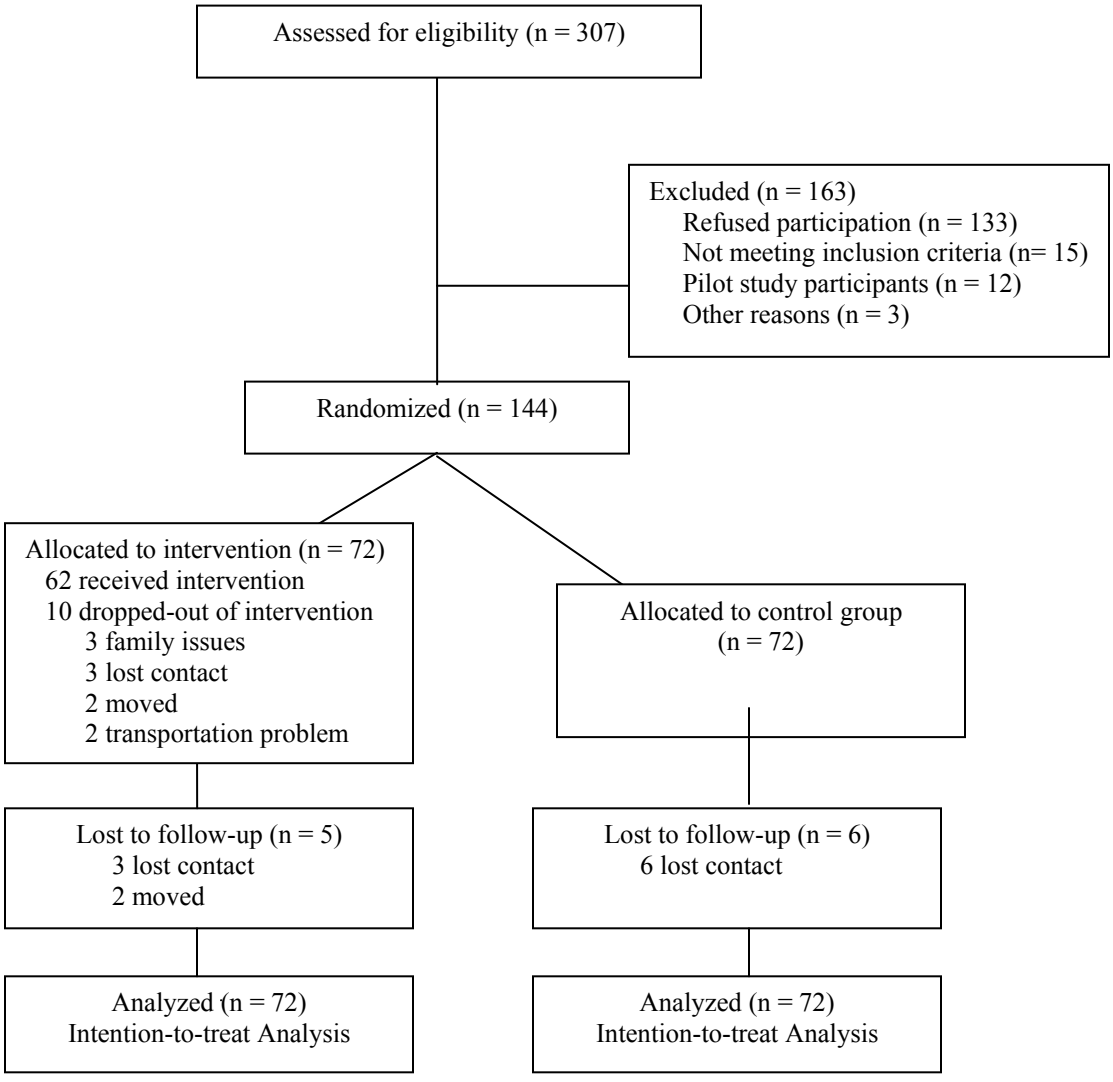
Due to great variability of data, changes in dietary intake of vitamin and minerals from baseline (6 months) to 12 months after surgery were tested using Wilcoxon signed rank test within groups and Mann-Whitney *U* test or Wilcoxon rank sum test between groups. Intent-to-treat analysis was applied on missing anthropometric data at 12 months after surgery using the sixth month data. The effectiveness of the comprehensive nutrition and lifestyle education intervention was mainly assessed by differences in mean % of excess weight loss between the comprehensive and comparison groups from baseline to final time points, 6 to 12 months following surgery. In order to determine if the number of sessions attended was associated with change in outcome variables, regression analysis was performed for the intervention group using the number of sessions attended and the 6 months anthropometric variables as independent variables.

CHAPTER IV. RESULTS

Study Participants

The flow of participants through the study is shown in Figure 2. Of the 307 participants assessed for eligibility, 163 were excluded for refusing participation, not meeting the inclusion criteria, participating in the initial pilot study described in the research design and methodology chapter, or other reasons.

Figure 2. Flowchart for Enrollment, Randomization, and Follow-up of Study Participants



Demographic characteristics of the study population are presented in Table 5.

Table 5. Demographic Characteristics of Study Participants [a]

Characteristic	Total (n= 144)	Intervention (n = 72)	Comparison (n = 72)	*P* Value [b]
Age, y. *mean ± SD*	44.5±13.5	44.2±12.6	44.8±14.4	.791
Education , y. *mean ± SD*	13.7±2.7	14.0 ± 2.8	13.4 ± 2.6	.200
Children, no. *mean ± SD*	1.6±1.3	1.8 ± 1.4	.4 ± 1.3	.136
Gender no. *(%)*				.371
Female	120(83.3)	62 (86.1)	58(80.6)	
Male	24(16.7)	10 (13.9)	14(19.4)	
Marital status no. *(%)*				.706
Married	66(45.8)	34 (47.2)	32 (44.4)	
Single	38(26.4)	21 (29.2)	17 (23.6)	
Divorced	35(24.3)	15 (20.8)	20 (27.8)	
Widowed	5(3.5)	2 (2.8)	3 (4.2)	
Nationality no. *(%)*				.257
Cuba	71(49.3)	38 (52.8)	33 (45.8)	
United States	38(26.4)	21 (29.2)	17 (23.6)	
Puerto Rico	20(13.9)	6 (8.3)	14 (19.4)	
Other	15(10.4)	7 (9.7)	8 (11.1)	
Language spoken no. *(%)*				.413
English and Spanish	75(52.1)	39 (54.2)	36 (50.0)	
Spanish	57(39.6)	25 (34.7)	32 (44.4)	
English	12(8.3)	7 (7.9)	5 (6.9)	
Occupation no. *(%)*				.053
Office-administrator	40(27.8)	13 (18.1)	27 (37.5)	
Professional	26(18.1)	18 (25.0)	8 (11.1)	
Housewife	33(22.9)	14 (19.4)	19 (26.4)	
Student	14(9.7)	8 (11.1)	6 (8.3)	
Educator	11(7.6)	6 (8.3)	5 (6.9)	
Others	20(13.9)	13 (18.1)	7 (9.7)	
Employment no. *(%)*				.149
Employed	82(56.9)	46 (63.9)	36 (50.0)	
Unemployed	34(23.6)	16 (22.2)	18 (25.0)	
Disabled	21(14.6)	9 (12.5)	12 (16.7)	
Retired	7(4.9)	1 (1.4)	6 (8.3)	
Insurance no. *(%)*				.084
Private	50(34.7)	25 (34.7)	25 (34.7)	
Uninsured self-paid	43(29.9)	25 (34.7)	18 (25.0)	
Medicaid	36(25.0)	19 (26.4)	17 (23.6)	
Medicare	15(10.4)	3 (4.2)	12 (16.7)	
Smoking habit no. *(%)*				.670
Never Smoked	91(63.2)	47 (65.3)	44 (61.1)	
Former Smoker	29(20.1)	15 (20.8)	14 (19.4)	
Current Smoker	24(16.7)	10 (13.9)	14 (19.4)	

[a] Plus-minus values are means ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.

The sample consisted of 144 participants who were randomized into the intervention (n= 72) and comparison groups (n=72). There were no significant differences in demographic characteristics at baseline between intervention and comparison groups. Participants had a mean age of 44.5 ± 13.5 years and the majority were females (83.3%). About two-thirds of the participants were married (45.8%) or single (26.4%), almost one-quarter were divorced (24.3%), and the remaining were widowed (3.5%).

All the participants considered themselves Hispanic-Americans. Nearly half of them stated that they were born in Cuba (49.3%) while the other half were born in Puerto Rico (13.9%), United States (26.4%), or other countries in Latin-America (10.4%). The majority of the participants spoke English and Spanish equally (52.1%).

Participants reported having 13.7 ± 2.7 mean years of education. Approximately one-fifth of the participants were professionals (18.1%) or educators (7.6%) and the remaining were office-administrators (27.8%), students (9.7%), housewives (22.9%), or had other occupations. The majority (56.9%) indicated that they were employed, 14.6% were disabled and 4.9% were retired. The remaining were unemployed (23.6%).

Most of the participants paid for the surgical procedure (29.9%) or their private insurance paid the expenses (34.7%). The rest of the patients utilized their social healthcare benefits from Medicaid (25%) and Medicare (10.4%) to cover the costs. The percentage of smokers was 16.7%.

Anthropometric Outcomes

Table 6 shows the anthropometric characteristics and weight history of the study participants. There were no significant differences in anthropometric characteristics

between intervention and comparison groups before surgery (preoperative) and at 6 months after surgery (baseline assessment).

Table 6. Anthropometric Characteristics and Weight History of Study Participants [a]

Characteristic	Total (n=144)	Intervention (n=72)	Comparison (n=72)	*P* Value [b]
Preoperative weight, *lb*	294.65±70.36	288.82 ± 61.76	300.47 ± 78.02	.322
Height, *in*	64.63± 3.56	64.26 ± 3.72	65.00 ± 3.39	.216
Preoperative BMI, *kg/m* ^{2}	49.26± 9.06	48.98 ± 8.48	49.54 ± 9.65	.709
Preoperative EBW, *lb*	159.17±61.31	154.47 ± 52.59	163.88 ± 69.00	.359
Ideal body weight, *lb*	135.47±15.05	134.35 ± 16.34	136.60 ± 13.66	.372
Onset of obesity, *y*	18.02±13.18	21.53 ± 14.52	14.51± 10.69	.001**
Diets before surgery	4.78± 1.93	4.68 ± 1.96	4.88 ± 1.92	.548
Six month weight, *lb*	214.83±51.18	208.50 ± 46.72	221.17 ± 54.88	.138
Six month BMI, *kg/m* ^{2}	35.94± 6.93	35.37 ± 6.83	36.51 ± 7.03	.323
Six month weight lost, *lb*	79.81±26.57	80.32 ± 21.84	79.31 ± 30.73	.826
Six month EBW, *lb*	79.36±43.27	74.15 ± 38.92	84.57 ± 46.91	.149
Six month % EWL, %	52.62±12.99	54.56 ± 12.90	50.68 ± 12.89	.073

** $P < .01$.

[a] Plus-minus values are means ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.
Abbreviations: BMI, body mass index; EBW, excess body weight; % EWL, percentage of excess weight loss.

Patients in the comparison group reported a younger age of onset of obesity than those in the intervention group (14.5 ±10.7 years versus 21.5 ± 14.5 years, $P < .01$). Participants stated that they unsuccessfully attempted on average, five different diets for losing weight before surgery.

The mean height was 64.63 ± 3.56 inches. The mean preoperative weight and mean preoperative BMI were 294.65 ± 70.36 lb. and 49.26 ± 9.06 kg/m ^{2} respectively. Patients had a mean preoperative excess body weight (EBW) of 159.17 ± 61.31 lb.

Overall, participants lost an average of 52.62 ± 12.99 % of their excess body weight (EBW) at 6 months and 71.68 ± 16.82% at 12 months.

Table 7 displays the anthropometric changes in weight, body mass index, weight lost, excess body weight, and percentage of excess weight lost over time within and between groups. Missing values at 12 months (5 in the intervention group and 6 in the comparison group) were calculated by intent-to-treat analyses using the 6 month values.

Table 7. Anthropometric Changes Over Time by Group [a]

Anthropometric Characteristic	Within Groups		Between Groups		
	Intervention (n=72)	Comparison (n=72)	Intervention (n=72)	Comparison (n=72)	*P* Value [b]
Weight, *lb*			38.21±25.88	22.11±20.78	<.001***
Six months	208.50±46.72	221.17±54.88			
Twelve months	170.29±42.36	199.06±48.35			
P value	<.001***	<.001***			
BMI, k*g/m* [2]			6.48± 4.37	3.63±3.41	<.001***
Six months	35.37±6.83	36.51±7.03			
Twelve months	28.88±6.49	32.89±6.18			
P value	<.001***	<.001***			
Weight lost, *lb*			38.21±25.88	22.11±20.78	<.001***
Six months	80.32±21.84	79.31±30.73			
Twelve months	118.53±33.83	101.42±41.60			
P value	<.001***	<.001***			
EBW, lb			38.21±25.88	22.11±20.78	<.001***
Six months	74.15±38.92	84.57±46.91			
Twelve months	35.94±34.86	62.46±40.41			
P value	<.001***	<.001***			
Percentage EWL, %			25.04±14.31	13.08±11.28	<.001***
Six months	54.56±12.90	50.68±12.89			
Twelve months	79.60±15.48	63.76±14.24			
P value	<.001***	<.001***			.

*** *P* <.001.

[a] Plus-minus values are mean ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.
Values between groups are anthropometric differences between 6 and 12 months after RYGB.
Abbreviations: BMI, body mass index; EBW, excess body weight; Percentage EWL, percentage of excess weight loss.

Both groups lost weight significantly, but the reduction in weight (Figure 3), body mass index (Figure 4), and excess body weight (Figure 5) between 6 to 12 months following surgery were significantly greater in the intervention group than in the

comparison group (*P*< .001). Furthermore, the percentage of excess weight lost (%EWL) over time was significantly greater in the intervention group than in the comparison group (*P*<.001), as shown in Figure 6. Although there was a significant difference between groups at baseline on age at onset of obesity, the unadjusted and adjusted results of the weight variables were similar, so only unadjusted results are given.

Figure 3: Weight Change by Group

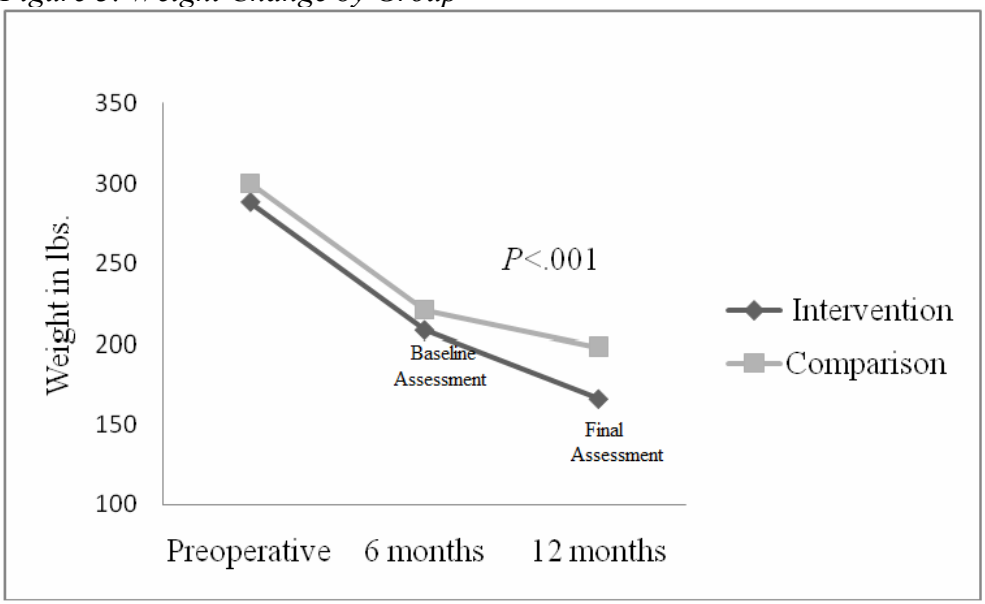


Figure 4: BMI Change by Group

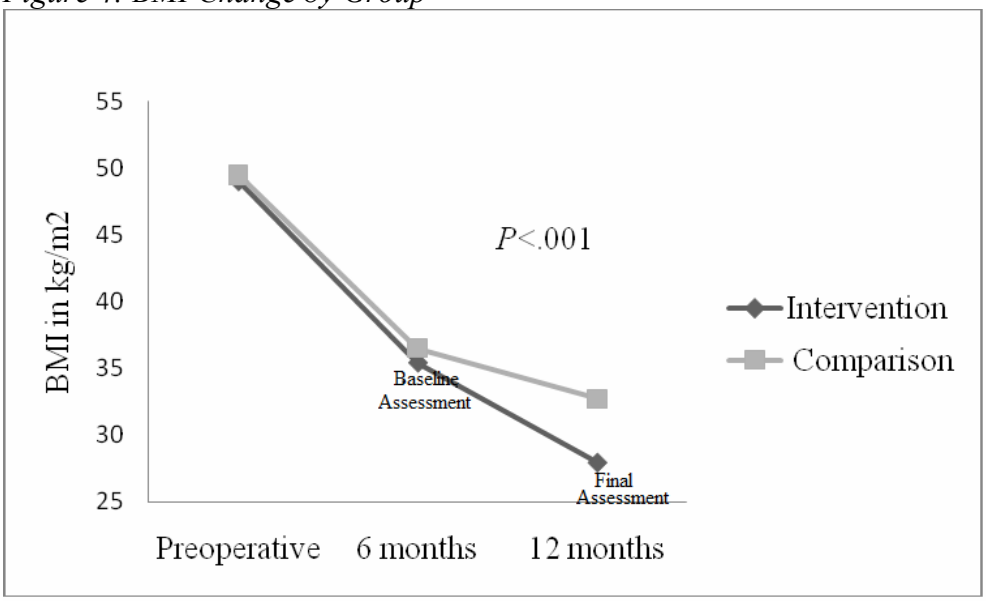


Figure 5: Excess Weight Change by Group

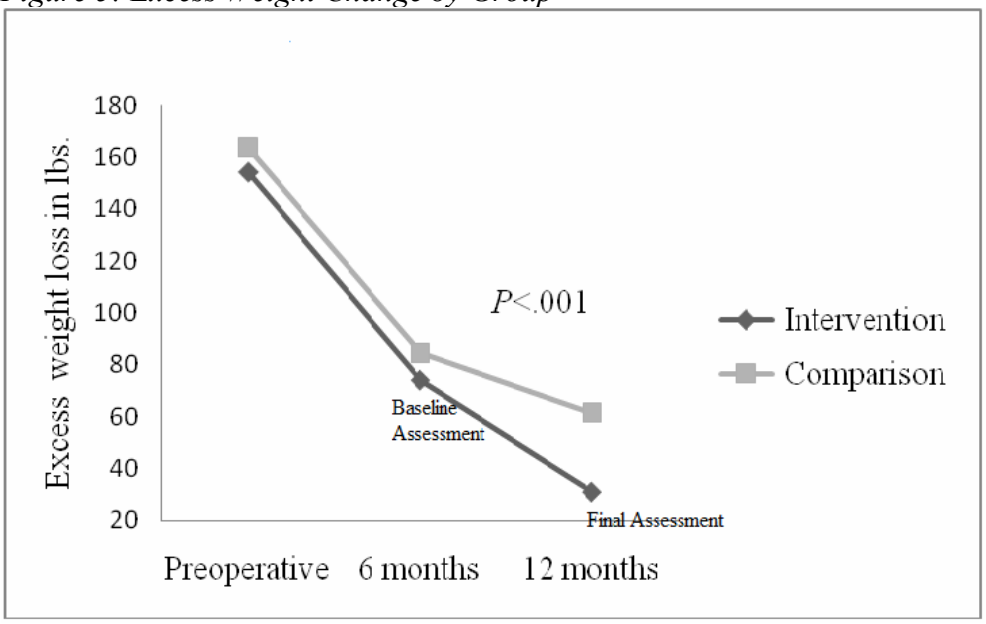
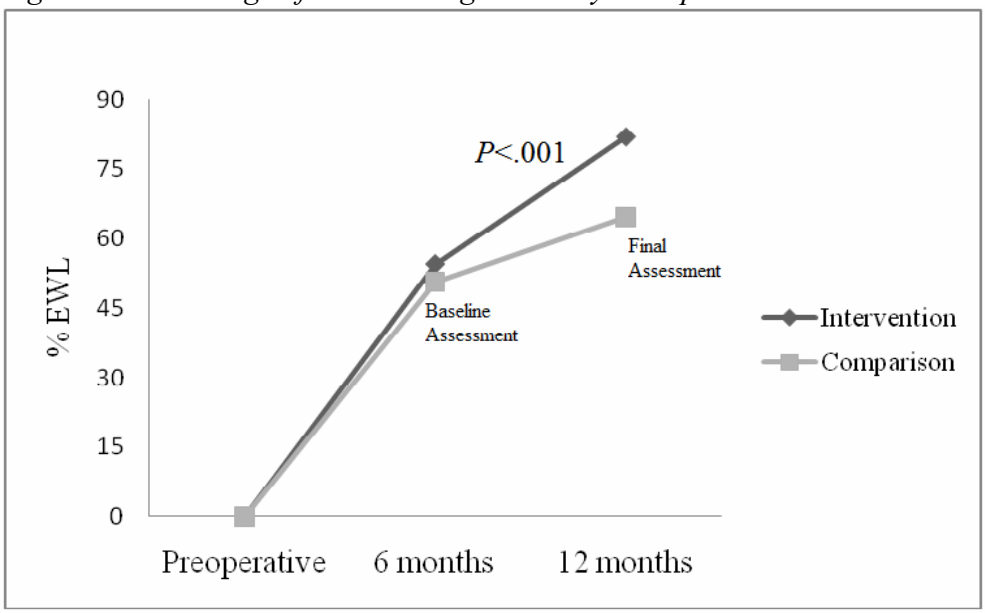


Figure 6: Percentage of Excess Weight Loss by Group



Participants in the intervention group lost approximately 55% of their excess weight at 6 months after surgery and almost 80% at one year following surgery (25% weight reduction). Participants in the comparison group lost nearly 51% of their excess

weight at 6 months and nearly 64% at one year after RYGB (approximately 13% weight reduction).

Medical Outcomes

Obesity-related comorbid conditions experienced overtime (at preoperative, 6 months or baseline assessment, and 12 months or final assessment) following surgery are shown by group in Table 8.

Table 8: Obesity-Related Comorbid Conditions Over Time by Group [a]

Obesity Comorbidities	(n=144)	Group		*P* value [b]
		Intervention n=72	Comparison n=72	
Joint illness				
Preoperative	97(67.4)	49(68.1)	48(66.7)	.859
Six months	77(53.5)	38(52.8)	39(54.2)	.867
Twelve months	52(39.1)	22(32.8)	30(45.5)	.029*
Depression				
Preoperative	81(56.3)	39(54.2)	42(58.3)	.614
Six months	57(39.6)	30(41.7)	27(37.5)	.609
Twelve months	31(23.3)	10(14.9)	21(31.8)	<.001***
Hypertension				
Preoperative	77(53.5)	40(55.6)	37(51.4)	.616
Six months	47(32.6)	23(31.9)	24(33.3)	.859
Twelve months	22(16.5)	8(11.9)	14(21.2)	.181
Sleep apnea				
Preoperative	74(51.4)	38(52.8)	36(50.0)	.739
Six months	31(21.5)	15(20.8)	16(22.2)	.839
Twelve months	2(1.5)	2 (3.0)	0(0.0)	.966
GERD				
Preoperative	72(50.0)	40(55.6)	32(44.4)	.182
Six months	35(24.3)	19(26.4)	16(22.2)	.560
Twelve months	14(10.5)	4(6.0)	10(15.2)	.036*
Hypercholesterolemia				
Preoperative	59(41.0)	31(43.1)	28(38.9)	.611
Six months	29(20.1)	16(22.2)	13(18.1)	.533
Twelve months	8(6.0)	3 (4.5)	5(7.6)	.157.
Diabetes mellitus				
Preoperative	59(41.0)	27(37.5)	32(44.4)	.397
Six months	25(17.4)	11(15.3)	14(19.4)	.509
Twelve months	16(12.0)	7(10.4)	9(13.6)	.720
Hypertriglyceridemia				
Preoperative	54(37.5)	24(33.3)	30(41.7)	.302
Six months	23(16.0)	12(16.7)	11(15.3)	.820
Twelve months	4(3.0)	2(3.0)	2(3.0)	.638
Urinary incontinence				
Preoperative	54(37.5)	27(37.5)	27(37.5)	1.000

Six months	25(17.4)	13(18.1)	12(16.7)	.826
Twelve months	7(5.3)	4(6.0)	3(4.5)	.821
Asthma				
Preoperative	28(19.4)	16(22.2)	12(16.7)	.400
Six months	20(13.9)	10(13.9)	10(13.9)	1.000
Twelve months	15(11.3)	7(10.4)	8(12.1)	.083
Insulin requirement				
Preoperative	25(17.4)	10(13.9)	15(20.8)	.271
Six months	18(12.5)	7(9.7)	11(15.3)	.313
Twelve months	9(6.8)	3(4.5)	6(9.1)	.454
Other diseases				
Preoperative	22(15.3)	14(19.4)	8(11.1)	.165
Six months	10(6.9)	5(6.9)	5(6.9)	1.000
Twelve months	2(1.5)	0(0.0)	2(3.0)	.481

***P<.001, ** P <.01,* P <.05.

[a] Values are number of observations (%).At 12 months intervention group n = 67, control group n= 66.

[b] P values are two-sided for the comparison between intervention and comparison groups.

Abbreviations: GERD, gastroesophageal reflux disease.

Joint illness was the most frequent medical condition associated with morbid obesity before surgery (67.4 %) and at 6 and 12 months following RYGB. It was followed by depression (56.3 %), hypertension (53.5 %), sleep apnea (51.4%), gastroesophageal reflux disease (50.0 %), diabetes (41%) and dyslipidemia (hypercholesterolemia 41% and hypertriglyceridemia 37.5%). There were no significant differences in obesity-related comorbid conditions between groups prior to surgery and at 6 months following surgery. Diabetes mellitus was completely resolved in 89.6% and 86.4% of the intervention and comparison groups, respectively at 12 months after surgery. Only 10.4% of the intervention and 13.6% of the comparison group participants still had diabetes at one year after surgery.

Table 9 shows the resolution in obesity-related comorbid conditions from baseline to final assessment (6 to 12 months following surgery). Within the intervention group, joint illness, depression, hypertension, sleep apnea, gastroesophageal reflux disease, hypercholesterolemia, hypertriglyceridemia, urinary incontinence, and other diseases

(*P*<.01) were resolved. There was no change for diabetes mellitus, insulin requirement, and asthma (*P*>.05). Within comparison group participants, hypertension, gastroesophageal reflux disease, hypercholesterolemia, hypertriglyceridemia, sleep apnea, and urinary incontinence changes (*P*<.05) significantly decreased over time.

Table 9. Comorbidity Resolution Six to Twelve Months Following Surgery by Group [a]

Obesity-Related Comorbidities	Within Groups		Between Groups
	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Joint illness	14(20.9)	5(7.6)	.029*
P value	<.001***	.063	
Depression	20(29.9)	4(6.1)	<.001***
P value	<.001***	.125	
Hypertension	15(22.4)	8(12.1)	.181
P value	.001***	.008**	
Sleep apnea	13(19.4)	13(19.7)	.966
P value	<.001***	<.001***	
Gastroesophageal reflux	15(22.4)	6(9.1)	.036*
P value	<.001***	.031*	
Hypercholesterolemia	13(19.4)	7(10.6)	.157
P value	<.001***	.016**	
Diabetes mellitus	3(4.5)	6(9.1)	.720
P value	.250	.289	
Hypertriglyceridemia	10(14.9)	8(12.1)	.638
P value	.002**	.008**	
Urinary incontinence	9(13.4)	8(12.1)	.821
P value	.004**	.008**	
Asthma	3(4.5)	0(0.0)	.083
P value	.250	1.000	
Insulin requirement	3(4.5)	5(7.6)	.454
P value	.250	.063	
Other diseases	5(7.5)	3(4.5)	.481
P value	<.001***	.250	

****P*<.001, ** *P* <.01,* *P* <.05.

[a] Values within groups are frequencies (%) of cases that had the obesity-related comorbidities at 6 months and resolved the conditions at 12 months.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.

Between groups, there were significant differences in the resolution of depression (*P*<.001), joint illness (*P*<.029), and gastroesophageal reflux disease (*P*<.036) from 6 to 12 month time points. For those who had depression at 6 month after surgery, 29.9 % of the intervention group participants completely resolved their depression at 12 months

following surgery compared to only 6.1 % of the control group participants. For those who had joint illness at 6 months after surgery, 20.9 % of the intervention group participants completely resolved their joint illness at 12 months compared to 7.6 % of the comparison group. For those who had gastroesophageal reflux disease (GERD) at 6 month after surgery, 22.4 % of the intervention group participants completely resolved their GERD at 12 months following surgery compared to 9.1 % of the comparison group participants.

Medications and Supplements Intake Outcomes

Changes in the number of medications taken by group for obesity comorbidities and the number of supplements taken for avoiding nutritional deficiencies over the period of 6 to 12 months following surgery are shown in Table 10.

Table 10: Medications and Supplements Intake Over Time by Group [a]

Change	Within Groups		Between Groups		*P* value [b]
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	
Medications			-1.37±1.24	- .80±.93	.003*
Six months	1.84±1.73	2.45±1.83			
Twelve months	.46±.91	1.65±1.51			
P value	<.001***	<.001***			
Supplements			.15±.78	- .33±.79	.001**
Six months	3.25±1.13	2.89±.90			
Twelve months	3.40±1.09	2.56±.88			
P value	.124	.001**			

***P<.001, **P<.01, *P<.05.

[a] Values are means ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.

Intervention and comparison group participants significantly decreased the number of medications they took over time for obesity-related comorbid conditions (P<.001).

Between 6 and 12 months after surgery, the decrease in the number of medications taken for comorbidities for participants in the intervention group was significantly greater than that for participants in the comparison group (P=.003). Participants in the intervention group did not significantly change the number of multivitamin and mineral supplements taken from 6 to 12 months after surgery (P>.05) although the participants in the comparison group significantly decreased their intake (P<.001). Between groups, the number of supplements taken from 6 to 12 months following surgery for comparison group participants significantly decreased compared to that for intervention group participants (P=.001).

Private Counseling Outcomes

Table 11 shows the number of visits to healthcare professionals, such as Registered Dietitians, psychologists, or other professionals (Primary Care Physicians or other physicians) by group over time. The information is shown between surgery and 6 months following surgery and between 6 and 12 months following surgery. Patients needed to have at least 5 nutrition counseling sessions with a Registered Dietitian at the time of recruitment as a criterion for inclusion in the study.

Within the comparison group, the mean number of visits to Registered Dietitians (P<.001), psychologists (P<.001), and Primary Care Physicians (PCPs) or other physicians (P=.007) decreased significantly from six to 12 months following surgery. However, within the intervention group, only the number of visits to psychologists decreased significantly six to 12 months following surgery (P<.001). Between groups, the mean decreases in number of visits to Registered Dietitians, psychologists, and PCPs or other physicians were not significantly different (P>.05).

Table 11: Private Counseling with Healthcare Professionals Over Time *by Group* [a]

Visits	Within Groups Intervention (n=67)	Within Groups Comparison (n=66)	Between Groups Intervention (n=67)	Between Groups Comparison (n=66)	*P* value [b]
Registered Dietitians			4.40± 2.07	4.73± 1.22	.274
0-6 months	5.81± .96	5.53± 0.71			
6-12 months	1.40± 2.05	0.80± 1.53			
P value	.077	<.001***			
Psychologists			1.07± .79	.97± .63	.398
0-6 months	1.37±1.11	1.20± .81			
6-12 months	.30±1.00	.23± .87			
P value	<.001***	<.001***			
PCPs or other physicians			.075±.40	.167±.48	.234
0-6 months	1.87±.76	2.17± .74			
6-12 months	1.79±.71	2.00± .78			
P value	.133	.007**			

***P<.001,**P <.01.

[a] Values are mean number of visits ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.
Abbreviation: PCP, Primary Care Physician.

Eating Behavior Outcomes

Table 12 presents the eating behavior patterns to which respondents attributed their excess body weight over time, including eating in response to negative or positive emotions, binge or unrestrained eating, eating at night avoiding breakfast, and eating due to environmental cues other than hunger.

Table 12: Eating Behavior Changes Over Time by Group [a]

Eating Behavior	Within Groups Intervention (n=67)	Within Groups Comparison (n=66)	Between Groups Intervention (n=67)	Between Groups Comparison (n=66)	*P* value [b]
Negative emotions			8(11.9)	3(4.5)	.003**
Six months	17(25.4)	8(12.1)			
Twelve months	15(22.4)	23(34.8)			
P value	.791	.001**			
Positive emotions			11(16.4)	7(10.6)	.025*
Six months	19(28.4)	14(21.2)			
Twelve months	11(16.4)	19(28.8)			
P value	.057	.359			
Binge eating			1(1.5)	3(4.5)	.305
Six months	2(3.0)	4(6.1)			
Twelve months	1(1.5)	1(1.5)			
P value	1.000	.250			

Night eating			6(9.0)	1(1.5)	.001**
Six months	8(11.9)	3(4.5)			
Twelve months	2(3.0)	9(13.6)			
P value	.031*	.070			
Environmental cues			8(11.9)	2(3.0)	.008**
Six months	13(19.4)	9(13.6)			
Twelve months	5(7.5)	11(16.7)			
P value	.008*	.687			

***P<.001, **P <.01, *P<.05.

[a] Values within groups are frequencies (%) of cases that answered Yes at six and 12 months following surgery; values between groups are frequencies (%) of cases that answered Yes at 6 months and No at 12 months.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.

At 6 months following surgery, approximately 25% of the intervention group participants and 12% of the comparison group participants reported eating in response to negative emotions (such as stress, anger, loneliness, anxiety, depression, boredom, and/or tiredness). At one year, those in the comparison group significantly increased their negative eating behavior (P= .001) while those in the intervention group did not (P =.791). Between groups, there was a significant difference for eating in response to negative emotions from 6 to 12 months following surgery (P=.003). Of those who ate in response to negative emotions at 6 months following surgery, approximately 12% of the intervention group participants no longer did so at 12 months compared to only 4.5% of the comparison group.

At 6 months following surgery, approximately 28% and 21% of the intervention and comparison group participants respectively reported eating in response to positive emotions (such as happiness with family and friends, socializing, celebrating, and business functions) while at one year 16.4% and 28.8% of the intervention and comparison group participants respectively did. These changes were not significant

(*P* >.05). However, between groups, there was a significant difference for eating in response to positive emotions from 6 to 12 months following surgery (*P*=.025). Of those who ate for positive emotions at 6 months, approximately 16% of intervention group participants no longer ate in response to positive emotions at one year after surgery compared to 10% of the comparison group.

At 6 months following surgery, approximately 12% and 4.5% of the intervention and comparison group participants respectively reported eating at night avoiding breakfast. At one year following surgery, intervention group participants significantly decreased their nigh eating behavior (*P*=.031) while comparison group participants did not (*P*>.05). Between groups, there was a significant difference for eating at night avoiding breakfast from 6 to 12 months following surgery (*P*<.01). Of those who ate at night avoiding breakfast at 6 months, approximately 9% of intervention group participants no longer did at one year after surgery compared to only 1.5% of the comparison group.

At 6 months following surgery, approximately 19.4% and 13.6% of the intervention and comparison group participants respectively reported eating in response to environmental cues other than hunger (such as eating at a specific time of the day or in response to specific kind of food). At one year, intervention group participants significantly decreased their eating behavior in response to environmental cues (*P*=.008) while comparison group participants did not (*P*>.05). Between groups, there was a significant difference for eating in response to environmental cues from 6 to 12 months following surgery (*P*=.008). Of those who ate in response to environmental cues at 6 months, approximately 12% of intervention group participants no longer ate in response

to environmental cues at one year after surgery compared to only 3% of the comparison group.

At 6 months following surgery, approximately 3% and 6% of the intervention and comparison group participants respectively reported unrestrained or binge eating while at one year 1.5% and 1.5% of the intervention and comparison group participants respectively did. However, groups did not differ significantly in respect to unrestrained or binge eating (*P*=.305).

Physical Activity Outcomes

Table 13 shows the physical activity changes over time by group. This information includes the number and percentage of participants that reported doing some type of physical activity over time, frequency of exercise in days per week, time in minutes per week, and intensity of exercise in Metabolic Equivalent Task per hour .

Table 13: Physical Activity Changes Over Time by Group [a]

Physical Activity	Within Groups		Between Groups		
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Frequency (%)			5(7.0)	- 4(6.0)	.131
Six months	50(74.6)	48(72.7)			
Twelve months	55(82.1)	44(66.7)			
P value	.302	.503			
Intensity, MET-h			8.85±14.9	1.35± 12.5	.002**
Six months	11.83±11.3	10.98±10.2			
Twelve months	20.68±18.0	12.33±13.6			
P value	<.001***	.386			
Frequency, days per week			.66±2.7	- .02±2.8	.159
Six months	3.22±2.4	3.18±2.3			
Twelve months	3.88±2.2	3.17±2.7			
P value	.052	.965			
Time, minutes per week			13.66±46.7	-3.56±38.9	.023*
Six months	45.97±37.0	42.88±34.1			
Twelve months	59.63±48.1	39.32±33.7			
P value	.019*	.460			

***P<.001, ** P <.01, * P <.05.

[a] Abbreviations: MET-h= Metabolic Equivalent Task per hour.

[b] *P* values between groups are two-sided for the comparison between intervention and comparison groups.

At 6 months following surgery, approximately 75% and 73% of the intervention and comparison group participants respectively reported doing some type of physical activity. At one year, approximately 82% and 67% of the intervention and comparison group participants respectively stated that they regularly exercise. Walking was reported as the most frequent physical activity over time.

The intervention group participants significantly increased their mean time (P=.019) and intensity of exercise (P<.001) from 6 to 12 months after surgery. Comparison group participants did not significantly changed their physical activity behavior from 6 to 12 months after surgery (P>.05).

Between groups, there were significant differences in mean intensity and mean time of exercise from baseline to final assessment points (P=.002, P=.023, respectively). The intervention group participants increased the mean intensity of exercise by approximately 9 metabolic equivalents task per hour (MET-h), while comparison group participants slightly increased the intensity by 1.35 MET-h. In addition, intervention group participants increased the mean time of exercise by approximately 14 minutes per week, while comparison group participants decreased the mean time by approximately 4 minutes per week. There was no significant difference between groups in frequency of physical activity in days per week from 6 to 12 months following surgery (P>.05).

Dietary Intake Outcomes

Table 14 shows dietary intake changes of calories, macronutrients (proteins, carbohydrates, and fat), saturated, polyunsaturated, and monounsaturated fat, cholesterol, fluid, fiber, and number of meals consumed over time by intervention and comparison groups.

Table 14: Daily Dietary Intake of Calories, Macronutrients, Meals, Fluids, and Fiber Over Time by Group [a]

Intake	Within Groups		Between Groups		
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Calories, *kcal*			.1±301.6	4.6±271.6	.857
Six months	935.7±292.3	959.9±261.1			
Twelve months	935.8±289.4	964.5±258.1			
P value	.574	.383			
Proteins, *g*			.1±23.6	- 6.5±15.7	.024*
Six months	69.2± 27.0	64.8± 21.8			
Twelve months	69.3± 28.3	58.3± 19.0			
P value	.232	.020*			
Proteins, *%*			3.4±16.2	1.4±13.8	.707
Six months	31.0± 9.0	27.7±7.8			
Twelve months	34.4±15.7	29.1±12.6			
P value	.494	.965			
Carbohydrates, *g*			- 4.1±57.2	2.1±47.0	.831
Six months	111.2± 49.7	120.7± 46.2			
Twelve months	107.1± 44.5	122.8± 46.2			
P value	.637	.793			
Carbohydrates, *%*			- 3.4±15.3	- 2.3±14.9	.778
Six months	47.7± 12.8	51.0± 13.6			
Twelve months	44.3± 13.5	48.7± 12.1			
P value	.186	.106			
Fat, *g*			1.5±11.9	2.4±13.7	.306
Six months	22.6± 15.7	23.4± 13.1			
Twelve months	24.1± 14.2	25.8± 13.4			
P value	.268	.019*			
Fat, *%*			2.1±9.2	2.2±10.2	.951
Six months	21.1± 9.2	21.3±9.7			
Twelve months	23.2± 8.8	23.4±8.8			
P value	.037*	.030*			
Saturated fat, *%*			2.5± 8.5	.4±5.8	.450
Six months	7.3± 4.1	7.2±4.5			
Twelve months	9.8± 8.1	7.6±4.6			
P value	.025*	.260			
PUFA, *%*			.5±3.6	.8±2.0	.147
Six months	2.1± 1.7	2.0±1.2			
Twelve months	2.6± 3.1	2.8±1.7			
P value	.210	.003**			
MUFA, *%*			1.5±7.8	1.0±3.8	.601
Six months	5.6± 4.5	5.0±3.7			
Twelve months	7.1± 6.8	6.0±3.5			
P value	.094	.016*			
Cholesterol, *g*			43.9±128.3	12.2±142.3	.535
Six months	188.3±135.0	177.2±142.7			
Twelve months	232.2±143.5	189.4±126.2			
P value	.009**	.115			
Fiber, *g*			-.7± 7.3	.4±4.5	.616
Six months	10.4±7.6	9.3±4.9			
Twelve months	9.7±5.7	9.7±4.2			
P value	.805	.583			

Fluids, *ml*			65.7±748.4	118.0±854.7	.721
Six months	1787.2±794.6	1759.9±761.4			
Twelve months	1852.9±768.6	1877.9±607.7			
P value	.205	.077			
Meals, *no.*			.3± .9	.2±.9	.168
Six months	5.3±1.0	5.4± .8			
Twelve months	5.0±.9	5.2± .9			
P value	.009**	.184			

**$P<.01$; * $P<.05$.

[a] Values are means ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups
Abbreviations: PUFA= Polyunsaturated fatty acid or polyunsaturated fat. ; MUFA= monounsaturated fatty acid or monounsaturated fat.

Between 6 and 12 months following surgery, the mean total daily caloric intake in both groups was slightly below the recommended for gastric bypass surgery, which is in the range of 1,000 to 1,400 calories as lifelong guidelines for weight maintenance to avoid stimulation of starvation mechanisms that can prevent weight loss overtime. [55] Within both groups, the mean daily intake of proteins was in the low range of the recommended for gastric bypass patients, which is 60 to 105 g based on a 1,000 to 1,400 calorie diet. [78] Comparison group participants reported a significant decrease in the intake of proteins over time (*P*=.020).

Intervention participants reported a significant increase in the total intake of cholesterol (*P*=.009) and saturated fat (*P*=.025) over time. Comparison participants significantly increased their total fat intake (*P*=.019), percentage of calories from fat (*P*=.030), polyunsaturated fat (*P*=.003) and monounsaturated fat (*P*=.016). However, neither of those changes were significantly different between intervention and comparison groups (*P*>.05).

Intervention group participants significantly decreased the mean number of daily meals (*P*=.009). Fluids and fiber intake did not significantly change over time in either intervention or comparison groups (*P*>.05).

Between groups, there were no significant differences in daily caloric intake, number of meals, and macronutrients intake. However, the mean intake of proteins by comparison group participants was significantly lower than that of the intervention group participants (*P*<.024). Table 15 shows the daily dietary intake of some vitamins and minerals from six to 12 months following surgery by group.

Table 15: Daily Dietary Intake of Vitamins and Minerals Over Time by Group [a]

Intake	Within Groups		Between Groups		
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Iron, *mg*			.3±8.9	.9±6.5	.168
Six months	8.7±6.4	8.8±7.3			
Twelve months	9.0±8.8	9.6±7.8			
P value	.437	.180			
Vitamin B1, *mg*			-2.0±15.5	.0±1.1	.102
Six months	2.7±15.7	.8±.9			
Twelve months	.7±.6	.8±.8			
P value	.098	.556			
Vitamin B12, *mcg*			.3±6.7	1.1±5.2	.205
Six months	4.2±5.0	4.4±5.0			
Twelve months	4.5±6.6	3.3±3.4			
P value	.463	.253			
Folate, *mcg*			14.9±350.4	9.5±219.0	.694
Six months	228.0±295.1	176.9±166.9			
Twelve months	242.9±330.7	186.3±168.2			
P value	.980	.555			
Calcium, *mg*			7.8±392.6	-53.1±275.5	.599
Six months	623.6±350.5	578.9±323.7			
Twelve months	631.4±385.7	525.8±263.7			
P value	.856	.621			

[a] Values are means ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups

There were no significant differences within and between groups regarding the dietary intake of vitamin B1, vitamin B12, folate, iron, and calcium from 6 to 12 months following surgery (*P*>.05).

Supplements Intake Outcomes

Table 16 displays the daily intake of some vitamin and minerals from supplements, including vitamins B1, B12, folate, iron, and calcium over time by group.

Table 16: Daily Intake of Micronutrient from Supplements Over Time by Group [a]

Micronutrient Change	Within Groups		Between Groups		
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Iron, *mg*			-1.03±14.44	-.67±13.30	.883
Six months	53.08±12.38	50.97±14.34			
Twelve months	52.05±15.97	50.30±15.00			
P value	.561	.682			
Vitamin B1, *mg*			-2.88±30.35	.14±25.92	.538
Six months	114.23±29.19	105.90±32.46			
Twelve months	111.35±34.05	106.05±32.69			
P value	.440	.964			
Vitamin B12, *mcg*			50.01±247.16	16.48±210.30	.401
Six months	272.63±145.39	264.55±185.85			
Twelve months	322.64±244.86	281.03±228.62			
P value	.102	.526			
Folate, *mcg*			29.85±160.51	24.24±119.05	.820
Six months	811.94±170.14	753.03±179.93			
Twelve months	841.79±198.59	777.27±170.79			
P value	.133	.103			
Calcium, *mg*			-88.81±561.71	-153.26±521.45	.494
Six months	1348.73±585.05	1184.32±616.21			
Twelve months	1259.93±539.99	1031.06±501.67			
P value	.200	.020*			

* $p<.05$.

[a] Values are means ± SD.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.

Within groups, comparison group participants significantly decreased the amount of calcium from supplements ($P<.05$) from 6 to 12 months following surgery. Between groups, there was no significant difference in daily intake of micronutrients from supplements over time ($P>.05$).

Laboratory Blood Tests Outcomes

Laboratory blood test results over time are shown in Table 17. Values within groups are frequencies and percentages of cases that had abnormal blood test results at 6 and 12 month time points. Values between groups are frequencies and percentages of cases that had normal blood test results at 6 months but abnormal blood test results at 12 months after surgery.

Table 17: Laboratory Blood Tests Abnormalities Over Time by Group [a]

Blood Level	Within Groups		Between Groups		
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Hemoglobin			1(1.5)	4(6.1)	.865
Six months	8(11.1)	9(12.5)			
Twelve months	2(3.0)	5(7.6)			
P value	.125	.388			
Iron			1(1.5)	5(7.6)	.365
Six months	8(11.1)	7(9.7)			
Twelve months	2(3.0)	6(9.1)			
P value	.125	1.000			
Glucose			3(4.5)	7(10.6)	.329
Six months	6(8.3)	10(13.9)			
Twelve months	3(4.5)	4(6.1)			
P value	.250	.070			
HbA1c			3(4.5)	4(6.1)	.815
Six months	3(4.2)	6(8.3)			
Twelve months	0(0.0)	2(3.0)			
P value	N/C	.125			
Vitamin B12			0(0.0)	1(1.5)	.570
Six months	1(1.4)	4(5.6)			
Twelve months	0(0.0)	4(6.1)			
P value	N/C	1.000			
Folic acid			0(0.0)	4(6.1)	.014*
Six months	3(4.2)	3(4.2)			
Twelve months	1(1.5)	7(10.6)			
P value	.500	.125			
Total Protein			0(0.0)	0(0.0)	.321
Six months	1(1.4)	0(0.0)			
Twelve months	0(0.0)	0(0.0)			
P value	N/C	N/C			
Albumin			0(0.0)	1(1.5)	.314
Six months	0(0.0)	0(0.0)			
Twelve months	0(0.0)	1(1.5)			
P value	N/C	N/C			

Creatinine			2(3.0)	1(1.5)	.570
Six months	4(5.6)	1(1.4)			
Twelve months	2(3.0)	0(0.0)			
P value	.500	N/C			
BUN			4(6.0)	1(1.5)	.178
Six months	4(5.6)	2(2.8)			
Twelve months	0(0.0)	1(1.5)			
P value	N/C	1.000			

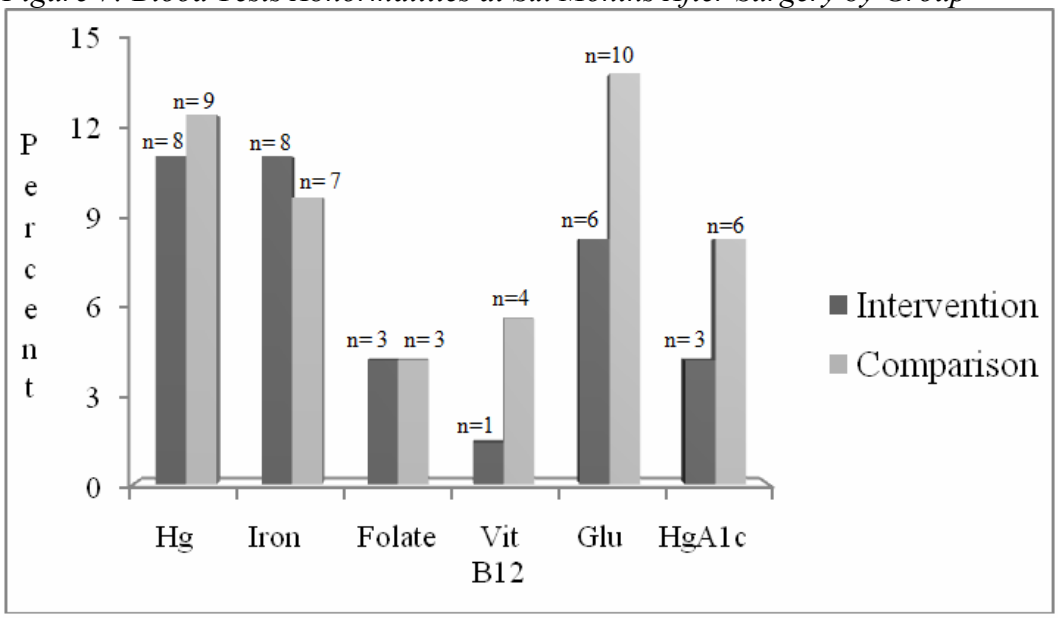
*p<.05.

[a] Values within groups are frequencies (%) of cases that had deficient or elevated levels at 6 and 12 months after surgery. Values between groups are frequencies (%) of cases that had normal levels at 6 months and abnormal levels at 12 months.

[b] *P* values are two-sided for the comparison between intervention and comparison groups.
Abbreviations: 6m. = six months following surgery; 12 m.= 12 months following surgery. HbA1c= hemoglobin A1c. N/C= Mc Nemar test *p* value not computed: cells must be greater than 1.

Figures 7 and 8 show the percentages of individuals that had abnormal blood tests at 6 and 12 months after surgery, including deficient levels of hemoglobin, iron, folate, and vitamin B12, and increased levels of glucose and hemoglobin A1c.

Figure 7: Blood Tests Abnormalities at Six Months After Surgery by Group [a]

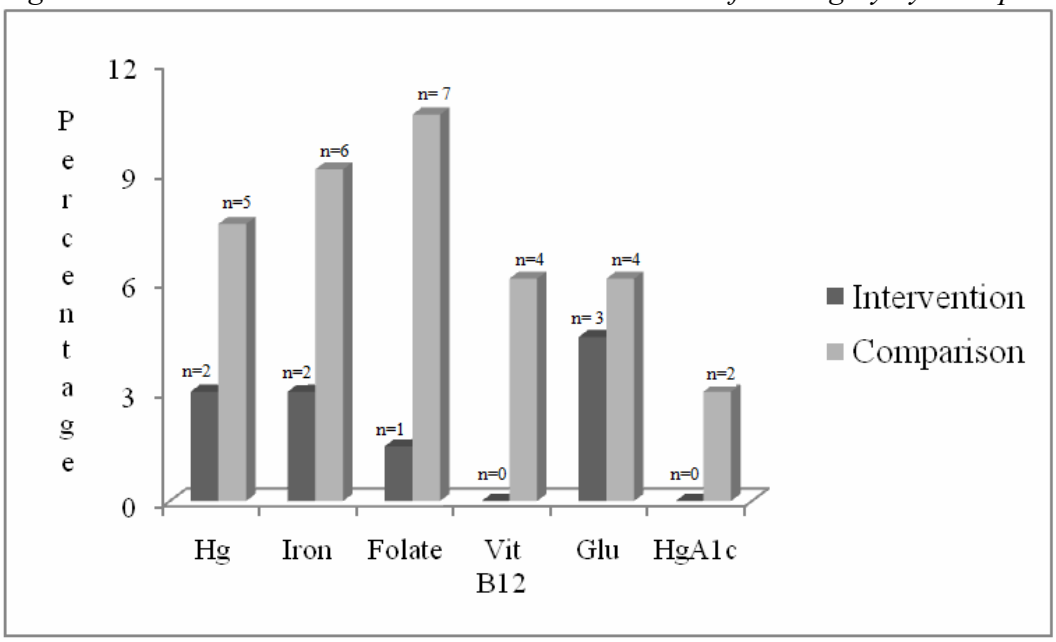


[a]Abbreviations: Hg= hemoglobin; Vit B12= vitamin B 12; Glu= glucose; HgA1c= hemoglobin A1c. Hemoglobin, iron, folate, and vitamin B12 are deficient levels. Glucose and hemoglobin A1c are elevated levels.

At 6 month after surgery, the most frequent blood test abnormalities, overall, in descending order were hemoglobin deficiency (12%), hyperglycemia (11%), iron

deficiency (10.4%), folate deficiency (4.2%) and vitamin B12 deficiency (3.5%). Approximately 6% of those who had diabetes had elevated hemoglobin A1c at 6 months. At 12 months after surgery, the most frequent blood test abnormalities, overall, were iron and folate deficiencies (6.1%, 6.1% respectively), low hemoglobin (5.3%), hyperglycemia (5.3%), and vitamin B12 deficiency (3.1%). Approximately 1.5% of those who had diabetes had elevated hemoglobin A1c at 12 months. There were no significant differences between groups in blood test abnormalities from 6 to 12 months following surgery, except for folate deficiency.

Figure 8: Blood Tests Abnormalities at Twelve Months After Surgery by Group[a]



[a]Abbreviations: Hg= hemoglobin; Vit B12= vitamin B 12; Glu= glucose; HgA1c= hemoglobin A1c. Hemoglobin, iron, folate, and vitamin B12 are deficient levels. Glucose and hemoglobin A1c are elevated levels.

Patients who received comprehensive nutrition and lifestyle education intervention reported less folic acid deficiency (1.5%) than those in the comparison group (10.6%) who did not receive the intervention. Of those who had normal levels of folic

acid at 6 months, approximately 6% of the comparison group participants had folate deficiency at one year compared to 0% of the intervention group participants (*P*=.014).

Complications

Table 18 shows the complications reported by participants between surgery and baseline assessment (zero to 6 months following surgery) and between baseline and final assessments (6 and 12 months following surgery). This data included episodes of dumping syndrome, vomiting, diarrhea, constipation, and other complications.

Table 18: Complications Over Time by Group [a]

Complications	Within Groups		Between Groups		
	Intervention (n=67)	Comparison (n=66)	Intervention (n=67)	Comparison (n=66)	*P* value [b]
Dumping Syndrome			29(43.3)	20(30.3)	.026*
0-6 months	39(54.2)	38(52.8)			
6-12 months	8(11.9)	25(37.9)			
P value	<.001***	.061			
Vomiting			36(53.7)	29(43.9)	.127
0-6 months	45(62.5)	43(59.7)			
6-12 months	10(14.9)	19(28.8)			
P value	<.001***	.001***			
Diarrhea			17(25.4)	22(33.3)	.675
0-6 months	22(30.6)	30(41.7)			
6-12 months	3(4.5)	11(16.7)			
P value	<.001***	.001***			
Constipation			20(29.9)	8(12.1)	.005**
0-6 months	48(66.7)	38(52.8)			
6-12 months	32(47.8)	43(65.2)			
P value	.019*	.210			
Other Complications			1(1.5)	6(9.1)	.127
0-6 months	5(6.9)	7(9.7)			
6-12 months	5(7.5)	3(4.5)			
P value	1.000	.289			

***p<.001; **p<.01; *p<.05.

[a] Values within groups are frequencies (%) of cases. Values between groups are frequencies (%) of cases that answer yes at six months and no at 12 months.

[b] *P* values are two-sided for the comparison between intervention and coparison groups.

At 6 months following surgery, constipation (66.7%) and vomiting (59.7%) were the most frequent complications reported by both intervention and comparison group respectively, followed by dumping syndrome, diarrhea, and others. At one year following

surgery, constipation was the most frequent complication reported by both intervention and comparison group.

Both groups reported a significant decrease in the number of episodes of dumping syndrome, vomiting, and diarrhea ($P<.01$) from 6 to 12 months after surgery. Intervention group significantly decreased the number of episodes of constipation over time from 66.7% to 47.8%, ($P=.019$). However, comparison group participants did not ($P>.05$).

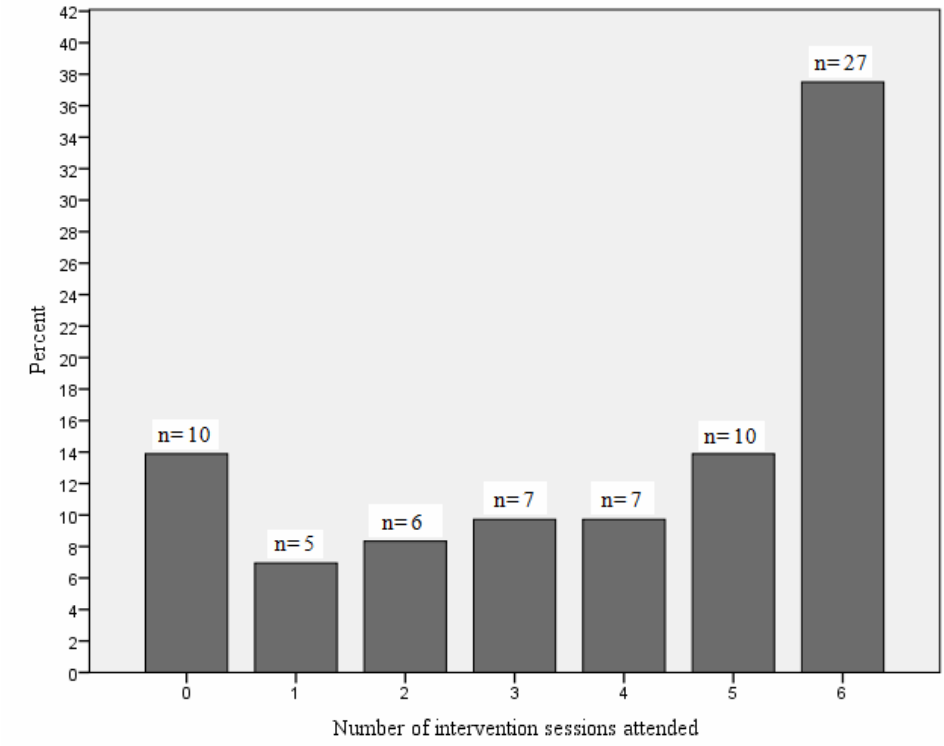
Between groups, there was a significant difference in the percentage of participants reporting episodes of dumping syndrome ($P<.05$) and constipation ($P<.001$) over time. Of those who reported episodes of dumping syndrome at 6 months, approximately 43% of the intervention group participants did not report any episode of dumping syndrome at 12 months compared to 30% of the comparison group participants ($P<.05$). Of those who reported constipation occurrence at 6 months following surgery, approximately 30% of the intervention group participants did not report constipation at 12 months after surgery compared to only 12% of comparison group participants ($P<.001$).

Adherence to Intervention Sessions

Patients randomized to the intervention received a total of 6 comprehensive nutrition and lifestyle education sessions in 6 groups of 12 participants each. Five groups were conducted in Spanish while the final one in English, according to the participants' language preference. Sessions were carried out every other week by the investigator starting immediately after the initial assessment (sixth month following surgery). Each comprehensive educational session took place at the Laparoscopic Institute of South

Florida and lasted approximately 90 minutes. Figure 9 shows participants' attendance record at the nutrition education and lifestyle intervention sessions.

Figure 9: Attendance to Intervention Sessions by Participants[a]



[a] *Number of intervention participants: n=72*

Twenty seven out of 72 participants randomly assigned to the intervention group attended the entire program (37.5%). Ten individuals attended five sessions (13.9%) and the rest attended four (9.7%), three (9.7%), two (8.3%), and one sessions (6.9%) respectively. Ten participants (13.9%) did not attend any sessions. The overall attendance rate was 64.35%. The nutrition session was the session with the highest attendance (76.39%). Session 2, which discussed the importance of physical activity in the post-operative bariatric life, had an attendance rate of 66.67%.

The number of sessions attended was not associated with change in outcome variables. However, the majority (61%) of the participants attended 5 or 6 sessions with the remaining 39% attending 1 to 4 sessions, so not much variability was observed for number of sessions.

All regressions were significant with the 6 months anthropometric variables predicting the anthropometric change scores ($P< .001$). The number of sessions was significant for supplement change (standardized beta=.261, $P=.032$). The higher amount of sessions attended was associated with a greater supplement increase from 6 to 12 months controlling for 6 months supplement intake.

CHAPTER V. DISCUSSION

The study findings add to a growing body of information on the characteristics associated with weight loss 6 to 12 months following laparoscopic Roux-en Y gastric bypass surgery. More importantly, it provides new evidence of the post-surgery behavior of morbidly-obese adult Hispanic-Americans. In addition, this study supports the feasibility of implementing a comprehensive nutrition and lifestyle education program, which incorporates behavioral change and motivational strategies to nutrition counseling, on Hispanic-Americans who have recently undergone surgery to reverse morbid obesity. Following surgery, patients are at risk for premature weight loss plateau or weight regain if they fail to be actively involved in postoperative healthy lifestyle changes.[20,21] The broad surgically induced anatomical change of the gastrointestinal tract can lead to nutritional deficiencies in those unable to comply with strict adherence to vitamin and mineral supplementation.[22–25]

The majority of the study participants were obese Hispanic-Americans primarily Cuban-born married women. There was high attendance (64.35%) for the comprehensive nutrition and lifestyle educational intervention sessions and low attrition (13.9%), both essential elements for the prevention of weight loss plateau, weight regain, nutritional deficiencies, and relapse of preoperative unhealthy lifestyle habits.

Primary or Main Hypothesis

Hypothesis 1: Patients who receive a comprehensive nutrition and lifestyle education intervention will experience greater weight loss from total baseline weight, greater excess weight loss from total baseline excess weight, and greater decrease in BMI without weight loss plateau or weight regain during the period from 6 to 12 months

following surgery than those patients in the comparison group who will be provided with printed guidelines for healthy eating and physical activity recommendations at the first assessment visit[29] *(Appendix 1).*

All participants lost weight significantly overtime, as expected from the pilot study and prior evidence from the literature.[13-20,36,37,39,40,41,43,44,46,50] However, patients who received the comprehensive nutrition and lifestyle educational intervention experienced significantly greater weight loss from total baseline weight (38.21±27.88 lb. vs. 22.11±20.78 lb.) and greater decrease in BMI (6.48±4.37 kg/m^2 vs. 3.63 ±3.41 kg/m^2) without weight loss plateau or weight regain during the period of 6 to 12 months following surgery than those patients in the comparison group.

Participants in the intervention group lost approximately 80% of their preoperative excess weight at one year following surgery (25% weight reduction from 6 to 12 months after RYGB surgery). Participants in the comparison group lost nearly 64% of their preoperative excess weight at one year following surgery (approximately 13% weight reduction from 6 to 12 months after RYGB surgery). The higher percent weight loss from 6 to 12 months was significant and seems to be a successful outcome of the intervention of this study.

The significant effect of the intervention has been predicted by other studies that showed that in weight loss programs motivational interventions might increase patients' motivation toward behavior change.[128,129] Even those with poor compliance with session visits seemed to obtained benefits from the intervention when compared to those more

compliant, as demonstrated by the non significant effect of attendance on weight outcomes.

Secondary Hypotheses

Hypothesis 2: Patients in the comprehensive nutrition and lifestyle education group will experience greater improvement of their obesity-related health conditions than those in the comparison group, *as measured by improved glycemic control, improved depression, and decreased need of medications for obesity-related comorbidities.*

In the present study, all participants decreased the number of medications taken for obesity-related comorbidities from 6 to 12 months after surgery. However, the decrease in number of medications taken for comorbidities in the intervention group was significantly greater than that for participants in the comparison group.

The results are in accordance with similar studies showing that laparoscopic RYGB resulted in a significant improvement in comorbidities. Improvements were detected as early as 6 months after surgery,[14–20,36] especially in those patients with diabetes, gastroesophageal reflux disease, hypertension, and hypercholesterolemia.[231,232]

A number of studies suggested that nutrition intervention sessions were beneficial beyond their effect on weight loss.[27,28,120,123–127] This study supported the hypothesis that a well-implemented educational intervention can make a positive impact on obesity-related health conditions after RYGB. From 6 to 12 months following surgery, patients in the comprehensive nutrition and lifestyle education intervention group experienced greater improvement of their depression, joint illness, and gastroesophageal reflux disease than those in the comparison group.

There is some controversy regarding the effect of depression in predicting weight loss following bariatric surgery.[233–235] This study has shown that as morbid obesity declined there was a significant decrease in depression symptoms in many, but not all patients. From 6 to 12 months following surgery, those in the comprehensive nutrition and lifestyle education intervention group experienced greater improvement of their depression symptoms than those in the comparison group.

Like other preceding studies,[14-17,36,236] diabetes mellitus was completely resolved in 89.6% and 86.4% of the intervention and comparison groups respectively at 12 months after surgery. The impressive resolution of diabetes might be attributed to the weight loss experienced as well as the modification of the pancreatic axis.[236]

Similar to findings in other studies,[237,238] joint disease decreased significantly over time along with greater weight loss and physical activity. Joint illness was the most frequent medical condition associated with morbid obesity before surgery, and at 6 and 12 months following RYGB. Those in the comprehensive intervention experienced greater improvement of their joint illness than those in the comparison group.

The significant effect of the intervention on obesity-related comorbidities is probably multifactorial. It might be mainly mediated by the greater weight loss experienced by the intervention group participants. Motivational techniques were used to encourage patients to develop strategies to apply the knowledge acquired. In addition, the extra attention and feedback provided by the instructor in each intervention session might have emotionally influenced patients to accept and feel more positively towards their comorbidities, contributing to their general well-being.

Hypothesis 3: Patients who receive comprehensive nutrition and lifestyle education will report fewer negative nutritional outcomes such as less micro and macronutrient deficiencies than those in the comparison group.

In the present study, the average iron and vitamin B12 intake over time in both groups was below the recommended for bariatric surgery. As described in the most recent medical guidelines for bariatric clinical practice,[230] patients might have developed low tolerance to meat after RYGB procedure, leading to decreased intake of iron and vitamin B12.

As reported in the bariatric literature, patients who underwent RYGB surgery are at increased risk of iron deficiency anemia, vitamin B12, folate, and other micronutrients deficiencies.[24,54–58,82–84] In the present study, nutritional deficiencies at one year following surgery were consistent with previous reports.[26,54–59,72–74,84–86] However, as hypothesized, the beneficial impact of the study intervention was evident by fewer patients having folic acid deficiency in the intervention group (1.5%) than those in the comparison group (10.6%).

Prior research has shown that despite strong advice concerning the need of lifelong multivitamins intake following bariatric surgery the adherence rate to supplements remains low.[25,26,111] This study showed that participants in the intervention group did not significantly change the multivitamin and mineral supplements intake from 6 to 12 months after surgery compared to participants in the comparison group who significantly decreased their intake.

The motivational lectures provided reinforcement of one of the most important nutritional recommendations for patients undergoing bariatric surgery, taking their vitamin and mineral supplements as prescribed.[111,113] In the intervention, patients were reminded by the instructor about the importance of taking the supplements and helped them to develop strategies not to forget. Reasons for forgetting the supplements were discussed and strategies were developed to address the specific barriers for adherence to the nutritional supplements. This continuous reinforcement formed part of every session, in which the issue of adherence to the patient's medical and dietary treatment was brought as part of the motivational strategy, throughout the intervention.

Hypothesis 4: Patients receiving comprehensive nutrition and lifestyle education will be more actively involved in physical activity than those in the comparison group as measured by greater weekly exercise frequency and intensity.

At one year following surgery, approximately 82% and 67% of the intervention and comparison group participants respectively stated that they regularly exercise. These findings are in contrast to a retrospective review reporting that the lack of exercise was the most likely area of non-compliance following RYGB.[48] In this study, patients receiving comprehensive nutrition and lifestyle education were more actively involved in physical activity than those in the comparison group as measured by greater weekly time and intensity of exercise.

The second session of the intervention addressed how to begin a consistent exercise program and why exercise is key to keeping weight off after bariatric surgery (Appendix 10, Session 2). Participants in the intervention group were counseled about the benefits of physical activity and how to find the internal motivation to exercise. Stressing

the idea of self-rewards as a motivation strategy to stick to exercise might explain the differences between groups in outcomes.

This study showed that assisting postoperative patients to increase their physical activity, by an effective education intervention, contributes to optimization of their weight loss. Greater improvement of joint illness in response to greater weight loss among the intervention group participants might have potentiated patients' motivation to exercise. In turn, actively exercising contributed to further weight loss and greater joint flexibility, magnifying the cycle of improvement and reinforcing physical activity.

There are no standardized guidelines for the appropriate amount of exercise for bariatric patients. The present study findings are in accordance to prior studies showing that few more minutes per week of exercise can make a significant difference in improvement of physical and psychological wellbeing.[157,159,239] A recent review by Livhits et al reported that regular physical activity following bariatric surgery was associated with a greater weight loss of over 4% of the BMI.[240]

Hypothesis 5: Patients in the comprehensive nutrition and lifestyle education will have better eating habits reflected by fewer episodes of dumping syndrome and binge eating than those in the comparison group.

From 6 to 12 months after surgery, there were significant differences between groups regarding eating behaviors other than binge eating. Of those who reported eating in response to negative emotions, positive emotions, eating at night avoiding breakfast, and eating due to environmental cues other than hunger at 6 months, a greater amount of intervention participants no longer presented these behaviors at 12 months compared to comparison participants. At one year following surgery, those in the comparison group

significantly increased their eating behavior in response to negative emotions while intervention group participants significantly decreased their night eating behavior. There was no significant difference between groups regarding binge eating. Merely 1.5% of the intervention and comparison group participants respectively reported unrestrained or binge eating at one year after surgery.

As evidenced in previous research,[114–116] the participation in support groups is an essential tool for patients regarding weight loss, lifestyle changes, and the postoperative nutrition management process. However, helping patients achieve their healthy weight and changing their diet and lifestyle habits after RYGB is a challenging task. Several reasons might explain the favorable impact of the current study's comprehensive nutrition and lifestyle education intervention on body weight and health-related outcomes at one year following surgery:

(1) The comprehensive educational approach enhanced participants' skills regarding life after surgery, stressing the concept that the surgery component is separate from the lifestyle change component.

(2) The intervention was implemented during a critical phase, between 6 and 12 months after surgery, when the surgically-induced rapid weight loss may start to naturally decline. Patients start to consume the highest calorie-intake diet since surgery and are prone to weight regain if they fail to comply with healthy lifestyle changes.

(3) The implementation of 6 educational sessions every other week by the investigator has not proved to be the adequate number of sessions in an acceptable time frame. However, as previous evidence has shown, even a single nutrition counseling session can improve short-term health-related outcomes.[189] The extent of the lifestyle

changes and the time needed for motivational strategies to be implemented in support groups, probably warrants 3 to 4 sessions to attain outcomes similar to those achieved by this experimental intervention.

(4) Adding motivation toward behavior change in a non-judgmental and non-confrontational approach might have increased patients' awareness of the potential problems, risks, and consequences faced as a result of their post-operative unhealthy behavior.

(5) As obesity increasingly affects minorities in the United States,[1,12] this research study was focused on adult Hispanic-Americans who have undergone RYGB surgery for losing weight. Conducting a culturally-sensitive program, by understanding participants' values and beliefs, delivering sessions in their mother tongue, showing respect and patience, and allowing a great deal of dialogue between group participants, to allow them to learn from each other, might have been fundamental means facilitating behavioral change. These program characteristics were fundamental in facilitating behavioral change.

Limitations of the Study

While providing a great deal of information, the present study has a number of limitations. The study participants were those who were willing to comply with the study protocol and might not have been a representative sample from all those who go through this surgery (selection bias). This potential selection bias may limit the ability to generalize the findings to the entire population of adult Hispanic-American morbidly-obese population who had recently undergone RYGB surgery.

As seen in control groups in other lifestyle trials,[124,231] there might be an attention effect of the comparison group. The comparison group only received minimal intervention, printed guidelines for healthy eating and physical recommendations at the first encounter with the investigator. However, the fact that weight loss occurred in a substantial proportion of those in the comparison group who did not receive the 6 educational sessions, simply reflect the long-term effect of undergoing RYGB surgery and/or that the study population was highly motivated to lose weight after the surgical procedure. Although an attention-intervention effect might have occurred during the semi-annual data collection visits, the randomization should have reduced or eliminate it. However, due to the nature of this educational intervention, it could not be blinded to the type of intervention received.

The sample size was calculated based on an 80% power, meaning that the probability that a statistically significant medium effect between the two groups could not be obtained is as high as 20%. In addition, power was calculated based on weight loss only, which was the main outcome of the study. Some attrition bias resulted from those participants who did not attend all educational sessions or were lost to follow-up.

Conclusion

This study provides important new information on the impact of a comprehensive nutrition and lifestyle education intervention on body weight and health-related outcomes on adult Hispanic-Americans who have recently undergone RYGB surgery.

The comprehensive educational approach, which incorporated behavior change and motivation strategies with nutrition counseling, significantly increased weight loss between 6 and 12 months following surgery. Furthermore, the comprehensive

intervention significantly affected the patients' lifestyle, evidenced by improved involvement in physical activity and increased protein consumption, both critical elements to avoid weight regain, relapse of comorbidities, and nutritional deficiencies. Further research studies should be performed in ethnically diverse samples to identify relevant socio-cultural parameters that may be associated with, or promote, a positive response to comprehensive nutrition and lifestyle education interventions following bariatric surgery.

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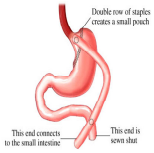
APPENDICES

APPENDIX 1: HEALTHY EATING AND PHYSICAL ACTIVITY GUIDELINES FOLLOWING GASTRIC BYPASS SURGERY

HEALTHY EATING AND PHYSICAL ACTIVITY GUIDELINES FOLLOWING GASTRIC BYPASS SURGERY



Chew slowly and thoroughly

Each meal should take at least 15 to 20 minutes to eat. The pouch can hold only a small amount of food after surgery, and eventually it can hold more. If you eat large amounts of food, you may stretch the stomach pouch.

Fullness Signs

Pay close attention to early signs of fullness and stop eating. This may be discomfort at the breastbone. If you ignore it, vomiting or pain may follow. Over time, eating too much may stretch the stomach pouch. You do not need to feel full.

Avoid concentrated sugars and fat

They can lead to slower weight loss. Avoid high calorie liquids and high fat foods that can dissolve in your mouth, such as milkshakes. These foods will likely to cause you dumping syndrome. Remember that not all people will experience dumping.

Drink fluids

Drink at least 75-100 oz of fluid per day to prevent dehydration and constipation. Take frequent sips. Drinking 1 to 1.5 cups per waking hour equals 12 cups a day. Remember not to eat and drink together at the same time and do not drink for 60 minutes after eating. Always carry a bottle of water.

Do not Drink

- Carbonated drinks can cause gas and bloating. They should not be used after surgery.
- Limit coffee and caffeine drinks: can cause dehydration and can stimulate the bowel, causing cramps or diarrhea.

Eat

Eat three small high-protein, low-fat meals and one or two snacks containing protein each day.

Meals, in the beginning, will be mostly soft proteins, and then it will progress to more solid protein. Eat fruits (without skins), soft cooked vegetables, and firmer proteins.

Tips

- If you cannot tolerate dairy, try using lactaid milk.
- Introduce new foods slowly, one food at a time in order to rule out intolerance. If a food causes discomfort, wait before trying it again.
- Food reheated in the microwave may become tough and difficult to digest.

Supplements

Be consistent about taking your vitamin and mineral supplements.

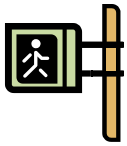
Set up a schedule for supplements. Remember to take calcium and iron separately.

Exercise regularly

- At least 5 to 7days per week for 30 minutes each day. Regular exercise and physical activity are extremely important and beneficial for long-term health and well-being after bariatric surgery.
- Exercise during weight loss will help you to stay more toned, feel more energetic, and become stronger. Walk the dog; go for a walk with a friend, a neighbor, or your children.

Exercise regularly

- Take the bus or car less often. If you take public transportation, get off a few stops early, take the stairs instead of the elevators, park your car far away at shopping centers and walk through the parking lot.



Exercise regularly

- Take a walking break at work instead of a coffee break, do some yards work gardening, or household chores that require brisk movement. During bad weather, get exercise by walking in the mall. Check exercise videos out of the library.

APPENDIX 2: LETTER OF SUPPORT

LAPAROSCOPIC INSTITUTE
of South Florida
General, Laparoscopic & Bariatric Surgery
3499 West 4th Avenue • Suite 201 • Hialeah, FL 33012
305-558-0411 • Fax: 305-863-3802

JORGE L. SOSA, M.D., F.A.C.S.
Diplomate American Board of Surgery
American Society for Bariatric Surgery
Bariatric Surgery Center of Excellence

HECTOR I. PALLAVICINI, M.D.
General & Laparoscopic Surgery

February 8, 2007

Monica Petasne-Nijamkin

RE: Impact of intensive nutrition education on health related outcomes in morbidly obese Hispanic patients following laparoscopic Roux-En-Y gastric bypass

Dear Monica:

I was very happy to meet with you regarding your research project the other day in the office. As I told you I will very much support your PHD research study you will conduct in my office, on my private patients. I and my staff are committed to offering you support including access to my clinic, medical and nutritional charts, laboratory patients and any other material we have available to conduct your dietetic and nutritional PHD research activities at FIU. Considering the obesity epidemic and quickly expanding field of bariatric surgery, I think research like yours is essential to provide insights into the best management alternatives for this complex group of patients. As a doctoral student I think this experience will be very useful to you, becoming proficient in using research activities to grow in your field of academic endeavor.

I am looking forward to the commencement of your project.

Sincerely,

Jorge L. Sosa, M.D., F.A.C.S.
Bariatric Surgery Director, Palmetto General Hospital

JLS:rs

APPENDIX 3: FLYER FOR PARTICIPANTS RECRUITMENT

PARTICIPATE IN A RESEARCH STUDY

The impact of a Comprehensive Nutrition and Lifestyle Education Intervention on Body Weight and Health-related Outcomes Following Laparoscopic Roux-en-Y Gastric Bypass

Dear Patient:

If you underwent Gastric Bypass 4 to 6 months ago and are being followed-up at the Laparoscopic Institute of South Florida, you are being asked to participate in a research study that aims to prevent premature weight loss plateau or weight regain, vitamin deficiencies, and relapse of obesity-comorbidity following surgery.

If you decide to participate, you will be asked to complete some questionnaires. Then, you will be assigned at random to an intervention group that will receive six completely free, intensive nutrition, behavioral, and motivational education sessions in small groups, in Spanish or English, or a comparison group that will receive printed materials about healthy eating and physical activity recommendation after surgery. You may increase your skills regarding healthier lifestyle choices and how to prevent weight regain.

If you decide to be a part of this study, you can contact the investigator and a Dietetics and Nutrition PhD student at Florida International University, Mrs. Monica Petasne Nijamkin at the front desk after your follow-up visit with your surgeon.

THANK YOU.

APPENDIX 4: CONSENT TO PARTICIPATE IN A RESEARCH STUDY

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Impact of a Comprehensive Nutrition and Lifestyle Education Intervention on Body Weight and Health-related Outcomes Following Laparoscopic Roux-en-Y Gastric Bypass

You are being asked to be in a research study. The investigator of this study is Monica Petasne Nijamkin and she is a PhD Dietetics and Nutrition student at FIU. The study will include about 250 people who are being followed-up at the Laparoscopic Institute of South Florida following obesity surgery. In this study we are looking at the relationship between a comprehensive nutrition education intervention that includes behavior change tips and the improvement of body weight and health-related outcomes 6 to 12 months following surgery.

If you decide to be a part of the study you will be asked to complete some questionnaires for approximately 30 minutes duration that will be giving to you at your 6th month visit to your surgeon. Then, you will be assigned by random to one of 2 groups, one group will receive a total of 6 free, comprehensive nutrition education sessions of approximately 90 minutes duration each by the investigator, and the other group will not receive those sessions. In case you will be part of the first group, we will tell you what day and time to come to the nutrition education sessions. All participants will have to complete the same questionnaires at the end of the study at the annual follow-up visit to the surgeon for approximately 20 minutes duration.

Your questionnaires will be identified by a random number not your name. All of your answers are private and will not be shared with anyone unless required by law. Your data will be compared to the data of other subjects. You may ask questions about the study at any time.

You understand that you may increase your skills regarding healthier lifestyle choices and that the risks involved in participating are minimal. You freely and voluntarily agree to participate in this program, but if you choose not to participate no one will be upset with you. You may also choose to stop your participation at any time. There is no monetary compensation for your participation in the study.

If you would like more information about this research after you are done, you can contact Dr. Jorge Sosa, your bariatric surgeon, or me at 954-3497226. If you would like to talk with someone about being a subject in this study you may contact Dr. Patricia Price, the Chairperson of the FIU Institutional Review Board at 305-348-2618 or 305-348-2494.

Your signature below indicates that all questions have been answered to your liking. You are aware of your rights and you would like to be in the study.

_ _ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _
Signature of participant	Printed Name	Date

I have explained the research procedure, subject rights and answered questions asked by the participant. I have offered him/her a copy of this informed consent form.

_ _ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _ _
Signature of Witness	Date

APPENDIX 5: ASSESSMENT QUESTIONNAIRE

FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Participant Research ID: _ _ _
Date of Surgery: _ _/_ _/_ _ _ _
MM DD YYYY
Visit Code: _____
1 = Initial assessment visit
2 = Final assessment visit

Date of visit: _ _/_ _/_ _ _ _
MM DD YYYY

SOCIO-DEMOGRAFIC INFORMATION:	FIELD CODE
[READ]: Next, I/we would like to ask a few questions about you. 1. What is your AGE? [RECORD AGE] _____	_____ AGE
2. What is your GENDER? 1= Male 2= Female	_____ GENDER
3. What is your MARITAL STATUS? 1 = Married 2 = Single 3 = Divorced 4 = Widowed 9 = Unknown	_____ MARITAL STATUS
4. How many GRADES OF SCHOOL have you completed? [RECORD GRADES] _____ NOTE: COUNT EACH YEAR OF SCHOOL AS ONE GRADE	_____ GRADES
[READ]: I/we would like to ask about your family unit. 5. Do you have CHILDREN? 1 = No 2 = Yes If you answered yes, specify how many children live in your home with you? [RECORD NUMBER OF CHILDREN LIVINH AT HOME _____]	_____ CHILDREN
[READ]: I/we would like to ask about the NATIONALITY of your family. As a reminder, all the information you have given today will be kept strictly confidential. 6. In what country were you born? [READ CHOICES AND CIRCLE RESPONSE] 1 = United States 2 = US Territory (Puerto Rico, Virgin Island, other) 3 = Other Country (Specify _____) 9 = Unknown [DO NOT READ]	_____ NATIONALITY

7. What LANGUAGE is spoken most often in your home? Is it: [READ CHOICES AND CIRCLE RESPONSE] 1 = English 2 = Spanish 3 = English and Spanish equally 4 = Other (Specify _____) 9 = Unknown [DO NOT READ]	_____ LANGUAGE
8. What ETHNIC/RACE group you identify yourself with: [READ CHOICES AND CIRCLE RESPONSE] 1= Hispanic or Latino 2= Non-Hispanic 3=African-American 4=American Indian 5=Asian origin 6=Other (Specify _____) 9=Unknown	_____ RACE/ETHN
9. [READ]: Next, I/we would like to ask about your OCCUPATION: [READ CHOICES AND CIRCLE RESPONSE.] 1= Office/Administrative 2= Student 3= Physical Labor 4= Professional 5= Educator 6= Housewife 7= Other (Specify_____) 9=Unknown	_____ OCCUPATION
[READ]: Next, I/we would like to ask about your current EMPLOYMENT: Are you currently employed? 10. [READ CHOICES AND CIRCLE RESPONSE] 1= Yes, I am employed 2= No, I am retired 3= No, I am disabled 9=Unknown	_____ EMPLOYMENT
[READ]: Next, I/we would like to ask about your HEALTH INSURANCE: 11. What HEALTH INSURANCE paid for your surgery? [READ CHOICES AND CIRCLE RESPONSE] 1= Medicaid 2= Medicare 3= Private Insurance 4= Uninsured/Self pay	_____ INSURANCE
12. [READ]: Next, I would like to ask about your SMOKING habits: [READ CHOICES AND CIRCLE RESPONSE.] 1= Never smoked 2 =Former smoker 3= Current smoker If you answered current smoker, specify how many cigarettes do you smoke per day [RECORD NUMBER OF CIGARRETES PER DAY_____	_____ SMOKING

ANTHROPOMETRIC INFORMATION	FIELD CODE
13. [DO NOT READ]. THIS INFORMATION WILL BE OBTAINED FROM YOUR MEDICAL CHART. PLEASE, CONTINUE WITH ITEM 16. HEIGHT_____' _____'' IDEAL BODY WEIGHT (IBW)_____	_____ HEIGHT _____ IBW
14. PREOPERATIVE INFORMATION: PREOPERATIVE WEIGHT_____ PREOPERATIVE BODY MASS INDEX_____ PREOPERATIVE EXCESS BODY WEIGHT_____ PREOPERATIVE % OF EXCESS BODY WEIGHT_____	_____ PREOP WT _____ PREOP BMI _____ PREOP EBW _____ PREOP % EBW
15. POSTOPERATIVE INFORMATION: POSTOPERATIVE WEIGHT_____ POSTOPERATIVE BODY MASS INDEX_____ POSTOPERATIVE EXCESS BODY WEIGHT_____ POSTOPERATIVE EXCESS BODY WEIGHT_____	_____ POSTOP WT _____ POSTOP BMI _____ POSTOP EBW _____ POSTOP % EBW
WEIGHT HISTORY: [READ]: Next, I would like to ask about your weight history: 16. At what age did you become obese? [RECORD AGE OF ONSET OF OBESITY_____	_____ ONSET OBESITY
17. What weight loss dieting programs did you try before surgery? [READ CHOICES AND CIRCLE RESPONSE] 1= Weight Watchers 2=Atkins diet 3=Slim fast 4=Physicians Weight loss 5=Richard Simmons 6=Jenny Craig 9= Others	_____ DIETS
18. Did you take weight loss medications before surgery? [READ CHOICES AND CIRCLE RESPONSE] 1= No 2 = Yes [If you answered yes, RECORD the name of the medications] _____ _____	_____ WT LOSS MED
MEDICAL INFORMATION: [READ]: Next, I/we would like to ask a few questions about your medical history.	

19. Have you had SLEEP APNEA before surgery? 1 = No 2 = Yes If you answered yes to sleep apnea, [READ CHOICES AND CIRCLE RESPONSE] 10. Sleep apnea has completely resolved. 20. Sleep apnea has improved. 30. Sleep apnea has not changed.	_____ SLEEP APNEA _____ SLEEP AP PROG
20. Have you had JOINT ILLNESS before surgery? 1 = No 2 = Yes If you answered yes to joint illness, [READ CHOICES AND CIRCLE RESPONSE] 10. Joint illness has completely resolved. 20. Joint illness has improved. 30. Joint illness has not changed.	_____ JOINT ILLNESS _____ JOINT ILL PROG
21. Have you had HYPERTENSION before surgery? 1= No 2 = Yes If you answered yes to hypertension, [READ CHOICES AND CIRCLE RESPONSE] 10. Hypertension has completely resolved. 20. Hypertension has improved. 30. Hypertension has not changed.	_____ HYPERTENSION _____ HYPERT PROG
22. Have you had HYPERCHOLESTEROLEMIA before surgery? 1= No 2 = Yes If you answered yes to hypercholesterolemia, [READ CHOICES AND CIRCLE RESPONSE] 10. Hypercholesterolemia has completely resolved. 20. Hypercholesterolemia has improved. 30. Hypercholesterolemia has not changed.	_____ HYPERCHOLEST _____ HYPERCHOLEST PROG
23. Have you had HYPERTRIGLYCERIDEMIA before surgery? 1= No 2 = Yes If you answered yes to hypertriglyceridemia, [READ CHOICES AND CIRCLE RESPONSE] 10. Hypertriglyceridemia has completely resolved. 20. Hypertriglyceridemia has improved. 30. Hypertriglyceridemia has not changed.	_____ HYPERTRIG _____ HYPERTRIG PROG
24. Have you had DEPRESSION before surgery? 1= No 2 = Yes If you answered yes to depression, [READ CHOICES AND CIRCLE RESPONSE] 10. Depression has completely resolved. 20. Depression has improved. 30. Depression has not changed.	_____ DEPRESSION _____ DEPRESS PROG
25. Have you had DIABETES before surgery? 1=No 2= Yes, I have had non-insulin dependent diabetes 3= Yes, and I require insulin If you answered yes to diabetes, [READ CHOICES AND CIRCLE RESPONSE]	_____ DIABETES _____

10. Diabetes has completely resolved. 20. Diabetes has improved. 30. Diabetes has not changed.	DIAB PROG
26. Have you had GASTROESOPHAGEAL REFLUX DISEASE (GERD) before surgery? 1= No 2= Yes If you answered yes to GERD, [READ CHOICES AND CIRCLE RESPONSE] 10. GERD has completely resolved. 20. GERD has improved. 30. GERD has not changed.	_____ GERD _____ GERD PROG
27. Have you had URINARY INCONTINENCE before surgery? 1= No 2= Yes If you answered yes to urinary incontinence, [READ CHOICES AND CIRCLE RESPONSE] 10. Urinary incontinence has completely resolved. 20. Urinary incontinence has improved. 30. Urinary incontinence has not changed.	_____ URIN INCONT _____ URIN INCONT PROG
28. Have you had ASTHMA before surgery? 1=No 2= Yes If you answered yes to asthma, [READ CHOICES AND CIRCLE RESPONSE] 10. Asthma has completely resolved. 20. Asthma has improved. 30. Asthma has not changed.	_____ ASTHMA _____ ASTHMA PROG
29. Have you had OTHER DISEASES before surgery? 1= No 2= Yes If you answered yes, specify what disease/s have you had? [RECORD OTHER DISEASES _____ _____ If you answered yes to other diseases, [READ CHOICES AND CIRCLE RESPONSE] 10= Other diseases have completely resolved. 20= Other diseases have improved. 30= Other diseases have not changed.	_____ OTHER DISEASES _____ OTHER DIS PROG
[READ]: Next, I/we would like to ask a question about MEDICATIONS for the above diseases you are currently taken. 30. [RECORD THE NAME AND DOSAGE OF ALL THE MEDICATIONS] MEDICATION 1._____ DOSAGE_____ MEDICATION 2._____ DOSAGE_____ MEDICATION 3._____ DOSAGE_____ MEDICATION 4._____ DOSAGE_____ MEDICATION 5._____ DOSAGE_____	_____ NUMBER MEDICATIONS
[READ]: Next, I/we would like to ask a question about VITAMIN AND MINERAL SUPPLEMENTS. 31. [RECORD THE NAME AND DOSAGE OF ALL THE VITAMIN AND MINERAL SUPPLEMENTS YOU ARE CURRENTLY TAKEN. SUPPLEMENT 1._____ DOSAGE_____ SUPPLEMENT 2._____ DOSAGE_____ SUPPLEMENT 3._____ DOSAGE_____	_____ NUMBER SUPPLEMENTS

SUPPLEMENT 4._____ DOSAGE_____	
[READ]: Next, I/we would like to ask a few questions about COMPLICATIONS you may have had over the last six (6) months. 32. Have you had episodes of DUMPING SYNDROME over the last six (6) months? 1. No 2. Yes If you answered yes, RECORD how many episodes of Dumping Syndrome have you had over the last six (6) months_____	_____ DUMPING SYNDROME
33. Have you had episodes of BLEEDING over the last six (6) months? 1. No 2. Yes If you answered yes, RECORD how many episodes of bleeding have you had over the last six (6) months_____	_____ BLEEDING
34. Have you had episodes of VOMITING over the last six (6) months? 1. No 2. Yes If you answered yes, RECORD how many episodes of vomiting have you had over the last six (6) months_____	_____ VOMITING
35. Have you had episodes of DIARRHEA over the last six (6) months? 1. No 2. Yes If you answered yes, RECORD how many episodes of diarrhea have you had over the last six (6) months_____	_____ DIARRHEA
36. Have you had episodes of CONSTIPATION over the last six (6) months? 1. No 2. Yes If you answered yes, RECORD how many episodes of constipation have you had over the last six (6) months_____	_____ CONSTIPATION
37. Have you had PAIN over the last six (6) months? 1. No 2. Yes	_____ PAIN
38. Have you had BILIARY COLIC due to gallstones? 1. No 2. Yes	_____ GALLSTONES
39. Have you had any OTHER COMPLICATIONS over the last six (6) months, such as pouch dilatation, anastomotic dilatation, gastric fistula, kidney, adrenal, or heart disease? 1= No 2= Yes If you answered yes, specify what complications have you had? [RECORD OTHER COMPLICATIONS _____	_____ OTHER COMPL
40. Are you PREGNANT? 1= No 2= Not applicable 3 = yes	_____ PREGNANCY

[READ]: Next, I/we would like to ask a few questions about PRIVATE COUNSELING over the last six (6) months. 41. Have you had any private counseling with a REGISTERED DIETITIAN over the last six (6) months? 1= No 2= Yes If you answered yes, specify how many sessions have you had. [RECORD number of sessions with a Registered Dietitian]_____	_____ RD COUNS
42. Have you had any counseling with a PSYCHOLOGIST over the last six (6) months? 1= No 2= Yes If you answered yes, specify how many sessions have you had. [RECORD number of sessions with a Psychologist]_____	_____ PSYCH COUNS
43. Have you had any counseling with ANOTHER PROFESSIONAL beyond your Surgeon, Registered Dietitian, or Psychologist over the last six (6) months? 1= No 2= Yes, Primary Care Physician 3= Yes, other [specify]_____ If you answered yes, specify how many sessions have you had. [RECORD number of sessions with another healthcare professional]_____	_____ OTHER COUNS
44. [DO NOT READ]. THIS INFORMATION WILL BE FILLED OUT BY THE INVESTIGATOR. 10-YEAR CARDIOVASCULAR RISK ASSESSMENT Patient age Total cholesterol HDL-c Blood pressure Anti hypertensive medications Yes/No Current smoker Yes/No	_____ CVD RISK
45. [DO NOT READ]. THIS INFORMATION WILL BE FILLED OUT BY THE INVESTIGATOR: LABORATORY TESTS WBC Hemoglobin Iron Glucose HemoglobinA1C Creatinine BUN Total Proteins Albumin Total Cholesterol HDL-c LDL-c Triglycerides Vitamin B12 Folate	

APPENDIX 6: PHYSICAL ACTIVITY QUESTIONNAIRE

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Participant Research ID: _ _ _
Date of Surgery: _ _/_ _/_ _ _ _
MM DD YYYY
Visit Code: _____ Date of visit: _ _/_ _/_ _ _ _
1 = Initial assessment visit MM DD YYYY
2 = Final assessment visit

Instructions: Please, answer the questions based on your average daily activity habits over the last seven (7) days.

1. Was a physical activity questionnaire completed for the participant (1= Yes, 2= No)

2. How much time do you spend walking in an average day? ☐ ☐
Hours Minutes

3. Do you engage in any sports or activities? (1= Yes, 2= No)
If you checked No, please continue with question 4.

Codes for Activity List
Light: 10.Walking at a slow pace (1-2 mi/hr) 11. Playing musical instrument Light Plus 12. Walking at an average pace (2-2.5 mi/hr) 13. Dancing (slow) 14. Golf, using power cart 15. Bowling 16. Fishing Moderately Vigorous 17. Walking at a brisk pace (1 mi every 20 min) 18. Weight lifting, water aerobics 19. Golf, not carrying clubs 20. Leisurely canoeing or kayaking 21. Walking at a very brisk pace (1 mi every 17 to 18 min) 22. Climbing stairs 23. Dancing (moderately fast) 24. Bicycling <10 mph, leisurely Moderately Vigorous Plus 25. Slow swimming 26. Golf, carrying clubs 27. Walking at a very brisk pace (one mi every 15 min) 28. Most doubles tennis

29. Dancing (more rapid)
30. Some exercise apparatuses
31. Slow jogging (one mi every 13 to 14 min)
Vigorous
32. Ice or roller skating
33. Doubles tennis (if you run a lot)
34. Hiking
35. Rowing, canoeing, kayaking vigorously
36. Dancing (vigorous)
37. Some exercise apparatuses
38. Bicycling 10 to 16 mph
39. Swimming laps moderately fast to fast
40. Aerobic calisthenics
41. Singles tennis, squash, racquetball
42. Jogging (1 mile every 12 min)
43. Skiing downhill or cross country
44. Running 6 mph (10-minute mile)
45. Running 8 mph (7.5-minute mile)
46. Running 10 mph (6-minute mile)
99= Other, specify

Activity			Specific Activity	Times/ week	Time/Episode				Time of Day
					Hours		Minutes		
3.a									
3.b.									
3.c.									
3.d.									
3.e.									

4. [DO NOT READ]. TO BE FILLED OUT BY THE INVESTIGATOR:
MET'S PER HOUR_____

APPENDIX 7: 24-HOUR DIETARY RECALL

FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Participant Research ID: _ _ _
Date of Surgery: _ _/_ _/_ _ _ _
MM DD YYYY

Visit Code: _____
1 = Initial assessment visit
2 = Final assessment visit

Date of visit: _ _/_ _/_ _ _ _
MM DD YYYY

Instructions: Please, list all foods and beverages that you have consumed in the past 24 hours.

Time	Serving Size	Meals:	How Prepared:	Where	Notes:
		Breakfast			
		Snack			
		Lunch:			

		Snack:			
		Dinner/Supper			
		Snack			
		Other			
		Fluids			
		Alcohol			

APPENDIX 8: EATING BEHAVIOR QUESTIONNAIRE

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Participant Research ID: _ _ _
Date of Surgery: _ _/_ _/_ _ _ _
MM DD YYYY

Visit Code: _____ Date of visit: _ _/_ _/_ _ _ _
1 = Initial assessment visit MM DD YYYY
2 = Final assessment visit

[READ]: Next, I/we would like to ask a few questions about your eating behavior:	FIELD CODE
1. Do you eat in response to negative emotions [negative emotions means when you are in situations of stress, anger, loneliness, anxiety, depression, boredom, and/or tiredness] 1= No 2= Yes	_____ NEGAT EMOT
2. Do you eat in response to positive affect and social cues [positive affect means when you are happy and social cues means when you are celebrating with family and/or friends, socializing, and /or during business functions] 1= No 2= Yes	_____ POSIT EMOT
3. Do you engage in excessive unrestrained eating or general overeating? 1= No 2= Yes	_____ BINGE EATING
4. Do you eat large amount of food at night and/or avoid breakfast? 1= No 2= Yes	_____ NIGHT EATING
5. Do you eat in response to environmental cues [environmental cues means that you eat according to the time of day or the type of food rather than feeling hunger] 1= No 2= Yes	_____ ENVIR CUES

APPENDIX 9: BECK'S DEPRESSION INVENTORY-II

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Participant Research ID: _ _ _
Date of Surgery: _ _/_ _/_ _ _ _
MM DD YYYY

Visit Code: _____ Date of visit: _ _/_ _/_ _ _ _
1 = Initial assessment visit MM DD YYYY
2 = Final assessment visit

Instructions: Please, circle the number by the response for each question that best describes how you have felt during the past seven (7) days. Please do not omit any questions. Make sure you check one answer for each question. If more than one answer applies to how you have been feeling, check the higher number. If in doubt, make your best guess.

1. 0 - I do not feel sad.
   1 - I feel sad.
   2 - I am sad all the time and I can't snap out of it.
   3 - I am so sad or unhappy that I can't stand it.

2. 0 - I am not particularly discouraged about the future.
   1 - I feel discouraged about the future.
   2 - I feel I have nothing to look forward to.
   3 - I feel that the future is hopeless and that things cannot improve.

3. 0 - I do not feel like a failure.
   1 - I feel I have failed more than the average person.
   2 - As I look back on my life, all I can see is a lot of failures.
   3 - I feel I am a complete failure as a person.

4. 0 - I get as much satisfaction out of things as I used to.
   1 - I don't enjoy things the way I used to.
   2 - I don't get real satisfaction out of anything anymore.
   3 - I am dissatisfied or bored with everything.

5. 0 - I don't feel particularly guilty.
   1 - I feel guilty a good part of the time.
   2 - I feel quite guilty most of the time.
   3 - I feel guilty all of the time.

6. 0 - I don't feel I am being punished.
   1 - I feel I may be punished.
   2 - I expect to be punished.
   3 - I hate myself.

7. 0 - I don't feel disappointed in myself.
   1 - I am disappointed in myself.
   2 - I am disgusted with myself.
   3 - I hate myself.

8. 0 - I don't feel I am any worse than anybody else.
   1 - I am critical of myself for my weaknesses or mistakes.
   2 - I blame myself all the time for my faults.
   3 - I blame myself for everything bad that happens.

9. 0 - I don't have any thoughts of killing myself.
   1 - I have thoughts of killing myself, but I would not carry them out.
   2 - I would like to kill myself.
   3 - I would kill myself if I had the chance.

10. 0 - I don't cry any more than usual.
    1 - I cry more now than I used to.
    2 - I cry all the time now.
    3 - I used to be able to cry, but now I can't cry even though I want to.

11. 0 - I am no more irritated by things than I ever am.
    1 - I am slightly more irritated now than usual.
    2 - I am quite annoyed or irritated a good deal of the time.
    3 - I feel irritated all the time now.

12. 0 - I have not lost interest in other people.
    1 - I am less interested in other people than I used to be.
    2 - I have lost most of my interest in other people.
    3 - I have lost all of my interest in other people.

13. 0 - I make decisions about as well as I ever could.
    1 - I put off making decisions more than I used to.
    2 - I have greater difficulty in making decisions than before.
    3 - I can't make decisions at all anymore.

14. 0 - I don't feel that I look any worse than I used to.
    1 - I am worried that I am looking old or unattractive.
    2 - I feel that there are permanent changes in my appearance that make me look unattractive.

3 - I believe that I look ugly.

15. 0 - I can work about as well as before.
    1 - It takes an extra effort to get started at doing something.
    2 - I have to push myself very hard to do anything.
    3 - I can't do any work at all.

16. 0 - I can sleep as well as usual.
    1 - I don't sleep as well as I used to.
    2 - I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
    3 - I wake up several hours earlier than I used to and cannot get back to sleep.

17. 0 - I don't get more tired than usual.
    1 - I get tired more easily than I used to.
    2 - I get tired from doing almost anything.
    3 - I am too tired to do anything.

18. 0 - My appetite is no worse than usual.
    1 - My appetite is not as good as it used to be.
    2 - My appetite is much worse now.
    3 - I have no appetite at all anymore.

19. 0 - I haven't lost or gained much weight, if any, lately.
    1 - I have lost or gained more than five pounds.
    2 - I have lost or gained more than ten pounds.
    3 - I have lost or gained more that fifteen pounds.

20 - I am no more worried about my health than usual.
    1 - I am worried about physical problems such as aches and pains, or upset stomach, or constipation.
    2 - I am very worried about physical problems and it's hard to think of much else.
    3 - I am so worried about my physical problems that I cannot think of anything else.

21. 0 - I have not noticed any recent change in my interest in sex.
    1 - I am less interested in sex than I used to be.
    2 - I am much less interested in sex now.
    3 - I have lost interest in sex completely.

Total_____

1-10 Normal; 11-16 Mild; 17+ Clinical Depression: 17-20 Borderline, 21-30 Moderate, 31-40 Severe, 41+ Extreme

Note: Question 19 will count zero points.

APPENDIX 10

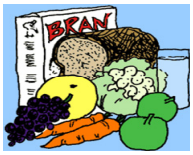
SESSION 1: DAILY MEAL PLANNING GUIDE: THE MAINTENANCE DIET

Slide 1

DAILY MEAL PLANNING GUIDE

The maintenance Diet

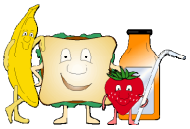
Session 1



Slide 2

Diet from 6 to 12 m. after LRYGB

- Estimated calorie intake is based on 1000-1400 cal/day
- Maintenance is generally easier when eating habits have changed
- The diet must include:
  - Proteins, carbohydrates, fats
  - Vegetables, fruits, fluids
  - Nutrient-dense foods



Slide 3

Proteins

- Should be the foundation of the diet
- Make sure you eat 60-70 grams of protein daily
- Always eat protein first & the other food afterwards
- You do not want to fill-up w/food that are not good sources of protein
- Remember: a cell phone is approx. 3-4 ounces piece chicken, fish, or meat (depending on thickness). A computer mouse is about 5-6 ounces.
- Protein sources include: low-fat or fat-free dairy, legumes, lean fish, poultry, meat, and soy-based products

Slide 4

Vegetables

- This is the next food group to focus on
- Vegetables are loaded w/ vitamins & minerals and they are also excellent source of fiber
- Two servings are recommended daily
- A half-cup cooked vegetable serving is probably easier to tolerate than 1 cup raw
- Remember, the more colorful the vegetable is, the more nutritious it is

Slide 5

Fruits

- Two servings of fruit are recommended
- Remember to peel skins to avoid blocking the gastric outlet
- One serving of fruit would be a small fruit that fits in the palm of your hand or half-cup sliced
- Fruits do not contain proteins at all

Slide 6

Carbohydrates

- Grains, legumes (beans), & starchy vegetables fall under this category
- Gummy breads, rice, & pasta may still be difficult to tolerate
- Adding 2-3 ounces of whole grains to your diet will not affect your wt loss
- The high fiber content will actually make you feel full
- You should have 2 servings of grains daily. The rest of the carbohydrates should come from legumes, vegetables, & fruits
- Legumes are excellent source of protein & fiber

Slide 7

Fats

- You should still be aware of your fat intake, since larger quantities mean more calories
- Fat is necessary for vitamin absorption, so you do not want to completely eliminate it from your diet
- Select healthy fats for cooking, choose low fat dairy products, & select lean meats
- Remember, each tablespoon of oil contains approximately 130 calories

Slide 8

Fluids

- Make sure you stay hydrated well choosing non-carbonated low calorie beverages
- Drink at least 64 ounces of liquids daily
- Do not drink w/ your meal & stop drinking 15 minutes prior to the meal & 60 minutes after
- This will help you stay full in-between meals
- Be careful of high-sugar beverages, even if you no longer experience the Dumping Syndrome
- High-sugar beverages are empty calories. It is best to eat your calories than to drink them

Slide 9

Nutrient Density Foods

- Food is nutrient dense when the level of nutrients is high in relation to the # of calories it contains
- By eating foods that are nutrient dense, you will get all essential nutrients that you need for excellent health (vitamins, minerals, phytonutrients, essential fatty acids, fiber, & more) for the least calories
- Nutrient-dense foods are the opposite of empty-calorie foods, which are low in nutrients when compared to their calorie content
- Nutrient dense foods are whole grains, fruits & vegetables, legumes & seeds, herbs & spices, oils, fish, poultry, & meats

Slide 10

Mealtime Tips

Slide 11

Establish routine eating habits at mealtimes

- Eat slowly; allow at least 30 minutes for each meal
- Set fork down between bites & chew 25-30 times per bite
- Eat a maximum of 3 meals/day & 1 or 2 high-protein snacks (unless otherwise specified by RD)
- Do not skip meals
- Always eat protein first & make sure you get enough protein daily
- Do not consume soft protein (yogurt, cottage cheese) as the sole source of protein in a meal. Soft proteins empty out of the pouch quicker

Slide 12

Establish routine eating habits at mealtimes

- Choose complex carbohydrates that will have a lower impact on blood sugar (avoid simple carbohydrates that greatly impact blood sugar)
- Limit sauces while losing weight
- Do not drink fluids while eating: stop drinking 15 minutes before meals & wait 60 minutes after a meal to resume liquids
- Sip on water during the day to prevent dehydration
- Drink 8 glasses of water daily (64 oz.). Avoid carbonated beverages. Choose low- calorie or calorie free beverages. It is better to eat your calories than to drink them

Slide 13

Establish routine eating habits at mealtimes

- Limit liquid meals (soup, protein shake), they empty out of the pouch quicker
- Limit alcohol: Your tolerance to alcoholic beverages may have significantly declined
- Avoid extreme hot or cold food temperatures. This may produce chest pain when ingested
- Take all vitamins & minerals recommended by your doctor daily. Remember, it is a LIFETIME commitment! Even though portion sizes have increased, there is still malabsorption

Slide 14

Replace food with activities

- Now is a good time to practice other things besides eating when you are stressed, bored, or upset
- Examples: Clean around the house, limit TV time, drink more fluids, play with pets, read, do stretching or meditation, do some type of physical activity five to seven days a week
- (More details about physical activity in next session)

Slide 15

When dining out

- Order only a beverage & a side dish or half-portion, or a children menu
- Fish (soft piece with no added fat), cottage cheese, eggs, apple sauce, mashed potatoes, egg drop soup, & broth-based soups are tolerated best
- Chinese food & pizza are not well tolerated & are also high in fat & calories
- You may want to limit the social activities centered on food following your surgery
- Expect some frustration over food intolerances

Slide 16

Other tips

- Sleep at least 7 hours each night. Sleep deprivation increases your appetite & susceptibility to illness
- Exercise regularly. At least 5 to 7 days per week for 30 minutes each day
- Take personal responsibility for your wt loss. Weigh yourself once a week
- Follow the guidelines of your program
- Keep follow-up appointments with your Doctor & Registered Dietitian
- Participate in a behavior modification program that will instruct you how to incorporate healthy nutrition practices into your lifestyle
- KEEP FOOD RECORDS

Slide 17

Control your portion size

- Eat in a smaller plate: it helps eat smaller meals
- Toddler spoon and fork: helps take smaller bites of food and eat slowly
- Toddler sipper cup or shot glass: helps drink smaller amounts at a slower rate
- Measuring spoons helps measure serving sizes
- Kitchen timer: time your meals
- Food scale: helps measure smaller serving sizes

Slide 18

Control your portion size

- One cup of fruits or vegetables equals the size of a baseball
- A medium potato equals the size of a computer mouth
- One serving of meat equals the size of a deck of cards

Slide 19

Recommended and not-recommended food

Slide 20

Meat and High protein Food:
3 servings of 2-3 oz serving

Slide 21

Foods Recommended	Foods not Recommended
Well cooked soft, lean poultry & fish Fish canned in water	Fried fish, fish canned in oil, breaded fish Fried poultry, poultry skin, goose, duck
Lean, fat-trimmed beef pork, veal or lamb (USDA Select or Choice). Limit 1 time/week. 95% fat- free luncheon meats	USDA grade Prime meats, hot dogs, sausages, bacon, regular cold cuts, tongue
Eggs with yolk (limit 3 per week) Egg substitute/ egg whites	Fried eggs or omelets with added fat
Low-fat/non-fat cottage cheese, part skim milk cheese; Borden Lite-Line cheese; Laughing Cow reduced calorie cheese, Cabot light cheese	Regular hard and soft cheeses (cheddar, American, Camembert, Brie cream cheese, etc.)
	Peanut butter, nuts

Slide 22

Vegetables: 2 servings of ¼ cup each

Foods Recommended	Foods not Recommended
Vegetable juices, well cooked or canned vegetables	Raw or fried vegetables, vegetables with tough membranes or skins (broccoli, cauliflower), lettuce, vegetables cooked with added fat or cream, cheese sauce Olives, Avocados

Slide 23

Fruits: 2 servings of ¼ cup or ¼ whole fruit each

Foods Recommended	Foods not Recommended
Banana, skinless peach or pear, unsweetened applesauce, any fruit canned in water	Fruits canned in light or heavy syrup, coconut, fruits with seeds, tough membranes and skins. Dried fruit

Slide 24

Bread, cereals and Starches: 2 servings per day, ¼ cup or ½ slice each

Foods Recommended	Foods not Recommended
Toast, low-fat crackers, cooked cereals, cold cereal Rice cakes, pretzels, breadsticks Squash, turnips Legumes, lima beans, parsnips	Sugar-coated cereal, granola Biscuits, Wheat-Thins, popcorn French-fries, potato and tortilla chips Macaroni and chee Alfredo sauce, rice pa

Slide 25

Soup: 6 oz

Food Recommended	Food not Recommended
Broth, bouillon, vegetable or broth based soups, cream soups made with skim milk, egg drop soup	Cream soups or chowder made with whole milk or cream

Slide 26

Beverages: 64 oz each day, drink sips at a time

Fluids Recommended	Fluids not Recommended
Skim milk, Fat-free yogurt drink, Crystal light, water, V8, sugar-free drinks, Gatorade (limit 8oz per day)	Carbonated beverages, chocolate milk, Kool-Aid, sugared iced tea, coffee

Slide 27

Dessert: ¼ cup or 2 oz

Food Recommended	Food not Recommended
Sugar-free Jell-O, sugar-free popsicles, sugar-free nonfat yogurt, sugar-free pudding/custard (limit 2 times each week)	Doughnuts, pastries, muffins, croissants, regular Jell-O and popsicles, ice cream, pies, cookies, cakes, ice milk, sherbet

Slide 28

Fat

Food Recommended	Food not Recommended
Oil, low fat salad dressings, or low fat mayonnaise (limit to 2 Tbsp per week), Butter Buds, Molly McButter, cooking spray	Regular salad dressings, regular mayonnaise, butter or margarine (all kinds), cream cheese, sour cream, nuts, olives

Slide 29

Bariatric Exchange list for weight management

Protein (Eat 8-10 ounces daily)
One serving equals 7 grams protein

- 1/2 cup legumes
- 1/4 cup cottage cheese
- 1 oz. cooked lean meat, poultry, fish, cheese
- 6 oz. sugar-free yogurt
- 8 oz. nonfat milk
- 1 egg or 1/4 cup egg substitute

Slide 30

Bariatric Exchange list for weight management

Leafy Vegetables (Eat 2 servings daily)
One serving equals:

- 1 cup raw vegetables
- 1/2 cup cooked vegetables

Slide 31

Bariatric Exchange list for weight management

Grains, Beans, and Starchy Vegetables (Eat 2 servings daily)

One serving equals:

- 3/4 cup cereals (< 6 grams sugar)
- 1 small sweet potato (1/2 cup)
- 1 slice 40 calorie bread
- 1/3 cup brown rice or wheat pasta

Slide 32

Bariatric Exchange list for weight management

Fruits (Eat 2 servings daily)

One serving equals:

- 1 cup berries
- 1 small banana
- 1 small peeled apple

Slide 33

Bariatric Exchange list for weight management

Fats (Eat 4 servings daily)

One serving equals:

- 1 Tbsp. avocado
- 1 tsp. olive oil or spread

Slide 34

Vitamin and Mineral Supplements

- Remember, you require vitamin & mineral supplements for life in order to prevent deficiencies because you are eating much less food & absorbing fewer nutrients
- Take your vitamins & supplements on time!
- This is vital to your overall health & well being
- Your Dr. will prescribe supplements as needed

Slide 35

Recommended Supplements

- Multi-Vitamin: Centrum A to Zinc or Centrum with Iron (best if taken with food)
- Calcium: should be from the citrate form; carbonate is not well absorbed. Calcium with Vitamin D is the best. Take 1 tablet w/breakfast & 1 table w/ lunch. Do not take w/Iron
- Iron: will be prescribed by your surgeon as needed
- Vitamin B12: If prescribed take sublingual, oral 350-500 mg once a week, nasal sprays, or monthly injections

Slide 36

Protein Supplement

- Protein: add protein powder to 4-8 oz Skim plus Milk, skim milk or Low fat Lactaid daily. If unable to consume 50-60 g protein per day from diet, then protein supplement may be needed. Check with your RD

Slide 37

Example of Breakfast

2 servings Protein	6 oz. sugar-free yogurt w/ 1 tbsp. silvered almonds 1 laughing cow light baby bell cheese
1/2 serving fruit	1/2 small banana

Slide 38

Example of Snacks

1 serving Protein	1 oz. string cheese
1/2 serving Fruit	1/4 cup mixed berries with 2 tbsp. light cool whip 1/4 cup cantaloupe

Slide 39

Example of Lunch

3 servings Protein	3 oz. tilapia
1 serving Leafy Vegetables	1/2 cup broccoli
1 serving Grains	1 small backed potato
2 servings Fat	1 tsp olive oil to cook tilapia & 1 Tbsp. fat free sour cream for baked potato

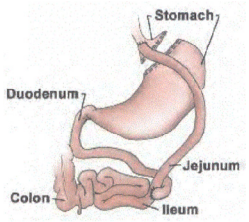
Slide 40

Example of Dinner

3 servings Protein	3 oz. canned tuna packed in water
1 serving Leafy Vegetables	lettuce leaves, tomato slices, and sliced onions
1 serving Grains	1 whole wheat pita (4 inches)
2 servings Fat	2 tbsp. light mayonnaise
1/2 Serving Fruit	1/2 banana baked top w/ cinnamon and fat-free ready whip

Slide 41

The End



FIU
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Miami's public research university

SESSION 1 QUIZ: DATE:_ _/ _ _/ _ _

QUESTION 1:
The 6-12 month maintenance diet following gastric bypass surgery should include:

1) Proteins and carbohydrates only.
2) Nutrient-dense foods only.
3) Proteins, carbohydrates, fats, vegetables, fruits, fluids, and nutrient-dense foods.

QUESTION 2:
Proteins should be the foundation of the diet. Protein sources include:

1) Low-fat or fat-free dairy products, legumes, fish.
2) Poultry, meat, and soy-based products
3) All of the above.

QUESTION 3:
One tablespoon of oil contains approximately:

1) 130 calories.
2) 30 calories.
3) 13 calories.

SESSION 2: BEGINNING A CONSISTENT EXERCISE PROGRAM*

Slide 1

BEGINNING A CONSISTENT EXERCISE PROGRAM

Session 2

Slide 2

Objectives

- Identify why lifelong exercise is key to keeping weight off after bariatric surgery
- Describe how self-talk influences motivation to exercise
- Describe how to choose the type of exercise that is right for you
- List motivational tips for exercise
- Describe the 5- minute rule
- Create long-term and short-term exercise goals
- Choose exercise rewards

*Reproduced with permission from Matrix Media Communication. Alexander C. The Emotional First Aid Kit: A Practical Guide to Life After Bariatric Surgery. Edgemont, PA: Matrix Medical Communications, Inc., 2006:77-102.

Slide 3

Physical Activity

- Regular physical activity is extremely important and beneficial for long-term health and well-being after surgery
- Exercise during wt loss will help you to stay more toned, feel more energetic, and become stronger. It can burn more calories and assist in the wt loss program
- Exercise is even more important after you reach your goal weight
- Remember: Successful weight maintenance is a product of life-long adherence to healthy eating and continued exercise.

Slide 4

Preparation

- Start by getting into the habit of scheduled exercise and to overcome the excuses used to skip workouts
- It is possible to lose weight without exercising, but it will be very difficult to keep the weight off without exercise

Slide 5

Benefits of Exercise

- Reduce and maintain body weight
- Reduce body fat
- Build and maintain healthy muscles, bones, and joints
- Reduce depression, stress, and anxiety
- Improve psychological well-being: decrease anger and hostility
- Enhanced work, recreation, and sport performance

Slide 6

Benefits of Exercise

- Reduce high blood pressure or the risk of developing high blood pressure
- Reduce high cholesterol or the risk of developing high cholesterol
- Reduce the risk of premature death
- Reduce the risk of developing and/or dying from heart disease.

Slide 7

Tips to keep you on track:
Exercise and Self-talk

- We all enjoy exercise immediately after the workout. The problem occurs just before, when we start making excuses not to do it
- Example of excuses are: "I'm too tired", "It's too late", "It's going to rain", or "I don't have to exercise on vacation." The list is endless
- These thoughts are absolutely normal however if you want to be successful, it is time to learn to ignore these excuses. It isn't possible to stop exercising and keep all the weight off for life

Slide 8

Tips to keep you on track:
Exercise and Self-talk

- Use motivational techniques to avoid going back into your old habits (in next slide)
- When you get to the maintenance stage, focus on your program, your habits, and the avoidance of excuses
- In order to motivate yourself, it helps to discover your long range goals
- These goals will become part of your positive self-talk and that will help motivate you to exercise, even when you don't feel like it.

Slide 9

Tips to find your internal motivation to exercise

Slide 10

Motivation to exercise

- Say to yourself: "If I exercise today, I am one step closer to my goal of good health and feeling good again"
- If your real motivation is to look good, then say: "each time I exercise, I get closer to my goal of looking great and wearing that bathing suit"
- You may wish to look at a picture of yourself when you were once at the weight you now hope to achieve, or use a magazine picture of your fantasy goal.

Slide 11

Motivation to exercise

- If your goal is to have energy to get involved in activities, then say: "a little work today will help me be able to hike in the woods with energy, or swim in the ocean, or shop at the mall without shortness of breath"
- If your goal is to be able to keep up with your kids and spouse, then say: "I am doing this for my kids and spouse, they are not going to recognize me, and they will love having an active parent/spouse again"
- Your motivation might include several of the above.

Slide 12

Starting an exercise program

Slide 13

Starting an Exercise program

- Starting an exercise program can be both exciting and frustrating
- It takes approximately six months for exercise to become a habit
- The first few weeks you will be more tired than usual, but if you stick with it, you will notice an increase in energy
- One of the most elusive aspects of exercise adherence is making it a priority
- As a BARIATRIC patient, your health has to be a priority and exercise is an integral part of your health.
- Remember: exercise is one of the most important components to long-term weight loss maintenance.

Slide 14

Question 1

How much should I exercise?

- You should exercise 3 to 5 times per week or more for at least 30 to 45 minutes per workout
- Aerobic exercise is excellent, and adding free weights or equipment is a good supplement
- Walking is a great way to begin, inexpensive, simple to do, and can be as intense as you choose
- Make a commitment to yourself that if there is not enough time to exercise, something else will have to go, not the exercise. There is always time for exercise if you make it a priority

Slide 15

Question 2

Do I have to spend a lot of money to join a gym?

- No. You do not have to spend a lot of money by joining a gym
- You can exercise from your home and still achieve your weight loss and weight maintenance goals.

Slide 16

Question 3

What exercises should I choose?

- Boredom is an enemy in a exercise program
- Try activities you are interested in or ones that you may have enjoyed in your past
- Choose between walking, swimming, pool walking, joining a gym, bicycling, hiking, water aerobics, rollerblading, tennis, golf without a cart, using free weights, mall walking, etcetera. You can choose several activities and alternate them
- Expect exercise to be boring, but you are doing it for your health and your future.

Slide 17

Question 4

Are there alternatives to the 30 to 40 minute workout?

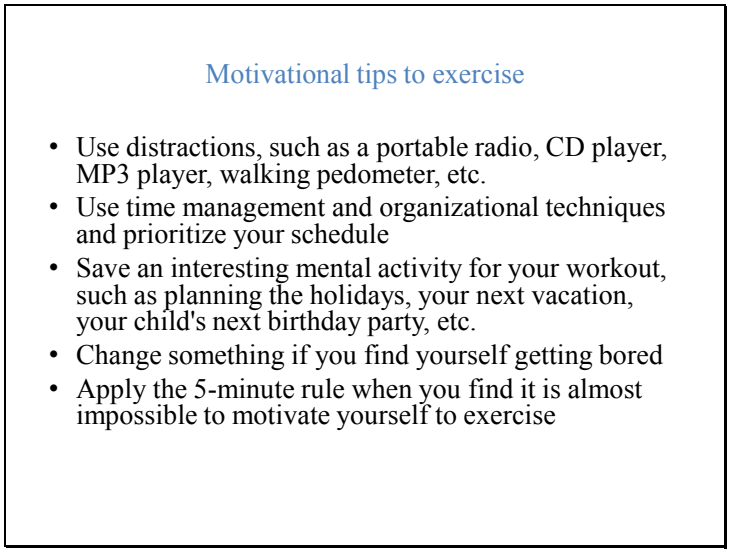
- Sure, an interesting variation is to do three or four 10-minute workouts during the day
- To take this way requires extraordinary determination because you must motivate yourself to exercise several times each day
- You can buy a pedometer to wear all day. By the time you reach your goal weight, you should be able to accumulate at least 10,000 steps per day

Slide 18

Motivational tips to exercise

- Play some optimistic music as you get dressed to exercise
- Buy some magazines that feature your sport or activity
- Join a group. Get others involved: Make a pact with your partner to be there for him/her can help you to stay consistent with your program
- Enter an event, such as a 3-mile walk for charity. Set goals and rewards for sticking to your program.
- Start a pre-exercise routine that gets you in the mood to exercise.

Slide 19



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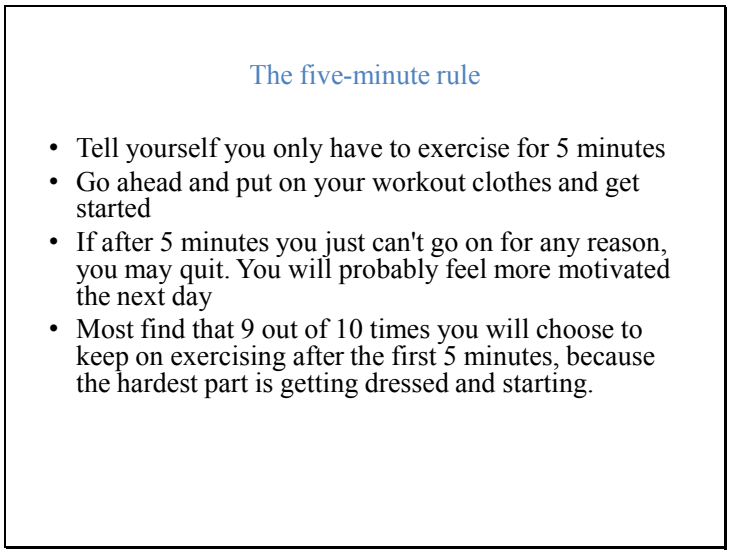


Slide 21

Goal Setting

- This is a little known and highly motivational technique
- It is based on goals that challenge you
- There are 2 types of goals:
  - Long-term and
  - Short-term goals

Slide 22

Long-term Goals

- There are the BIG goals
- It may be walk 5 miles
- Participate in a triathlon
- Play hockey.

Slide 23

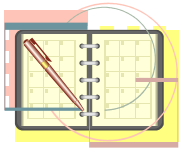
Short-term Goals

- There are STEPS needed to achieve the long-term goal. Short-term goals should be:
- REALISTIC: If you have not exercised in 20 years, you may be able to walk only 100 yards at first. You can always add time, speed or distance as you meet each short-term goal
- MEASURABLE: You should be able to measure your progress in miles, time, number of days per week you workout, etcetera.

Slide 24

Short-term Goals

- MODERATELY DIFFICULT: Research showed that people work harder for goals that are not too hard and not to easy.
- SPECIFIC: Write down you short-term goals. State how many days per week, and how much time you intend to do what you have chosen.



Slide 25

Rewards

- Achieving goals is much more motivating if you attach a reward
- If you cannot motivate yourself for a health reason, do that for a new clothing or DVD
- There are two types of rewards:
  - Internal rewards and
  - External rewards.

Slide 26

Internal Rewards

- Are the physical and psychological benefits we get from doing the activity
- They include a sense of accomplishment, pride, energy, strength, enjoyment, pleasure, satisfaction, and feeling better
- These are potentially present every time we exercise.

Slide 27

External rewards

- Are treats we promise ourselves for meeting our goal
- It should be something you desire enough to work toward and something you would not ordinarily purchase for yourself
- For instance, a new DVD, new clothing, a mini-vacation, etcetera.
- Whatever you choose, it can serve as a great motivator when you really need one

Slide 28

Remember

- It takes about 6 months for exercise to become a habit
- The external rewards will help get you to that point. After it becomes a habit it will be more difficult to skip your workout
- The internal rewards may be enough to sustain your motivation. You can reintroduce rewards into your program any time that you need them.
- A large percentage of people quit their exercise programs. Do not let that be an option for you.

Slide 29

Tips to be successful in sticking to your exercise program

Slide 30

Tips

- List your long-term and short-term goals, and attach rewards to your effort
- Log all workouts
- Use the motivational tips
- Prioritize exercise in your life. Your weight and health depend on it.
- Do not expect instant results: give it a chance, it takes about 6 months to become a habit.
- Learn to ignore the negative self-talk and turn it into positive.
- Remember that exercise works to prevent weight regain in the maintenance stage of weight loss.

Slide 31

Physical activity options

Slide 32

Look for Everyday Opportunities

Short bursts of these activities throughout the day make a difference:

- Use steps instead of elevators or escalators.
- Park your car in a distant section of the parking lot.
- After living your work take a walk around the building.
- Take a walk during lunch.

Slide 33

Look for Everyday Opportunities

- Get off the train or bus one stop earlier and walk the rest of the way.
- March or do squats while brushing your teeth.
- Pace around the house or do arm curls with a can of food while talking on the phone.
- Jump rope, stretch, jog in place, or lift weights while watching T.V.
- Be prepared: keep walking shoes in your car or in your desk.

Slide 34

Plan PA in your leisure-time events

Look for activities the whole family can enjoy:

- Have a family baseball or soccer game.
- Plan a bike tour, mountain hike, or canoe trip.
- Have a basketball web in your backyard and enjoy it every time you came back from work.
- Explore a cave.

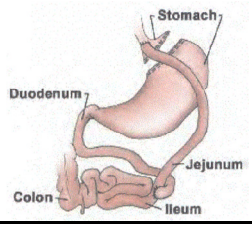
Slide 35

Physical Activity Log

Day of the Week	Type of Activity	Amount of Time
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Slide 36

The End



FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

SESSION 2 QUIZ: DATE:_ _/ _ _/ _ _

QUESTION 1: Mark True or False:
It is possible to lose weight without exercising, but it is very difficult to keep the weight off without exercise.

1) True
2) False

QUESTION 2:
How long it takes for exercise to become a habit?

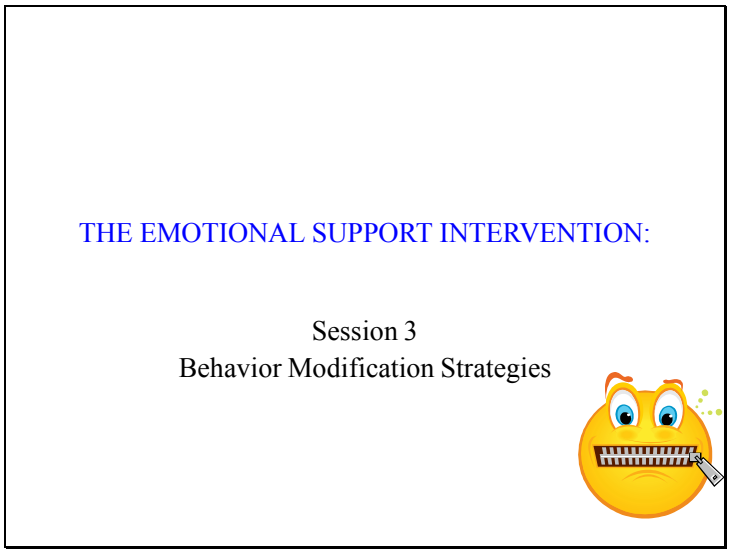
1) Approximately 6 months.
2) Approximately 12 months
3) Never becomes a habit.

QUESTION 3:
What are some of the benefits of regular physical activity?

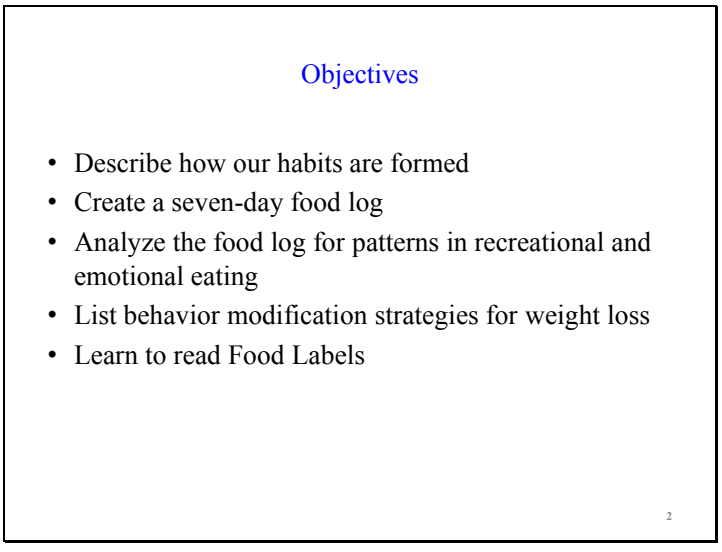
1) Exercise helps reduce and maintain body weight
2) Exercise reduces depression, stress, and anxiety
3) Exercise reduces the risks of developing high blood pressure and premature death from heart disease.
4) All of the above are correct.

SESSION 3: BEHAVIOR MODIFICATION STARTEGIES, AND FOOD LABELS*

Slide 1



Slide 2



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Slide 3

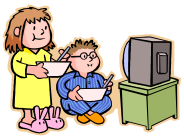
What is behavior modification?

- Is a set of small changes you can make that will assist you in learning new habits
- Habits are very difficult to change (certain aspects of your environment will make it more difficult)
- Is based on the idea that powerful psychological connections between certain cues and eating are established over time

3

Slide 4

Psychological connections



Examples:

- Watching T.V. and eating chicken wings or sugar-candy
- Coming home from work and immediately making a sandwich
- These habits are normal for most of us but must be changed in order to be successful with wt loss after bariatric surgery.

4

Slide 5

How habits are formed?

- Habits are formed by repeating an action over time
- New habits are formed in much the same way. Starting new habits is more difficult because it also involves resisting an old habit
- This transition is stressful for most people. When we resist an old comfortable habit, we will usually feel some anxiety (does not mean that you must go back to the old habit to feel better)

5

Slide 6

Changing bad habits

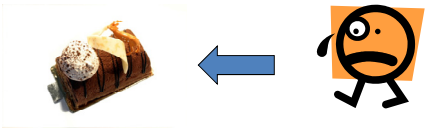
- A better alternative is to learn behavior modification techniques and cope with anxiety in a healthy way so you can progress with your lifestyle change goals
- Learn to cope with anxiety by using relaxation and deep breathing techniques
- Cope with the transition period and you will be successful at changing the habits that make weight loss difficult

6

Slide 7

Changing bad habits

- The first step to starting behavior modification is to figure out your particular triggers, cues, emotions, and situations that lead to emotional, recreational, or habitual eating



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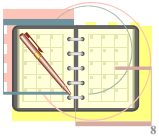
Slide 8

Homework to do

- All that you require for this activity is paper and a pen
- For the next 3 days you will record everything:
  - What you eat
  - What was going on at that time
  - The predominant emotion just before you want to eat. For example: loneliness, tired, stressed, happy, etcetera



8

Slide 9

Predominant emotion just before you want to eat

- Negative Emotions: Stress, anger, loneliness, depression, anxiety, boredom, and tiredness
- Positive Emotions: Happiness with family or friends, celebrating, business functions

Slide 10

Predominant emotion just before you want to eat

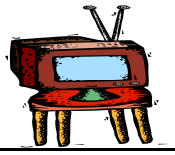
- General Overeating or Binge Eating: engage in excessive unrestrained eating
- Eat large amount of food at night and avoid breakfast
- Eat in response to environmental cues: time of day or kind of food, rather than hunger cues

10

Slide 11

Look for patterns

- When you have at least 7 days of information, sit down and look for patterns:
- Are there one or more predominant emotions that seem to lead to eating?
- Is there a particular time of day or night that appears to be more troublesome for you?
- Is there a particular place that triggers eating?
- Is there an activity that triggers eating, e.g. watching T.V.?



11

Slide 12

Look for patterns

- Is the presence of particular foods a trigger?
- Is a particular day more of a problem than others?
- What about automatic or mindless eating, such as snacking or nibbling while cooking?
- Try to distinguish between internal cues (e.g. sadness, excitement) versus external cues (e.g. TV commercials or the scent of food cooking)

12

Slide 13

Make changes

- Once you have this information, you are in a much better position to begin making changes
- When you understand the places, emotions, foods, time of day, and other patterns that lead you to eat, you can commit to avoiding these triggers, changing your environment or recreational pattern, and looking for alternatives
- Change the routines that always lead to eating. The key is to become aware of the triggers, and then to make planned, alternative choices to avoid the trigger or change the situation

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Slide 14

Specific behavior modification strategies for weight loss

Slide 15

Specific behavior modification strategies for weight loss

- Eat only as advised by your bariatric doctor or dietitian. Try not to allow yourself to snack between recommended meals. If you must, make it a bariatric-friendly snack
- Eat very slowly and place your utensil on the plate between bites. Chew your food at least 25 times.
- Do not engage in other activity except eating at meal time. Avoid reading, watching T.V., or to much conversation while eating

15

Slide 16

Specific behavior modification strategies for weight loss

- Eat in a specific place. Do not eat anywhere else. If possible eat in the same chair. Do not eat while driving or doing other activities as you will quickly lose track of the amount you have consumed
- Stay out of the kitchen except when absolutely necessary. Keep the kitchen light off and try to take alternate routes that don't lead you pass it if possible. Make sure food is stored only in your kitchen.
- Use small plates, bowls, and utensils.

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Slide 17

Specific behavior modification strategies for weight loss

- Do not keep leftovers on the table to invite additional nibbling after you finish. Get up from the table immediately and do something else.
- Keep food out of sight as much as possible. Keep your healthier choices in see-through containers so you learn to choose those before the others.
- Do not leave bowls of small snacking foods on the counter or table. We will eat "one or two" every time we pass.

17

Slide 18

Specific behavior modification strategies for weight loss

- Use these principles at work, too. Take all snacks out of your drawers and off your desk, including candy dishes for clients or coworkers
- Bring healthy snacks and meals with you to work so, you will not be able at the mercy of the cafeteria, fast food, or vending machines
- Do not eat lunch at your desk. Go to the lunchroom or a picnic table outside, but break the psychological connection between your desk and eating

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Slide 19

Specific behavior modification strategies for weight loss

- At break time, avoid the break room where others may be eating or where vending machines are located. Instead, make phone calls, do some stretching, or take a stroll outside or inside your building
- Learn to change your routine. If you go to the refrigerator first thing after work, learn to go directly to another room so you will eventually break that connection

19

Slide 20

Specific behavior modification strategies for weight loss

- Learn to read labels on grocery store items. Shop only when you are not hungry, and bring a prepared list. Avoid certain aisles that may be tempting for you, like crackers and cookies aisles
- Play soothing music while eating. It tends to slow us down.
- Try not to nibble while preparing foods. Plan ahead so you are not hungry while preparing meals, and try strategies such as brushing you teeth or keeping sugar-free hard candy around if you need something

20

Slide 21

Specific behavior modification strategies for weight loss

- If eating while you cook is a problem for you, try to prepare several meals at once to decrease the amount of time you will be vulnerable
- Keep healthy snacking alternatives available, such as sugar-free hard candies, sugar-free popsicles, or sugar-free flavored gelatin
- Always keep a bottle of water with you. It will keep you feeling fuller between meals and is very healthy

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Slide 22

Specific behavior modification strategies for weight loss

- Always have an escape route. Do not put yourself in a situation where you feel unable to control your eating. If you find yourself overwhelmed at any time, have a plan for how you will allow yourself to leave
- Monitor your progress. Assess your BMI on a weekly or monthly basis. Many people have difficulty when they stop monitoring themselves

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Slide 23

Specific behavior modification strategies for weight loss

- Be aware of visual cues for eating. Try to alter the connection between cues and eating. Go to a movie instead of dinner
- When you have a craving, try waiting for 10 minutes before you eat anything. When do not immediately respond to cravings, they tend to decrease in intensity. If you do this overtime, the craved food will lose its strength and power over you

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Slide 24

Understanding food labels

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Slide 25

Food Labels

- Food labels appear on virtually every food item.
- The only foods that do not need to carry nutrition labels are plain coffee, tea, and spices.
- Foods produced by small companies and those prepared and sold in the same establishment also are exempt. However, many of these producers choose to use nutrition labels.

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Slide 26

Food Labels

- Every food label will show total calories, food energy from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugar, protein, and dietary fiber.
- Labels present nutrition information in two ways: quantities (such as grams or milligrams) and percentages of daily values.
- The amount of fat that every person should consume in a day is not a set amount. Instead, recommendations are based on a percentage of calories.

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Slide 27

Serving Size

- The first place to start when reading a nutrition label is the serving size and the number of servings in the package. This is a crucial piece of information, and it's easy to miss.
- Be careful! Serving sizes on the label may differ from those of what you need to eat.
- For example, a serving of rice on the box may be 1 cup, but you may need only ½ cup.

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Slide 28

Serving Size

- FDA has established specific serving sizes on some foods. For example, a beverage serving size is 8 fluid ounces and an ice cream serving size is ½ cup.
- Some food serving sizes are not regulated. This is why it is so important to read the serving size first.
- It is easy to assume that some food packages only hold one serving. E.g. little bags of potato chips actually contain 2½ servings. If you just look at calories and see 150 calories, you would think that the entire bag contains 150 calories, when in fact it contains 375.

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Slide 29

Calories

- Calories provide a measure of how much energy you get from a serving of this food. Many Americans consume more calories than they need without meeting recommended intakes for a number of nutrients.
- The calorie section of the label can help you manage your weight (i.e., gain, lose, or maintain.)
- Remember: the number of servings you consume determines the number of calories you actually eat (your portion amount).

Amount Per Serving	
Calories 250	Calories from Fat 110

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Slide 30

The Nutrients: How Much?

- Eating too much fat, saturated fat, *trans* fat, cholesterol, or sodium may increase the risk of certain chronic diseases, like high blood pressure, heart disease, stroke, or some cancers.
- Health experts recommend that you keep your intake of saturated fat, *trans* fat and cholesterol as low as possible as part of a nutritionally balanced diet.

LIMIT THESE NUTRIENTS

Total Fat 12g	**18%**
Saturated Fat 3g	**15%**
Trans Fat 3g	
Cholesterol 30mg	**10%**
Sodium 470mg	**20%**

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Slide 31

The Nutrients: How Much?

- Most Americans don't get enough dietary fiber, vitamin A, vitamin C, Calcium, and Iron in their diets.
- Eating enough of these nutrients can improve health & help reduce the risk of some diseases & conditions. E.g. Calcium may reduce the risk of osteoporosis, fiber (a diet rich in fruits, vegetables, and grain products) promotes healthy bowel function.

GET ENOUGH OF THESE NUTRIENTS

Dietary Fiber 0g	0%
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

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Slide 32

Percentage of Daily Value

- The % of daily value column provides a figure of how individual foods contribute to the overall diet. You can see that every food label bases the % daily value on a 2,000 and a 2,500 calorie diet.
- 5% DV or less is LOW and 20% DV or more is HIGH
- Our needs may differ based on our age, sex, physical activity, etc. These figures still provide a way for you to compare different food items. E.g.: if one type of food contains 25% of the DV for fat based on a 2000-calorie diet and another provides 30%, it's wiser to choose the one containing 25%.

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Slide 33

Vitamins and Minerals

- Some vitamins and minerals appear on every food label: they are vitamin A, vitamin C, Calcium, and Iron.
- Manufacturers may choose to include other vitamins or minerals on the label, but this is not required.

Nutrition Facts

Serving Size 1 cup (236ml)
Servings Per Container 1

Amount Per Serving
Calories 80 Calories from Fat 0

	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol Less than 5mg	**0%**
Sodium 120mg	**5%**
Total Carbohydrate 11g	**4%**
Dietary Fiber 0g	**0%**
Sugars 11g	
Protein 9g	**17%**

Vitamin A 10% • Vitamin C 4%
Calcium 30% • Iron 0% • Vitamin D 25%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

Slide 34

Ingredients

- Ingredients listed on the label are in descending order of predominance by weight.
- If a canned fruit label reads “sugar, fruit, water,” the item actually contains more sugar than fruit by weight.
- Fruit is pretty heavy; so, just imagine how much sugar is in this food.

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Slide 35

Conclusion

- Perfect foods do not exist.
- Every food you eat has pluses and minuses.
- Look at the entire label to see if the food is a good source of vitamins and minerals.
- Don’t forget to look at the serving size first!

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Slide 36

Food Labels Comparison Example

- Below are two kinds of milk: one is "Reduced Fat," the other is "Nonfat" milk. Each serving size is one cup.
- Answer the following questions:
- Which has more calories and more saturated fat?
- Which one has more calcium?

36

Slide 37

REDUCED FAT MILK

Nutrition Facts
Serving Size 1 cup (236ml)
Servings Per Container 1

Amount Per Serving
Calories 120 Calories from Fat 45

	% Daily Value*
Total Fat 5g	8%
Saturated Fat 3g	15%
Trans Fat 0g	
Cholesterol 20mg	7%
Sodium 120mg	5%
Total Carbohydrate 11g	4%
Dietary Fiber 0g	0%
Sugars 11g	
Protein 9g	17%

Vitamin A 10% • Vitamin C 4%
Calcium 30% • Iron 0% • Vitamin D 25%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

NON-FAT MILK

Nutrition Facts
Serving Size 1 cup (236ml)
Servings Per Container 1

Amount Per Serving
Calories 80 Calories from Fat 0

	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol Less than 5mg	0%
Sodium 120mg	5%
Total Carbohydrate 11g	4%
Dietary Fiber 0g	0%
Sugars 11g	
Protein 9g	17%

Vitamin A 10% • Vitamin C 4%
Calcium 30% • Iron 0% • Vitamin D 25%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

37

Slide 38

ANSWER

- Both have the same amount of calcium, but the nonfat milk has no saturated fat and has 40 calories less per serving than the reduced fat milk.

The End

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SESSION 3 QUIZ: DATE:_ _/ _ _/ _ _

QUESTION 1:

Mark TRUE or FALSE:
Habits are formed by repeating an action over time and new habits are formed in much the same way
1) True
2) False

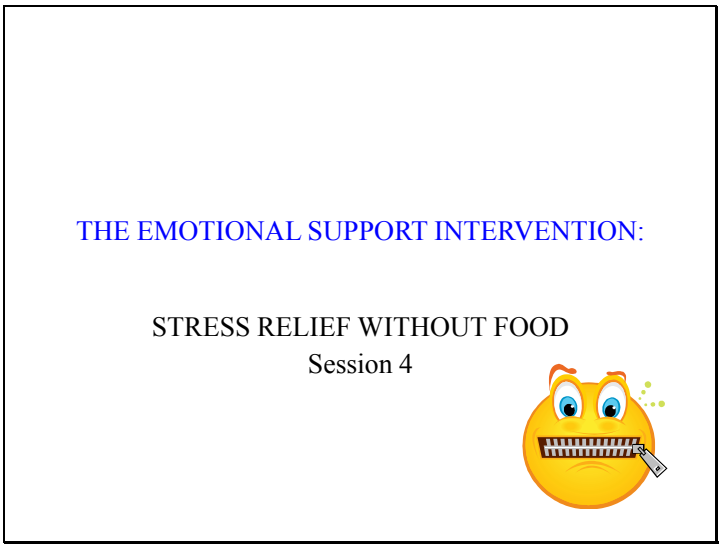
QUESTION 2:
What are specific behavior modification strategies for weight loss?
1) Do not engage in other activity except eating at meal time
2) Use small plates, bowls, and utensils.
3) Bring healthy snacks and meals with you to work
4) Learn to read labels on grocery store items.
5) All of the above.

QUESTION 3:
In what order are ingredients in food labels listed?
1) Alphabetically
2) Randomly
3) In descending order of predominance by weight.

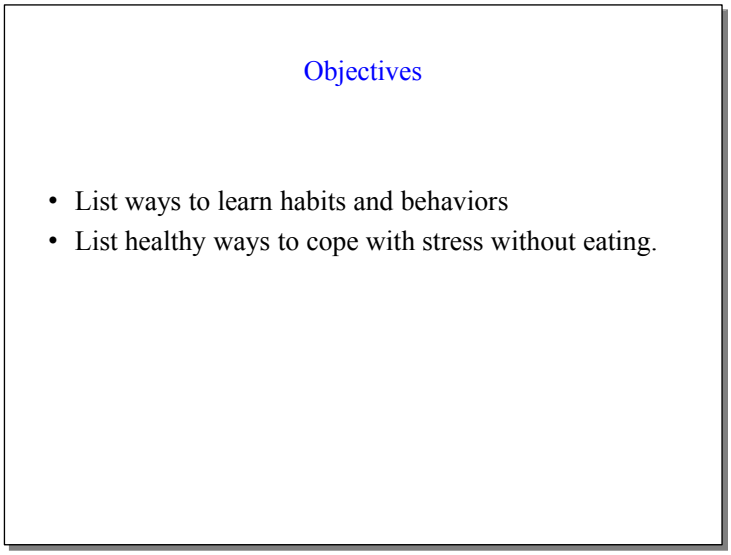
QUESTION 4:
Mark the correct sentence:
1) We can eat as much "low-fat" food as we want, because it's a good diet food and will keep us full without too many calories.
2) The first thing that we want to look at when reading a nutrition label is the amount of sugar.
3) Serving sizes on the label may differ from those of what we need to eat.

SESSION 4: STRESS RELIEF WITHOUT FOOD*

Slide 1



Slide 2



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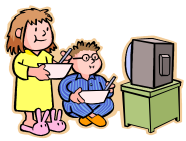
Slide 3

Introduction



- Food is an American stress reliever.
- We eat because we are hungry and we eat for many other recreational and emotional reasons, such as boredom, stress, excitement, habit, anger, depression, comfort, and celebration.
- Just about every social activity revolves around food.
- Food is almost always the main event. The advertising industry spends billions of U$S per year to keep all of us for recreational and emotional reasons.

Slide 4

Emotional Eating

- Even though it is normal many people gain large amounts of weight living this way and find it very difficult to alter this life long habit.
- Bariatric surgery will decrease your perception of hunger, but it will not help you to stop your recreation or emotional eating, since this type of eating is not based on hungry cues.
- The key to gaining control over emotional eating is all in your mind.

Slide 5

Life after Surgery

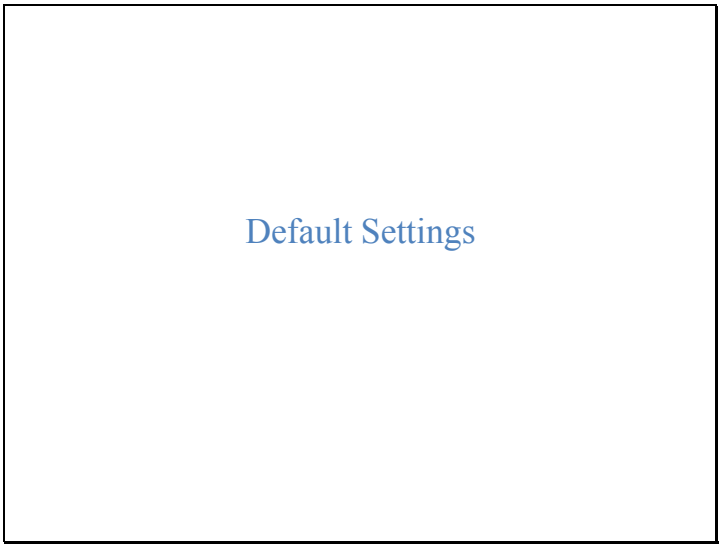
- Life after surgery will be stressful in ways you may not have considered. E.g. what will you eat out at your favorite restaurant, Thanksgiving, or Christmas festivities?
- You will feel a heightened sense of anxiety when you can't eat the foods you used to love, or must stop after just a couple of bites.
- This anxiety is normal, but you must learn some healthy ways to cope with the emotions caused by drastically altering your lifestyle.

Slide 6

Stress

- Stress is an eating trigger for many people.
- It can also make it difficult to focus on the long term goals.
- Stress can make you feel tired and drain your energy and motivation, making it difficult to stick to healthy habits.

Slide 7



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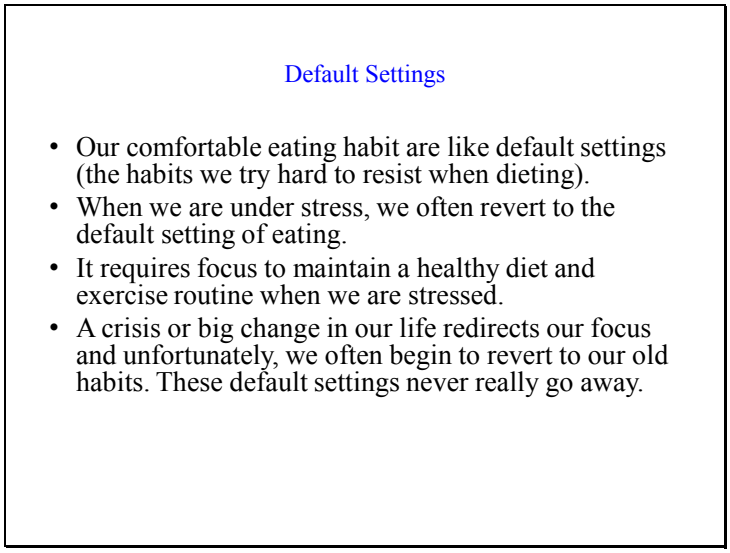


Slide 9

How our original default settings formed?

- Our response to food and food related cues is established over many years and in several different ways.
- First, as children we may have eaten when we were upset and food calmed us down.
- Or we were given a bottle when we cried and then we felt better.

Slide 10

How our original default settings formed?

- Eventually we learned to eat in certain situations because we knew we would feel better afterwards. This is a type of conditioning that strengthens over time with repetition.
- A second way we learn is by associating a food with an unrelated, separate thing, such as having popcorn when watching football, donuts on Friday morning at work, or Danish while reading the newspaper. Over time, we feel forced to do the two things together and feel anxiety if we don't.

Slide 11

How our original default settings formed?

- Another way we learn habits and behaviors is by listening to what our parents told us and by observing others.
- This experiences form the basis of our default settings that represent our early learning and connections strengthened over many years of repetition.

Slide 12

Breaking this Connections

- Breaking this connection is difficult because they are often connected to feelings of safety, security, celebration, family, and other intense emotions.
- To break these habits, we must repeatedly break the connection between the newspaper and the Danish and eventually the compulsion to eat while reading the newspaper will diminish.
- At the same time, a bariatric surgery patient may begin to establish new default settings by drinking a protein shake while reading the paper.

Slide 13

Set New Defaults

- It is possible to set new defaults, but it takes time and conscious effort. Remember: in times of personal crisis or stress, we have a tendency to revert to the old default settings. This is when it becomes important to pay special attention to our habits of eating and exercise so we will resist reverting to old habits.
- Excuses are our subconscious way of allowing us to slip back to our default settings. Learn to recognize these and say NO.

Slide 14

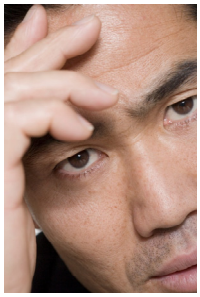
Set New Defaults

- In stressful situations, there can be additional stress on bariatric surgery patients because of the conflict between wanting to eat for comfort and not wanting to cheat. Most people do not realize how stressful this can be, and many people do cheat.
- Don't expect the surgery to give you willpower during stressful times. The surgery only keeps you from being hungry for a few months. It does nothing to stop emotional food cravings.

Slide 15

Coping Strategies

- It is very important to have a few healthy coping strategies, or you may find yourself regaining weight.
- If you must eat to cope with stress, make sure it is something allowed on your diet.



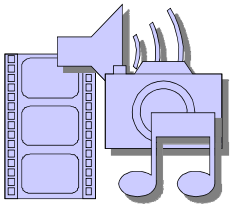
Slide 16

Healthy ways to deal with stress and anxiety without food

Slide 17

Coping Strategies

- Talk to a friend or family member about your feelings.
- Spend time in a social activity not related to food.
- Go to a movie, play, concert, or sport event.
- Take a leisurely drive and listen to music.



Slide 18

Coping Strategies

- Go to a library, mall, or bookstore.
- Go to a park with the dog, the kids, a friend, or alone.
- Meditate.
- Use progressive muscle relaxation tapes.

Slide 19

Coping Strategies

- Exercise.
- Do some stretching.
- Use the computer.
- Write down your thoughts in a journal or diary.
- Get involved in a hobby or craft.
- Reward yourself for all your hard work with something new.

Slide 20

Coping Strategies

- Plan a vacation.
- Get involved in a home improvement project.
- Do some volunteer work.
- Doodle, draw, or paint.
- Learn a new skill, such as a sport or a language.
- Make a list of all the things you will do when you achieve your weight goal.
- Listen to relaxing music.

Slide 21

Coping Strategies

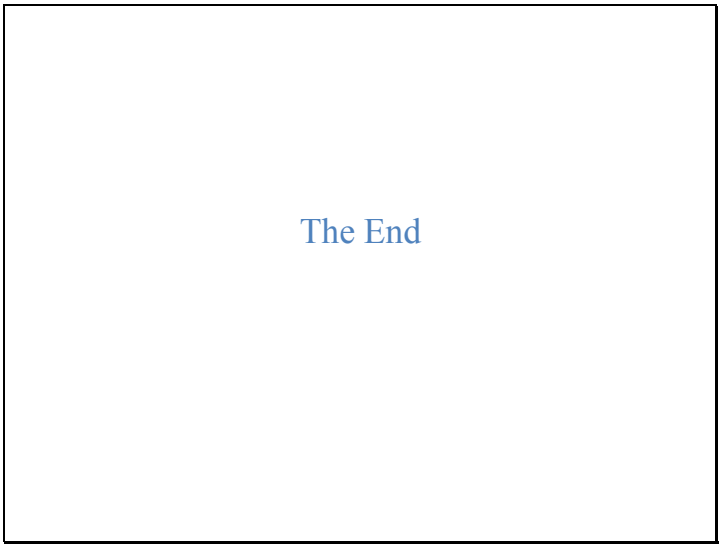
- Use positive and motivating self-talk, give yourself a pep talk.
- Take a hot bath.
- Do some research on your home town and do some tourist activities.
- Practice deep breathing exercises.

Slide 22

Coping Strategies

- Close your eyes for a few minutes and visualize a safe, relaxing place.
- Schedule time for yourself so you do not feel rushed.
- Simplify your life whenever and wherever possible.
- Remember: It may take months or even years to replace food with an acceptable alternative. If you can overcome the crutch of food dependency, you will succeed.

Slide 23



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SESSION 4 QUIZ: DATE:_ _/ _ _/ _ _

QUESTION 1: TRUE or FALSE?
The key to gaining control over emotional eating is all in our mind.

1) True
2) False

QUESTION 2: TRUE or FALSE?
Bariatric surgery does not give you willpower during stressful times. The surgery only keeps you from being hungry for a few months. It does nothing to stop emotional food cravings.

1) True
2) False

QUESTION 3:
Which one is a good strategy to deal with stress and anxiety without food?

1) Spend time in a social activity not related to food.
2) Meditate or exercise.
3) Use progressive muscle relaxation tapes.
4) Write down your thoughts in a journal or diary.
5) Use the computer.
6) Get involved in a hobby or craft.
7) All of the above

SESSION 5: SELF TALK*

Slide 1

THE EMOTIONAL SUPPORT INTERVENTION:

SELF-TALK
Session 5

Slide 2

Objectives

- Differentiate between positive and negative self-talk
- Explain how self-talk influences motivation to exercise, or adhere to bariatric diet
- List positive motivating phrases that can be used to increase motivation
- Use the thought stopping technique to stop negative, self-defeating thoughts
- Construct a motivating visual of your goal weight

2

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Slide 3

What is Self-Talk?

- A very important key to success following bariatric surgery is your ability to control your own self-talk.
- The concept of self- talk is what goes on inside your head automatically when trying to adjust to lifestyle changes overcoming recreational and emotional eating.

3

Slide 4

What is Self-Talk?

- What you say to yourself will either put you in control of your life or give you a passive role in your own health.
- Controlling your self-talk is key to dietary and exercise adherence after surgery.

4

Slide 5

When Using Self-Talk?

- We can use self-talk in many different contexts, such as to increase motivation to exercise, to control emotional eating, for long-term maintenance, etcetera
- Self-talk determines if you will eat the cheeseburger or say NO and have a chicken breast.

Slide 6

When Using Self-Talk?

- Self-talk determines if you skip your workout or go outside and walk for 30 minutes.
- Self-talk determines if you eat cookies because you are depressed or pick up the phone and call a friend instead.

6

Slide 7

Self-Talk

- Self-talk plays a large part in life after bariatric surgery, and for many, it can ultimately determine success or failure.
- Most people are unaware of the conversation that goes on inside their own heads all day, being unaware of the great effect it has on how they feel and act.
- In order to control your self-talk, you must first become aware of its existence.

7

Slide 8

Activity

- Try saying something positive to yourself, and you will find that you instantly feel better than when you say something negative to yourself. For example, say, "this is going to be a good day." You will feel better than if you say, "here comes another terrible day."
- This internal dialogue takes place constantly, but most of us are not aware of it.

8

Slide 9

Activity

- Think back to when you learned a new skill, such as using a computer, riding a bicycle, or playing a sport.
- If you said to yourself "this is fun, I know I can do it" chances are that you did it.
- If you said to yourself " I will never be able to do this," chances are that you will have difficulty.

9

Slide 10

Self-Talk and Diet

- Everyone has self-talk and can learn to control it. It is just a matter of learning to recognize it.
- The messages you give yourself every day will have an impact on your ability to succeed in weight loss after surgery.
- When it comes to diets, self-talk can determine success or failure.

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Slide 11

Self-Talk and Diet

- People start diets full of hope and motivation, but often that determination disappears by the third or fourth day.
- The reason is usually self-defeating self-talk:
- How many times have you been on a diet and said to yourself: "I deserve a treat. I have been good all day"; "I just will eat a little bit less tomorrow to make up for it", or" it is a special occasion, I will just have a little bit of the cake".
- The next day you find that your motivation has greatly decreased, and you may cheat again. By the following day you are off the diet completely.

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Slide 12

Self-Talk and Diet

- If this same person had said to himself/herself, "I don't need that treat because this diet is about my feeling better and looking better" or "if I exercise for 45 minutes today, then I can have that treat", she might not have cheat.

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Slide 13

Why Self-Talk is Important?

- Our minds actually send us messages that give us long lists of really good reasons to stop dieting and exercising.
- This is why self-talk is important. When it is time for workout, our minds will begin to go through a list of possible reasons that allow us to skip that workout.
- Almost everyone's mind works in this way.

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Slide 14

Excuses

- Call them "excuses" because that is the purpose they serve. Many times, the excuses may be true. The gym may be very expensive, and it may be very cold outside.
- They are called excuses because we do not find a way around them. We do not exercise inside if it is cold. We let the excuses stop us from exercising.

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Slide 15

Excuses

- Your challenge as a bariatric patient is to learn to ignore the excuses by overriding them through positive self-talk and behavioral strategies.
- Those who successfully lose the weight and keep it off are the ones that learn to recognize the excuses and decide to ignore them.
- Use the power of your mind to tip the scales in your favor. You can make the excuses ineffective.

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Slide 16

To Do:

- Make your long-term goals part of your own self-talk.
- If your choice is between eating the treat or not, you will probably end up eating it. But if your choice is between eating the treat and working toward good health and you say to yourself, "I am working toward a healthier life, and I already feel better," you will have a better chance of saying NO to the treat.

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Slide 17

Remember how it works

- Positive self-talk creates positive feelings which lead to positive behavior.
- Negative self-talk creates negative feelings which lead to negative behavior.

17

Slide 18

Cheating to yourself

- You can increase your control over eating and exercise if your self-talk motivates you and increases your determination.
- Example: you are at the grocery store. Listen to your self-talk: "I know I am on a diet, but that doesn't mean my kids, spouse, or wife should be deprived of their favorite cookies."
- This is one of many good excuses for bringing inappropriate foods into the home and is the first step of cheating. We know that being on a diet is no fun and quickly becomes boring.

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Slide 19

Stick to Your Diet

- We miss eating what we like and we look for excuses to break our diets.
- Remember that sticking to the prescribed diet after surgery is much like sticking to any other diet, and you will encounter the same temptation, negative self- talk, and excuses that you had in the past.
- Our excuses may be very clever. If you find your self skipping work-outs or eating the wrong foods, ask yourself why. Is this an excuse? What am I really doing? What are the consequences of that?

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Slide 20

Activity: Your Own Self-Talk

Slide 21

Activity: your own self-talk

- Spend several days tuning into your own self-talk.
- Become aware of the rationalizations and justifications you give yourself to eat something that is not on your diet.
- Then decide that you will not listen to this talk and that you intend to be successful.

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Slide 22

Motivate Yourself

- Make a list of positive phrases you can say to motivate yourself.
- Every day will bring many opportunities to cheat on your diet, and having a few positive thoughts will help you succeed. (e.g. "food in not my friend, I have power over food, I am feeling better than I have in years")
- Use your new positive self-talk when in stressful eating situations. Keep the phrases that work and discard those that don't.

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Slide 23

Expect some anxiety

- Expect to experience heightened anxiety when choosing not to eat in these eating situations.
- Remember that anxiety is only a feeling. It will go away. Use your self-talk.
- If anxiety is a problem, use a deep breathing technique. Take five slow, deep breaths, and remind yourself why you had bariatric surgery.

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Slide 24

Use the Thought-Stopping Technique (TST)

- This is a strategy for stopping a negative or self-defeating thought in its track. Do two things:
  - Picture a large, red stop sign in your mind
  - Say stop to yourself

- It will help you clear your mind and replace the thought with one that will assist you in meeting your goals.
- An alternative to the stop sign is to wear a rubber band around your wrist, and snap it gently when you find your thoughts are out of control.

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Slide 25

Change your negative self-talk

- Replace negative self-talk (excuses) with realistic self-talk. E.g." I am miserable without my favorite food. Maybe I should not have had the surgery."
- A more realistic and positive self-talk would be, "I am progressing daily, I can walk two miles now, and I could not walk out the door three months ago. I am feeling good and that is what matters. I can do this."

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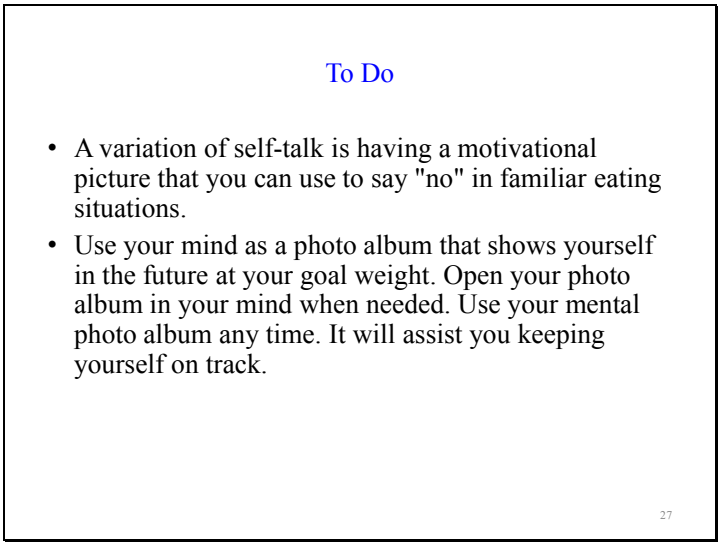
Slide 26

To Do

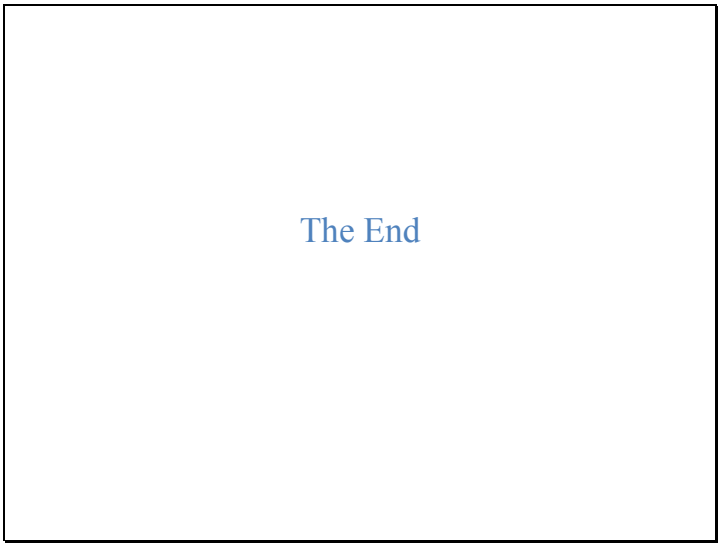
- Tune into your self-talk
- Recognize excuses
- Use the thought-stopping technique
- Override excuses
- Replace excuses with realistic self-talk

26

Slide 27



Slide 28



SESSION 5 QUIZ: DATE:_ _/ _ _/ _ _

QUESTION 1: A very important key to success following bariatric surgery is your ability to control your own self-talk.
1) True.
2) False.

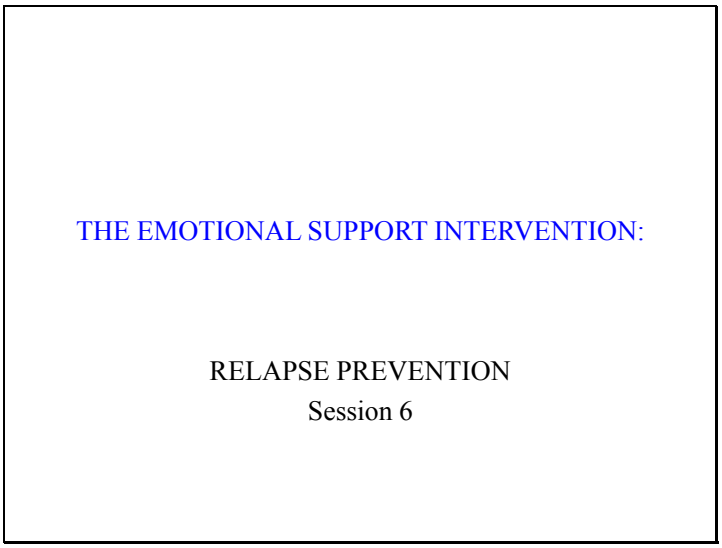
QUESTION 2:
Check the phrases that represent negative, self-defeating thoughts, or excuses for dieting:

1) "I know I am on a diet, but that doesn't mean my kids should be deprived of their favorite cookies."
2) “I deserve a treat. I have been good all day".
3) "I just will eat a little bit less tomorrow to make up for it"
4) “Today, it is a special occasion; I will just have a little bit of the cake".
5) All of the above.

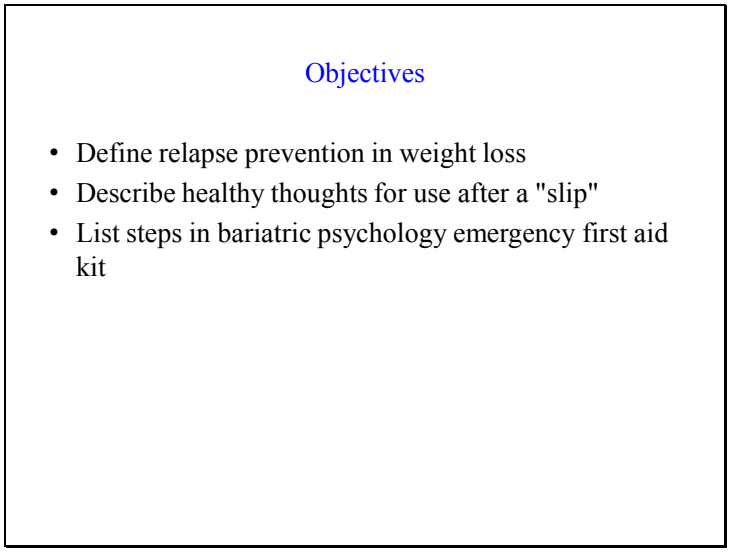
QUESTION 3: Fill the blanks:
These are strategies for stopping a negative or self-defeating thought in its track: Picture a large, red_____ sign in your mind and say _____to yourself.

SESSION 6: RELAPSE PREVENTION*

Slide 1



Slide 2



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Slide 3

All-or-Nothing Thinking

- Human Beings have a tendency to try to be perfect, and if we are not, then we just go back to our old habits.
- In psychology, this is called “ALL-or-NOTHING thinking". It just means we either watch our diets perfectly, or we do not watch at all.

Slide 4

All-or-Nothing Thinking

- An important key to long-term weight maintenance is learning relapse prevention techniques.
- These allow you to stay on your diet even though you may have eaten something you regret.
- Those techniques teach you to ignore "all-or-nothing thinking".

Slide 5

To Do

- Realize no one is perfect. You are not a robot. Do not expect to be 100 % adherent with your bariatric diet.
- When you do "slip", you then have a choice. You can either, revert to the old eating patterns of the past and eventually begin to gain weight, or learn from the "slip". Ask yourself some questions: Why did it happen? What can I learn from it so I will not make this mistake in the future?

Slide 6

To Do

- Stop the thoughts that say, "I already blew it, I will start again next Monday." Replace that thinking with, "I only ate one piece of candy. It was 300 calories. I will not let this ruin all my progress. I am in charge."
- Use positive self-talking to your advantage. It is easier to stop yourself after one or two slips than after letting go for weeks or months.

Slide 7

To Do

- Recognize that there is no end to a lifestyle change. It will go on forever.
- Focus on the big picture. In any lifestyle change, there is a general trend toward success, but there are hundreds of daily and weekly ups and downs. Do not focus on the tiny ups and downs; focus rather on the big picture.

Slide 8

To Do

- Try a new mindset. Change your thinking from "if this does not work, I' will just go back to my old habits", to "no matter what happens I will get back on the horse. I will be successful, and not let small slips keep me from my goal of lifelong good health and excellent quality of life".
- Remember: lifestyle changes never end.

Slide 9

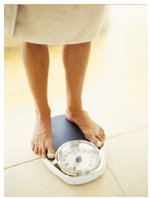
Emergency First Aid Kit

- There will be times when you completely fall off the wagon.
- You slip into your old, comfortable eating pattern and stop exercising. Perhaps it will be a family crisis, relocation, or major change in your job.
- When this happens, it is time to go back to the basics of your emergency first aid kit:

Slide 10

Emergency First Aid Kit

- Scrutinize your environment for obstacles, and take all trigger foods out of the house.
- Commit to monitoring yourself until you feel confident:
  - Weight yourself weekly
  - Start a new food log
  - Start a new exercise log
- Exercise immediately to reestablish the habit.
- Set up rewards for exercise.



Slide 11

Emergency First Aid Kit

- Shop for healthy food and snacks.
- Use positive self-talk. Remember where you started.
- Look at your habits and obstacles to success. Rearrange and prioritize.
- Contact a local bariatric program for support groups and attend several meetings.

Slide 12

Emergency First Aid Kit

- Remember: Almost everyone will experience these episodes. Your choice is always to continue down that path

- or to use your emergency first aid kit.

Slide 13

NO QUIZ TODAY!!!

APPENDIX 11: PERMISSION FOR REPRODUCTION

September 4, 2007

Ms. Monica Petasne-Nijamkin
590 Pigeon Plum Way
Weston, FL 33327

Dear Ms. Petasne-Nijamkin:

This letter serves as permission for you to utilize portions of "The Emotional First Aid Kit: A Practical Guide to Life After Bariatric Surgery," in your dissertation research project, provided proper credit is given to the original source, as such:

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Thank you for your interest in our book. Feel free to contact me with questions.

Best regards,

Elizabeth A. Klumpp

Elizabeth A. Klumpp
Executive Editor
eklumpp@matrixmedcom.com

APPENDIX 12: EVALUATION SATISFACTION SURVEY

SESSION #:_____

1. Did you find the lecture material helpful?
   1) Yes
   2) No

2. How difficult did you find this session?
   1) Very difficult
   2) Somewhat difficult
   3) Not difficult

3. Overall, how would you rate the lecture?
   1) Excellent
   2) Good
   3) Fair
   4) Poor

4. After taking this session, how educated do you feel you are on the content of this lecture?
   1) Very educated
   2) Somewhat educated
   3) Not educated

5. Please, add any comments you have on this session:

APPENDIX 13

Table 19. Evidence-Based Rating of Some Articles Used in Literature Review

Article 1

Author, year	Knowler WC, 2002
Study design and rate	Class A RCT +
Sample size and characteristics	*N*= 3234 non-diabetic people with elevated fasting and post-load plasma glucose concentrations.
Intervention	Participants were randomly assigned to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 % weight loss and at least 150 minutes of physical activity per week. The curriculum, taught by case managers on a one-to-one basis during the first 24 weeks after enrollment, was flexible, culturally sensitive, and individualized. Subsequent individual sessions (usually monthly) and group sessions with the case managers were designed to reinforce the behavioral changes. The participants were followed for an average of 2.8 years.
Outcomes	The lifestyle intervention reduced the incidence of increased plasma glucose by 58 % and metformin by 31%, as compared to placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle intervention program, and 13.9 would have to receive metformin.
Limitations	The study was not designed to test the relative contributions of dietary changes. Increased physical activity and weight loss on the reduction of the risk of diabetes remain to be determined.

Article 2

Author, year	Whittemore R, 2009
Study design and rate	Class A RCT +
Sample size and characteristics	N= 58 Obese, moderately low-income participants.
Intervention	Given by nurse practitioners. Length of program: 9.3 months. Attendance: 98%. Attrition: 12.
Outcomes	Significant improvement in both groups for nutrition and exercise behavior. Participants of lifestyle program had better high density

	lipoprotein (HDL) and better exercise behavior compared to enhanced standard care participants. Twenty-five % of lifestyle participants met treatment goals of 5% weight loss compared to 11% of standard care participants. There was a decrease in depressive symptoms over time; however this change was not significant.
Limitations	It was a pilot study focused on the reach, implementation and efficacy of the program. Inadequate power prevents strong conclusions with clinical implications.

Article 3

Author, year	Greaves CJ, 2008
Study design and rate	Class A RCT +
Sample size and characteristics	N= 141with BMI of 28 kg/m2 or more, but without diabetes or heart disease.
Intervention	Motivational interviewing for modifying diabetes risk. Intervention was delivered by 5 counselors recruited from the local community. The primary outcomes were proportion of participants meeting 5% weight loss and moderate physical activity (150 minutes/week) after 6 months.
Outcomes	Using intention-to-treat analysis, 24% of people in intervention group achieved the weight-loss target of 5% reduction compared to only 7% for controls. The proportion achieving the physical activity target did not increase significantly (38% versus 28% for controls). Short-term weight loss, at a level that was clinically meaningful for reducing diabetes risk, was achievable in primary care, without excessive use of NHS monetary or personnel resources.
Limitations	Insufficient power to detect the smaller than expected changes in proportions achieving the physical activity target. Low response rate for physical activity questionnaires. Self-report of physical activity has low sensitivity and limited validity (a tendency for over-estimation and low-to-moderate correlations with objective measures). Generalization of results may be limited by the self-selecting nature of the sample (around 57% agreed to take part). Limited representation of ethnic minority groups.

Article 4

Author, year	Edelman D, 2006

Study design and rate	Class A RCT +
Sample size and characteristics	N= 154 outpatients age 45 or over, with 1 or more known cardiovascular risk factors.
Intervention	Intervention delivered at a University Center for Integrative Medicine. Intervention delivered by a health coach and a medical provider. Techniques used in implementation included mindfulness meditation, relaxation training, stress management, motivational techniques, and health education. Subjects randomized to the comparison group received usual care without access to the intervention. Primary outcome measure was 10-year risk of CHD, as measured by a standard Framingham risk score, and assessed at baseline, 5, and 10 months.
Outcomes	Baseline 10-year risk of CHD was 11.1% for subjects randomized to intervention (n=77), and 9.3% for subjects randomized to comparison (n=77). Over 10 months of the intervention, CHD risk decreased to 9.8% for intervention subjects and 7.8% for comparison subjects. There was a statistically significant difference in the rate of risk improvement between the groups (P=.04). Subjects in the intervention were found to have increased number of days of exercise per week compared with controls (3.7 vs 2.4, P=.002), and subjects who were overweight on entry into the study had greater weight loss in the intervention group compared with comparison (P=.06).
Limitations	Subjects were predominantly female, educated, and had family incomes well above median. Difficulty to translate the results to a more heterogeneous population. Inadequate statistical power to measure clinically relevant effects on individual risk factors. Limited time frame of follow-up did not permit to draw inference about the sustainability of this intervention beyond the year in which subjects were studied, and were part of the intervention.

Article 5

Author, year	Ma J, 2009
Study design and rate	Class A RCT +
Sample size and characteristics	N= 240 overweight or obese adults with pre-diabetes and/or metabolic syndrome recruited from a community-based primary care clinic.

Intervention	This is a study protocol of a randomized-controlled trial that aims to evaluate lifestyle interventions to treat elevated cardiometabolic risk in primary care (E-LITE). Participants will be randomly assigned to one of three treatment conditions. Treatment will last 15 months and will involve a three-month intensive treatment phase followed by a 12-month maintenance phase. Follow-up assessment occurs at three, six, and 15 months. Two lifestyle interventions: information technology-assisted self-management, either alone or in combination with care management by a dietitian and an exercise counselor, in comparison to usual care.
Outcomes	Primary outcome is change in BMI. Secondary outcomes include glycemic control, additional cardiovascular risk factors, and health-related quality of life. Potential mediators (e.g., treatment adherence, caloric intake, physical activity level) and moderators (e.g., age, gender, race/ethnicity, baseline mental status) of the intervention's effect on weight change will be also examined. Study will provide evidence on the extent of reductions in BMI and related cardiometabolic risk factors from two lifestyle intervention programs of varying intensity that could be implemented as part of routine health care.
Limitations	Results are not provided since this is a description of the study protocol that will be conducted in a community-based primary care clinic. The study participants will be those who are willing to comply with the study protocol and might not be a representative sample from the general population (selection bias). Participants will be randomly assigned to one of the three treatment conditions; however, the blind method will not be applied. As a consequence, research outcomes might be influenced by either the placebo effect or the observer bias.

Article 6

Author, year	Lombard CB, 2009
Study design and rate	Class A RCT +
Sample size and characteristics	N= 250 mothers of young children (BMI 27.9 kg/m2 ± 5.6) recruited from the community in Melbourne, Australia.

Intervention	Intervention group (n = 127) attended four interactive group sessions over 4 months, held in 12 local primary schools in 2006, and was compared to a group (n = 123) receiving a single, non-interactive, health education session. Study evaluated the short term effect of a community-based self-management intervention to prevent weight gain. Data collection included self-reported weight (both groups), measured weight (intervention only), self-efficacy, dietary intake and physical activity.
Outcomes	More intervention women reported weight loss or maintenance than in the comparison group. Both intervention and comparison groups decreased weight, -0.75 kg (95% CI; -1.57 to 0.07, p = 0.07) and -0.72 kg (95% CI; -1.59 to 0.14 p = 0.10) respectively with no significant difference between groups (-0.03 kg, 95% CI; -1.32 to 1.26, p = 0.95). More women lost or maintained weight in the intervention group. Intervention group had the greatest effect in those who were overweight at baseline and in those who weighed themselves regularly. Intervention women who rarely self-weighed gained weight (+0.07 kg) and regular self-weighters lost weight (-1.66 kg) a difference of -1.73 kg (95% CI; -3.35 to -0.11 p = 0.04). Intervention reported increased physical activity although the difference between groups did not reach significance. Both groups reported replacing high fat foods with low fat alternatives and self-efficacy deteriorated in the comparison group only.
Limitations	Not able to show significant difference between groups in weight change and some specific lifestyle behaviors (may reflect the inadequacy of the self-report questionnaires to detect small changes). Cannot eliminate the possibility that self-reported improvements in diet and physical activity may be result of positive response bias. Study was powered to detect a 600 g difference between groups in the long term, and not adequate power to detect small difference observed here at four months.

Article 7

Author, year	Rubak S, 2005
Study design and rate	Class M + systematic review and meta-analysis of RCTs.
Sample size and characteristics	N= 72 randomized controlled trials using motivational interviewing as the intervention.
Intervention	Counselors included: psychologists, MD's, nurses and dietitians. MD's obtained an effect from motivational interviewing in 83%

	of the studies, psychologists in 79%, and the rest healthcare providers obtained an effect in 46% of the studies. Intervention targeted alcohol abuse, psychiatric diagnoses, and different aspects of addiction in 47 out of the 72 studies, and motivational interviewing was applied as traditional advice giving in 75% of these studies. Motivational interviewing targeted physiological problems, such as weight loss, lowering of lipid levels, increasing physical activity, diabetes, asthma, and smoking cessation in 25 of 72 studies and had an effect in 72% of them. Studies involving the treatment of diabetes, asthma, and weight-related problems reported an effect in 77%.
Outcomes	Meta-analysis showed a significant effect (95% confidence interval) for motivational interviewing for combined effect estimates for BMI, total blood cholesterol, systolic blood pressure, blood alcohol concentration and standard ethanol content, while combined effect estimates for cigarettes per day and for HbA_{1c} were not significant. Motivational interviewing had a significant and clinically relevant effect in approximately three out of four studies, with an equal effect on physiological (72%) and psychological (75%) diseases. Psychologists and physicians obtained an effect in approximately 80% of the studies, while other healthcare providers obtained an effect in 46% of the studies. When using motivational interviewing in brief encounters of 15 minutes, 64% of the studies showed an effect. More than one encounter with the patient ensures the effectiveness of motivational interviewing.
Limitations	The meta-analysis was only performed on 19 studies (out of 42) that stated objective measures and statistical data needed for the meta-analysis in the article or delivered these data afterwards on request. Of the remaining 23 studies, 17 concluded that there was a significant effect of motivational interviewing and 6 showed a nonsignificant effect. These remaining studies did not deliver the statistical data needed for meta-analysis either in the article or afterwards.

Article 8

Author, year	Tsai AG, 2005
Study design and rate	Class M + systematic review of randomized trials and case-series.
Sample size and characteristics	Randomized trials at least 12 weeks in duration that enrolled only adults and assessed interventions as they are usually provided to the public, or case series that met these criteria, stated the number

	of enrollees, and included a follow-up evaluation that lasted 1 year or longer.
Intervention	Data were extracted on study design, attrition, weight loss, duration of follow-up, and maintenance of weight loss. Studies of eDiets.com, Health Management Resources, Take Off Pounds Sensibly, OPTIFAST, and Weight Watchers were included.
Outcomes	Of 3 randomized, controlled trials of Weight Watchers, the largest reported a loss of 3.2% of initial weight at 2 years. One randomized trial and several case series of medically supervised very-low-calorie diet programs found that patients who completed treatment lost approximately 15% to 25% of initial weight. These programs were associated with high costs, high attrition rates, and a high probability of regaining 50% or more of lost weight in 1 to 2 years. Commercial interventions available over the Internet and organized self-help programs produced minimal weight loss. With the exception of 1 trial of Weight Watchers, the evidence to support the use of the major commercial and self-help weight loss programs is suboptimal.
Limitations	Because many studies did not control for high attrition rates, the reported results were probably a best-case scenario. More controlled trials are needed to assess the efficacy and cost-effectiveness of these interventions.

Article 9

Author, year	West DS, 2007
Study design and rate	Class A RCT +
Sample size and characteristics	N= 217 overweight women (38% African American) with type 2 diabetes treated by oral medications who could walk for exercise.
Intervention	All participants received an 18-month, group-based behavioral obesity treatment and were randomized to individual sessions of motivational interviewing or attention control (total of five sessions) as an adjunct to the weight control program.
Outcomes	Primary outcomes were weight and A1C, assessed at 0, 6, 12, and 18 months. Retention rate was 93%. Women in motivational interviewing lost significantly more weight at 6 months (P = 0.01) and 18 months (P = 0.04). Increased weight losses with motivational interviewing were mediated by enhanced adherence to the behavioral weight control program. African-American

	women lost less weight than whites overall and appeared to have a diminished benefit from e addition of motivational interviewing. Significantly greater A1c reductions were observed in those undergoing motivational interviewing at 6 months (P = 0.02) but not at 18 months.
Limitations	Study did not identify parameters that may be associated with or promote a positive response to motivational interviewing for weight management in ethnically diverse groups, as well as mechanisms responsible for facilitating behavioral change. Study did not include evaluation of motivational interviewing for weight management among men and the non-diabetic population.

Article 10

Author, year	Stanley MA, 2009
Study design and rate	Class A RCT +
Sample size and characteristics	N= 134 older adults with anxiety disorder recruited in two primary care settings.
Intervention	Cognitive behavior therapy was provided for 3 months; assessments were conducted at baseline, 3 months, and over 12 months of follow-up, with assessments at 6, 9, 12, and 15 months. Treatment included education and awareness, motivational interviewing, relaxation training, cognitive therapy, exposure, problem-solving skills training, and behavioral sleep management.
Outcomes	Primary outcomes included worry severity (WS) and generalized anxiety disorder severity (GADS). Secondary outcomes included anxiety ratings, coexistent depressive symptoms, and physical/mental health quality of life. Cognitive behavior therapy compared with enhanced usual care significantly improved WS (45.6 [95% CI, 43.4-47.8] vs. 54.4 [95% CI, 51.4-57.3], respectively; *P*=.001), depressive symptoms (10.2 [95% CI, 8.5-11.9] vs. 12.8 [95% CI, 10.5-15.1], *P*=.02), and general mental health (49.6 [95% CI, 47.4-51.8] vs. 45.3 [95% CI, 42.6-47.9], *P*=.008). There was no difference in GADS in patients receiving cognitive behavior therapy versus those receiving enhanced usual care (*P*=.19).
Limitations	The sample size seems inadequate to measure differences in cognitive behavior although a trend seems present.

APPENDIX 14

Table 20. Summary of Hypotheses, Data Analysis, and Results

Primary or Main Hypothesis:

Hypothesis 1:

Patients who receive a comprehensive nutrition and lifestyle education intervention will experience greater weight loss from total baseline weight, greater excess weight loss from total baseline excess weight, and greater decrease in BMI without weight loss plateau or weight regain during the period from 6 to 12 months following surgery than those patients in the comparison group who will be provided with printed guidelines for healthy eating and physical activity recommendations at the first assessment visit[29] (Appendix 1).
Data Analysis Paired-samples *t* tests within each group and independent samples *t* tests between groups. Intention-to-treat analysis was applied.
Results Both groups lost weight significantly, but the reduction in weight (Figure 3), body mass index (Figure 4), and excess body weight (Figure 5) between 6 to 12 months following surgery was significantly greater in the intervention group than in the comparison group ($P< .001$). Furthermore, the percentage of excess weight lost (%EWL) over time was significantly greater in the intervention group than in the comparison group ($P<.001$), as shown in Figure 6. From 6 to 12 months after surgery, participants in the intervention group lost 38.21±25.88 lbs. while participants in the comparison group lost 22.11±20.78 lbs. ($P< .001$). BMI change was 6.48± 4.37 kg/m^2 for the intervention group vs. 3.63±3.41 kg/m^2 for the comparison group ($P< .001$). Participants in the intervention group lost approximately 80% of their excess weight at one year following surgery (25% weight reduction from 6 to 12 months after surgery). Participants in the comparison group lost nearly 64% of their excess weight at one year after RYGB (13% weight reduction from 6 to 12 months after surgery).

Secondary Hypotheses:

Hypothesis 2:

Patients in the comprehensive nutrition and lifestyle education group will experience greater improvement of their obesity-related health conditions than those in the comparison group, as measured by improved glycemic control, improved depression, and decreased need of medications for obesity-related comorbidities.
Data Analysis Changes from baseline (6 months) to one year after surgery in obesity-related comorbidities were tested using McNemar's test within groups and Mann-Whitney *U* test or Wilcoxon rank sum between groups. Depression scores and intake of medications for comorbidities were compared using paired-samples *t* tests within each group and independent samples *t* tests between groups.

Results Diabetes mellitus was completely resolved in 89.6% and 86.4% of the intervention and comparison groups, respectively at 12 months after surgery. Only 10.4% of the intervention and 13.6% of the comparison group participants still had diabetes at one year after surgery. There were more patients requiring insulin in the comparison group (9%) than in the intervention group (4.5%) at 12 months after RYGB surgery. Within the intervention group, joint illness, depression, hypertension, sleep apnea, gastroesophageal reflux disease, hypercholesterolemia, hypertriglyceridemia, urinary incontinence, and other diseases (P<.01) were resolved (Table 9). There was no change for diabetes mellitus, insulin requirement, and asthma (P>.05). Within comparison group participants, hypertension, gastroesophageal reflux disease, hypercholesterolemia, hypertriglyceridemia, sleep apnea, and urinary incontinence changes (P<.05) were statistically significant. Between groups, there were significant differences in the resolution of depression (P<.001), joint illness (P<.029), and gastroesophageal reflux disease (P<.036) from 6 to 12 month time points. For those who had depression at 6 month after surgery, 29.9 % of the intervention group participants completely resolved their depression at 12 months following surgery compared to only 6.1 % of the control group participants. For those who had joint illness at 6 months after surgery, 20.9 % of the intervention group participants completely resolved their joint illness at 12 months compared to 7.6 % of the comparison group. For those who had gastroesophageal reflux disease (GERD) at 6 month after surgery, 22.4 % of the intervention group participants completely resolved their GERD at 12 months following surgery compared to 9.1 % of the comparison group participants. Intervention and comparison group participants significantly decreased the number of medications they took over time for obesity-related comorbid conditions (P<.001). Between 6 and 12 months after surgery, the decrease in the number of medications taken for comorbidities for participants in the intervention group was significantly greater than that for participants in the comparison group (P=.003).

Hypothesis 3:

Patients who receive comprehensive nutrition and lifestyle education will report fewer negative nutritional outcomes such as less micro and macronutrient deficiencies than those in the comparison group.
Data Analysis Blood tests abnormalities and other dichotomous data at 6 (baseline) and 12 months (final) assessment points were tested using McNemar's test within groups and Mann-Whitney U test or Wilcoxon rank sum between groups.
Results At 6 month after surgery, the most frequent blood test abnormalities, overall, in descending order were hemoglobin deficiency (12%), hyperglycemia (11%), iron deficiency (10.4%), folate deficiency (4.2%) and vitamin B12 deficiency (3.5%).

Approximately 6% of those who had diabetes had elevated hemoglobin A1C at 6 months. At 12 months after surgery, the most frequent blood test abnormalities, overall, were iron and folate deficiencies (6.1 %, 6.1% respectively), low hemoglobin (5.3%), hyperglycemia (5.3%), and vitamin B12 deficiency (3.1%). Approximately 1.5% of those who had diabetes had elevated hemoglobin A1C at 12 months. There were no significant differences between groups in blood test abnormalities from 6 to 12 months following surgery, except for folate deficiency. Patients who received comprehensive nutrition and lifestyle education intervention reported less folic acid deficiency (1.5%) than those in the comparison group (10.6%) who did not receive the intervention. Of those who had normal levels of folic acid at 6 months, approximately 6% of the comparison group participants had folate deficiency at one year compared to 0% of the intervention group participants (P=.014).

Hypothesis 4:

Patients receiving comprehensive nutrition and lifestyle education will be more actively involved in physical activity than those in the comparison group as measured by greater weekly exercise frequency and intensity.
Data Analysis Changes from baseline (6 months) to 12 months following surgery in physical activity time and energy expenditure (METs) were compared using paired-samples *t* tests within each group and independent samples *t* tests between groups.
Results At 6 months following surgery, approximately 75% and 73% of the intervention and comparison group participants respectively reported doing some type of physical activity. At one year, approximately 82% and 67% of the intervention and comparison group participants respectively stated that they regularly exercise. Walking was reported as the most frequent physical activity over time. The intervention group participants significantly increased their mean time (P=.019) and intensity of exercise (P<.001) from 6 to 12 months after surgery. Comparison group participants did not significantly changed their physical activity behavior from 6 to 12 months after surgery (P>.05). Between groups, there were significant differences in mean intensity and mean time of exercise from baseline to final assessment points (P=.002, P=.023, respectively). The intervention group participants increased the mean intensity of exercise by approximately 9 metabolic equivalents task per hour (MET-h), while comparison group participants slightly increased the intensity by 1.35 MET-h. In addition, intervention group participants increased the mean time of exercise by approximately 14 minutes per week, while comparison group participants decreased the mean time by approximately 4 minutes per week. There was no significant difference between groups in frequency of physical activity in days per week from 6 to 12 months following surgery (P>.05).

Hypothesis 5:

Patients in the comprehensive nutrition and lifestyle education will have better eating habits reflected by fewer episodes of dumping syndrome and binge eating than those in the comparison group.
Data Analysis Changes from baseline (6 months) to one year after surgery in eating behaviors were tested using McNemar's test within groups and Mann-Whitney *U* test or Wilcoxon rank sum between groups.
Results Between groups, there was a significant difference for eating in response to negative emotions from 6 to 12 months following surgery (*P*=.003). Of those who ate in response to negative emotions at 6 months following surgery, approximately 12% of the intervention group participants no longer did so at 12 months compared to only 4.5% of the comparison group. From 6 to 12 months following surgery, there was a significant difference for eating in response to positive emotions between groups, (*P*=.025). Of those who ate for positive emotions at 6 months, approximately 16% of intervention group participants no longer ate in response to positive emotions at one year after surgery compared to 10% of the comparison group. At one year following surgery, intervention group participants significantly decreased their nigh eating behavior (*P*=.031) while comparison group participants did not (*P*>.05). Between groups, there was a significant difference for eating at night avoiding breakfast from 6 to 12 months following surgery (*P*<.01). Of those who ate at night avoiding breakfast at 6 months, approximately 9% of intervention group participants no longer did at one year after surgery compared to only 1.5% of the comparison group. At one year, intervention group participants significantly decreased their eating behavior in response to environmental cues (*P*=.008) while comparison group participants did not (*P*>.05). Between groups, there was a significant difference for eating in response to environmental cues from 6 to 12 months following surgery (*P*=.008). Of those who ate in response to environmental cues at 6 months, approximately 12% of intervention group participants no longer ate in response to environmental cues at one year after surgery compared to only 3% of the comparison group. At 12 months following surgery, approximately 1.5% and 1.5% of the intervention and comparison group participants respectively reported unrestrained or binge eating (*P*=.305).

VITA

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