IMPACT OF A WELLNESS COACHING PROGRAM ON BARIATRIC SURGERY CANDIDATES FOLLOWING WEIGHT LOSS

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Effect of Method of Weight Loss on Health Behaviors and Quality of Life

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ABSTRACT

A lifestyle approach toward weight loss, encompassing behavior modification strategies, education, and new coping skills may be most effective in adoption of the healthy behaviors necessary for achievement and maintenance of successful weight loss. Limited research exists on the effectiveness of pre-surgery wellness programs on post-surgical health behaviors for bariatric surgery candidates. The purpose of this study was to determine the impact of a pre-bariatric surgery wellness coaching program on health behaviors, quality of life (HRQoL), and psychosocial factors.

A questionnaire containing measures of weight (self-report), dietary and physical activity (PA) (7-day IPAQ-short) behaviors, exercise motivation (BREQ-2), HRQoL (SF-12v2), and open-ended questions evaluating the wellness program, was sent out to all participants who engaged in a 12-week weight loss wellness coaching program and all bariatric surgery patients from 2009-2012 (n=782). From the 118 returned surveys (15.0%), participants (age = 51.46 years ± 12.98, BMI = 30.31 ± 7.70) were placed in either the wellness-coaching only group (n=16), surgery-only group (n=58), or surgery plus wellness coaching group (n=44) based on whether they participated in, and completed, the 12-week program and/or surgery. The wellness-coaching only group was excluded for the first set of analysis where weight loss, PA, dietary factors, exercise motivation and HRQoL were analyzed between a control (surgery only) group and intervention (surgery + wellness coaching) group. Compared to controls, participants in the wellness-coaching group had significantly more weekly vigorous PA, total minutes of MVPA, and total weekly PA. Significant differences were also found for two measures of exercise motivation and vitality scores.

The second set of analysis excluded the surgery only group to analyze the impact of the wellness coaching program. Results indicate favorable results for health behaviors. A qualitative analysis found positive results for several psychosocial factors, motivation, and new skills learned. A comprehensive, wellness approach encompassing evidence based strategies toward weight loss had positive results towards health related behaviors and emotional and social well-being. Additionally, participants reported responses consistent with continued engagement in health behaviors and weight loss maintenance.

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DEDICATION

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CHAPTER I: INTRODUCTION

As obesity rates continue to rise and remain an epidemic in the United Sates, bariatric surgery has become an increasingly common recommended treatment option for obesity and associated health problems for clinically severe obese individuals (National Institute of Health, 2012). Data from the latest National Health and Nutrition Examination Survey (NHANES, 2009-2010) indicate more than one-third (35.7%) of U.S. adults are obese, constituting more than 78 million American men and women (Ogden, Carroll, Kit, & Flegal, 2012). Approximately five percent of this subpopulation (about four million Americans) is determined to be morbidly, or clinically severe, obese. Clinically severe obesity is defined as a body mass index (BMI) of > 40 or a BMI > 35 with a serious health problem, such as type two diabetes, heart disease, or severe sleep apnea linked to obesity (National Institute of Health, 2012). Individuals who are considered morbidly, or clinically severely, obese are potential candidates for bariatric surgery. Individuals elect to undergo bariatric surgery to achieve long-term weight loss and to improve obesity-related comorbid conditions. It has been established bariatric surgery is a safe and effective, and often recommended weight loss treatment option for the morbidly obese (The National Heart, Lung, and Blood Institute, 2012). Although lifestyle and behavior modifications seem to be most effective for modest weight loss, bariatric surgery appears to be a more effective treatment for excessive weight loss (EWL) in the severe obese and obesity related comorbidities. However, questions still arise on long-term success and its effect on weight loss maintenance and prevention of the return of lifestyle diseases. It has been suggested that perhaps the combination of lifestyle and behavior modification with bariatric surgery may be most effective for long-term

success. Lifestyle modification includes substantial changes in both eating behavior and physical activity levels.

Strategies have emerged to counter the increasing rates of obesity. At the population level, strategies include social marketing campaigns, environmental changes to encourage increased physical activity, and regulations, such as bans on sugar-sweetened beverages. At the individual level, strategies range from books and television shows on exercise and diet to surgery. Bariatric surgery has become a popular method of treating obesity; gastric bypass surgery has emerged as the most widely used of these surgical procedures (American Society for Metabolic and Bariatric Surgery, 2012).

Types of Procedures

There are many types of procedures that fall under the category of bariatric surgery. One of the most common forms of bariatric surgery is gastric bypass surgery, where the basic goal is to reduce stomach size so that the user will not be able to gain weight as easily. Gastric bypass surgery reduces the size of your stomach and allows food to bypass a large part of your stomach and part of the small intestine. The small stomach means the patient will feel full more quickly, thus reducing the amount of food eaten. Bypassing a section of the small intestine allows absorption of fewer calories as well, which also aids weight loss (Sandford Health, 2012). These types are diversionary in nature and include jejunioleal bypass (JB), mini-gastric bypass (MGB), and biliopancreatic diversion (BPD). The safety of this type of surgery has made it a very popular option among these various different forms of surgery.

Another category includes those that are restrictive in nature, such as sleeve gastrectomy (SG) horizontal gastroplasty (HBG), vertical banded gastroplasty (VBG), and adjustable gastric

banding (AGB). Sleeve Gastrectomy involves removing the majority of the stomach which reduces the size of the portion of the stomach that remains which allows for less consumption and feeling full on a smaller portion while food passes through on its normal route. Adjustable gastric banding, which constitutes the LAP-BAND® involves placing an adjustable silicone band around the top portion of the stomach, which limits the amount of food the stomach can hold, thus contributing to eating less and feeling full on a smaller portion (Sanford Health, 2012). A combination/hybrid of a diversionary and restrictive procedure is called Roux-en-Y gastric bypass (RYGB), which is the most common form of gastric bypass surgery (American Society for Bariatric Surgery, 2012).

Four of these types of operations are commonly offered in the United States: AGB, Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with a duodenal switch (BPD-DS), and vertical sleeve gastrectomy (VSG). RYBG is the most commonly performed operation for weight loss in the United States, with approximately 140,000 gastric bypass procedures being performed in 2005, far outnumbering the LAP-BAND®, duodenal switch, and vertical banded gastroplasty procedures (American Society for Bariatric Surgery, 2012).

Trends of Bariatric Surgery

The increased popularity of bariatric surgery among patients and health care professionals is due to several factors, including improved surgical techniques, reduction in the postoperative mortality rate, substantial improvement in obesity-related comorbid conditions, and increased media attention and profitability (Kushner & Nobel, 2006). Data from 1996 to 2007 from the New Hampshire Inpatient Hospital Discharge data report annual rate of gastric bypass surgery increased significantly from 3.3 to 22.4 per 100,000 adults between 1996 and

2007; the in-hospital death rate decreased significantly from 11% in 1996 to 1% in 2007; and a greater proportion of women (78.1% during the study period) than men had this surgery. (Cherala, 2012). In 2008, nearly 350,000 procedures were performed globally (Buchwald & Oien, 2009). However, the most recent data comparing the five-year trend from 2003 to 2008 indicate an absolute growth rate of bariatric surgery decreased over the past five years in comparison to the preceding five years; 135% increase down from a 266% increase. Bariatric surgery continues to grow worldwide, but less so than in the past (Buchard & Oien, 2009).

Successful Weight Loss

In order to discuss successful weight loss, it is important to first define what is meant by successful weight loss. The majority of the literature uses a weight loss of 5-10% of body weight. Weight losses of this amount can lead to substantial improvement in risk factors associated with heart disease and diabetes (Wing & Hill, 2001). This amount has also been determined to be "significant" when conducting research regarding weight loss. Many factors have been evaluated for successful weight loss and the National Weight Control Registry is often a source for information on successful weight loss. The National Weight Control Registry (NWCR) is the largest prospective investigation of long-term successful weight loss maintenance (The National Weight Control Registry, 2012). The NWCR is tracking over 10,000 individuals who have lost significant amounts of weight and kept it off for long periods of time. Detailed questionnaires and annual follow-up surveys are used to examine the behavioral and psychological characteristics of the members of the NWCR, as well as the strategies they use to maintain their weight losses. In general, the most common successful strategies and behavioral factors that have been identified to predict long-term success of weight loss maintenance, were eating a diet low in

fat and high in carbohydrates, frequent self-monitoring of their weight and behavior related to weight (e.g. food intake), and regular physical activity, with the most frequent form being walking (Wing & Hill, 2001).

Wellness and Wellness Coaching

Health and wellness are often terms that are used interchangeably and have had various definitions. The World Health Organization (WHO) defines health as a "state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (Edlin & Golanty, 2012, p. 4). The term wellness follows a similar definition and is often used to describe a point among a continuum from premature death as a result of disease or disability, to pursuing a high level of wellness due to awareness, education and personal growth. Both terms refer to a dynamic process rather than a state of being and involve one's everyday decisions that affect one's health. What foods to consume, how much physical activity to engage in, and whether to wear a seat belt or not are examples of these decisions. The wellness approach to health is a more holistic and multidimensional model compared to other approaches such as a medical or environmental models. Wellness typically involves five to nine dimensions, each interacting with each other to contribute to the overall health and quality of life of an individual. These dimensions include physical, emotional, social, spiritual, environmental, intellectual, occupational, financial, and aesthetic. A wellness approach emphasizes the integration of the individual dimensions as a way to address a certain health issue. This approach attempts to discover the underlying cause or source of the problem as well as potential barriers of various solutions.

Wellness coaches are educated professionals who have adopted the wellness approach toward health and well-being. Wellness coaching is becoming a popular strategy for people wishing to make improvement in their lives. Individuals may seek a wellness coach to help with stress management, improve general fitness, provide interventions for an illness or reduce risk of developing illness or disease, improve overall well-being, or achieve various life or health-related goals. Wellness coaching use an interdisciplinary approach, focusing on helping clients who are well to stay well and helping others, not only to recover from illness, but to focus on wellness and improving themselves overall. The role of the coach is to help the individual identify personal reasons for pursuing greater wellness, and to enhance motivation for behavior change using evidence-based strategies (Mayo School of Health Science, 2012). Wellness Coaches are experts in establishing relationships and practicing core-coaching skills that assist the individual in identifying values and desires, transforming them into action, and maintaining lasting change over time. Wellness coaching programs have been implemented as worksite wellness programs, weight loss programs in clinics and hospitals, and as fitness programs in sports or fitness facilities. Many Wellness Coaches work as independent consultants and have a private office. Other Wellness Coaches work within sports or fitness facilities and offer on-site coaching, as well as health-related wellness seminars to members. Opportunities exist for Wellness Coaches to provide care as part of the interdisciplinary team in clinics and hospitals (Mayo School of Health Sciences, 2012).

Since it is believed that obesity is a chronic disease that affects all areas of life, causing both medical and psychological morbidity, and has multiple causes such as genetics, social factors, environmental factors, and psychological issues (Ensberger & Koletsky, 1999), it is

feasible that a wellness approach may be effective in treating such a disease. A wellness approach toward obesity recognizes the whole person and treats the disease with a multidisciplinary approach. Obese patients often lack full access to medical services owing in part to social stigma and low self-esteem, which impair self-care activities, and the bias of health professionals (Ensberger & Koletsky, 1999). As opposed to treating the symptoms of obesity and focusing on the body weight itself, a wellness approach focuses on addressing the behaviors causing obesity, the barriers toward behavior change, a healthy lifestyle, and a positive attitude to health and self-care, thus improving the physical and mental well-being of obese patients.

Problems Stated and Purpose of Study

Research on bariatric surgery is extensive, with the primary focus on the health-related outcomes. Limited research exists examining lifestyle and behavior change following bariatric surgery. Additionally, very limited research exists on the effects of a pre-surgery weight loss and behavior change program on behavior change. Some participants may opt out of surgery after finding success in a pre-surgery program. Since bariatric surgery is a costly weight loss method, finding successful alternatives offering comprehensive, evidence-based strategies, warrants examination. Additionally, many weight loss interventions for severe obese individuals involve strategies that may be difficult to maintain, such as prepackaged, home-delivered meals and very low calorie diets.

Although wellness coaching has become a popular strategy for improving health, many programs have not been substantially evaluated for their effectiveness. Many programs are "feel good" programs, and/or may satisfy a wellness requirement for employers for health insurance purposes, but outcomes of many programs have not been evaluated. The limited research on the

effectiveness of wellness coaching mainly involves worksite wellness programs, with no data to date on the effect of wellness coaching on bariatric surgery candidates.

Therefore the purpose of the study is to evaluate the impact of a weight loss wellness coaching program, in a regional clinic, on health related outcomes and behaviors and quality of life in bariatric surgery candidates. A secondary purpose is to determine differences among participants of a weight loss coaching program in health related behaviors, health outcomes, quality of life and exercise motivations in those who elected to participate in bariatric surgery and those who did not.

Significance of the Study

This study is significant since limited published research exists examining health behaviors following bariatric surgery. The majority of the research examines the actual health outcomes following weight loss such as amount of weight loss and regain, improvement of comorbidities associated with weight loss, and health-related quality of life. This study will examine if participants are engaging in behavior change as related to weight management, overall health, and quality of life. Additionally, since bariatric surgery is a costly method of weight loss and may come with its own health risks and complications, this study examines a possible alternative method to weight loss to determine its effectiveness on weight loss and maintenance, its impact on behavior change and its impact on quality of life. Lastly, wellness coaching programs are becoming increasingly popular for addressing various health behaviors such as stress management, weight loss, and disease management. However, very limited research exists on evaluating the effectiveness and impact of such programs. To date, no study exists objectively evaluating a weight loss wellness program for its effectiveness in a regional

health facility. Therefore, this study is also significant in that it will evaluate such a program providing valuable information to the coaching staff of the program and administration of the facility in which the program exists. This study will also contribute evidence for creating new effective wellness weight loss programs and evaluating and modifying existing wellness programs pertaining to weight loss.

Limitations

Limitations of this study include self-reported measures of weight, physical activity (PA) and nutritional behaviors and adherence, which may not be as accurate as other objective measures, particularly in the bariatric population. Additional limitations include small return rate of surveys, no baseline data to compare pre- and post- measures, and generalizability of the results, as this sample was taken from a Midwestern community with little ethnical diversity. Furthermore, gender was not assessed; therefore gender differences were not included in this study. Additionally, due to a small sample of participants who did not undergo bariatric surgery, group comparisons of that nature could not be made, and it was problematic to assess if the improvements in physical and psychosocial well-being were the result of the coaching program or the weight loss itself due to surgery, or other possible confounding variables, such as gender.

Dissertation Organization

This dissertation will be organized into chapters as follows: Chapter one consists of the introduction to the study including the purpose and significance of the study, potential limitations of the study, a list of definition of terms, and a description of how the dissertation is organized. Chapter two consists of a review of the literature containing the most recent studies conducted using all the tools used in this study as they pertain to the bariatric population. Chapter three

consists of the methods used to conduct the study, including a description of the sample, a description of the wellness coaching program, tools used, data collection procedure and method of data analysis. Chapter four consists of two manuscripts: Paper one: Impact of a Weight Loss Wellness Coaching Program on Bariatric Surgical Candidates; and Paper two: An Evaluation of a Weight Loss Wellness Coaching Program. The results of the data collected in this study were reported and discussed within each paper as they pertain to each individual purpose. Concluding the dissertation will be chapter five, which will consist of a summary of the overall study, conclusions drawn, limitations of the study and recommendations for further study.

Definition of Terms

Amotivation - a lack of intention to engage in a behavior

Bariatric - relating to or specializing in the treatment of obesity

Bariatric Surgery – any surgical procedure used to in the treatment of obesity

Body Mass Index (BMI) - a number calculated from a person's weight and height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems

Cardiovascular Disease - refers to any disease that affects the cardiovascular system; involving the heart and/or blood vessels.

Comorbidities – conditions existing simultaneously with and usually independently of another medical condition such as obesity

Exercise – planned and structured physical activity involving repeated bodily movements for the sake of developing and maintaining physical fitness

Extrinsic Motivation – motivation to participate in a behavior that is outside or separate from the activity itself

Excess Weight Loss (EWL) - the amount of weight that is in excess of the ideal body weight (IBW).

Health-Related Quality of Life - encompasses those aspects of overall quality of life that can be clearly shown to affect health - either physical or mental.

Health Outcomes - An outcome or result of a medical condition that directly affects the length or quality of a person's life

Hypertension - a health problem defined by high blood pressure; typically measured as equal to or more than 140/90 mmHg. Blood pressure is the force of blood pushing against the walls of arteries as it flows through them.

Ideal body weight (IBW) - determined by the Metropolitan Life Tables, or as a BMI of 25 kg/m2.

Intervention - any measure whose purpose is to improve health or alter the course of disease.

Intrinsic Motivation - an internal motivation to participate in a behavior is enacted out of pleasure and joy from the behavior or activity itself.

Obesity – a medical term that labels a range of weight that is greater than what is generally considered overweight for a given height. The term also identifies a range of weight that has been shown to increase the likelihood of certain diseases and other health problems. An adult who has a body mass index of 30 or higher is considered obese.

Physical Activity - athletic, recreational or occupational activities that require physical skills and utilize strength, power, endurance, speed, flexibility, range of motion or agility.

Psychosocial - involving both psychological and group aspects of an issue; relating societal conditions to mental health

Quality of Life (QOL) - a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life

Self-determination Theory - a macro theory of human motivation and personality, concerning peoples' inherent growth tendencies and their innate psychological needs. It is concerned with the motivation behind the choices that people make without any external influence and interference. SDT focuses on the degree to which an individual's behavior is self-motivated and self-determined

Sleep Apnea - brief periods of recurrent cessation of breathing during sleep that is caused especially by obstruction of the airway or a disturbance in the brain's respiratory center

Transtheoretical Model of Change - assesses an individual's readiness to act on a new healthier behavior, and provides strategies, or processes of change to guide the individual through the stages of change to action and maintenance

Type 2 Diabetes - a common form of diabetes mellitus that develops especially in adults and most often in obese individuals and that is characterized by hyperglycemia resulting from impaired insulin utilization coupled with the body's inability to compensate with increased insulin production

Wellness - an active process of becoming aware of and learning to make choices (healthy choices) that lead toward a longer and more successful existence

Wellness Coaching – a combination of using a facilitation approach and an instructional approach to unlock a person's potential to maximize their own performance. It is directly concerned with the immediate improvement of performance and development of skills by a form of tutoring or instruction.

CHAPTER II: REVIEW OF LITERATURE

Outcomes of Bariatric Surgery

Research on bariatric surgery and its outcomes is extensive. The majority of the literature involving bariatric surgery focuses on its effect on excessive weight loss (EWL); improvement and/or elimination of comorbidities, such as type 2 diabetes, cardiovascular disease, hypertension, and hyperlipidemia, sleep apnea; as well as quality of life. However, despite the overall exponential growth in procedures and anticipated improvement in body weight and associated comorbid conditions, few randomized, controlled prospective trials have compared currently performed surgical to nonsurgical weight-loss treatments, and a systematic method of prospectively analyzing surgical outcomes has not been established. In addition, although the economic impact of severe obesity on health care expenditures has been calculated, the value of surgical intervention remains uncertain.

Weight Loss and Associated Comorbidities

Hsu, et al., (1998) presented a review of the outcomes of bariatric surgery involving overall weight loss, improvement in health status, changes in eating behavior, and psychosocial adjustment. At the time of the study, available data indicated favorable weight loss in the short term, but other outcomes were variable, and weight regain was indicated at two years post-surgery. Hsu et al. (1998) reported that participants lost 40-60% of excess weight depending on procedure type, and about 30% of patients displayed weight regain between 18 months and two-year post-surgery. The authors suggest binge eating behavior and lowered energy metabolism may be associated with weight regain. The authors also reported general positive psychosocial outcomes in the short term, with reports of poor long-term adjustment including alcohol abuse

and suicide. Additional longitudinal studies were suggested to accurately account for the long-term outcomes of bariatric surgery.

Buchwald, et al., (2004) have systematically reviewed the literature of published observational and interventional trials that focused on comorbidity outcomes of bariatric surgery. The authors' meta-analysis concentrated on the impact of bariatric surgery on four selected obesity co-morbidities: diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea. The main objectives of their review were to analyze the impact of bariatric surgery on diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea, as well as on health care economics and disease impact; to analyze weight reduction efficacy outcomes for the comorbid conditions; and to summarize operative mortality outcomes. Weight loss efficacy and operative mortality data in these studies were also analyzed.

After identifying, screening, and excluding studies based on pre-established criteria, the authors analyzed 136 primary studies. Among these studies, there were a total of 179 treatment groups and 22,094 patients either controlled or analyzable in the data set. Included were five randomized controlled trials, 28 nonrandomized controlled trials, or series with comparison groups, and 101 uncontrolled case series. At least one categorical outcome of interest (e.g. proportion of patients with resolution or improvement in diabetes, hyperlipidemia, hypertension, or obstructive sleep apnea) or one continuous outcome of interest (change in a laboratory or physiological measure) was reported by each of the extracted studies. Patient characteristics, such as mean age and BMI, at baseline were relatively similar across surgical procedure types. The majority of the participants in th3e Buchwald, et al., (2004) study were women, (72.6%); the

age range was 16.20-63.60 years in studies for which this was reported; and the mean BMI at baseline was 46.85.

Upon examining weight loss, substantial weight reduction was found in all of the studies that were evaluated (Buchwald, et al., 2004). The mean percentage of EWL by meta-analysis was 47.5% for gastric banding, 61.6%, for gastric bypass, 68.2% for gastroplasty, and 70.1% for biliopancreatic diversion or duodenal switch. The overall percentage of EWL across all surgery types was 61.2%. Although less common, weight loss outcomes were also reported as a decrease in BMI and a decrease in absolute weight. In most cases, weight loss outcomes did not differ significantly for assessments at two years or less compared with those at more than two years. Operative mortality (mortality at 30 or less days) was minimal across the studies; 0.1% for the purely restrictive procedures, 0.5% in gastric bypass procedures, and 1.1% in biliopancreatic diversion or duodenal switch procedure. With respect to comorbidity outcomes, 85.4% of patients experienced either improvement or complete resolution of diabetes, 70% of patients experienced an improved lipid profile; 61.7% of patients experienced total resolution of hypertension; 85.7% of patients experienced a resolution of obstructive sleep apnea. The authors concluded from this meta-analysis that bariatric surgery in morbidly obese individuals reverses, eliminates, or significantly improves diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea and that these benefits occur in the majority of patients who undergo surgery.

Although a wide range of weight-related conditions and co-morbidities appear to improve, or even be resolved, as discussed in the Buchwald et al. (2004) review, limited data suggest that overall mortality decreases in patients undergoing bariatric surgery. Long-term studies are needed to assess this and other long-term outcomes.

Douketis, Macie, Thabane, and Williamson, (2005) systematically reviewed 44 long-term (more than two years) studies investigating dietary, lifestyle, pharmacologic, and surgical weight loss methods to assess weight loss efficacy, effects of weight loss on cardiovascular risk factors, and applicability of findings from studies to everyday clinical practice. Upon systematic analysis of data from these studies, the researchers found ambivalent results, yet drew the following conclusions. In terms of weight loss efficacy the first conclusion drawn was that surgical therapy provided the greatest amount of weight loss after 2-4 years (25–75 kg) compared to dietary/lifestyle therapy (< 5kg) and pharmacologic therapy (5–10 kg). The second conclusion drawn was that weight loss of more than five percent was not consistently associated with improvements in cardiovascular risk factors. When improvements did occur, they were mainly in high-risk groups, such as those with impaired glucose tolerance, type 2 diabetes, or hypertension, as changes in risk factors are more likely in subjects with abnormal baseline levels and appear to be intervention specific. Lastly, weight loss studies have methodological limitations that restrict their application to everyday clinical practice.

The Douketis, et al., (2005) study, however, also had potential clinical implications as indicated by the authors. One of the clinical implications the authors indicated was that, in obese people with cardiovascular risk factors, weight loss can provide some health benefits. However, the effects of weight loss on cardiovascular risk factors were found to be modest and inconsistent, and were predicated on sustained, long-term, weight loss. Second, in obese people without cardiovascular risk factors, maintenance of a stable weight is reasonable given the limited efficacy of weight loss interventions. Third, because weight loss is difficult to achieve and maintain, the prevention of obesity, rather than its treatment, may be a more worthwhile

clinical focus. These limitations suggest the need for additional interventions (e.g. lipid-lowering and antihypertensive drug therapy) to attain long-term, clinically significant improvements in risk factors.

Kushner and Noble (2006) attempted to review the long-term outcomes of bariatric surgery regarding weight loss, improvement of selected comorbid conditions, and economic impact. However, the authors discovered only two recent studies that published prospective randomized controlled studies comparing bariatric surgery with nonsurgical approaches, with the exception of two studies published more than 20 years ago. Regardless, these authors support previously discussed reviews (Hsu, 1998, Buchwald et al., 2004, & Douketis, et al., 2005) in that bariatric surgery has been shown to be an effective treatment for patients with extreme obesity.

Upon examining the economic outcomes, a factor not previously reviewed, authors determined the cost-effectiveness of bariatric surgery as an important outcome measure that requires additional study. Although definitive conclusions cannot be made, Kushner and Noble (2006), suggested, based on their review, that surgical obesity treatment decreases the use of medications for diabetes and cardiovascular disease, the frequency of outpatient visits, and long-term direct health care costs and appears to be worth the costs of the intervention. In contrast, one study in their review (Encinosa, Bernard, Chen, & Steiner, 2006) which assessed insurance claims for 2522 bariatric surgeries at more than 300 hospitals, identified a significant high complication rate during the six months after surgery resulting in costly readmissions and emergency department visits in nearly 40% of patients. The authors suggested future health and economic outcome studies are needed to assess all aspects of preoperative, perioperative, and postoperative care. The authors also determined that analyzing outcome data for bariatric

surgery has many limitations. In general, published data are often reported in case studies and case series involving a single surgeon or institution. Furthermore, parameters used to define diagnosis, improvement, resolution, or cure of selected comorbid diseases have not been standardized. Follow-up and reporting are often incomplete, which may allow selection bias. The other major limitation in reporting long-term outcome for bariatric surgery is that some of the data currently available for review and analysis originated from outdated procedures.

A more recent review by Padwell, et al., (2011) systematically reviewed the clinical efficacy and safety of bariatric surgery trials, selecting randomized controlled trials comparing bariatric surgery to standard care (e.g. diet and exercise) for meta-analysis. Thirty-one randomized controlled trials were selected for analysis and compared to standard care. Significant differences were found with all types of surgeries in BMI at one year follow up. Those individuals who had surgery had greater decreases in BMI compared to those utilizing standard care methods. From this review and meta-analysis, the authors concluded bariatric surgery appears to be substantially more effective for weight loss in severely obese adults, independent of type of surgery. Although all types of surgery resulted in significant weight loss, operations of the diversion type (e.g. jejunioleal bypass and biliopancreatic diversion) resulted in the greatest amount of weight loss, whereas purely restrictive procedures resulted in least amount of weight loss, and the hybrid procedure (e.g. Roux-en-Y gastric bypass) fell in the middle. Other differences were discovered by the authors regarding type of procedure. Compared with Roux-en-Y gastric bypass (RYGB), early forms of restrictive (horizontal gastroplasty (HBG), vertical banded gastroplasty (VBG) and malabsorptive (jejunioleal bypass) procedures are

associated with a greater failure rate and/or need for downstream revisions or reoperations; may explain why the RYGB procedure is now the most common procedure.

Of the different surgical procedures mentioned in the Padwell, et al, (2011) reviewed, only RYGB, adjustable gastric banding (AGB), and sleeve gastrectomy (SG) are frequently performed in contemporary practice. The data the authors reviewed and analyzed suggested that RYGB had a greater reduction of BMI compared with standard care; that RYGB reduced BMI to a greater extent than AGB; and that the risk of post-operative complications may be lowered with AGB as compared with RYGB. Sleeve gastrectomy was found to be increasing in popularity and appears similar to RYGB in efficacy; however, further study is needed as only two small trials, reporting 1-year or less outcomes, were identified in this review. These results imply that the choice between the two most commonly performed surgeries (RYGB and AGB) is a trade-off between safety and efficacy, and the information synthesized in the Padwell, et al. (2011) review may be helpful to patients and providers when making decisions regarding the type of surgery to undergo or to perform. The authors also concluded that high-quality data, particularly examining the effects of bariatric surgery on mortality and cardiovascular disease, from large, adequately powered, long-term randomly controlled trials are lacking and that more studies are needed to directly compare clinical benefits of different surgical procedures on clinically relevant outcomes over long follow up periods.

Quality of Life

In addition to weight loss and the reduction and/or elimination of comorbidities associated with extreme obesity, the results of bariatric surgery's effect on quality of life (QOL) are frequently examined. Extreme obesity has been associated with a reduced QOL, and QOL is

significantly improved after surgery; those improvements in QOL are positively associated with amount of weight loss (Sarwer, Wadden & Fabricatore, 2005). Several studies (Kolotkin, et al., 2003; Bond, et al., 2006; Karlson, Taft, Ryden, Sjostorm, & Sullivan, 2007; Forbush, Nof, Esternach, & Hill, 2011; Osei-Assiby, Kumar, Saravan, & Matyka, 2010; Sutton & Raines, 2010; Kolotkin, et al.,, 2011) investigated the impact of significant weight loss, particularly as a result of bariatric surgery, on health-related quality of life (HRQoL)

Many factors have an impact on one's QOL. Factors specific to the bariatric population include overall weight loss, the presence of binge eating (Hsu, et al 1998), cardiorespiratory fitness level (CRF) (Kolotkin, et al., 2011), stage of behavioral change (Romain, et al., 2012), and physical activity participation (Bond, et al., 2006). Kolotkin, et al. (2011) hypothesized that higher fitness levels would be associated with better health related quality of life (HRQoL). Researchers recruited patients from the Utah Obesity Study and included data from 326 patients. Upon assessing HRQoL via the Impact of Weight on Quality of Life (IWQoL) Questionnaire and Short Form Health Survey (SF-36), and cardiorespiratory fitness (CRF) via a submaximal treadmill exercise protocol, they found that higher fitness levels were associated with better weight-specific and physical HRQoL, but poorer mental HRQoL. Significant positive correlations were found between treadmill duration and scores on the IQWoL and the physical component of the SF-36, but a significant negative correlation with the mental component of the SF-36.

The SF-36 is a multi-purpose, short health survey with 36 questions. It yields an eight scale profile of functional health and well-being scores, as well as psychometrically based physical and mental health summary measures, and a preference-based health utility index. It is a

generic measure, as opposed to one that targets a specific age, disease, or treatment group. Accordingly, the SF-36 has proven useful in surveys of general and specific populations in comparing the relative burden of diseases and in differentiating the health benefits produced by a wide range of different interventions. The experience to date with the SF-36 and subsequent revisions has been documented in nearly 4,000 publications. The items selected for the questionnaire represent multiple operational indicators of health, including behavioral function and dysfunction, distress and well-being, objective reports and subjective ratings, and both favorable and unfavorable self-evaluations of general health status. After adjusting for BMI and gender, however, the relationship between fitness and IQWoL were no longer significant in the Kolotkin, et al. (2011) study.

Upon examination of the relationship between HRQoL and stage of behavior change regarding exercise in obese and overweight adults, Romain, et al., (2012) concluded that those individuals with more advanced stages of behavioral change reported better HRQoL. Researchers used the Quality of Life, Obesity and Dietetics (QOLOD) rating scale, which is a French questionnaire, adapted from the IWQoL to assess HRQoL and the physical activity staging questionnaire assessing their past, current, and/or intend level of physical activity participation. Precontemplation, contemplation, and preparation were classified as inactive, and slightly more than 62% of the sample did not exercise regularly, therefore they were considered inactive. Researchers' suggested, that by beginning a regular exercise program, patients may expect an improvement in HRQoL. Karlson, et al., 2007) conducted a 10-year follow up of the Swedish Obese subject intervention study (SOS) to examine the trends and effects of weight loss treatment on HRQoL. The SOS study was a controlled, longitudinal trial of the health effects of

weight loss in the severely obese. Researchers from this follow-up study compared ten year data on 655 surgical cases and 621 conventionally treated cases. It should be noted that the conventional treatments were not standardized and left up to the local facility to administer. Participants completed a battery of generic and condition-specific measures, including the SOS Quality of life survey, used for HRQoL assessment; the Current Health Scale, measuring general health perceptions; the Mood Adjective Check List (MACL), measuring mental well-being; the Hospital Anxiety and Depression Scale (HAD), detecting mood disorders; the social interaction category (SI) from the Sickness Impact Profile (SIP) assessing health-related dysfunction, and the obesity-related problems scale (OP), measuring the impact of obesity on psychosocial functioning. Results indicated significant changes in HRQoL during the 10-year observation period which predominantly followed phases of weight loss, weight regain, and weight stability. Improvements and deteriorations in HRQoL were associated with the magnitude of weight loss or regain, except for anxiety. Peak improvements in the surgical group were observed during the first year of weight loss, whereas the weight regain phase (mainly between one- and six-year follow-up) was accompanied by a gradual decline in HRQoL. The period from six- to ten-year follow-up was characterized by relatively stable observations in both weight and HRQoL. At ten years, net gains were noted in all HRQoL domains compared to baseline. Comparisons of treatment effects on HRQoL in the surgical vs. conventional group after ten years showed significantly better outcome in the surgical group on current health perceptions, social interaction, psychosocial functioning and depression, whereas no significant differences were found for overall mood and anxiety.

Long-term results of the study suggested that a maintained weight loss of about ten percent is sufficient for positive long-term effects on HRQoL, a limit that was reached in about two-thirds of the surgically treated patients who completed ten years of the study. Researchers concluded that long-lasting weight reduction in the severely obese had a general long-standing positive outcome on HRQoL and that bariatric surgery is a favorable option for the treatment of severe obesity, resulting in long-term weight loss and HRQoL improvements in a majority of patients. However, difficulties among some surgical patients to control and maintain weight loss over time should not be ignored. Once again, researchers suggested future research studying the long-term effects of bariatric surgery from implementation of lifestyle modification techniques and postoperative management of patients.

Improvements in measures of quality of life following gastric bypass surgery have typically been attributed amount of percent of excessive weight loss (%EWL) following surgery. However, few studies have examined other variables as they relate to improvements of QOL. As a result, Forbush, et al., (2011) conducted an evaluative, retrospective study to examine variables that may additionally contribute to improvements in quality of life post-surgery, particularly physical activity and eating behaviors. Researchers hypothesized that QOL indicators would be significantly improved if patients had more activity in their lifestyle after Roux-en-Y gastric bypass surgery, regardless of their overall weight loss. In addition to percent weight loss, energy intake and energy type consumed (via Arizona Food Frequency Questionnaire); and activity levels (via the Arizona Activity Frequency Questionnaire (AAFQ)) categorized by intensity, hours/day, and calories expended were included in the variables examined. The purpose of the Forbush, et al., (2011) study was to determine if the combination of physical activity and other

behaviors necessary to improve QOL after RYGBP have the best effect on maintaining QOL in this previously morbidly obese population. A total of 805 patients were selected for assessment that was between one and five years post-surgery. Physical (PCS) and mental (MCS) quality of life (via the SF-36) were assessed and compared to the aforementioned variables. Results showed respondents who lost more weight and were less active had lower scores on the QOL outcome tool than those who were more active, whether they lost more weight or not after the RYGBP. The subjects worsened in their quality of life scores (PCS and MCS), the more years they were from their surgery. Participants who were four or five years post-surgery scored significantly lower on the PCS of the SF-36, version 2 (SF-36v2) outcome tool. This change in perception of quality of life might be attributed to a gradual increase in BMI over the period from three to five years. Participants displayed excellent PCS and MCS scores in the first two years and then a significant decline in these factors accompanied by a slight decline in overall %EWL by the fourth to fifth years.

Upon comparing the physical activity levels of the sample from the Forbush, et al., (2011) study to normative data, these group of respondents were less active than the general population in total hours of activity per day (HOAD) and most did not participate at a level necessary for improvement in QOL (Bond, et al., 2006); less than 20% of the respondents reported participating in recreational activity for at least the recommended 60 minutes per day to lost and control body weight for an overweight population. Although 150-200 minutes of moderate to vigorous physical activity (MVPA) per week is suggested for the general population to achieve health benefits, including weight management, the Forbush, et al. (2011), study suggested that more time is necessary to have optimal improvements in quality of life, especially

for the PCS of the SF-36v2 QOL tool. The persons in this study, active at the suggested levels, were the persons scoring higher on the sub-components of the QOL tool. These results indicated that these respondents generally expended less than the suggested levels of energy expended in activity each day (EEAD) to optimize health. In fact, approximately nine percent of the respondents reported no activity that would expend energy in a typical week, and over 75% of the respondents expended less than the recommended 1,050 kJ per day in any activity. Daily energy expenditure was strongly correlated with both categories of quality of life scores (PCS and MCS) scores, suggesting that persons who are moderately active had a better outcome related to QOL scores. Researchers also suggested that the post-surgical client would need to be active one-and-a-half hours per day to alter the PCS on the SF-36v2 and would need to be active one hour per day to significantly alter the MCS score on the same tool. This result demonstrated that increases in hours of activity in a day (HOAD), beyond the half hour, made a significant improvement in QOL scores than others in the study who lost similar amounts of weight and were active less than a half an hour per day. No relationship was found, however, between the amount of time spent in higher levels of physical exertion (MET levels) or in levels of energy consumption and either the PCS or MCS.

The Forbush, et al., (2010) study was one of the first studies to show significant improvement in quality of life scores through the institution of general activity as part of the post-surgical regime and reinforces previous research showing increasing HOAD in improvement of QOL scores. The participants showed a slow increase in body weight and a decrease in PCS and MCS quality of life scores as time passed since their surgery. This research suggests that regular physical activity and improvements in energy expenditure, will lead to a

better quality of life, for patients post-RYGBP. This improved QOL will be greater than just attributed to the success in weight lost after the surgery.

In an attempt to understand the patient's perspective of the impact of weight loss surgery, Sutton and Raines (2010) examined health related quality of life post-operatively using a cross sectional design with a convenience sample of patients attending a post-surgery support group. Eighty-seven individuals completed the three questionnaires used in this study (a demographic form, a single item Likert scale measure of overall QOL, and a twelve-item short form health survey (SF-12v2). Overall, 86.1% (n= 74) of the participants rated their quality of life as excellent or very good with only four participants rating it as less than good. Physical function was reported higher than mental functioning, with two of the four mental functioning domains (social function and role emotional) having lower mean scores than the general U.S. population. The results of this study support the evidence that most individuals who undergo weight loss surgery report their quality of life as very good or excellent. The domains with higher mean scores, bodily pain (pain impact on activities), physical functioning (activities such as climbing stairs), and role physical (accomplishing activities), all have a clear relationship to a decrease in body mass, whereas domains of social function (impact on social activities) and vitality (amount of energy) were rated lower than the physical functioning domains. Researchers suggested that these findings may be explained by the relationship between the physical functioning summary scale of health-related quality and the physical changes that occur following significant weight loss as a result of surgery. The rapid decrease in body weight has an immediate impact on the person's ability to be mobile and to experience decreased joint and bone pain, whereas improvement in social and emotional functioning may take more time.

Weight Regain

Early studies found weight regain to be common, often commencing around the two- year mark post-operation, with an average estimated weight regain of 15% of maximum weight loss (Pories, et al., 1992; MacLean, Rhose, Samplalis, & Forse, 1993) to 30% of initial body weight in some patients (Pories, et al, 1995). Weight regain within the first two years was typically associated with poor adherence to postoperative diet, (Sarwer, Wadden & Fabricatore, 2005). Psychosocial and behavioral factors may also play a role in this lack of adherence and other postoperative outcomes. Sarwer, et al., (2005) reviewed several studies that investigated preoperative psychosocial status, including psychiatric comorbidity, eating behavior and quality of life, and studies investigating changes in these factors postoperatively. Many of the conclusions drawn from these studies collectively, should be interpreted with caution due to many methodological issues, such as differences in diagnostic criteria, lack of structured criteria, and lack of an appropriate control or comparison group. In spite of a lack of cohesiveness of the methodology, the authors confidently suggested, that extreme obesity is associated with a reduced quality of life and that significantly improved post-surgery, and that improvements in quality of life are positively associated with amount of weight loss.

With respect to post-operative eating behavior, it is suggested that many patients struggle to adhere to the extreme low calorie post-operative diet (Sarwer, et al., 2005). Additionally, as caloric intake increases over time in the months to years following surgery, patients may return to their pre-surgery caloric intake, typically around the two to two-and-a-half year mark, consuming more calories than they are expending, thus resulting in weight regain.

Negative Impact of Bariatric Surgery

Due to the some early reports of poor adjustment after bariatric surgery, including alcohol abuse and suicide (Hsu et al., 1998), Tindle, et al., (2010) examined suicide rates as a function of, time post-surgery, sex, age, and suicide death rates, and compared them with overall U.S. suicide rates. Results from data obtained from the Division of Vital Records, Pennsylvania State Department of Health between September 1996 and December 2006, indicated there were 31 suicides from 16,683 operations, for an overall rate of 6.6/10,000; 13.7 per 10,000 among men and 5.2 per 10,000 among women. About 30% of suicides occurred within the first two years following surgery, with almost 70% occurring within three years. For every age category except the youngest, suicide rates were higher among men than women. Age- and sex-matched suicide rates in the U.S. population (ages 35-64 years) were 2.4/10,000 (men) and 0.7/10,000 (women). Researchers concluded there was a substantial excess of suicides among all patients who had bariatric surgery in this 10-year data sample compared to the U.S. population matched with age and sex. These data document a need to develop more comprehensive longer-term surveillance and follow-up methods in order to evaluate factors associated with post-bariatric surgery suicide, among other long-term outcomes.

Other potential negative outcomes may follow bariatric surgery including vitamin and mineral deficiencies, gastrointestinal symptoms, postprandial hypoglycemia, the need for anti-diabetic and blood pressure lowering medications, and the need for plastic surgery (Hofso, et al., 2011). Hofso, et al. (2011) made suggestions regarding follow-up to reduce these symptoms including nutritional supplements to prevent vitamin and mineral deficiencies, improved by dietary modifications, and dose adjustment of other medications.

Long-Term Efficacy

Since these reviews (Hsu, et al., 1998; Buchwald, et al., 2004; Kushner & Noble, 2006) a few studies have begun to examine the long-term outcomes of bariatric surgery, yet long-term results and influence of the procedures are still not well known. Preliminary studies suggest that a significant amount of patients have weight regain and have the return of comorbidities following surgery (Hsu, et al., 1998, Douketis, et al., 2005). Since those preliminary studies on long-term effects, Schouten, Wiryasaputra, van Dielen, van Gemert, and Greve, (2010) have examined and compared the long-term results of two bariatric restrictive procedures, laparoscopic adjustable gastric banding (LABG) and vertical banded gastroplasty (VBG). One hundred patients were included in the study with 50 patients who underwent LAGB and 50 patients, open VBG. Researchers collected data on weight loss, changes in obesity-related comorbidities, long-term complications, re-operations including conversions to other bariatric procedures and laboratory parameters such as vitamin status. Data were obtained from 91 of the 100 patients with a mean follow-up duration of 84 months (seven years). Researchers found those who underwent VBG lost significantly more weight compared with LAGB, 66% versus 54%, respectively. All comorbidities significantly decreased in both groups. Long-term complications after VBG were mainly staple line disruption (54%) and incisional hernia (27%). After LAGB, the most frequent complications were pouch dilatation (21%) and anterior slippage (17%). Major re-operations after VBG were performed in 60% of patients. All re-operations following were conversions to Roux-en-Y gastric bypass (RYGB). In the LAGB group, 33% of patients had a refixation or replacement of the band, and 11% underwent conversion to another bariatric procedure. There were no significant differences in weight loss between patients with or

without re-interventions. This long-term follow-up study confirms the high occurrence of late complications after restrictive bariatric surgery. The failure rate of 65% after VBG was determined to be too high, and this procedure is no longer performed anymore at the institution where the study took place. The re-operation rate after LAGB is decreasing as a result of new techniques and materials. Results of the re-operations were reported as "good" with sustained weight loss and reduction in comorbidities. However, in order to achieve the desired results, researchers suggested that a durable and complete follow-up after restrictive procedures be imperative.

Upon interviewing 98 patients who had undergone gastric bypass surgery 13-15 years prior, Mitchell, et al., (2001), discovered most patients had an overall favorable physical and mental experience. Relative to global health status (as measured via the SF-36), 54 (74%) participants responded positively to the question "Has the gastric bypass operation helped you with your physical health?;" 59 (75.6%) responded positively to the question "Has the operation helped you with your mental outlook." In looking at weight loss and weight regain, the mean BMI pre-surgery was 43.8 kg/m^2 (based on medical records), the mean BMI at maximum weight loss post-surgery was 25.9 (based on patient self-report) and at time of follow-up 32.8. The range for maximum weight loss was 19.5-93.6 kg., with a mean of 49.7 kg. Relative to baseline pre-surgery weight, the weight loss at long-term follow-up was a mean of 30.1 kg, with a range of -13.6 to 93.6 kg. Three subjects weighed more at follow-up than before surgery. This study suggests that at long-term follow-up, the majority of individuals who have undergone gastric bypass for treatment for obesity feel that the procedure benefited them in terms of their physical health and their "mental outlook". Despite this, many still reported a number of

gastrointestinal related problems, including episodic vomiting in approximately two-thirds, and diarrhea, heartburn, and "plugging" in one-third or more. Most denied that the gastrointestinal sequelae were a major concern. Therefore, most of the subjects clearly have learned to live with these problems. Of interest, the majority of individuals who met criteria for binge eating disorder did not meet such criteria at long-term follow-up, even if the criterion for eating a large amount of food is excluded. It is of note that hunger perception changes with gastric bypass, which may be involved in this finding. Those who re-developed problems with binge eating disorder symptoms after the gastric bypass tended to regain more weight. Although the rates of psychopathology were significant, the prevalence did not seem to be much more compared to rates in the general population, including the rate of depression, given the rates of other problems in this population. The results of this study can be interpreted to indicate that although careful education about possible complications, particularly gastrointestinal complications, appear indicated for individuals who are candidates for gastric bypass, approximately three-quarters of such patients will do well overall in terms of physical and psychiatric outcome.

Factors Affecting Surgical Outcomes

Although it has been well established that bariatric surgery is essentially safe and effective for weight loss, many factors affect the outcomes of bariatric surgery and its long-term success, such as physical activity level, stage of behavior change, socioeconomic factors, and psychosocial factors. Regardless of the type of procedure elected, it's initial effect, and potential long-term effect, on weight loss, co-morbidities, and QOL, it is imperative that patients adopt a healthy lifestyle and make significant changes in eating and exercise behaviors, in order to maintain the positive outcomes achieved from surgery. Surgical success also requires significant

behavioral changes and is largely dependent on an individual's ability to implement permanent lifestyle changes, such as adhering to a strict nutritional and exercise regimen, as well as acquiring new coping skills to decrease reliance on food for addressing emotional needs (Bauchowitz, et al., 2005). Whereas much research has focused on examining the patient's eating behaviors after surgery, questions remain with respect to the impact of other factors, such as physical activity, and socioeconomic status had on long-term weight loss and the contribution of one's physical capabilities to long- term surgical outcomes.

Lifestyle Behavior Change

Eating behavior

The obese population, specifically those seeking bariatric surgery, has diverse, yet similar characteristics. Although they may differ in many aspects, obese individuals seeking surgery appear to be more prone to psychological disturbances and eating disorders than not surgery-seeking obese individuals (de Zwann, et al., 2003). de Zwann, et al., (2003) examined the characteristics of a group of pre-bariatric surgery candidates and discovered the majority of the sample (82.7%) were *not* considered to have a binge eating disorder (BED). This result was in contrast to a wide range of ten percent to 50% of surgery patients suffering from BED as reported by Sarwer, Waden, and Fabricatore, (2005).

Those that were diagnosed to have BED (17.3%) in the deZwaan, et al., (2003) study, differed significantly on measures of variables such as QOL measures. Although binge eaters tend to be less in numbers than non-binge-eaters in this sample, their psychological profile appears to be significantly different than their non-binge eating counterparts. Upon comparing those with and without BED, researchers found that binge eaters had significantly lower QOL

scores overall and lower values on self-esteem, sexual life, and work-related quality of life compared to non-binge eaters also seeking bariatric surgery. Physical function also appeared to be more impaired in the smaller group of binge eaters in this study.

Green, Dymek-Valentine, Pytluk, Grange, and Alverdy (2004) also tested the hypothesis that the binge eating would demonstrate greater pathology on measures of eating pathology, psychological well-being, and quality of life than those who did not binge eat both pre-and post-surgery. Upon comparing the two groups (binge eaters (BE) and non-binge eaters (NBE)), the BE group had significantly higher levels of disinhibited eating, and hunger, and significantly lower levels of social functioning at pre-surgery and six months post-surgery. The BE group also had a significantly lower percentage of excess weight lost than the NBE group at six months post-surgery. These findings indicate a less successful outcome for the BE patients compared with the NBE patients.

Other eating behaviors, such as night eating disorder, disinhibition, cognitive restraint, and hunger have also been studied. Sarwer, et al., (2005) reported that, up to 40% of surgery patients have been characterized as having features of night eating syndrome (NES), which is currently believed to consist of four core symptoms: morning anorexia, evening hyperphagia, nocturnal awakenings, and eating during waking episodes. Although not a formally recognized psychiatric diagnosis at present, authors suggested that preliminary data involved may be indicative of the eating patterns of persons with NES and are distinct from those seen in other eating disorder diagnoses. Sarwer, et al., (2005) reported at least two studies used the Eating Inventory to assess cognitive restraint, disinhibition, and hunger. Preoperatively, bariatric surgery candidates reported increased levels of disinhibition and hunger and lower levels of

restraint compared with norms for the measure or with obese controls. The question arose from this study as to whether pre-operative behaviors, such as the presence or absence of the various eating behaviors, have an impact on post-operative outcomes.

In a qualitative assessment of postoperative eating behaviors, Zunker, Karr, Saunders, and Mitchell, (2012) found that eating behaviors after bariatric surgery played an important role in postoperative outcomes. Researchers explored eating behaviors among 29 post-bariatric surgery patients at a research institute with a community-based sample to develop a better understanding of the term "grazing", as interpreted by patients. Structured focus groups using the nominal group technique were conducted with five groups of post-bariatric patients who were at least one year post-surgery Participants were asked to produce responses to the question: "What does grazing mean to you?" Then, they were instructed to rank their responses to the questions: "What is grazing?" and "How does grazing affect you?" The group members generated a total of 105 responses, which were categorized into 17 themes. Common responses included eating frequently all through the day, out of control eating, and eating due to boredom, and not hunger. Researchers determined that grazing has a number of unique interpretations, including mindful and mindless behaviors and that post-bariatric surgery patients seem to view grazing as a healthy eating behavior characterized by mindful food choices that are consumed in small amounts frequently throughout the day. However, grazing may also be viewed as an unhealthy eating pattern when it is perceived as unplanned, mindless, continuous food consumption and may have a significant negative impact on post-bariatric success, thus contributing to weight regain (Zunker, et al., 2012).

Physical activity

Physical activity is recommended as an important part of weight management by virtually all public health agencies and scientific organizations including the National Heart, Lung, and Blood Institute (NHLBI), Centers for Disease Control (CDC), American College of Sports Medicine (ACSM) and various medical societies (e.g. American Heart Association, American Medical Association, American Academy of Family Physicians) (Donnelly, Blair, Jakiicic, Manore, Rankin, & Smith, 2009). In the 2009 Position Stand on appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults (Donelly, et al., 2009), it is recommended that overweight and obese adults may need greater amounts of physical activity to achieve desired weight loss and/or prevent weight regain compared to those recommended for most individuals for healthy weight management (150 minutes per week of MVPA). Donnely et al., (2009) examined the evidence on successful weight loss and prevention of weight regain, data from the National weight control registry, and determined that 200-300 minutes per week of MVPA is recommended for long-term weight loss. For most individuals, MVPA of 150- 250 minutes per week, energy equivalent of 1200 to 2000 kcal per week is usually sufficient to prevent weight gain greater than three percent in most adults and may also result in modest weight loss. However, greater doses of PA tend to show weight loss at or above three percent of initial weight, as demonstrated primarily by laboratory studies with direct supervision compared to outpatient studies. Physical activity combined with diet restriction provides a modest addition of weight loss compared to diet alone, and this additive effect is diminished as the level of diet restriction increases. There are cross-sectional and prospective data that suggest PA is associated with prevention of weight regain after weight loss; however,

there are no appropriately designed, randomized controlled trials to indicate whether PA is effective for the prevention of weight regain and no information regarding the existence of a potential dose effect (Donelly, et al., 2009). Lifestyle approaches for increasing PA and planned PA are consistently associated with less weight gain compared to inactivity. The effects of lifestyle PA for prevention of weight regain after weight loss are unknown owing to lack of available literature (Donelly, et al., 2009).

Although current recommendations for greater amounts of PA exist for more effective weight loss and prevention of weight gain, Evans, et al, 2007) found that participation in the 150 minutes per week postoperatively had favorable results on weight loss in gastric bypass patients during the months following surgery. Researchers compared the three, six, and 12-month postoperative weight loss between gastric bypass surgery (GBS) patients who met or exceeded the ACSM recommended of 150 minutes per week of MVPA and those not meeting the recommendation. A self-administered short version of the International Physical Activity Questionnaire (IPAQ-short) was used to assess moderate or higher intensity PA participation at three (n = 178), six (n = 128), and 12 months (n = 209) after GBS and survey results were compared to total weight lost, percentage of excess weight loss, body mass index change, and total weight loss percentage. Results indicated patients reporting 150 minutes per week of moderate or higher PA had significantly greater weight lost, percentage of excess weight loss, change in body mass index, and total weight loss percentage at six and 12 months postoperatively, with no significant differences at three months after GBS. Researchers concluded participation in a minimum of 150 minutes per week of moderate or higher intensity PA was associated with greater postoperative weight loss at six and 12 months postoperatively.

Researchers made the suggestion that patients should be encouraged to meet or exceed this recommendation until prospective, randomized studies have definitively established a link between PA and greater postoperative weight loss and maintenance.

Physical activity (PA) is an important component of weight loss programs and should be encouraged for severely obese patients undergoing bariatric surgery. However, few studies have determined the amount and intensity of activities undertaken preoperatively by bariatric surgery patients using objective measures. Bond, et al., (2010) compared 38 bariatric surgery candidates and 20 normal weight controls on activity counts per hour; the number of minutes daily spent in moderate-to-vigorous intensity PA (MVPA) and vigorous intensity PA; and the level of compliance with national recommendations to accumulate 150 minutes per week of MVPA in bouts of greater than or equal to ten minutes.

Surgery candidates, compared with controls, recorded significantly fewer activity counts per hour and spent fewer minutes per day engaged in MVPA and vigorous PA. More than two thirds (68%) of the surgery candidates versus 13% of the normal weight controls did not accumulate any MVPA in bouts of greater than or equal to ten minutes and only 4.5% of obese patients met the weekly MVPA recommendation versus 40% of the controls. Researchers concluded that bariatric surgery candidates have low PA levels and rarely engage in PA bouts of sufficient duration and intensity to maintain and improve health and suggest additional research is needed to determine how best to increase PA in bariatric surgery candidates.

To better understand the physical activity behavior of individuals who undergo bariatric surgery in order to develop more effective post-surgical exercise guidelines, Josbeno, Kalarcian, Sparto, Otto, and Jakicic (2011) conducted a study characterizing the physical activity profile

and physical function of 40 participants two to five years post-bariatric surgery and examined the association between physical function (what an individual is capable of doing), physical activity (what the individual is actually doing), and %EWL after surgery. Researchers used Body Media SenseWear® Pro (SWPro) armband to measure moderate-to-vigorous intensity physical activity (MVPA) and physical function (PF) was measured using the physical function subscale of the 36-Item Short Form Health Survey instrument (SF-36).

Researchers found a significant correlation between the amount of MVPA participation and weight loss post-bariatric surgery among the 40 participants. The study participants who participated in 150 minutes per week or greater of MVPA (n = 26) had a greater %EWL than the study participants (n = 14) who participated in less the 150 minutes per week of MVPA. With regards to physical function, there was a significant relationship between %EWL and physical function, but no significant correlation between physical function and physical activity. There was no significant difference between physical function of this sample and of the general US population as determined by the mean scores of the SF-36. Researchers concluded the amount of physical activity participation and the level of physical function are each independently associated with weight loss in the two to five years following bariatric surgery. This study demonstrated that physical function is not correlated with physical activity, which may suggest that the capacity to engage in physical activity does not necessarily result in more levels of activity participation. Researchers suggested more research to better understand post-surgery PA participation (or lack of) in order to develop more effective PA interventions and guidelines for long-term weight management.

Psychosocial Factors

Psychosocial factors likely play an influential role in postoperative behavior and subsequent outcomes. Therefore, most bariatric surgery programs require patients to undergo a psychological evaluation prior to being "approved" for surgery (Bauchowitz, et al., 2005). Sarwer, et al., (2005) reviewed the psychosocial and behavioral aspects of persons who undergo bariatric surgery. Included in their review were studies investigating patients' preoperative psychosocial status, encompassing a detailed over-view of psychiatric comorbidity, eating behavior, and quality of life; studies that have investigated changes in these domains postoperatively. Studies examining preoperative psychosocial status, collectively suggest a high rate of psychopathology among bariatric surgery candidates such as mood disorders (e.g. major depressive disorder, dysynthmia), anxiety disorders (e.g. generalized anxiety disorder, social phobia), substance abuse disorders, and personality disorders (e.g. histrionic, borderline, schizotypal, and passive-aggressive personality disorders). These findings were based on clinical interviews as well as Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria. Surgery candidates reported greater depressive symptoms compared with those with less extreme obesity with these symptoms typically found in younger candidates, women, and those with a poor body image, impairments in health-related quality of life, or a history of severe binge eating. Approximately 25%of bariatric surgery patients reported treatment from a mental health professional at the time of surgery, and 12% to 38% reported using psychiatric medication(s). Between three and twenty percent of surgery candidates have been excluded from surgical treatment because of psychiatric complications.

Studies using the Minnesota Multiphasic Personality Inventory (MMPI) to examine the personality characteristics of prospective patients found 44% of patients were classified as "well-functioning", 31% were categorized as "neurotic" (depressed and socially anxious), and 25%were categorized as character disordered. A subsequent study identified four groups of patients: 52% with modest elevations on the Hypochondriasis and Hysteria subscales, suggestive of a somatoform disorder; 20% with high scores on the Psychopathic Deviate subscale; 17% with scores characterized as "well-functioning"; and 11% with elevations on six subscales (Hypochondriasis, Depression, Hysteria, Psychopathic Deviate, Psychasthenia, and Schizophrenia), who were described as "emotionally disturbed." Although the various methodological issues may likely account for the wide range of psychopathology reported, it seems that a significant minority of bariatric surgery patients have some form of psychopathology, something that may need to be addressed for postsurgical success (Sarwer, et al., 2005).

The relationship between extreme obesity and psychopathology is complicated. It is unclear whether psychopathology is a cause or consequence of extreme obesity. However, the more important question is whether or not these preoperative psychopathologies impact postoperative outcomes. The answer remains unclear. As reported in the Sarwer, et al., (2005) review, some experts believe that psychiatric comorbidity, with the exception of uncontrolled substance abuse, does not contra-indicate bariatric surgery, while others have suggested that patients with psychopathology should not have surgery without concurrent psychiatric treatment. The authors state the lack of consensus may be attributed to the relative absence of methodologically sound studies and that future research will need to address the methodological

limitations of previous studies to establish the relationship between psychopathology and postoperative outcome, such as larger prospective studies that include widely used, standardized assessment methods, such as the Structured Clinical Interview for DSM Disorders and that follow patients for several years are needed to best characterize this relationship.

Neuropsychological performance may also be a factor in successful (or unsuccessful) weight loss in the extreme obese. Boeka and Lokken (2008) investigated this relationship in 68 patients seeking surgical treatment at a major medical center. It was hypothesized that overall, extremely obese individuals would display impairment in specific cognitive domains. After undergoing a comprehensive psychological assessment, including measures of intellectual and academic achievement, processing speed, executive functioning, verbal fluency, and memory, as part of standard pre-surgery evaluation, and comparing to normative data matching age and education level, it was found that extremely obese individual scored significantly lower on many measures of executive functioning. However, obese individuals score significantly higher on one measure; verbal fluency. Executive functioning is associated with the inability to control nonstandard behavior, such as chronic or binge eating, a behavior of particular interest in the obese population. Researchers suggested possible explanations for this association between obesity and cognitive dysfunction, including blood flow deprivation to the brain due to increased body fat and associated body mass and/or abnormal protein secretion by the adipocytes. However, these are just speculations and the researchers suggested further research into this growing relationship to explain causality.

Little empirical research existed that described the demographic, psychosocial, and cognitive characteristics of patients who qualify for, and seek bariatric surgery (Lokken, Boeka,

Yellumahanthi, Wesley, and Clements, 2010). Therefore, Lokken, et al., (2010) included cognitive evaluations, psychological evaluations, evaluations of eating behavior and eating pathology, and evaluations of health behavior compliance, social support, and expectations of and motivations for bariatric surgery to describe specific demographic, psychosocial, and cognitive characteristics and to identify whether a specific cognitive deficit is present in this patient population of morbidly obese individuals seeking surgery. Cognitive and psychosocial evaluations included measures of intelligence, reading ability and intellectual functioning, executive functions, and depression. The sample of morbidly obese individuals seeking surgery was similar in education, income status, and IQ when compared to normative data. IQ was average, did not correlate with BMI, and reflected a normal distribution. As a group the sample endorsed minimal levels of depression and low levels of psychopathology. However, upon comparing data to normative data matching age and education level, obese individuals scored significantly lower on measures of problem solving and planning. Based on these results, the researchers suggested an impairment of being able to substitute certain behaviors (e.g. overeating) when presented with unclear information due to decreased problem solving skills. This may imply difficulty in selecting appropriate coping strategies in stress management or difficulty in implementing appropriate exercise and eating habits without clear instructions on how to do so. Additionally, meal and snack planning and exercise planning may prove to be difficult due to a deficiency in planning skills. Once again, researchers suggested more research into this area to explain a cause or effect relationship on executive function on obesity.

Exercise Motivation

Understanding why people, especially those with weight management difficulties, choose to, or not to, engage in regular physical activity (or terminate their involvement) has become a focal point of research in exercise psychology (Wilson, Sabiston, Mack, & Blanchard, 2012). It has already been established there is a strong link between lower levels of physical activity and physical (e.g. obesity, hypertension, type 2 diabetes, etc.) and psychological (e.g., depression) health problems that reduce the quality and longevity of life (Bouchard, Blair, & Haskell, 2007). Despite these health threats, a substantial portion of the U.S. population remain insufficiently active (Bouchard, et al, 2007.) while an estimated 50% of adults starting an exercise program will discontinue participation within six months (Wilson, et al., 2012). Considering these participation trends, and the link to physical inactivity and health problems, it is important to know *why* some people engage in physical activity whilst others remain less active.

One theoretical perspective that appears useful for understanding motivational issues in physical activity settings is self-determination theory (SDT; Ryan & Deci, 2000). Research guided by self-determination theory has focused on the social-contextual conditions that facilitate versus expect the natural processes of self-motivation and healthy psychological development. Specifically, factors have been examined that enhance versus undermine intrinsic motivation, self-regulation, and well-being. The findings have led to the postulate of three innate psychological need: competence, autonomy, and relatedness, which when satisfied, yield enhanced self-motivation and mental health and when thwarted lead to diminished motivation and well-being (Ryan & Deci, 2000). SDT accounts for the quality of motivation regulating behavior, as well as, the processes that facilitate motivational development (Deci & Ryan, 2002)

that holds considerable appeal for understanding "why" people initiate, persist, and terminate their involvement in various physical activities (Wilson, Mack & Gratten, 2008). An application of research embracing SDT as a guiding framework has examined the applicability of the theory to exercise contexts.

Wilson, et al., (2008) conducted a literature review that focused on the application of SDT to the study issues useful to exercise. The authors centered their review around three principal questions: 1) does the quality of motivation regulating exercise behavior "matter"?, 2) how important are basic psychological needs within exercise contexts?, and 3) can contextual variables be manipulated to create adaptive environments for exercise? The available evidence is supportive of many suggestions expressed within SDT. The authors stated that although research embracing SDT in exercise science is limited in scope and quality compared to applications of the theory in other life domains, the available data are largely in line with many of Deci and Ryan's (2002) assertions. The authors also ascertained that SDT offered a foundation for examining a range of motivational phenomena integral to understanding exercise behavior. Since exercise provides substantial grounds for testing and refining SDT, the authors make the suggestion that a number of areas could benefit from careful attention in future applications of SDT to unravel the challenges inherent in understanding exercise motivation.

With respect to weight loss, Williams, Grow, Freedman, Ryan and Deci (1996) tested the SDT theory with 128 patients in a six-month, very-low-calorie weight-loss program with a 23-month follow-up. Based on the notion that SDT states that behavior will continue if it is autonomously motivated, Williams, et al. (1996) proposed to predict which people who participated in the weight loss program would lose the most weight and which individuals would

maintain the greatest weight loss over a two year period. More specifically, researchers used psychological and environmental variables related to participants' motivation to predict patients' attendance at weekly meetings of the program, weight loss during the six-month period, and maintenance of exercise and weight loss at a 23-month follow-up. After assessing various measurements of autonomy, control, impersonal orientations, internal beliefs of control of health outcomes, reasons for staying on the program, autonomy support, and exercise behavior, researchers confirmed their predictions that those participants whose motivation for weight loss was more autonomous attended the program more regularly, lost more weight during the program, and maintained weight loss at follow-up. The degree of patients' autonomous motivation for participating in the program was found to predict attendance at weekly meetings of the program and weight loss during the period. More important, autonomous motivation for participating also predicted maintenance of weight loss at the 23-month follow-up. Therefore, individuals' autonomous motivation is an important predictor of whether a weight-loss program is likely to be effective not only in promoting weight loss but also, more important, in facilitating its maintenance.

The degree to which patients experienced the staff as autonomy supportive was also a significant positive predictor of autonomous reasons for persisting in the program, thus supporting the researchers' hypothesis. Researchers stated that although the former finding is certainly of interest, the latter is of greater practical significance; for it suggests that the interpersonal climate created by the health-care staff of a weight loss program will influence the relative autonomy of patients' motivation, which in turn will affect both their weight loss during program and their maintenance of those losses. The Wilson et al., (1996) study therefore

suggests that self-determination theory, which differentiates between autonomous and controlled forms of motivation, is useful for predicting continued participation in health-promoting treatments and the maintenance of health-relevant behavior change.

Also drawing on self-determination theory, Mullan, Markland, and Ingledew (1997) developed the Behavioral Regulation in Exercise Questionnaire (BREQ) to measure the continuum of behavioral regulation in exercise contexts. The BREQ assesses external, identified, introjected, and intrinsic regulations. Wilson, Rodgers, and Fraser (2002) designed a study to examine selected psychometric properties of the BREQ to determine the adequacy of the scale for conducting research in exercise contexts based on the propositions embedded within SDT.

To accomplish this aim, data were gathered in two phases to evaluate the BREQ's factorial composition and structure and the relation between the BREQ, need satisfaction, exercise behavior, and relevant motivational constructs. Participants completed measures assessing psychological need satisfaction, optimism, perceived behavioral control, exercise behavior, and the BREQ. In phase one, researchers hypothesized that self-determined exercise regulations (identified and intrinsic) would be more positively correlated with exercise behavior. The purpose of Phase one was to test the measurement and structural properties supporting the BREQ and examine the relations between BREQ subscales and both psychological need satisfaction and exercise behavior. The findings of Phase one support the underlying factor and simplex structure of the BREQ, the internal consistency of the items comprising BREQ subscales, and a pattern of relations between BREQ subscales, psychological need satisfaction, and exercise behavior that are consistent with SDT.

The purpose of phase two was to extend the construct validity evidence for the BREQ by examining relations between BREQ subscales and motivational constructs relevant to the promotion of exercise behavior. Researchers hypothesized that identified and intrinsic regulations would be more positively correlated with optimism and perceived behavioral control than either introjected or external regulations. In general, the results of phase two further support the psychometric integrity of the BREQ as a multidimensional measure of exercise motivation. In addition, the results provide some support for SDT given the positive relations exhibited between more self-deter-mined regulations (intrinsic and identified) and perceived behavioral control. Collectively, the results of the Wilson, et al., (2002) study further support the psychometric properties of the BREQ and lend credence to the notion of measuring exercise motivation from a multidimensional perspective using self-determination theory as a framework of SDT.

A revised version of the BREQ, the BREQ-2, was developed by Markland and Tobin (2004) after the addition of an amotivation sub-scale. Both the BREQ and BREQ-2 assess the different types of extrinsic motivation, intrinsic motivation, and amotivation, with the Exercise Motivation Scale (EMS) assessing three types of intrinsic motivation in contrast to the BREQ-2 that assesses intrinsic motivation in a unidimensional fashion. Moustaka, Vlachopoulous, Vazou, Kaperoni, and Markland (2010) aimed to test the factorial validity of the modified BREQ-2 with amotivation items reinstated in a sample likely to exhibit a wider range of amotivation responses. The sample in the Moustaka et al., (2010) study consisted of 733 exercise participants from various private fitness centers in northern Greece. Researchers compared participants'' results on the BREQ-2 to measures of basic psychological need for autonomy, competence, and relatedness

as they related to exercise; perceptions of autonomy support by the exercise instructor; and frequency of leisure time exercise. Researchers scrutinized the latent structure of the responses on the BREQ-2 by comparing the 18-item five factor correlated model with a 1) a single-factor model, hypothesizing that all items were indicators of a single construct; 2) a five factor uncorrelated model, hypothesizing that the five factors are completely un-correlated constructs; and 3) a hierarchical model, hypothesizing that the correlations between the five factors were explained by a higher order factor. To examine the extent of factor separability, researchers compared the 18-item five factor correlated model with a series of four factor correlated models specifying in each model item from each possible pair of factors to load onto the same factor. Lastly, Pearson's correlations were computed between the Greek BREQ-2 subscales to examine whether correlations conform to a simplex pattern. Upon analysis of the assessments and results, researchers were able to provide initial support for various psychometric aspects of the BREQ-2 scores and determining the questionnaire a valid and reliable instrument for the study of behavioral regulations energizing and directing exercise behavior. Researchers conclude the BREQ-2 could prove useful to researchers wishing to assess amotivation in order to develop a more complete understanding of motivation for exercise.

Upon assessing the various instruments associated with motivation of exercise, Wilson, et al, (2012) aimed examine the tenability of the different scoring protocols applied to the BREQ, and the BREQ-2. Specifically, the researchers explored the utility of using different scoring protocols across four samples of adults who provided data using the instruments. It was hypothesized that motives spanning the continuum of self-determination would display a quasi-simplex pattern of relationships whereby constructs adjacent to one another (e.g. external-

introjected) would correlate more positively than distal constructs (e.g. external-intrinsic). It was also hypothesized that autonomous (not controlled) motives would be associated with more frequent physical activity behavior; and lastly, it was hypothesized that the item-aggregation approach would be the most informative scoring protocol.

A multi-sample investigation was conducted by Wilson, et al., (2012) to assess these protocols. Summary observations indicated that people endorsed more autonomous than controlled motives for physical activity, identified regulation was the strongest correlate and predictor of physical activity, and the scoring protocol used with SDT instruments holds the potential to unveil (or mask) the forces motivating physical activity behavior. Overall, the results support the central assumption set forth by Deci and Ryan (2002): The 'quality' (or type) of human motivation that regulates behavior matters at least as much as the 'quantity' (or level) of that motivation. Based on these observations, researchers concluded that the continued application of SDT to the study of motivation within and across diverse domains and types of physical activity seems well justified. Researchers identified the key finding of this investigation to be that scoring protocols represent an important consideration for research attempting to unravel the dynamics linking human motivation with physical activity behavior using SDT as a framework. Use of the item-aggregation approach seems justifiable on the grounds that identified regulation was consistently a key source of physical activity motivation linked with more frequent behavior.

Pre-Surgery Interventions

It has been hypothesized that modest, preoperative weight loss will improve perioperative outcomes among high-risk, morbidly obese patients undergoing gastric bypass (Evans, et al.,

2007). To test this hypothesis, Evans, et al., (2007) conducted a prospective, longitudinal assessment of various characteristics and outcomes of gastric bypass patients. Researchers analyzed 884 patients who underwent gastric bypass surgery for morbid obesity or its comorbid medical problems over a three-year period. All patients were required to participate in a standardized multidisciplinary preoperative program that encompassed medical, psychological, nutritional, and surgical interventions and education. In addition, patients were encouraged to achieve a ten percent loss of excess body weight prior to surgical intervention. Of the 884 subjects, 425 (48%) lost more than ten percent of their excess body weight prior to the operation. After surgery (mean follow-up, 12 months), this group was more likely to achieve 70% loss of excess body weight. Those who lost more than five percent of excess body weight prior to surgery were statistically less likely to have a length of stay of greater than four days. Researchers concluded that high-risk morbidly obese candidates for bariatric surgery who are able to achieve a loss of five to ten percent excess body weight prior to surgery have a higher probability of a shorter length of hospital stay and more rapid postoperative weight loss.

Many comprehensive bariatric surgery programs have implemented preoperative behavioral interventions for patients, particularly for high-risk patients, and those experiencing problematic eating behaviors. These programs are in an effort to enhance postoperative weight loss and improve psychosocial adjustment. A modest weight loss of up to ten percent of excess body weight has been recommended to help control existing medical problems such as diabetes, obstructive sleep apnea, cardiometabolic syndrome, among other co-morbidities associated with obesity (Center for Nutrition and Weight Management, 2007). The premise behind preoperative intervention is that weight loss will improve the outcomes following surgery. However, it is

unknown whether these interventions are best delivered pre- or post-operatively. The purpose of a study by Leahey, Bond, Irwin, Crowther, and Wing (2009) was to determine when bariatric surgery patients are most receptive to a behavioral intervention, before or after surgery. A total of 32 pre- and post-operative patients were referred to a ten week intervention designed to reduce eating behaviors associated with postoperative weight gain (e.g. loss of control while eating, grazing). The patients were tracked prospectively to determine whether pre- or postoperative patients were more likely to attend and complete the behavioral intervention. Compared with the preoperative patients, the postoperative patients were more likely to follow-up with their referral and initiate treatment, attended more intervention sessions, and were more likely to complete the intervention. Of the postoperative patients, 100 percent attended the first intervention session compared with only 43% of preoperative patients. Only 14% of the preoperative referral patients completed the program compared with 91% of the postoperative patients. Researchers recommended that comprehensive bariatric surgery programs ought to consider balancing the needs of the preoperative patients presenting with maladaptive eating behavior with the likelihood of them participating in a behavioral intervention before surgery.

Still, et al., (2007) aimed to determine the impact of a modest weight loss on factors surrounding surgery (e.g. length of hospital stay) and following surgery (e.g. overall weight loss). Initial weight loss was attempted through an approximate 500-kcal deficit from estimated calories consumed as determined by a registered dietitian; primarily through a low-fat diet. However, if patients had not reached their weight loss goal by month four, they were instructed to follow a 1000- to 1500-kcal liquid diet. In addition, patients were encouraged to wear a pedometer and walk at least 8000 steps per day and drink at least 1.92 liters of water daily, while

avoiding caloric beverages. Monthly behavior modification modules were also reviewed with patients. A significant correlation between preoperative weight loss and postoperative weight loss was found in the 884 participants. Those with the largest excess body weight loss prior to surgery reached their goal excess body weight loss more quickly than those who had low excess body weight loss prior to surgery or those who had excess body weight gain prior to surgery. Those individuals who lost more than ten percent of excess body weight prior to surgery were 2.12 times more likely to achieve 70% EWL loss postoperatively. Additionally, those individuals with five to ten percent excess body weight loss and those with more than ten percent excess body weight loss prior to surgery were less likely to have a length of stay of four days or more compared with those with zero to ten percent excess body weight loss prior to surgery. Results of this study indicated that preoperative weight loss impacts both the perioperative length of stay and the extent of weight loss in the first postoperative year. Patients who lost more than ten percent of excess body weight preoperatively were more than two times more likely to achieve 70% EWL. They were also less likely to have a prolonged length of hospital stay. Researchers concluded preoperative weight loss resulted in a shorter length of stay and a more rapid weight loss post-operatively.

In addition to eating behavior modification, it is imperative patients adopt a complete lifestyle change and incorporate physical activity into their daily weight management regimen. There is some limited evidence that a preoperative behavior modification program may be useful in facilitating the necessary lifestyle changes (Bradendburg & Kotlowski, 2005). Physical activity is one health behavior that is of particular interest to some researchers as it relates to improvement in quality of life and surgical related outcomes. Physical activity attitudes and

behavior prior to surgery may assist in the development of a structured physical activity intervention tailored to one's physical activity level of readiness and physical activity level that could enhance and/or maintain positive QOL changes as well as maximize the amount of postsurgical excess weight loss (Bond, et al., 2006).

Bond, et al. (2006) designed a study to examine the relationships among changes in HRQoL (via the SF-36v2); physical activity readiness (PAR) as measured by stage of change using the transtheoretical model as a framework; and physical activity (as measured by the International Physical Activity Questionnaire – short). Quality of life differences between self-reported sufficiently physically active (SPA) and insufficiently physically active (IPA) groups were also examined. The International Physical Activity Questionnaire-Short (IPAQ-short) is a self-administered short version of the IPAQ to assess the physical activity behavior of individuals. The IPAQ-Short consists of four items that ask information about three types of physical activity (walking, moderate and vigorous activity) across various physical activity domains (i.e. leisure time, occupational, domestic, and transport) using the "last seven days" as the reference period. Using both the total volume of activity and the number of activity days/sessions per week, the IPAQ generates a categorical indicator of regular physical activity; classified as sufficiently active or not sufficiently active, for example. For this study, those who reported engaging in three or more days of vigorous activity of at least 20 minutes per day, five or more days of moderate activity or walking of at least 30 minutes per day, or any five days of any (combination of) activities per week and achieving a minimum of 600 MET-minutes per week were classified as sufficiently physically active (SPA), whereas those participants who did not achieve this criterion were classified as insufficiently physically active (IPA).

To determine physical activity readiness (PAR), participants were asked to choose one of five options that best matched their intention to engage in regular moderate-intensity physical activities that involved moderate physical effort and caused light sweating and breathing that was harder than normal such as brisk walking and carrying light loads. These options permitted the classification of participants into one of five stages of readiness or motivation regarding regular engagement in moderate physical activity: (1) Precontemplation (I do not engage in regular moderate physical activity, and I do not intend to in the next six months), (2) Contemplation (I do not engage in regular moderate physical activity but I intend to in the next six months), (3) Preparation (I do not engage in regular moderate physical activity, but intend to in the next 30 days), (4) Action (I do engage in regular moderate physical activity, but have been doing so for less than six months), and (5) Maintenance (I do engage in regular moderate physical activity and have been doing so for more than six months). The different stages demonstrate that prior to performing a target behavior, individuals will vary in their level of intention to perform that behavior (i.e. precontemplation through preparation) whereas upon performance of the target behavior, the duration with which the target behavior is performed over time becomes of central importance (i.e. action and maintenance).

Researchers administered these three questionnaires to bariatric surgery seeking patients at two different pre-surgical visits; during their initial surgical consult and again approximately one to two weeks prior to surgery with an average of 12 weeks in between. During this period participants did not receive any structured physical activity intervention component nor any specific physical activity requirements that served as prerequisite for surgery to be performed. Brief statements, however, that emphasized the importance of physical activity and exercise for

post-surgical weight loss and recovery were issued in various forms, including written materials sent to individuals inquiring about the surgery, a surgery risk/benefit videotape aired during the initial consult visit, and face-to-face interactions with surgeons, a registered nurse surgical coordinator, and dietitian. With respect to QOL, the only significant difference between the two visits was found on the mental health domain; which were found to be nearly equivalent to the U.S. population norm at the second visit.

Significant increases in all measures of physical activity (moderate, vigorous and total) were found between the first and second visits. Regarding PAR, a greater number of participants at the second visit reported being in the preparation and action stages, whereas fewer participants reported being in the precontemplation, contemplation, and maintenance stages. An examination of within stage frequencies showed that of the 40 participants in the preparation stage at the second visit, 17 participants progressed to this stage from the first visit, whereas 15 participants stayed constant and eight participants regressed. Of the 30 individuals in the action stage at the second visit, 14 progressed to this stage from the first visit, nine remained constant, and seven regressed. Overall, approximately 40% of the sample (n = 34) reported being in a higher stage of change at the second visit as compared to the first visit. Of this group, 14 participants progressed to action. Forty-two percent (n = 36) of the sample remained constant between pre-surgical visits including nine participants in the action stage and eight participants in the maintenance stage. Nineteen percent (n = 16) of the sample regressed to an earlier stage at the second visit. Generally, the increases in physical activity behavior between pre-surgical visits were supported by increases in moderate physical activity readiness with a portion of the sample at the second pre-surgical visit reporting that they were making some "preparations" to engage in regular

moderate physical activity (i.e. in the preparation stage) and another portion of the sample reporting that they had begun to engage in regular moderate physical activity (i.e. in the action stage). A decrease was found, however, in a small percentage of participants who reported being in the maintenance stage from the first pre-surgical visit to the second pre-surgical visit. Of the 20 participants who reported being in the maintenance stage at the first visit, seven participants reported regressing to action at the second visit, suggesting that they had stopped and restarted their moderate physical activity routine between their pre-surgical visits, whereas five of the participants reported regressing to the preparation stage. The regression pattern of the latter group suggests that they stopped engaging in regular moderate physical activity between their pre-surgical visits but expressed a strong intention to restart their routine.

Overall, the researchers concluded that readiness to participate in moderate physical activity improved the closer patients' came to their surgical date, demonstrating a strong intention to engage in regular moderate physical activity routine. Many may likely have already made some specific plans towards achievement of this target behavior and some may have already begun engaging in regular moderate physical activity. Researchers made the suggestion that physical activity before surgery may further enhance surgical weight-loss outcomes by stimulating an increase in metabolism leading to minor weight losses before surgery and other benefits such as greater physical mobility that may translate into a quicker recovery from the surgery, earlier initiation of physical activity, and more progression of physical activity following surgery. Although there is clear and extensive evidence of postsurgical improvements in physical impairments and mental health as measures of QOL indicate, this study was the first to document physical activity-related improvement in perceived physical impairments and

energy prior to surgery. Researchers suggest that future studies incorporate a prospective design that includes both multiple pre-surgical and postsurgical measures to document pre- and postsurgical changes in physical activity and related QOL variables.

As previously mentioned, physical activity is an important health behavior that should be targeted preoperatively to help improve post-operative outcomes and aid in adopting healthy lifestyle changes. Although bariatric surgery candidates may express a desire to change their physical activity habits (Bond, et al., 2006) and view it important for good health (Snuggs McIntyre, & Cowdery, 2010), most bariatric surgery candidates spend very little time in moderate-to-vigorous physical activity (MVPA) (Bond, et al., 2011). Using an objective PA measure (SenseWear Pro Armband), on a group of bariatric surgery candidates, Bond et al., (2011) reported this group to be extremely sedentary preoperatively, spending about 80% of their waking time in sedentary behavior (e.g. sitting), suggesting this group is considerably more sedentary compared to the general population.

Although, bariatric surgery candidates' physical activity (PA) level might contribute to the variability of weight loss and body composition changes following bariatric surgery, there is little research describing the PA of patients undergoing bariatric surgery to inform PA recommendations in preparation for, and following, surgery. King, et al., (2008) describe the PA assessment in the Longitudinal Assessment of Bariatric Surgery-2 study at six sites in the United States and report preoperative PA level. Researchers also examined the relationships between objectively determined PA level and the patient's body mass index and self-reported purposeful exercise. Participants in the King, et al., (2008) study wore an accelerometer and completed a PA diary. Of the 757 participants, 20% were sedentary (<5000 steps/day), 34% had low activity

(5000–7499 steps/day), 27% were somewhat active (7500–9999 steps/day), 14% were active (10,000–12,499 steps/d), and only six % were highly active (≥12,500 steps/day). Body mass index was inversely related to the mean number of steps daily and the mean number of steps each minute during the most active 30 minutes of each day. The most commonly reported activities were walking (44%), gardening (11%), playing with children (10%), and stretching (7%). Bariatric surgery candidates displayed a wide range of PA levels, with almost one half categorized as somewhat active or active. Few patients reported a regular preoperative exercise regimen, suggesting most PA is accumulated from activities of daily living. Patients' report of daily minutes of walking or exercise might not be a reliable indication of their PA (King, et al., 2008).

As a response to the nonexistent guidelines or widely accepted standards regarding the use of pre- or postoperative dietary counseling or comprehensive lifestyle intervention, Papalazarou, et al., (2010) evaluated the effects of lifestyle modification on weight loss and maintenance, eating behavior, physical activity, and dietary patterns for up to three years following bypass surgery. Thirty seven female patients were randomly assigned to one of two intervention groups postoperatively: usual care (UC) or lifestyle intervention (LS), both of which followed dietary guidelines directed by an appropriately trained dietitian for 30 sessions spanning over three years. These assessment sessions provided general information on adopting healthier eating and physical habits. In addition to these general information sessions, (UC) those in the LS group attended additional 40 minutes individualized sessions with the dietitian during these assessment visits. The aim of the intervention was to help patients to overcome barriers and regulate their body weight by adopting healthier eating habits and a less sedentary lifestyle. A

patient-centered collaborative approach was used, along with behavior modification techniques, such as self- monitoring, self-evaluation, goal setting, reinforcement, stimulus control, and relapse prevention.

Eating behavior, via Dutch Eating Behavior Questionnaire, (DEBQ), and PA, via Harokopio Physical Activity questionnaire, were assessed at three, 12, and 36 months postoperatively, with dietary intake and meal patterns being assessed for seven days, via food record, at 12 and 36 months postoperatively. Although PA was assessed via a self-report questionnaire, it was not directly involved as in intervention. Analysis of the data revealed the LS group had significantly lower body weight and had a significantly greater percent excess weight loss after 12 months, 24 months and 36 months following surgery. The only statistically significant factor related to either weight loss or %EWL at 12, 24, and 36 months, after adjusting for potential confounders, namely age, marital status, PAL, and total DEBQ preoperatively was group. Significant differences were also found in favor of the LS group for TV viewing and leisure time PA. The premise of this study is that the application of a lifestyle intervention postoperatively can increase the effectiveness of the surgical procedure in both weight loss and maintenance by affecting factors such as eating behavior, and dietary patterns leisure time PA (PAL). The results suggested that the implementation of a lifestyle intervention can potentially result in greater decreases in both external and restraint eating patterns, increased physical activity and healthier dietary patterns, even at three years post-surgery. Researchers agree the results of this study would be enhanced by inclusion of behavioral intervention sessions preoperatively as well, although recent evidence suggests that preoperative patients may not be very receptive in participating in a behavioral intervention for maladaptive eating.

It has been well established that weight loss efficacy is dependent on behavior modification. Colles, Dixon, and O'Brien (2008) assessed the extent and nature of change in dietary intake, and patterns of physical activity and identified factors associated with weight loss twelve months following the laparoscopic adjustable gastric banding method of weight loss surgery. Eating behavior was assessed using a food frequency questionnaire and an eating behavior questionnaire (the Cancer Council Victoria Food Frequency Questionnaire, and the Three Factor Eating Questionnaire, respectively). Additionally, at twelve months, a series of questions also obtained information on subjective feelings of fullness, the return of "old eating habits," and situations or emotions considered by the subject to stimulate eating or overeating. Physical activity habits were assessed using the Baeke Physical Activity Questionnaire and physical component summary score (PCS) of the SF-36 short form was used as a measure of physical function well-being. A self-made questionnaire was used to assess the presence of possible barriers to regular physical activity. Participants were also encouraged, but not required, to record pedometer step counts at baseline and twelve months in a seven-day pedometer diary.

At twelve months, the Baecke Leisure Index Score was positively correlated with %EWL the mean SF-36 PCS score increased significantly, and in the group that returned the pedometers (37.2%), daily step counts rose by 2655 steps to an average of 8716. Walking further was positively associated with the Baecke Leisure Index Score. However, researchers suggested it was possible that those who failed to return the paired pedometer diaries were more likely to be walking less regularly or had not significantly changed their physical activity patterns from baseline. However, the correlation between poorer %WL and lower daily step counts still suggests that regular walking is associated with better weight outcomes. With regards to dietary

patterns at twelve months, total energy intake was inversely correlated with %WL and there was a high overlap between behaviors influencing %WL and total energy intake. Those who loss greater percentages of weight, had better dietary restraint, better physical activity levels (according to the Baecke Leisure Index Score), fewer disinhibition, lower hunger scores, fewer episodes of eating in response to anxiety, infrequent recurrence of " old eating patterns," and fewer symptoms of depression (as measured by the Beck Depression Inventory). Less weight loss was also recorded in those who admitted eating despite feeling full and eating when depressed or upset and in those who recorded a lower minimum pedometer step-count, and a higher number of barriers to physic al activity. Subjects who ate four or more times per day lost a similar amount of weight to those who ate one to three times per day. Researchers deemed it important to note that non-respondents (25%) were distinguished by a poorer %WL and fewer clinic visits, supporting the observation that patients who do more poorly are less inclined to attend follow-up visit. This study highlighted a variety of postoperative behaviors associated with variations in energy balance and weight outcomes twelve months after LAGB surgery. Researchers suggested that although these subjects had undergone LAGB, low physical function and activity, elevated hunger and non-hungry eating, symptoms of depression, and higher intakes of energy and fat are universal possibilities after any bariatric procedure. Identification of any or a combination of these characteristics can help identify persons who may need more intensive interventional therapy. Regular clinic contact and band volume adjustment are vital to optimize weight loss after any weight loss surgery. Researchers also suggested controlled studies are required to define optimal management strategies by testing the impact of approaches, such as

cognitive behavioral therapy and intensive exercise therapy after LAGB and other bariatric procedures.

Although it appears pre-operative weight loss and behavior modification programs may be beneficial to post-surgical outcomes and long-term success, pre-bariatric surgery requirements vary between surgeons and surgical centers, with standards of practice not yet established Ochner, Dambkowski, Yeomans, Teixeira, and Xavier Pi-Sunyer. (2012) conducted a systematic review to summarize and evaluate the available literature on pre-bariatric surgery weight loss requirements and the relationship between preoperative weight loss and postoperative outcomes.

Data on the effect of preoperative requirements on preoperative weight loss, insurance-mandated preoperative requirements, the contingency of receipt of surgery, preoperative weight loss on postoperative weight loss, and preoperative weight loss on perioperative and postoperative complication and comorbidity rates were analyzed. The majority of studies suggest that: 1) current preoperative requirements held by the majority of third party payer organizations in the United States are ineffective in fostering preoperative weight loss; 2) making receipt of surgery contingent upon achieving preoperative weight loss, and meal-replacement diets, may be particularly effective in fostering preoperative weight loss, and 3) preoperative weight loss may lead to improvements in at least some relevant postoperative outcomes, such as prevention of weight regain and behavior modification. However, a preoperative weight loss mandate may lead to the denial of surgery and subsequent health benefits to individuals who are unable to achieve a pre-specified amount of weight. Researchers concluded that overall, the limited number and quality of prospective studies in this area prohibits the much-needed establishment of standards of practice for pre-bariatric requirements

Other Predictors of Weight Loss Success

One major factor essential for long-term success of weight loss is quality follow up, post-surgical care (Gould, Beverstein, Reinhardt, & Garren, 2007). However, costs, due to lack of insurance coverage, and travel to and from appointments may hinder adherence to follow up appointments. Gould et al, (2007) conducted a retrospective analysis of patients with three to four years of follow-up data after laparoscopic gastric bypass comparing relationship between the length of follow-up and EWL. The patients were divided into three groups: group one patients had attended every scheduled postoperative appointment, group two patients had attended every appointment for one year before being lost to follow-up, and group three patients had been lost to follow-up before one year. Result of this comparison showed that although the EWL did not differ at one year of follow-up (mean EWL 70% for group one versus 65% for group two), a significant difference in the EWL was observed at longer follow ups of three to four years (74% for group versus 61% for group two versus 56% for group three). The most common explanation for missed follow-up appointments was a lack of insurance coverage. Researchers concluded gastric bypass patients who attended all scheduled follow-up appointments experienced greater long-term weight loss than those who did not and that on-going, multidisciplinary care is likely a critical component in maintaining the benefit after surgery.

Lutfi, Torquati, Sekhar, and Richards, (2006) set out to identify particular demographic and other independent predictors of successful weight loss after gastric bypass surgery such as age, gender, marital and parental status, employment status, race, history of depression, and smoking. In this study, success was defined as the patient having lost at least 53% of excess body

weight (%EWL) after one year post surgery. The only two predictors that were statistically significant were pre-surgical BMI and marital status. Patients with a BMI of less than 50 achieved a higher percentage of weight loss compared to those who were superobese (BMI >50). With regards to the other predictor, single patients also achieved a higher percentage of EWL than married patients. Specifically, married patients were at more than 2.6 times less likely to achieve optimal weight loss than those who were unmarried, suggesting that social or family support is a predictor for weight loss success.

Ortega, et al., (2012) also examined potential predictors of excess body weight loss following bariatric surgery. This retrospective study collected baseline and one year follow up data on 407 patients who underwent either RYGB or sleeve gastrectomy (SG). Those who were referred for SG were more obese that those referred for RYGB; however, after adjusting for baseline BMI difference, type of procedure was not a predictor of %EWL. Characteristics that were significant predictors of %EWL were baseline BMI, age, and presence of pre-surgery diabetes. Older patients with higher BMIs had less %EWL one year after surgery than younger patients with lower BMI's. Although the reasons why are not well known, diabetes also negatively influenced %EWL. It was speculated that insulin resistance and improved insulin action may play a role in limiting further weight loss. Researchers concluded younger age, lower BMI, and less obesity-associated complications (e.g. diabetes) were associated with higher EWL and lower risk of a nonsuccessful surgery.

In addition to demographic characteristics, individual's beliefs, preferences, and attitudes toward follow-up care and health behaviors; particularly physical activity may also be a significant factor in successful weight management. Snuggs, et al., (2010) conducted a

qualitative study exploring sedentary overweight and obese adults' communication practices and preferences related to physical activity. Researcher interviewed focus groups that touched on actual behavior; constructs from Health Belief Model, Theory of Planned Behavior, and Social Cognitive Theory; information seeking and communication practices in an attempt to understand the factors that serve as barriers or facilitators to physical activity behavior and preferences for physical activity communication. Upon analysis, researchers discovered participants were unfamiliar with any ACSM recommendations. When asked to guess what they were, participants underestimated the current guidelines. The majority of participants recognized that they should be more physically active and believed that physical activity is associated with good health, but almost all participants (n=12, 92%) stated that they lacked the motivation to initiate or sustain regular physical activity. Participants indicated that the strongest motivators for physical activity were to feel good, lose weight, and be able to do activities with family or friends. Participants wanted the effects of physical activity, longed to be happy with their size, and wanted more self-esteem (as a result of being smaller and setting a goal and sticking to it), yet they felt physical activity was hard, difficult work and they were unsure whether they were capable of incorporating that type of activity into their lives. Additionally, most of the participants did not have strong self-efficacy in being able to perform physical activities. Many said they lacked the information and ability to properly use exercise equipment or design a workout plan. Participants also wanted other people to motivate them to be more active and expressed a need for a social network involving motivation, friendly competition, and social norms for physical activity. Other barriers discovered in this analysis were low self-esteem, exemplified by sharing feeling of being uncomfortable exercising next to a smaller, more-fit person, limited economic resources, time

constraints, and environmental factors, such as well-lit and safe neighborhoods, and weather. Participants did, however, discuss the fact that they wanted health information and assistance in practical needs, such as childcare and wanted more effective communication to take account of their preferences and personal situation, thus addressing the barriers discussed.

Another factor involved in successful weight loss may be the expectations the patient or client has regarding their weight loss. Crawford and Glover (2012) conducted a review of the literature exploring the relationships between initial weight-loss expectations with actual outcome in terms of weight loss, weight regain, and attrition/attendance of weight loss programs. The purpose of the review was to collate research exploring the impact of weight-loss expectations on weight loss, weight regain, and attendance/attrition in hopes to further the current understanding of the relationship between expectations and outcome. Researchers qualitatively reviewed 13 relevant papers in which weight-related behaviors by adults (>18 years of age) were assessed and analyzed expectations between higher and lower expectations were distinguished. The findings were largely unclear. The relationship between expectations and weight loss appears to change with time, while the findings from studies looking at weight regain suggest that there is no association. The relationship between expectations with attendance/attrition is also unclear as a number of discrepancies emerged. Exploration of these discrepancies enabled an understanding to be developed of the complex relationship between expectations and weight-loss treatment outcome. Researchers of this review suggest further research on the importance of the terminology used in examining weight loss expectations and the ways in which expectations are assessed.

Bariatric Surgery vs. Other Weight Loss Methods

It has been suggested the most effective treatment approach to overweight and obesity is the use of lifestyle modification and behavior therapy, which can be delivered alone, or in conjunction with pharmacotherapy or bariatric surgery (Burke & Wang, 2011). Intensive behavioral treatment with meal replacements had also been shown to be a safe and effective weight-loss strategy for severely obese individuals (Anderson, Grant, Gotthelf, & Stifler, 2007). Behavioral strategies developed from social learning theory have been the most thoroughly tested interventions for the treatment of obesity. Nevertheless, descriptions of behavioral techniques and their theoretical foundations have been minimal in the literature. Levy, Finch, Crowell, Talley, and Jeffery, (2007) presented a brief history of these foundations of behavioral strategies for obesity management, emphasizing some of the key components, treatment effectiveness data, and needed areas for further research. Overall, the authors concluded that behavior therapy is both the most studied and most effective therapy for treating obesity at present and gastroenterologists are encouraged to use it as a first line of treatment for most obese patients, and as a key component of therapies that involve pharmacologic and surgical components.

One if the first steps in treating an individual with excess weight is to discuss the topic and assess how the person perceives it, if he or she wishes to address it and, if so, his or her goals and personal resources. Undertaking a weight loss program requires a change in lifestyle with realistic goals and expectations. Standard behavioral therapy (SBT) for weight loss, usually delivered in clinical treatment centers f or weight loss or in clinical trials, has three main components: dietary modification, regular exercise to increase energy expenditures, and behavior

therapy, which are integral to lifestyle modification (Burke & Wang, 2011). Behavior therapy involves strategies based on Bandura's (1977) social learning theory with the assumption that eating and exercise are learned behaviors and that by modifying them, body weight can be changed (Burke & Wang, 2011). The behavioral strategies typically include goal setting, self-monitoring, stimulus control, problem solving, relapse prevention, and cognitive reconstruction. Upon reviewing these treatment options, along with pharmacotherapy and bariatric surgery, Burke and Wang (2011) found most effective approach to be a combination of behavioral strategies and diet and exercise to support sustained lifestyle change. Pharmacotherapy and bariatric surgery have better outcomes when augmented by lifestyle treatment compared with either approach alone. Bariatric surgery is reserved for those with a body mass index (BMI) of greater than or equal to 40, or a BMI of 35 to 39.9 in the presence of comorbidities and that the biggest treatment challenge is the prevention of weight regain.

Powell, Calvin, and Calvin, (2007) surveyed the available literature, evaluating the effectiveness of treatments that were aimed at producing sustained change in weight. Included in their review were rigorous randomized trials (nine lifestyle trials, five drug trials, and two surgical trials) on the efficacy and risk-benefit profile of lifestyle, drug, and surgical interventions aimed at promoting sustained ($\geq$2 years) reductions in weight. Researchers found both lifestyle and drug interventions consistently produced an approximate seven pound weight loss that was sustained for two years and was associated with improvements in diabetes, blood pressure, and/or cardiovascular risk factors. Surgical interventions have a less solid empirical base but offer promise for the promotion of significant and sustained weight reduction post-treatment in the morbidly obese but with possible significant short-term side effects. Researchers

concluded there was strong and consistent support from the rigorous randomized trials they reviewed, that lifestyle or drug interventions result in modest weight loss with minimal risks but inconsistent clinical benefit. Combinations of lifestyle, drug, and, where appropriate, surgical interventions may be the most efficacious approach to achieving sustained weight loss for the widest diversity of patients. The following section reviews the literature comparing bariatric surgery to on surgical approaches.

Although bariatric surgery typically produces large initial weight losses, it is not clear whether surgical patients are more successful at maintaining their weight losses than individuals who have lost comparable amounts of weight through non-surgical means. Many past lifestyle interventions have proven ineffective, yet some intensive behavioral interventions for severely obese persons have been successful in achieving at least a weight/BMI that is at a non-obese level (Anderson, Conley, & Nicholas, 2007). An observational study with the objectives of determining the benefits and risks of a weight loss of 100 pounds achieved by following an intensive behavioral program and of assessing long-term maintenance of weight loss was conducted by Anderson et al., (2007). Researchers, prospectively identified patients, over a nine year period, who lost 100 pounds in a health and weight management program at the University of Kentucky (UK-HMR) reporting the outcomes of weight loss, risk factor changes, medication use, side effects, and long-term maintenance of weight loss. Patients with severe obesity entered into one of two treatment options, a "Medically Supervised" option or the "Healthy Solutions" option. Those in the Medically Supervised option were provided with only meal replacements (shakes or entrées) during the weight loss phase, and were seen weekly by program physicians for four weeks, then biweekly. Laboratory studies (chemistry, lipid, and hematology panels)

were also obtained biweekly or monthly in this group. Those in the Healthy Solutions option did not require medical supervision or laboratory studies but were also given shakes and entrees as a meal replacement; however, five daily servings of fruit and vegetables were included. Both groups of patients attended core classes for twelve weeks and then ongoing classes until they reached their weight goal or entered maintenance. These weekly 90-minute classes reiterated these treatment components of weekly attendance and midweek phone calls; daily record keeping; 2000 kcal of physical activity per week and 35 servings of meal replacements per week. Those in the Healthy Solutions option also received 35 servings of fruit and vegetables per week. A maintenance program was encouraged once an individual reached their weight loss goal, or weight loss slowed, which consisted of weekly 60 minute classes reiterating the components of daily record keeping, consuming four meal replacements per week, eating 35 servings of fruit and vegetables per week; and engaging in 2000 Kcals of physical activity per week. All patients were encouraged to participate in the maintenance program for six months, but many continued in that program for longer periods. Laboratory measurements included fasting blood work, (glucose, lipids, and triglycerides), blood pressure, and liver function tests.

Over the nine year study period, 656 patients with severe obesity enrolled in the UK-HMR program, with each year between nine and 27 patients achieving a 100 pound weight loss creating a total of 118 patients for the study sample. Most patients (80%) elected to use "shakes only" (five shakes) to initiate the diet; shakes and entrées (three shakes plus two entrees) were selected by 17% and only four percent selected the Healthy Solutions option (three shakes, two entrees, and five servings of fruits and vegetable) to initiate weight loss. As recommended by the program's strategy that "more is better," which encourages the consumption of additional shakes,

entrées, or nutrition bars to curb hunger and avoid other foods, 32% of subjects used additional meal replacements during the first week. The use of shakes alone declined slowly over time, but, at 40 weeks more than one-half of these patients were using shakes as their predominant meal replacement. Overall, 64% of patients lost more than half their weight by using shakes only for meal replacement, with only seven percent of patients losing half of their weight by using the Healthy Solutions option. Self-reported physical activity steadily increased from the first week through 40 weeks with patient initially averaging energy expenditure representing walking about seven miles per week to an amount representing walking about 21 miles per week. Follow up data (post-100 pound weight loss) were obtained for five years in this sample at six-month intervals. Patients regained almost half of the weight they lost over the first 30 months and then average weight gains stabilized and increased insignificantly over the next 30 months. Data on participants steadily declined from 118 to 31 patients (36%) at 60 months. Thus, for the 31 available patients who had weights at the five-year follow-up, the data indicated a maintained weight loss of about 46.5% of their initial weight loss and a weight-loss maintenance of 17.9% of initial body weight. Weights for 50 patients (73% of eligible patients) were available between 48 and 72 months. With the use of these additional values to impute weight changes at 60 months, the estimated amount of the weight loss from initial body weight that was maintained was 18.6%, or 49.3% of the initial weight loss. Sixty patients (65% of those eligible) visited the clinic for retreatment or maintenance between two-and-a-half and five years after completing the weight-loss program. Therefore, researchers concluded an intensive, medically supervised, behavioral weight-management intervention using meal replacements effectively enabled certain severely obese persons to lose 100 pounds and maintain approximately one-half of that weight

loss for 5 years. A limitation of this study, however, was the availability of long-term follow-up weights. Although weights for 80% of patients were obtained at two years, only 36% of patients weights that were measured between two-and-a-half and five years were measured at the five-year follow up.

Weight regain is of significant interest in both bariatric surgery efficacy and behavioral intervention programs. As discovered, many factors contribute to the success or failure of weight loss, particularly weight loss maintenance. Bond, Phelan, Leahey, Hill, and Wing (2009) used participants from the National Weight Control Registry (NWCR), an ongoing longitudinal study of successful weight-loss maintainer, thus providing a unique resource for comparing individuals using various parameter, to evaluate who had lost and maintained comparable large amounts of weight through either bariatric surgery or non-surgical methods differed in weight regain over time. In addition, researchers compared the two groups on weight-maintenance behaviors and psychological characteristics upon initial registry and one year after. Lastly, whether the contribution of behaviors and psychological characteristics to one year weight regain was a function of weight-loss method or not, was also evaluated. For each of the 105 bariatric surgery participants, two registry members who achieved weight loss through non-surgical means were matched on sex, weight at registry entry, maximum weight loss within ±15.9 kg. and weight-maintenance duration at the time of study entry within two years. Surgical (n=105) and non-surgical participants (n=210) were then compared on weight-loss maintenance; weight-maintenance behaviors, such as daily caloric intake, (via BLOCK Food Frequency Questionnaire) and PA behavior (via Paffenburger Activity Questionnaire); and psychological characteristics, such as eating factors (e.g. cognitive restraint, disinhibition, and hunger and

frequency of night eating), depression level and level of stress (via Centers for Epidemiological Studies Depression Scale) from registry entry to one year follow-up. Although both groups gained small amounts of weight from registry entry to one year they did not significantly differ in magnitude of weight regain after adjusting for educational differences at study entry. Differences were found, however, in dietary and physical activity behaviors between the surgical and non-surgical groups at both registry entry and one-year follow-up. Surgical participants reported consuming a greater proportion of calories from fat and a lesser proportion from carbohydrates than non-surgical participants. In addition, surgical participants reported consuming fast food more frequently and breakfast less frequently during the week compared with non-surgical participants. Surgical participants also reported expending fewer overall calories through physical activity and, specifically, calories expended in heavy-intensity activity. In a separate categorical analysis, total physical activity was split into two levels of caloric expenditure (0–2000 and > 2000 kcal) based on American College of Sports Medicine exercise recommendations for weight loss and prevention of weigh regain in adults. Results indicated that a smaller percentage of surgical participants as compared with non-surgical participants reported expending > 2000 kcal per week of physical activity at both registry entry and one year. Higher levels of depression and stress were reported in the surgical group, with both groups reporting significant increases in the intensity of depressive symptoms over one year. Lastly, only one predictor variable was significantly related to weight regain: disinhibition. Regardless of group, participants who had higher levels of disinhibition at the beginning of to the study and greater increases in disinhibition regained the most weight over one year.

Researchers from this study concluded that weight loss and maintenance comparable to those observed after bariatric surgery can be accomplished through behavioral methods alone, although this may involve more intensive efforts over a longer duration. Researchers suggest future research should focus on ways to increase and maintain physical activity and better monitor psychological parameters in bariatric surgery patients to facilitate optimal long-term weight control. In addition, designing methods to increase resistance to cues that trigger overeating among individuals who have achieved large weight losses through bariatric or non-surgical methods may assist in preventing weight regain.

A program developed at the McLaren Regional Medical Center which incorporated a pre-surgical behavior modification component as a standard part of the bariatric surgery program was evaluated by Brandenburg and Kotlowski (2005) to better understand patients' perceptions of a pre-bariatric behavioral modification program. The program follows a multi-modality treatment model that includes behavior modification, caloric restriction, nutritional education, and exercise prescription. The premise behind the development of the program is that behavior modification had been identified as an adjunct to increase the success of obesity treatment success, and a behaviorally oriented pre-surgical intervention program may assist bariatric patients to learn and practice the tools needed for the necessary post-surgical dietary and lifestyle changes and weight loss outcome. The researcher's objectives were to investigate patients' satisfaction and perceived usefulness of participation in the six-week pre-surgical program; to identify factors associated with higher rates of satisfaction with the program; and to identify components of the program that could be modified to better meet the needs of the participants and to facilitate post-surgical changes.

The pre-surgical program consists of a medically-supervised liquid supplement diet combined with attendance at weekly behavioral modification groups. The overall goal of the program is to assist patients in learning skills they will need to follow successfully their post-surgical eating plan and the intention of the liquid supplement portion of the program is to provide patients with guided practice establishing dietary habits that will benefit them postoperatively. Participants of the program attended weekly groups, which included time to discuss the previous week's successes and obstacles (i.e., support time), review of food diaries, use of exercise resistance bands, and the presentation of a psycho-educational topic, such as cognitive and emotional components to eating, relapse prevention, setting goals, exercise, stress management, and changing self-talk. Additionally, the participants met with a dietitian twice preoperatively and three times postoperatively for specific dietary information.

Study participants (n=124) completed a self-report questionnaire provided information about their personal background (demographic information), their lifestyle behaviors and health information at the time of receipt of the questionnaire, and their perceptions of various components of the pre-treatment program. Program information included assessment of the respondents' satisfaction and assessment of the perceived usefulness of the program. Patients were asked to rate their level of satisfaction with the program using a five-point Likert scale. The areas assessed included the overall program, the psychological evaluation, physician visits, dietitian visits, the liquid supplement diet, and the pre-surgery groups. Participants were then asked how useful they found the pre-surgery groups overall. Next, they were asked to rate the perceived usefulness of the different components of the groups including support time, educational topics, resistance exercise bands, food diaries, and visits from prior patients.

Participants were then asked to rate how useful they found each of the specific educational topics. Finally, an open-ended question was used which asked participants to provide comments and suggestions that they believed would assist in improving the program. Overall, participants who completed the survey were very satisfied with the program, giving it a mean rating of 4.51 (out of five on the 5-point Likert scale) Participants were also very satisfied with the psychoeducational pre-surgical behavioral modification groups (mean = 4.44 ± .90). They were slightly less satisfied with the liquid supplement diet portion of the program (mean = 3.7 ± 1.26). Participants perceived the program to be useful in helping them to make postoperative behavioral changes. The data was analyzed to determine if participants who experienced a greater decrease in their BMI postoperatively were more satisfied or found the program to be more useful. The correlations between the change in BMI and overall satisfaction and BMI and overall usefulness were not significant. The commentary section of the questionnaire suggested that exercise should be further emphasized within the preoperative program. The second area for improvement appeared to be the aftercare program. The majority of patients (67.6%) reported attending the after-care support group; yet, a significant amount of patients (55.9%) also indicated that it would be useful to have additional behavior modification groups available to them following surgery. Researchers suggested that as research on bariatric outcomes continues, particular psychosocial and behavioral characteristics that enhance postoperative success will be clarified. Future research is needed to obtain objective evidence about whether pre-surgical behavior modification programs enhance physiological and psychological outcomes, and decrease complications from patient non-compliance.

In an observational study describing self-reported psychosocial health before and after various health and weight management methods, Osei-Assiby, et al., (2010) suggested that certain weight management services can lead to psychosocial benefit in morbidly obese patients. Data from patients of three types of interventions, each with or without psychological counseling, were compared: dietary counseling (n=72), dietary counseling plus anti-obesity medication (n=35), and dietary counseling plus bariatric surgery (n=22). All three types of interventions resulted in significant weight loss and a significant reduction in anxiety with no significant differences between groups. However, when analyzing two groups at a time, those who underwent bariatric surgery or pharmacotherapy had scored significantly higher in reductions in depressive scores, physical function, public distress, and work function compared to dietary therapy alone. Upon comparing those who received psychological counseling with those who did not, no differences were found between the two groups who underwent bariatric surgery. Significant differences were found, however within the other two interventions. In the dietary therapy only group, those who received psychological therapy had greater reductions in anxiety and depression and greater improvements in two of the subscales of HRQoL (self-esteem and sexual life) as measured by the Impact of Weight on Quality of Life (IWQOL) questionnaire as well as greater improvement in eating attitudes. In the dietary plus pharmacotherapy group, those who received psychological therapy also displayed greater improvements in emotional well-being (greater reduction in anxiety and depression) and eating attitudes, but had greater improvement in all five subscales of HRQoL. These data suggest that improvements in psychosocial variables can be seen in patients attending a weight loss service that provides psychological counseling in addition to weight loss interventions.

Differences have been found in health-related quality of life (HRQOL) in those who seek bariatric surgery and those who seek other obesity treatments. Kolotkin, et al., (2003) analyzed 339 surgical cases and 87 non-surgical cases to determine their HRQOL and presence of co-morbid conditions. Researchers found the surgery-seeking group reported significantly poorer quality of life scores as assessed by the IWQOL-Lite, were more depressed, and had significantly more co-morbid conditions. Additionally, there was an inverse relationship between the number of co-morbid conditions and total QOL scores, physical function, and sexual life.

Health related quality of life is frequently examined in obese patients and research on bariatric surgery outcomes. The two most common methods for assessing quality of life as it relates to health are the IWQOL and the SF-36. Weight loss has been repeatedly shown to be a significant factor in improvements in HRQOL. To determine if the method of weight loss (surgical vs. non-surgical) is a factor for HRQOL, vanNunen, Wouters, Vingerhoets, Hox and Geenen (2007), conducted a meta-analysis of the literature of over the past two and a half decades examining the differences in baseline HRQOL between seekers of surgical treatment, seekers of non-surgical treatment, and non-treatment seekers; limiting their search to those studies using the IWQOL and/or SF-36. The IWQOL-Lite is a 31-item survey assessing the impact of weight on quality of life in five areas (physical function, self-esteem, sexual life, public distress, work) and additionally yields a total score. The five response categories range from “never true” to “always true”. The validity of the instrument is supported by findings such as sensitivity to weight loss and the results of confirmatory factor analysis. The SF-36 is a 36-item generic questionnaire measuring subjective health status. It comprises eight domains of functioning: 1) physical functioning, 2) role limitations due to physical problems, 3) bodily pain,

4) general health, 5) vitality, 6) social functioning, 7) role limitations due to emotional problems, and 8) mental health. Transformed scores range from 0 (poor health) to 100 (good health). The SF-36 has adequate psychometric characteristics, including good construct validity, high internal consistency, and high test-retest stability. A population difference of greater than or equal to five points on any scale is considered clinically significant (vanNunen, et al., 2007).

In this meta-analysis, five populations were distinguished: 1) the general population, 2) general obese people, 3) non-treatment-seeking obese people, 4) conservative treatment-seeking obese patients, and 5) surgical treatment-seeking obese patients. Participants who were recruited from the general population specifically because of their obesity were considered to be part of the 'general obese population'. This 'general obese population' differs from the 'non-treatment-seeking population' in the sense that non-treatment-seeking persons are known to intentionally choose not to be treated for their obesity. Gender differences, weighted means of BMI, age differences, and HRQoL variables were computed for each population. Weighted multiple regression analysis was used to examine the influence of person characteristics. The results of the literature search and analysis showed that obese persons experience a poorer HRQoL compared to the general population. In particular, those seeking surgical treatment reported by far the most severely reduced HRQoL. IWQOL-Lite quality of life scores of obese populations deviated very much from scores of the norm group. However, these differences disappeared after adjustment for body weight, suggesting that body weight is a main determinant of HRQoL as assessed with this instrument. In contrast to the IWQOL-Lite, the SF-36 questionnaire suggested a less extreme deviation from the norm for obese populations. Not surprisingly, the surgical treatment-seeking obese population demonstrated a large deviation from the norm on virtually all

aspects of HRQoL. The reduction in HRQoL for the other obese populations tended to be zero to moderate. The researchers suggest, based on their findings that other factors, besides weight alone, affect the quality of life of obese persons as measured by the SF-36. This result emphasizes the validity of the SF-36 as a partly weight-independent outcome measure for general quality of life. The current SF-36 findings suggest that obese persons experience limitations in their daily life and work due to emotional problems that are not fully explained by the magnitude of excess weight. An implication of this finding is that weight reduction alone will not suffice when attempting to positively affect mental health of these individuals. A sub-group of obese persons may need specific attention for emotional problems. Overall, the analyses of vanNunen, et al., (2007) suggest that only in the surgical treatment population, reduced physical functioning is a reason for seeking treatment over and above weight and weight-related quality of life. Therefore, it is imperative research examines all dimensions related to weight loss, including physical, emotional, and social.

Regardless of the weight loss method, follow up care is essential for prevention of weight regain and maintenance of a healthy lifestyle. Various methods of delivery have been implemented in weight loss interventions, such as in clinic visits and home-based methods. Although clinic-based models are generally successful, many barriers and burdens exist that can interfere with an individual's ability to adhere (Smith, et al., 2009). As reported by Smith, et al. (2009), individuals frequently indicate it is difficult to find enough time to attend weekly meetings. This time constraint, as well as other expenses associated with transportation, child care fees, and other programmatic costs is an additional barrier necessary to be overcome for successful weight loss to be achieved and maintained. In an effort to address and overcome

these barriers, non-clinic programs have been developed that can be delivered via the Internet telephone e-mail and regular mail. Smith, et al. (2009) designed a study to compare the efficacy of home-based weight loss interventions differing in outside support: 1) a home-based weight loss program receiving additional outside support in the form of a brief weekly contact by phone from an experienced health educator, and 2) a home-based weight loss program receiving no outside support. Researchers also compared the interventions to a no contact, non-diet control group. Both intervention groups were provided prepackaged meals (PM) and low calorie shakes that were delivered to the home on a regular basis. Researchers hypothesized that a home-based weight loss program utilizing PM and shakes will result in clinically significant weight loss over a 12-week intervention, and that a program providing limited weekly support would result in additional weight loss compared to a program in which participants received no weekly support.

Participants in the intervention groups received an instructional booklet in the mail prior to initiation of the study. The booklet included details regarding the diet, sample menus, suggestions for adding variety to the shakes and PM, details for initiation of the physical activity (PA) program and estimation of PA energy expenditure, weekly progress charts, and answers to commonly asked questions. Participants in both intervention groups also received a 45 min phone call from a weight loss health educator before beginning the diet at week one of the study. All participants were instructed to record PM, shake, fruit and vegetable intake (F/V), and PA energy expenditure each day on weekly progress charts that were provided in the instructional materials. The limited weekly support (LWS) group reported weekly totals to a health educator for PM, shake, F/V intake, and PA energy expenditure during the weekly phone call. The non-

weekly support (NWS) group was asked to return weekly progress charts at end-study testing. Participants in the control group were not asked to perform self-monitoring activities.

Participants in the LWS group received one ten-minute phone call per week during the 12-week intervention from an experienced health educator. The primary purpose of this phone call was to track adherence with the program by having the participants report their weekly totals. In addition, LWS participants were provided with suggestions that would aid in meeting the weekly program requirements. The primary finding of this study was that the percent weight loss in both intervention groups was greater than the control group and that percent weight loss in the limited weekly support group was greater than that of the no weekly support group, suggesting support from health educators improves the effectiveness and compliance of home-based weight-loss interventions.

As previously discussed, non-surgical methods, such as lifestyle interventions, of weight loss can be an effective strategy for managing obesity and associated comorbidities such as type 2 diabetes. Due to the rising health care costs, lifestyle interventions are becoming increasingly popular as a treatment option, Wolf, et al., (2007). However, comparisons of nonsurgical and surgical costs have yet to be researched and analyzed. Wolf, et al., (2007) did, however, compare the cost effectiveness of lifestyle interventions to the direct and indirect health costs of obesity and type 2 diabetes. The national cost of diabetes in the U.S. in 2007 exceeds $174 billion (American Diabetes Association, 2007). This estimate includes $116 billion in excess medical expenditures attributed to diabetes, as well as $58 billion in reduced national productivity. People with diagnosed diabetes, on average, have medical expenditures that are approximately 2.3 times higher than the expenditures would be in the absence of diabetes. Approximately $1 in

$10 health care dollars is attributed to diabetes. Indirect costs include increased factors such as absenteeism, reduced productivity, and lost productive capacity due to early mortality (American Diabetes Association, 2007). The medical care costs of obesity in the United States are staggering. In 2008 dollars, these costs totaled about $147 billion (Center for Disease Control, 2012). Overweight and obesity and their associated health problems have a significant economic impact on the U.S. health care system. Medical costs associated with overweight and obesity may involve direct and indirect costs. Direct medical costs may include preventive, diagnostic, and treatment services related to obesity. Indirect costs relate to morbidity and mortality costs. Morbidity costs are defined as the value of income lost from decreased productivity, restricted activity, absenteeism, and bed days. Mortality costs are the value of future income lost by premature death.

As a result of the astronomical costs of obesity and type 2 diabetes, Wolf et al., (2007) analyzed data from the results of a lifestyle intervention program (Improving Control with Activity and Nutrition (ICAN)) to evaluate within-program costs and economic outcomes associated with the one year lifestyle intervention. The purpose of the ICAN pilot project was to evaluate the differences in clinical, humanistic, and economic out-comes of a nutrition intervention involving lifestyle case management and medical nutrition therapy by an RD compared with usual medical care for obese individuals with type 2 diabetes. This program was previously determined to be a "modestly-priced," case management approach to lifestyle modification that was reported as being more effective than usual medical care for improving clinical and health-related quality of life (Wolf, et al., 2004). "Usual care" consisted of written educational material including the Lifestyles, Exercise, Attitudes, Relationships, Nutrition

(LEARN) manual. Usual care patients were seen by a research associate every three months for weight measurements and to complete questionnaires. The research associate was allowed to answer questions but did not assess, set goals, or have an ongoing dialogue about a participant's diet or physical activity level. The purpose of the ICAN pilot project was to evaluate the differences in clinical, humanistic, and economic out-comes of a nutrition intervention involving lifestyle case management and medical nutrition therapy by a registered dietitian (RD) compared with usual medical care for obese individuals with type 2 diabetes.

The primary outcome measures of the Wolf et al., (2007) study, were health care utilization, (e.g. number of claims) and health plan costs during the year of the trial. Services calculated into health care utilization costs included inpatient services, outpatient services, emergency room visits, procedures, and pharmaceutical costs. These costs were plotted against program costs, including patient care unit time (salary and overhead costs), and educational materials. Analysis of costs associated with the ICAN program as compared to health care costs associated with obesity and/or type 2 diabetes revealed that the addition of a clinically feasible, lifestyle intervention, involving an RD as a lifestyle case management for a high-risk obese population at best saved $8,046 per person per year and at worst did not increase health care costs (saved $25 per person per year) compared with usual medical care. Researchers remain cautious, however, in declaring a cost saving within this pilot project because of the relatively small sample size for an economic evaluation coupled with large confidence intervals in this study. Researchers suggest larger trials are needed to verify their results and assist with the growing evidence that lifestyle interventions among higher risk populations may be a cost-effective approach to obesity and type 2 diabetes management.

Wellness Coaching

An approach to weight loss that has not been explored extensively is wellness coaching. Wellness coaching offers a multidisciplinary approach to various aspects of health, such as mental illness, disease (e.g. cancer) management, weight loss and related health outcomes, goal setting and overall well-being and personal growth. Wellness coaching can be used as interventions for people who are at a high risk for illness, as interventions for people who are ill, and for those who wish to improve their general fitness levels Wellness coaches help clients set and reach goals using a variety of tools and techniques (Menon, Paulet, & Thomas, 2012). Despite the growing popularity of wellness coaching programs, the research on their effectiveness is minimal. The limited research on the effectiveness of wellness coaching mainly involves worksite wellness programs. Many worksite wellness programs simply assess various health outcomes of their employees, yet offer limited services to address health issues. However, a growing number of health management companies are going beyond simply assessing outcomes and are looking more in depth to their health coaching programs they have implemented recently; to make sure their services are actually causing the intended results. Some disease management (DM)/wellness companies are looking at health coaching programs' effectiveness (Disease Management Advisor, 2008). For example, Menon, Paulet, and Thomas, (2012) evaluated the effectiveness of coaching on HRQoL in a large corporation implementing various wellness coaching programs. The specific objectives of the study were to 1) determine association between completion of at least one wellness program and changes in HRQoL; and 2) assess associations between completion of various specific wellness-coaching programs and changes in HRQoL to determine any program-specific effects of individual programs over a 1-2

year period. Employees of a large state university who were identified as having moderate or high heath risk of some type after completing a health screening were offered wellness coaching services. Individuals who elected to participate were assigned a health coach based on the desired program. Programs offered included, back care, blood pressure management, cholesterol management, physical activity, nutrition, tobacco use, stress management, weight management, and other programs related to health problems associated with depression. Baseline health data and HRQoL (via SF-8) were assessed as well as stage of change. The Stages of Change model or transtheoretical model indicates that individuals move in stages while changing a particular behavior pattern. Individuals typically move from a state of disinterest (precontemplation) to considering a change (contemplation), preparing for the change (preparation), and then acting (action) and maintaining the new behavior pattern (maintenance) (Prochaska, DiClemente, & Norcross, 1992). The Stages of Change model has been found to be effective for multiple health behaviors including diet, stress, medication adherence, and exercise among others (Prochaska, et al., (2008). Different types of interventions are applied based on the state of change that the individual is in. After one to two years participation in a wellness coaching program, health outcomes and HRQoL were reassessed. After one year of coaching, no significant associations between coaching status and change in either the physical (PCS) or mental component summary (MCS) scores of HRQoL were observed. However, after one year, individuals who participated in nutrition coaching had more positive change in MCS scores than individuals who did not undergo coaching; individuals who participated in stress management coaching had more negative change in MCS scores than individuals who did not participate in stress management coaching; individuals who participated in back care coaching had more negative change than

individuals who did not participate in coaching in change in PCS scores; and individuals who participated in stress management coaching had more negative change in PCS scores than individuals who did not participate in stress management coaching. With respect to individual domains of HRQoL after one year of coaching, the only significant finding was a greater improvement in social function in those who participated in at least one coaching program. After two years of coaching and comparing to the baseline year, none of the mean scores of any of the domains on the HRQoL tool differed significantly across the coaching and non-coaching groups. The mean scores on the MCS score and on the PCS score also did not differ significantly across the two groups. There were no significant associations between coaching status and change over two years in either HRQoL component summary scores. However, individuals who participated in stress management coaching had comparatively negative change in MCS scores as compared with individuals who did not participate in stress management coaching. Physical functioning was the only individual domain in which displayed a significant improvement in those who participated in coaching compared to those who did not. The odds ratio (-.252) indicated that 25.2% fewer individuals who participated in at least one coaching program as compared with those who did no, had improvement in role physical scores. Researchers concluded that although some findings were opposite to what might be expected, the findings do provide some support for a positive impact of wellness coaching on HRQoL.

Beyond HRQoL, very few wellness programs have been evaluated for their effect on health outcomes. Waddington and Bailiff (2009) describe the wellness coaching process as used in the care of cancer patients, survivors, caregivers and those at high risk for cancer. Researchers discuss the fact that it has been well established that cancer risk, survival, and recurrence can be

attributed to lifestyle practices such as diet, physical activity, weight, and tobacco product exposure and that these practices also impact the management of cancer treatment and resulting side effects. Wellness coaches in a cancer care setting make use of inquiry, reflection and mindful listening that leads the patient to significant personal discovery that results in increased insight and awareness. This awareness guides patients in making sustainable changes in self-understanding, self-concept, and behavior while reaching behavioral and outcome goals. Researchers describe a typical coaching program utilization regular (usually weekly) face-to-face or telephone- coaching sessions take place over a minimum of three months. The first session includes development of a wellness vision, identification of motivators, obstacles and strategies to overcome obstacles, and three-month goals. Following sessions include a patient review of their experience related to their goals, processing of obstacles and exploring additional areas of interest. Weekly goals (leading to attainment of three-month goals) are made at each session. Outcome measurements completed after three months of coaching include the categories of wellness addressed and the percent of weekly and three-month goals attained. The practices described by these researchers may also be implemented in other health-related goals, such as weight loss. Although these practices are practical and desirable, their effectiveness in terms of measurable outcomes has yet to be researched and evaluated.

Regardless of the setting in which wellness coaching programs are implemented, program satisfaction is an important aspect of sustained participation and achievement of health goals. Ovbiosa-Akinbosaye, and Long (2012) assessed associations of survey-reported wellness program satisfaction with sustained coaching participation and odds of participants meeting their health goals in a workplace wellness program. Researchers found participants' health goals

depended on the coaching program in which they were enrolled. For example, those in the weight management program may have set a goal to lose weight by a set date. Additionally, assessment of achievement of health goals was based on participants' health goals at the beginning of the coaching program and a program-specific assessment completed at the end of the coaching program. For example, a participant who, in collaboration with his or her health coach, set a goal to lose 15 pounds, would be considered as having achieved his or her goal if the total weight loss at the end of the program period was at least 15 pounds. The main finding of this study was that program satisfaction is positively associated with better program participation and achievement of health goals. Although a positive correlation was found, results need not be interpreted as a causal relationship. That is, it cannot be concluded that program satisfaction caused the improvement in participation or achievement or health goals or that the improvement in participation or achievement or health goals created program satisfaction.

Summary

Research on wellness coaching programs relating to health outcomes such as weight loss, and associated HRQOL, are virtually nonexistent. Therefore, as wellness coaching programs evolve and increase in popularity, it is essential their effectiveness be evaluated. Additionally, although the research on bariatric surgery and their health outcomes is extensive and has shown positive results in initial weight loss and associated comorbidities, further research needs to be conducted on long-term weight management, behavior change, and how pre-surgery interventions may affect long-term outcomes and behavior change as well as HRQoL. The current research on weight loss interventions typically does not involve individuals with extreme obesity (BMI $\geq$ 40), or involves extensive behavior changes that may be difficult to adhere to

long-term such as very low calorie diets and pre-packaged meals. Further research also needs to be conducted on cost effectiveness of bariatric surgery and multidisciplinary weight loss approaches as they compare to the direct and indirect costs of obesity and associated comorbidities.

CHAPTER III: METHODS

Study Design and Participants

This study is a mixed methods study comparing the outcomes and health behaviors of bariatric patients who have either lost weight by surgical methods, participated in a weight loss coaching program, or participated in a weight loss coaching program in addition to surgery. Participants consisted of individuals who underwent bariatric surgery and/or participated in a weight loss coaching program at Sanford Regional Health Center in Fargo, North Dakota from 2009-2012.

Wellness Coaching Program

Sanford Health's weight loss coaching program is a 12-week theory based program designed to create lasting change in health and weight management. The program consists of an initial 1-1.5 hour visit with a clinical exercise physiologist or specialist and additional 11 weekly, 20 minute coaching sessions, either in person or via phone. The initial assessment consists of initial measurements of height, weight, blood pressure, and resting heart rate (HR) and a client/coach interview. The interview consists of assessments of medical history, previous weight loss attempt(s), and struggles and barriers associated with weigh management. An initial questionnaire is completed prior to the interview assessing physical limitations, tobacco use, dietary habits, medications, and the individuals own assessment of pain level, coping skills, social activities, social support, emotional state and overall health. The wellness coach assists the client with setting short term and long-term goals and provides education on exercise, nutrition, and stress management. Following the interview and discussion, an exercise session in conjunction with exercise prescription occurs, in which blood pressure and heart rate is taken

before, during and after the exercise session (duration is dependent on client's fitness level and capabilities). Following the exercise session, the wellness coach provides instructions related to the client's goals, including strength training methods and techniques, cardiovascular exercise instructions, stress management strategies, and dietary guidelines. Each follow up coaching session consists of conversations on goal evaluation and modification, education of weight loss strategies, motivational interviewing, planning and organizing weight loss strategies and behavior modification strategies. The final weekly session reassesses weight, BMI, BP and program evaluation. Participant of the program have the option to participate in supervised exercise at Sanford's Health facilities for an additional fee.

Tools and Measurements

Demographics and Anthropometrics

Demographic information was collected via a demographic, bariatric, and coaching information questionnaire designed by the researcher and wellness coaching staff (Appendix A). The questionnaire consists of demographic information, type of surgery if applicable, questions regarding health professional follow-up visits, and assessment of the coaching program (if applicable). Anthropometric measures include height, initial weight, and current weight. The questionnaire was approved by the research committee and determined to be a valid assessment tool.

Physical Activity

Physical activity (PA) was assessed via The International Physical Activity Questionnaire-Short (IPAQ-short). The International Physical Activity Questionnaire (IPAQ) was developed as an instrument for cross-national monitoring of physical activity and inactivity

and had been determined to contain acceptable and reasonable measurement properties, at least as good as other established self-reports, for monitoring population levels of physical activity among 18- to 65-yr-old adults in diverse settings (Craig, et al., 2003). The IPAQ-short is a self-administered short version of the IPAQ to assess the physical activity behavior of individuals. The IPAQ-Short consists of four items that ask information about three types of physical activity (walking, moderate and vigorous activity) across various physical activity domains (i.e. leisure time, occupational, domestic, and transport) using the "last seven days" as the reference period. Continuous outcomes of walking, moderate activity, and vigorous activity are calculated by the following IPAQ scoring protocol and reported in units of metabolic equivalent (MET) minutes per week: Walking = (3.3 × walking minutes × walking days); Moderate Activity = (4.0 × moderate activity minutes × moderate activity days); and Vigorous Activity = (8.0 × vigorous activity minutes × vigorous activity days) (Sjöström, et al., 2005). Based on the scoring protocol, participants are either categorized as low, moderate, on high on his or her physical activity level. High PA consists of meeting any one of the following two criteria: 1) engaged in vigorous-intensity activity on at least three days and accumulating at least 1500 MET-minutes per week, or 2) seven or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 3000 MET-minute per week. Moderate PA consists of meeting any one of the following three criteria: 1) three or more days of vigorous activity of at least 20 minutes per day, 2) five or more days of moderate-intensity activity or walking of at least 30 minutes per day, or 3) five or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min per week. Those individuals who not meet criteria for high or moderate categories are considered

low or inactive. Participants were also asked if they used any computer applications to assist them with their physical habits and caloric expenditure.

Quality of Life

Health Related Quality of Life (HRQoL) was assessed using QualityMetric's 12-question Short Form Health Survey (SF-12v2) (Appendix D). The SF-12v2 is a shorter version of the SF-36v2 Health Survey that uses just 12 questions to measure functional health and well-being from the patient's point of view. The paper form of the survey takes two to three minutes to complete, and is a practical, reliable, and valid measure of physical and mental health (Ware, Kosinski, Turner-Bowker, & Gandek, 2002; Ware, 2010). The SF-12v2 Health Survey was developed from the 36-item component summary and is used to measure eight domains of health related quality of life: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality, (VT), social functioning (SF), role-emotional (RE), and mental health (MH) in addition to the two component summary measures: physical component summary (PCS) and mental component summary (MCS). Quality of life will be scored using Quality Metric Health Outcomes Scoring Software 4.5 in which mean scores will be computed for the two component summary measures (PCS and MCS) and the eight of HRQoL (PF, RP, BP, GH, VT, SF, RE, MH).

Exercise Motivation

Exercise Motivation is assessed via the Behavioral Motivations in Exercise Questionnaire, revised (BREQ-2) (Appendix E). The BREQ assesses external, identified, introjected, and intrinsic regulations, with the BREQ-2 adding an amotivation subscale. The Behavioral Regulation in Exercise Questionnaire (BREQ) and its subsequent modification

(BREQ-2) have become the most widely used measures of the continuum of behavioral regulation in exercise psychology research (Markland, 2007). The BREQ-2 is a 19-item questionnaire assessing the five aforementioned subscales of self-determination via a five-point Likert scale, from 0-4; corresponding to and ranging from "not true for me," "sometime true for me," and "very true for me." The subscale score are calculated on multidimensional scales, by calculating the mean scores for each set of items as follows: amotivation items 5, 9, 12, and 19; external regulation items 1, 6, 11, and 16; introjected regulation items 2, 7, and 13; identified regulation items 3, 8, 14, and 17; and intrinsic regulation items 4, 10, 15, and 18. The BREQ-2 is the most widely used of the measures, and has been shown to have good factorial validity (Markland & Tobin, 2004; Wilson, Rodgers, & Fraser, 2002, Moustaka, et al., 2010).

Dietary Adherence

Nutritional factors were assessed from questions on the demographic, bariatric, and coaching information questionnaire (Appendix B). Questions on the questionnaire contained information regarding follow-up visits with a registered dietitian (RD), dietary adherence to nutritional guidelines set by an RD, estimated caloric consumption as compared to pre-weight loss, and an open-ended question regarding eating behavior. Participants were categorized as either adhering or non-adhering to dietary guidelines, and ranked from one to five based on estimated current caloric consumption as compared to pre-weight loss method (1= much less, 2=somewhat less, 3 = same, 4=somewhat more, and 5=much more). Participants were also asked if they used any computer applications to assist them with their nutritional habits and caloric consumption. Additionally, a qualitative analysis of current eating behavior was completed.

Procedure

The four tools described above were condensed into one questionnaire (Appendix A) and distributed to all bariatric patients and wellness coaching participants who underwent surgery and/or participated in the wellness coaching program from January 2009 through December 2012. Participants were identified by Sanford staff through a database of all bariatric surgeries performed during those years and wellness coaching participants during the same years. A total of 782 surveys were distributed along with an informed consent describing the study. Consent was implied if participants completed and returned the questionnaires. Participants completed the questionnaires and returned them to the researcher in a pre-addressed postage paid envelope. Four weeks following the initial data collection process, a reminder card was resent to all participants encouraging them to return the survey if they had not already done so and still intended to do so. The study was approved by the North Dakota State University Institutional Review Board (IRB) (Appendix B) and Sanford Health Institutional Review Board (Appendix C).

Statistical Analysis

Participants were placed into one of three categories of weight loss method: coaching only (C), surgery only (S) and coaching plus surgery (CS). All data were analyzed using Statistical Package for the Social Sciences (SPSS – version 21.0, Armonk, NY). Descriptive statistics were performed for, age (years), amount of weight loss (kg), current BMI (kg/m^2), months since surgery and/or completion of coaching program, and type of surgery performed, if applicable. Measures of PA were calculated via the IPAQ protocol. To analyze HRQoL and

Exercise Motivation (EM), mean scores were calculated on the two component summary scores, the eight domains of HRQoL, and the five subscales of self-determination.

An analysis of variance (ANOVA) was performed to determine mean differences among weight loss method on measures of HRQoL and EM and amount of weight loss. Tukey's post hoc analysis was performed to compare mean differences in measures of HRQoL, EM, and amount of weight loss between two of each of the three groups. Results of the ANOVA were not reported in the two manuscripts, however, as all three groups were not represented appropriately. A t-test analysis was then performed comparing mean differences of minutes of PA, exercise motivation scores, and quality of life scores, between the intervention (coaching plus surgery) and control groups (surgery-only). Results were reported in the paper one. Due to a small sample size, an unequal distribution of participants within the three groups, and lack of certain demographic variables, a multivariate analysis was deemed unsuitable for this study.

Chi square for independence, was performed for categorical variables of PA (low, moderate, or high), dietary adherence, caloric consumption comparison, app usage, and program responses. Results were reported appropriately in papers one and two. Chi square goodness of fit was performed to determine frequency distribution of participants in the same variables. A qualitative analysis was conducted on the wellness coaching program. Results were reported in paper two. This study was more of an exploratory study examining the wellness program to lay the foundation for further complex analysis of wellness coaching intervention.

CHAPTER IV: PAPERS

Paper I: Impact of a Weight Loss Coaching Program on Bariatric Surgical Participants

Abstract

Limited research exists on the effectiveness of pre-surgery wellness programs on post-surgical health behaviors for bariatric surgery candidates. The purpose of this study was to determine the impact of a pre-bariatric surgery wellness coaching program on levels of physical activity (PA), dietary habits, and health related quality of life (HRQOL). Questionnaires were distributed to all patients who underwent bariatric surgery and/or participated in a 12-week weight loss wellness coaching program during the years 2009-2012 (n=782). From the 118 returned surveys (15.0%), participants (age = 51.43 years ± 12.98, BMI = 29.34 ± 5.72) were placed in either the wellness coaching group (intervention) or surgery only group (control) based on whether they participated in, and completed, the 12-week program. Wellness coaching participants who elected not to have surgery were excluded from this study (n=16). Weight (self-report), weight loss (self-report), PA (7-day IPAQ-short), exercise motivation (BREQ-2), dietary adherence, a pre- and post- caloric comparison, and HRQOL (SV-12v2) were analyzed. Although researchers recognize self-report weight, weight loss and PA via the IPAQ-S have limitations in this population, significant differences were found. Pre-surgical body mass index (BMI) (45.97 ± 7.56 v. 45.5 ± 6.68), t(100) = -.32, p = .75; and time since surgery 28.05 ± 15.53 v. 34.87 ± 20.96), t(100) = 1.82, p = .07, were not statistically different between groups. Compared to controls (n=58), participants in the wellness coaching group (n=44) had significantly more weekly vigorous PA (min=264.14, ± 472.33 v. 100.17 ± 163.95), t(100)= -2.46, p = .02 and total minutes of MVPA (min=501.30 ± 544.87 v. 293.88, ± 445.50), t(100)= -

2.11, p = .04, and total weekly PA METS (4759.58 ± 5454.9 v. 2877 ± 3043.14), t(100) = -2.22, p = .03. Significant differences were also found for identified regulation (M=2.87 ±.79 v. 2.22, ± .98), t(100)= -3.61, p=.000; intrinsic regulation (M=2.40 ±.93 v. 1.69, ± 1.15), t(100)= -3.34, p=.001; and vitality scores (M=67.05 ± 20.72 v. 55.17 ± 23.76), t(100)= -2.64, p = .010. Participation in a pre-surgery wellness coaching program produced higher scores for positive effects on PA, exercise motivation, and HRQOL following bariatric surgery compared to those not receiving coaching.

Introduction

Bariatric surgery has become one of the most popular methods of treating obesity (American Society for Metabolic and Bariatric Surgery, 2012). Individuals who are considered morbidly, or clinically severe obese are potential candidates for bariatric surgery in an attempt to achieve long-term weight loss and thus improving obesity-related comorbid conditions, such as type II diabetes, hypertension and metabolic syndrome.

Although it has been well established that bariatric surgery is an essentially safe and effective method for treating weight loss and it's comorbidities (Buchwald, et al., 2004; Douketis, Macie, Thabane, & Williamson, 2005; Kushner & Noble, 2006; Padwell, et al., 2011), it is essential patients adopt a healthy lifestyle and make significant changes in eating and exercise behaviors to assist in maintaining the positive outcomes achieved from surgery. Acquiring new coping skills to decrease dependence on food and addressing emotional needs is also an important factor in achieving and maintaining long-term weight loss goals (Bauchowitz, et al., 2005). Much research has focused on examining the patient's eating behaviors after surgery (de Zwann, et al., 2003; Green, Dymek-Valentine, Pytluk, Grange, & Alverdy, 2004;

Sarwer, Waden, & Fabricatore, 2005; Zunker, Karr, Saunders, & Mitchell, 2012) yet little is known about what contributes to this behavior change. Additionally, little research exists on physical activity behavior in the months and years post-surgery.

Virtually all public health agencies and scientific organizations including the National Heart, Lung, and Blood Institute (NHLBI); Centers for Disease Control (CDC); American College of Sports Medicine (ACSM), and various medical societies, recommend physical activity (PA) as an important part of weight management (Donnelly, et al., 2009). Studies have found postoperative PA to be beneficial for greater excess weight loss (%EWL) and continued weight loss in the months and years following surgery. Evans, et al., (2007) found patients who met or exceeded the ACSM recommended 150 minutes per week of moderate to vigorous physical activity (MVPA) had significantly greater weight loss, %EWL, changes in body mass index, and total weight loss percentage at six and 12 months postoperatively compared to those not meeting the recommendation. Josbeno, Kalarcian, Sparto, Otto, & Jakicic (2011) also found participants who engaged in the ACSM recommended amounts of MVPA had a greater %EWL than those who did not meet the recommendation two to five years post-bariatric surgery.

It is recommended, however, that overweight and obese adults may need greater amounts of physical activity (200-300 minutes per week) to achieve desired weight loss and/or prevent weight regain compared to those recommended for most individuals for healthy weight management (150 minutes per week of MVPA) (Donnely et al., 2009). Lifestyle approaches for increasing PA and planned PA are consistently associated with less weight gain compared to inactivity, yet the effects of lifestyle PA for prevention of weight regain after weight loss are unknown owing to lack of available literature (Donelly, et al., 2009).

Comprehensive bariatric surgery programs have implemented preoperative eating behavioral interventions for patients prior to surgery in an attempt to enhance postoperative weight loss and improve psychosocial adjustment. Patients achieving a modest weight loss (approximately ten percent of excess body weight) preoperatively are more likely to achieve greater %EWL and have fewer complications (Still, et al., 2007). In addition to eating behavior modification, a complete lifestyle change and incorporating physical activity into daily weight management regimen post-surgery remains vital. There is some limited evidence that a preoperative behavior modification program may be useful in facilitating the necessary lifestyle changes (Bradendburg & Kotlowski, 2005).

Addressing physical activity attitudes, behavior, and stage of behavior change and physical activity readiness (PAR) prior to surgery may also help promote post- surgical physical activity, enhance and/or maintain positive quality of life (QOL), and maximize the amount of postsurgical excess weight loss (Bond, et al., 2006). Examining the relationships among changes in health related quality of life (HRQoL), PAR, and PA, Bond, et al., (2006) concluded readiness to participate in moderate physical activity improved the closer patients' came to their surgical date, demonstrating a strong intention to engage in regular moderate physical activity routine. Physical activity before surgery may further enhance surgical weight-loss outcomes by stimulating metabolic changes assisting in minor weight losses before surgery and resulting in earlier initiation of physical activity, and more progression of physical activity following surgery (Bond, et al., 2006).

As bariatric surgery continues to be a common recommended weight loss treatment option for the morbidly obese (The National Heart, Lung, and Blood Institute, 2012), the lifestyle

and behavior modifications and underlying causes of obesity are often left untreated, which may result in weight regain and decreased HRQoL. Studies examining weight regain found weight regain to be common, often commencing around the two year mark post-operation, with an average estimated weight regain of 15% of maximum weight loss (Pories, et al., 1992; MacLean, Rhode, Forse, & Nohr, 1995) to 30% of initial body weight in some patients (Pories, et al., 1995). Weight regain within the first two years was typically associated with poor adherence to postoperative diet, (Sarwer, Wadden & Fabricatore, 2005). Therefore, psychosocial and behavioral factors that influence dietary adherence (or lack of) need to be addressed to achieve long-term weight loss. Although health related quality of life (HRQoL) has been found to improve post-surgery in many patients (Kolotkin, et al., 2003; Sarwer, Wadden & Fabricatore, 2005; Bond, et al., 2006; Karlson, Taft, Ryden, Sjostorm, and Sullivan, 2007; Forbush, Nof, Esternach, & Hill, 2011; Osei-Assiby, Kumar, Saravan, & Matyka, 2010; Sutton & Raines, 2010; Kolotkin, et al., 2011), much of the improvement may be attributed more to improvement in physical function as a result of the weight loss rather than improvements in the mental domains (Sutton & Raines, 2010). Some patients, however, may display significant improvement in quality of life scores through the institution of general activity as part of the post-surgical regime, suggesting that regular physical activity and improvements in energy expenditure, will lead to a better quality of life for patients post-surgery (Forbush, et al., 2011).

A patient-centered collaborative approach to behavior and lifestyle modification toward weight loss and maintenance, eating behavior, physical activity, and dietary patterns following bypass surgery can potentially result in greater decreases in both external and restraint eating patterns, increased physical activity and healthier dietary patterns, even at three years post-

surgery (Papalazarou, et al., 2010). A positive, supportive attitude and encouragement from all professionals are crucial to the continuing success of the patient. Since it is believed that obesity is a chronic disease that affects all areas of life, causing both medical and psychological morbidity, and has multiple causes such as genetics, social factors, environmental factors, and psychological issues (Ensberger & Koletsky, 1999), it is feasible that a wellness approach may be effective in treating such a disease. A wellness approach toward obesity recognizes the whole person and treats the disease with a multidisciplinary approach. Obese patients often lack full access to medical services owing in part to social stigma and low self-esteem, which impair self-care activities, and the bias of health professionals (Ensberger & Koletsky, 1999). As opposed to treating the symptoms of obesity and focusing on the body weight itself, a wellness approach focuses on addressing the behaviors causing obesity, the barriers toward behavior change, a healthy lifestyle, and a positive attitude to health and self-care, thus improving the physical and mental well-being of obese patients. A wellness approach emphasizes the integration of the individual dimensions as a way to address a certain health issue. This approach attempts to discover the underlying cause or source of the problem as well as potential barriers of various solutions. Wellness coaches are educated professionals who have adopted the wellness approach toward health and well-being. Wellness coaching is becoming a popular strategy for people wishing to make improvement in their lives. Wellness coaching use an interdisciplinary approach, focusing on helping clients who are well to stay well and helping others not only to recover from illness but to focus on wellness and improving themselves overall. The role of the coach is to help the individual identify personal reasons for pursuing greater wellness, and to enhance motivation for behavior change using evidence-based strategies (Mayo School of Health

Science, 2012). Wellness Coaches are experts in establishing relationships and practicing core coaching skills that assist individuals in identifying values and desires, transforming those values and desired into action, and maintaining lasting change over time.

Much of the research regarding bariatric surgery surveys the actual health outcomes following weight loss such as amount of weight loss and regain, improvement of comorbidities associated with weight loss, and health-related quality of life. Wellness coaching programs are becoming increasingly popular for addressing various health behaviors such as stress management, weight loss, and disease management. However, very limited research exists on evaluating the effectiveness and impact of such programs. To date, no study exists objectively evaluating a weight loss wellness program for its effectiveness. Therefore the purpose of this study was to evaluate the impact of a weight loss wellness coaching program at a regional health facility on health behaviors and quality of life in bariatric surgery patients. This initial exploration of the impact of a wellness coaching program will provide a foundation for future research exploring the effectiveness of wellness coaching and the circumstances under which wellness coaching could be the most effective.

Methods

Questionnaires were distributed to all patients who underwent bariatric surgery and/or participated in a 12-week weight loss wellness coaching program during the years 2009-2012 (n=782) at a regional health facility in the Midwest. Clients of the weight loss wellness program visit with a clinical exercise physiologist or specialist weekly for approximately 1-1.5 hours to evaluate dietary and physical activity goals, discuss stress management techniques, and participate in an exercise session. The goal of the program is to create short and long-term

dietary and physical activity goals, learn exercise methods and techniques, and identify and create appropriate behavior modification strategies for effective weight management.

The questionnaires consisted of demographics, pre-surgical weight, current weight, a seven-day physical activity (PA) recall (IPAQ-short), a health related quality of life (HRQoL) tool (SF-12v2), and an exercise motivation tool (BREQ-2). The International Physical Activity Questionnaire-Short IPAQ-short is a self-administered short version of the IPAQ to assess the physical activity behavior of individuals. The IPAQ-Short consists of four items assessing three types of physical activity (walking, moderate and vigorous activity) using the "last seven days" as the reference period. Total weekly minutes of walking, moderate activity, and vigorous activity are calculated and reported. Metabolic equivalent (MET) minutes per week are calculated from the IPAQ scoring protocol: walking = (3.3 × walking minutes × walking days); moderate activity = (4.0 × moderate activity minutes × moderate activity days); and vigorous activity = (8.0 × vigorous activity minutes × vigorous activity days) (Hagströmer, Oja, & Sjöström, 2006). Participants are either categorized as low, moderate, or high the IPAQ score. High PA consists of meeting any one of the following two criteria: 1) engaged in vigorous-intensity activity on at least three days and accumulating at least 1500 MET-minutes per week, or 2) seven or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 3000 MET-minute per week. Moderate PA consists of meeting any one of the following three criteria: 1) three or more days of vigorous activity of at least 20 minutes per day, 2) five or more days of moderate-intensity activity or walking of at least 30 minutes per day, or 3) five or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min

per week. Those individuals who do not meet criteria for high or moderate categories are considered low or inactive.

The Behavioral Motivations in Exercise Questionnaire, revised (BREQ-2) was used to assess exercise motivation. The BREQ-2 is a 19-item questionnaire, based on self-determination theory, to measure the range of behavioral regulation in exercise contexts (Mullan, Markland, & Ingledew, 1997; Mullan, & Markland, 1997.). It assesses external, identified, introjected, intrinsic regulations, and amotivation subscales of self-determination via a five-point Likert scale. Subscale scores of 0-4 corresponding to and ranging from "not true for me," "sometime true for me," and "very true for me" are calculated on multidimensional scales, by calculating the mean scores for each set of items as follows: amotivation items 5, 9, 12, and 19; external regulation items 1, 6, 11, and 16; introjected regulation items 2, 7, and 13; identified regulation items 3, 8, 14, and 17; and intrinsic regulation items 4, 10, 15, and 18. The BREQ-2 is the most widely used of the measures, and has been shown to have good factorial validity (Markland & Tobin, 2004; Wilson, Rodgers, & Fraser, 2002; Moustaka, Vlachopoulos, Vazou, Kaperoni, & Markland, (2010).

Dietary adherence was based on follow-up visits with a registered dietitian (RD), and estimated caloric consumption was assessed as a comparison to pre-surgery. Participants were categorized as either adhering or non-adhering to dietary guidelines based on a "yes" or "no" response to the question "do your currently follow the nutrition guidelines as instructed by your dietitian?" Estimated current caloric consumption as compared to pre-weight loss method was assessed on a five point Likert scale: (1= much less, 2=somewhat less, 3 = same, 4=somewhat more, and 5=much more).

Health Related Quality of Life (HRQoL) was assessed using Quality Metric's 12-question Short Form Health Survey (SF-12v2), a measure of functional health and well-being from the participant's point of view. Mean scores for the two component summaries [physical component summary, (PCS) and mental component summary (MCS)], and the eight health domains [physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality, (VT), social functioning (SF), role-emotional (RE), and mental health (MH)] were scored using Quality Metric Health Outcomes Scoring Software 4.5 The SF=12v2 a practical, reliable, valid measure of physical and mental health (Cheak-Zamora, Wyrwich, & McBride, 2009; Ware, 2004).

From the 118 returned surveys (15.0%), participants (age = 51.48 years ± 12.98, BMI = 29.34 ± 5.72) were placed in either the wellness coaching group (intervention) or surgery only group (control) based on whether they participated in, and completed, the 12-week program. Wellness coaching participants who elected not to have surgery were excluded from this study (n=16). Weight (self-report), weight loss (self-report), PA (7-day IPAQ-short), exercise motivation (BREQ-2), estimated caloric consumption, dietary adherence, and HRQOL (SV-12v2) were analyzed using Statistical Package for the Social Sciences (SPSS – version 21.0, Armonk, NY). As a result of the small sample size and absence of certain demographic variables, multivariate analysis was not performed and the analysis remained simple and exploratory in nature. The study was approved by the North Dakota State University Institutional Review Board (IRB) and Sanford Health Institutional Review Board.

Results

Pre-surgical and current weight characteristics are presented in Table 1.There were no significant statistical differences between groups regarding age (50.25 years ± 12.18 v. 53.09 years ±12.13) t(100) = -1.17, p = .25; pre-surgical weight (125.11kg ± 22.61 v. 131.52 kg ± 22.14), t(100) = -1.43, p = .16 and body mass index (BMI) (45.52 ± 6.67 v. 45.97 ± 7.56), t(100) = -0.32, p = .75; and months since surgery (34.87 ± 20.96 v. 28.05 ± 15.23), t(100) = 1.82, p = .07. There were also no significant statistical differences between groups on current weight (79.59 kg ± 21.6 v. 84.0 kg. ± 16.7) t = -1.12, p = .26 and BMI (28.78 ± 6.45 v. 29.34 ± 5.73) t = -0.46, p = .65.

Table 1

Weight Characteristics and Months Since Surgery of Bariatric Patients

	Surgery Only N = 58		Wellness plus surgery N = 44		*T*	df
	M	SD	M	SD		
Age	50.25	12.18	53.09	12.13	-1.17	100
Initial Wt (kg)	125.11	22.61	131.52	22.14	-1.43	100
Initial BMI	45.52	6.67	45.97	7.56	-0.32	100
Current Weight	79.59	21.60	84.00	16.70	-1.12	100
Current BMI	28.78	6.45	29.34	5.73	-0.46	100
Months Since Surgery	34.87	20.96	28.05	15.23	1.82	100

Note. *p < .05

Physical activity (PA) levels are presented in Tables 2 and 3. Although participation in wellness coaching did not have an effect on PA category (low, moderate, or high), $X^2 = 1.28$, $\Phi = .11$, significant statistical differences were found on vigorous levels of PA, total moderate to vigorous PA (MVPA), and total weekly PA METS (walking + moderate PA + vigorous PA). Compared to the surgery only group (n=58), participants in the wellness coaching group (n=44)

had significantly more weekly vigorous PA minutes (264.14, ± 472.33 v. 100.17 ± 163.95), t(100)= -2.46, p = .02 more total weekly MVPA minutes (501.30 ± 544.87 v. 293.88, ± 445.50), t(100)= -2.11, p = .04, and total weekly PA MET minutes (4759.58 ± 5454.9 v. 2877 ± 3043.14), t(100) = -2.22, p = .03. The asymmetry of MVPA and PA METS is displayed in Figures 1 and 2.

Table 2

Weekly Physical Activity Levels of Participants Post-Surgery

	Surgery Only N = 58		Wellness plus surgery N = 44		*T*	df
	M	SD	M	SD		
Walking					-0.89	100
Total minutes	394.22	587.31	514.50	779.07		
MET minutes	1300.94	1938.11	1697.85	2570.93		
Moderate					-0.63	100
Total minutes	193.71	382.91	237.16	283.64		
MET minutes	774.83	1531.65	948.64	1146.57		
Vigorous					-2.46*	100
Total minutes	100.17	163.95	264.14	472.33		
MET minutes	801.38	1311.60	2113.09	3778.64		
Total MVPA minutes	293.88	445.50	501.30	544.87	-2.11*	100
Total PA MET minutes	2877.15	3043.14	4759.58	5454.90	-2.22*	100
Sitting minutes	335.69	261.14	269.27	184.26	1.44	100

Note. *p < .05

Table 3

Chi Square Results of Physical Activity Level of Participants Post-Surgery

	Physical Activity Level				
	Low	Moderate	High	X^2	Φ
Surgery Only	16	15	27	1.28	.11
Wellness plus Surgery	8	12	24		
Total	24	27	51		

Note. *p < .05

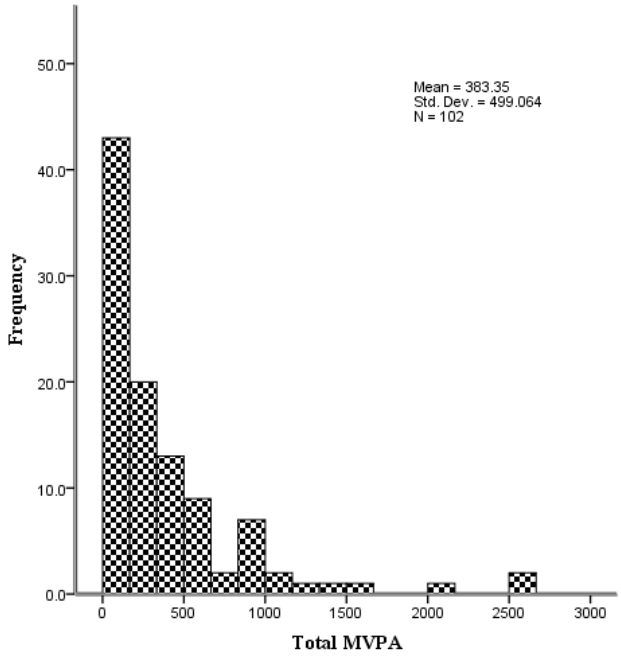


Figure 1. Frequencies of Total MVPA of All Participants

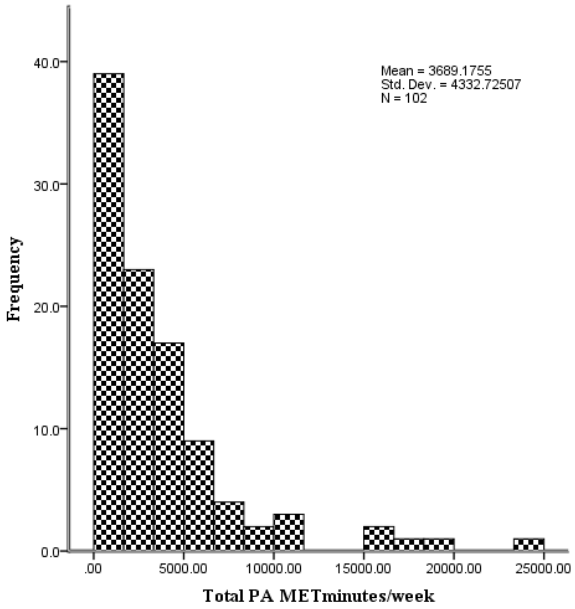


Figure 2. Frequencies of Total Weekly MET Minute for All Participants

Participants in the wellness coaching group scored higher on two subscale measures of exercise motivation. Significant statistical differences were found for identified regulation (M=2.87 ±.79 v. 2.22, ± .98), t(100)= -3.61, p=.000, and intrinsic regulation (M=2.40 ±.93 v. 1.69, ± 1.15), t(100)= -3.34, p=.001. Mean score results from the Behavioral Motivations in Exercise Questionnaire, revised (BREQ-2) are presented in Table 4.

Table 4

Exercise Motivation Scores of Participants Post-Surgery

	Surgery Only N = 58		Wellness plus surgery N = 44		*T*	df
	M	SD	M	SD		
Amotivation	0.53	0.75	0.38	0.69	1.00	100
External Regulation	0.95	1.05	0.63	0.61	1.79	100
Introjected Regulation	1.55	1.09	1.61	1.01	-0.28	100
Identified Regulation	2.22	0.98	2.87	0.79	-3.06*	100
Intrinsic Regulation	1.69	1.15	2.39	0.93	-3.33*	100

Note. *p < .05

Health related quality of life (HRQoL) scores from Quality Metric's 12-question Short Form Health Survey (SF-12v2) are presented in Table 5. No significant statistical differences were found between groups on component scores (PCS or MCS). Significant differences were found for the vitality domain score (M=67.05 ± 20.72 v. 55.17 ± 23.76), t(100)= -2.64, p = .010, with participants in the wellness group having higher vitality scores.

Table 5

Health Related Quality of Life Scores of Participants Post-Surgery

	Surgery Only N = 58		Wellness plus surgery N = 44		*T*	df
	M	SD	M	SD		
Component Summary Scores						
Physical CS	49.71	9.86	50.48	9.59	-0.39	100
Mental CS	49.56	10.44	51.83	9.04	-1.15	100
Domain Scores						
Physical Functioning (PF)	78.42	30.01	78.95	31.43	-0.09	100
Role Physical (RF)	76.29	29.77	81.53	25.50	-0.94	100
Bodily Pain (BP)	73.28	31.71	71.02	29.00	-0.37	100
General Health (GH)	66.29	22.33	68.07	21.95	-0.40	100
Vitality (V)	55.17	23.77	67.05	20.72	-2.64*	100
Social Functioning (SF)	78.45	29.04	82.39	23.86	-0.73	100
Role Emotional (RE)	82.54	25.43	83.81	23.89	-0.26	100
Mental Health (MH)	67.89	21.60	72.16	18.46	-1.05	100

Note. *p < .05

Participation in wellness coaching had a moderate effect on dietary adherence, $X^2 = 8.59$, $\Phi = -.29$, but did not have an effect on estimated caloric consumption as compared to before surgery, $X^2 = 3.94$, $\Phi = .19$. Chi Square analysis results on dietary characteristics are presented in Tables 6 and 7.

Table 6

Chi Square Results of Dietary Adherence of Participants Post-Surgery

	Dietary Adherence			
	Adhering	Non Adhering	X^2	Φ
Surgery Only	33	25	8.59*	-.29
Wellness plus surgery	37	7		
Total	70	32		

Note. *p < .05

Table 7

Chi Square Results of Caloric Consumption Comparison of Participants Post-Surgery

	Caloric Consumption Comparison						
	Much less	Somewhat less	Same	Somewhat more	Much more	X^2	Φ
Surgery Only	43	8	3	4	0	3.94	.19
Wellness plus surgery	38	5	0	1	0		
Total	81	13	3	5	0		

Note. *p < .05

Discussion

Although there were no significant statistical differences in the amount of weight loss as determined by current weight and BMI between groups, those who participated in the wellness coaching program prior to surgery had higher levels of vigorous physical activity, more MVPA, and more total weekly PA, which included both MVPA and walking. The average weekly MVPA in this sample ranged from approximately 300-500 minutes, well above the ACSM recommendation of 150 minutes per week and the amount recommended for long-term weight loss (200-300 minutes) as determined from the Donnely et al., (2009) study examining the data from the National Weight Control Registry. This may be due to the method of PA measurement. Bariatric patients tend to overestimate their self-report PA post-operatively (Bond, et al., 2012). Bond et al., (2012) compared self-report and objective measures of PA in a sample of bariatric patients and found a five-fold increase in self-report PA with 55% reporting ≥ 150 minutes per week, while objective measures found no significant changes in PA with only one participant meeting the ACSM requirement. Fifty percent of all participants from the present study were categorized as having high PA, 26% as moderate, and 24% as low. This is in contrast to the results of the King, et al., (2008) study where of the 757 participants from the Longitudinal

Assessment of Bariatric Surgery-2, where only 20% were active or highly active, 27% were moderately active, and 54% were had low activity or were sedentary; using an objective measure of PA.

Although both groups may be over-reporting PA, significant statistical differences were found between groups, nonetheless. Wellness coaching program participants had higher levels of vigorous physical activity, more MVPA, and more total weekly PA. This is similar to the results of the Papalazarou, et al., (2010) study in which lifestyle modification on weight loss and maintenance, eating behavior, physical activity, and dietary patterns were assessed for up to three years following bypass surgery. Those in the lifestyle intervention (LS) group, comprised of individualized sessions of 40 minutes aiming to help patients overcome barriers and regulate their body weight by adopting healthier eating habits and a less sedentary lifestyle, had more leisure time PA compared to those controls who did not receive the lifestyle intervention.

This study found no significant statistical differences in pre-surgical or current weight between groups suggesting no differences in amount of weight loss as a result of pre-surgery wellness coaching participation. This result is in contrast to those studies finding pre-surgical interventions to have positive effects on post-surgical weight loss. Papalazarou, et al., (2010) found those who received the pre-surgical lifestyle intervention had significantly lower body weight post-operatively and had a significantly greater percent excess weight loss in one to three years following surgery. Evans, et al,, (2007) found patients who participated in a multidisciplinary preoperative program that encompassing medical, psychological, nutritional, and education were more likely to achieve a greater percent of excess body weight and Still, et

al., (2007) concluded a modest pre-operative weight loss as a result of monitored behavioral modification resulted in greater percent excess weight loss.

Both groups were similar in weight loss, yet different in PA which is in contrast to studies finding greater amounts of postoperative PA to contribute to greater excess weight loss (%EWL) and continued weight loss in the months and years following surgery (Evans, et al., 2007; Josbeno, Kalarchian, Sparto, Otto, & Jakicic, 2011). However, these studies compared those meeting the ASCM recommendation to those who did not, while the majority (63%) of participants in the current study had ≥150 minutes of MVPA.

It has been found that bariatric surgery candidates spend less time in MVPA and vigorous PA when compared to normal weight controls (Bond, et al., 2010). Bond, et al. (2010) concluded that bariatric surgery candidates have low PA levels and rarely engage in PA bouts of sufficient duration and intensity to maintain and improve health. Since the two groups in our sample were similar to each other in pre-surgical weight, also classified as obese, and were perhaps similar in PA levels to participants in the Bond et al, (2010) study prior to surgery, the differences in PA levels may be attributed to physical activity attitudes, exercise motivation, and improved stage of change as a result of the concepts addressed in the wellness coaching program.

Bond, et al, (2006) examined these relationships and their impact on post-surgical outcomes and concluded readiness to participate in moderate physical activity improved the closer patients' came to their surgical date, demonstrating a strong intention to engage in a regular moderate physical activity routine. A significant portion of the participants in the Bond, et al. (2006) study also moved toward a higher stage of behavior change as the surgical date

approached. Participating in a wellness coaching program may aid in increasing PAR and improvements in stage of behavior change which may lead to increased levels of PA.

Josbeno, et al., (2011) found a significant relationship between %EWL and physical function, but no significant correlation between physical function and physical activity. The Josbeno, et al., (2011) study demonstrated physical function is not correlated with physical activity, suggesting the capacity to engage in physical activity does not necessarily result in more levels of activity participation. This supports the results in the present study. Although no significant differences were found between groups on physical functions scores, differences were found between groups on PA, supporting the notion PA differences were the result of the lessons learned in the wellness coaching program rather than weight loss and its associated improvements in physical function.

Participants in this study who engaged in the wellness coaching program had higher scores of intrinsic and identified regulation as it relates to exercise motivation, suggesting wellness coaching had a positive influence on motivation to exercise. Additionally, vitality scores were significantly higher in the wellness coaching group suggesting a wellness approach to weight management had a small effect on HRQoL. Results from the present study suggest weight loss, regardless of the wellness intervention, has a greater effect on HRQoL. Improvements in QOL are typically positively associated with amount of weight loss (Sarwer, Wadden, & Fabricatore, 2005). However, a wellness approach where psychological factors are addressed may contribute to higher HRQoL scores. Osei-Assibey, Kyrou, Kumar, Saravanan, & Matyka, (2010) compared data from patients of three types of interventions: dietary counseling, dietary counseling plus anti-obesity medication, and dietary counseling plus bariatric surgery; all

three types of interventions resulted in significant weight loss, but those who received psychological therapy had greater improvement in all five subscales of HRQoL.

Another factor contributing the difference in vitality scores may be the differences found between groups in PA amounts. Kolotkin, et al. (2011) assessed HRQoL and cardiorespiratory fitness (CRF) and found higher fitness levels (resulting from higher amounts of PA and/or exercise) were associated with better weight-specific and physical HRQoL.

Wellness coaching had a moderate effect on dietary adherence and no effect on post-surgical consumption as compared to pre-caloric consumption. This is similar to the Papalazarou, (2010) study in which the lifestyle intervention assisted patients in overcoming barriers and adopting healthier eating habits had positive results. Although participants in our study did not differ significantly in weight loss, Colles, Dixon, and O'Brien (2008) found those who lost greater percentages of weight had better dietary restraint, fewer disinhibition, lower hunger scores, fewer episodes of eating in response to anxiety, and infrequent recurrence of "old eating patterns."

Limitations

Limitations of this study include self-reported measures of weight, physical activity (PA) and nutritional behaviors and adherence, which may not be as accurate as other objective measures, particularly in the bariatric population. Additional limitations include small return rate of surveys (15%), no baseline data to compare pre- and post- measures, and generalizability of the results, as this sample was taken from a modest-sized Midwestern community with little diversity. Additionally, gender was not assessed; therefore gender differences were not included in this study. Suggestions for future research include using multivariate analysis to determine

potential confounding variables, such as age, gender, time since surgery, amount of weight lost, pre-surgical factors (e.g. PA, attitudes, expectations, eating behaviors), social support, and socioeconomic status, affecting group differences.

Conclusions

Participation in a pre-surgical wellness coaching program had positive effects for physical activity, exercise motivation, and one measure of HRQoL, vitality. Since our sample did not differ in pre-surgical weight, weight loss, or post-surgical physical function, it is suggested that differences in PA between groups were the result of the wellness coaching program. Those participants who completed a 12-week wellness coaching program, in which behavior change using evidence-based strategies is the goal, had more minutes of weekly MVPA, engaged in more vigorous PA minutes per week and had more total PA METs compared to those who did not participate in the program. Additionally, compared to controls, those who participated in the coaching program had higher intrinsic and identified regulation suggesting wellness coaching had an effect on motivation to exercise by improving an inherent interest in PA and feeling of personal importance. Lastly, participants in the wellness coaching group had higher vitality scores, which may be the result of increased energy levels due to higher amounts of PA. Overall, positive effects were found for the wellness coaching program.

References

American Society for Metabolic and Bariatric Surgery, (2012). http://www.asmbs.org/.

Bauchowitz, A., Gonder - Fredrick, L., Olbrisch, M., Azarbad, L., Ryee, M., … & Schirmer, B. (2005). Psychosocial evaluation of bariatric surgery candidates: A survey or present practices. *Pschyosomatic Medicine, 67*, 825-832.

Bond, D. S., Evans, R. K., DeMaria, E., Wolfe, L., Meador, J., Kellum, J., & Warren, B. J. (2006). Physical activity and quality of life improvements before obesity surgery. *American Journal of Health Behavior, 30,* 422-434.

Bond, D., Jakicic, J., Vithiananthan, S., Thomas, J., Leahey, T., Sax, H., …& Wing, R. (2010). Objective quantification of physical activity in bariatric surgery candidates and normal-weight controls. *Surgery for Obesity and Related Diseases: Official Journal of The American Society For Bariatric Surgery, 6,* 72-78.

Brandenburg, & Kotlowski, 2005, Practice makes perfect? Patient response to a pre-bariatric surgery behavior modification program. *Obesity Surgery, 15*, 125-132.

Buchwald, H., Avidor, Y., Braunwald, E. Jensen, M.D., Pories, W., Fahrbach, K., & Schoelles, K., (2004). Bariatric surgery, a systematic review. *Journal of American Medical Association, 292(14).* 1724-1737. Retrieved January 14, 2012 from www.jama.ama-assn.org.

Cheak-Zamora, N. C., Wyrwich, K. W., & McBride, T. D. (2009). Reliability and validity of the SF-12v2 in the medical expenditure panel survey. *Quality of Life Research, 18,* 727-735. doi:10.1007/s11136-009-9483.

Colles, S., Dixon, J., & O'Brien, P. (2012). Hunger control and regular physical activity facilitate weight loss after laparoscopic adjustable gastric banding. *Obesity Surgery, 18,* 1-8.

de Zwaan, M., Mitchell, J., Howell, L., Monson, N., Swan-Kremeier, L., Crosby, R., & Seim, H. (2003). Characteristics of morbidly obese patients before gastric bypass surgery. *Comprehensive Psychiatry, 44,* 428-434.

Donnelly, J., Blair, S., Jakicic, J., Manore, M., Rankin, J., & Smith, B. (2009). American College of Sports Medicine position stand. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. *Medicine and Science in Sports and Exercise, 4,* 459-471.

Douketis, J. D., Macie, C. C., Thabane, L. L., & Williamson, D. F. (2005). Systematic review of long-term weight loss studies in obese adults: Clinical significance and applicability to clinical practice. *International Journal of Obesity, 29,* 1153-1167. doi:10.1038/sj.ijo.0802982.

Ernsberger, P. &. Koletsky, R.J. (1999). Biomedical rationale for a wellness approach to obesity: An alternative to a focus on weight loss. *Journal of Social Issues, 55,* 221-260. DOI: 10.1111/0022-4537.00114.

Evans, R., Bond, D., Wolfe, L., Meador, J., Herrick, J., Kellum, J., & Maher, J. (2007). Participation in 150 min/week of moderate or higher intensity physical activity yields greater weight loss after gastric bypass surgery. *Surgery for Obesity and Related Diseases: 3,* 526-530.

Green, A., Dymek-Valentine, M., Pytluk, S., Grange, D., & Alverdy, J. (2004). Psychosocial outcome of gastric bypass surgery for patients with and without binge eating. *Obesity Surgery, 14,* 975-985.

Forbush, S., Nof, L., Echternach, J., & Hill, C. (2011). Influence of activity on quality of life scores after RYGBP. *Obesity Surgery, 21,* 1296-1304. DOI: 10.1007/s11695-010-0184-1.

IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.

Josbeno, D., Kalarchian, M., Sparto, P., Otto, A., & Jakicic, J. (2011). Physical activity and physical function in individuals post-bariatric surgery. *Obesity Surgery, 21,* 1243-1249. DOI:10.1007/s11695-010-0327-4.

Karlsson, J. J., Taft, C. C., Rydén, A. A., Sjöström, L. L., & Sullivan, M. M. (2007). Ten-year trends in health-related quality of life after surgical and conventional treatment for severe obesity: The SOS intervention study. *International Journal of Obesity*, *31,* 1248-1261. doi:10.1038/sj.ijo.0803573.

King, W. C., Hsu, J. Y., Belle, S. H., Courcoulas, A. P., Eid, G. M., Flum, D. R., & . Wolfe, B. M. (2012). Pre- to postoperative changes in physical activity: Report from the Longitudinal Assessment of Bariatric Surgery-2 (LABS-2). *Surgery for Obesity and Related Diseases,* 8, 469-496.

Kolotkin, R., Crosby, R., Pendleton, R., Strong, M., Gress, R., & Adams, T. (2003). Health-related quality of life in patients seeking gastric bypass surgery vs. non-treatment-seeking controls. *Obesity Surgery, 13,* 371-377.

Kolotkin, R., LaMonte, M., Litwin, S., Crosby, R., Gress, R., Yanowitz, F., & Adams,T. (2011). Cardiorespiratory fitness and health-related quality of life in bariatric surgery patients. *Obesity Surgery, 21*, 457-464.

Kushner, R. F., & Noble, C. A. (2006). Long-term outcome of bariatric surgery: An interim analysis. *Mayo Clinic Proceedings, 81(10),* S46-S51.

MacLean, L., Rhode, B., Forse, R., & Nohr, C. (1995). Surgery for obesity - An update of a randomized trial. *Obesity Surgery, 5*, 145-150.

Mayo School of Health Sciences (2011). http://www.mayoclinic.com/health/weight-loss/NU00266.

Markland, D., & Tobin, V. (2004). A modification to the behavioral regulation in exercise questionnaire to include an assessment of amotivation. *Journal of Sport and Exercise Psychology, 26,* 191-196.

Moustaka, F. C., Vlachopoulos, S. P., Vazou, S., Kaperoni, M., & Markland, D. A. (2010). Initial validity evidence for the behavioral regulation in exercise questionnaire-2 among Greek exercise participants. *European Journal of Psychological Assessment, 26*, 269-276. doi:10.1027/1015-5759/a000036.

Mullan, E., Markland, D., & Ingledew, D.K., (1997). A graded conceptualization of self-determination in the regulation of exercise behavior: Development of a measure using confirmatory factor analytic procedures. *Personality and Individual Differences, 23*, 745-752.

Mullan, E., & Markland, D. (1997). Variations in self-determination across the stages of change for exercise in adults. *Motivation and Emotion, 21*, 349-362.

National Heart, Lung and Blood Institute (2012). http://www.nhlbi.nih.gov/meetings/workshops/bariatric-surgery.htm.

Osei-Assibey, G., Kyrou, I., Kumar, S., Saravanan, P., & Matyka, K. (2010). Self-reported psychosocial health in obese patients before and after weight loss. *Journal of Obesity*, 2010. 1-6. DOI: 1155/2010/372463.

Padwell, R., Klarenbach,S., Weibe, N., Birch, D., Karmali, S., Manns, B., Hazel, M., Sharma, A.M., & Tonelli, M. (2011). Bariatric Surgery: A systematic review and network meta-analysis of randomized trials. *Obesity Reviews, 12*, 602-621.

Papalazarou, A., Yannakoulia, M., Kavouras, S., Komesidou, V., Dimitriadis, Papakonstantinou, A., & Sidossis, L. (2010). Lifestyle intervention favorably affects weight loss and maintenance following obesity surgery. *Obesity (Silver Spring, Md.), 18*, 1348-1353.

Pories, W., MacDonald, K., Morgan, E., Sinha, M., Dohm, G., Swanson, M., … & Caro, J.F. (1992). Surgical treatment of obesity and its effect on diabetes: 10-y follow-up. *The American Journal of Clinical Nutrition, 55*, 582S-585S.

Pories, W., Swanson, M., MacDonald, K., Long, S., Morris, P., Brown, B., … & Dolezal, J.M.. (1995). Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. *Annals of Surgery*, *222*, 339-350.

Sarwer, D., Wadden, T., & Fabricatore, A. (2005). Psychosocial and behavioral aspects of bariatric surgery. *Obesity Research, 13,* 639-648.

Still, C., Benotti, P., Wood, G., Gerhard, G., Petrick, A., Reed, M., & Strodel, W. (2007). Outcomes of preoperative weight loss in high-risk patients undergoing gastric bypass surgery. *Archives of Surgery 142*, 994-998.

Sutton, D., & Raines, D. (2010). Health-related quality of life following a surgical weight loss intervention. *Applied Nursing Research: 23,* 52-56.

Waddington, C. & Bailiff, M. (2009). Wellness coaching and cancer care. *Oncology Nursing Forum, 36,* 44.

Ware, J. E.. (2004). SF-36 Health Survey Update. In M. E. Maruish (Ed.). *The use of psychological testing for treatment planning and outcomes assessment: Volume 3: Instruments for adults (3rd ed.)* (pp. 693-718). Mahwah, NJ US: Lawrence Erlbaum Associates Publishers.

Wilson, P. M., Rodgers, W. M., & Fraser, S. N. (2002). Examining the psychometric properties of the behavioral regulation in exercise questionnaire. *Measurement in Physical Education and Exercise Science, 6,* 1-21.

Zunker, C., Karr, T., Saunders, R., & Mitchell, J. (2012). Eating behaviors post-bariatric surgery: A qualitative study of grazing. *Obesity Surgery*, *22,* 1225-1231.

Paper 2: An Evaluation of a Weight Loss Coaching Program

Abstract

A lifestyle approach toward weight loss, encompassing behavior modification strategies, education, and new coping skills, may be most effective in adoption of the healthy behaviors necessary for achievement and maintenance of successful weight loss. The purpose of this study is to quantitatively and qualitatively evaluate a weight loss coaching program for its impact on health-related behaviors and psychosocial factors related to weight loss in a regional health facility. A questionnaire containing measures of dietary and physical activity (PA) behaviors, exercise motivation, health-related quality of life, and open-ended questions evaluating the wellness program, was sent out to all participants who engaged in a weight wellness coaching program (n=392). PA (7-day IPAQ-short), dietary adherence, a pre- and post- caloric comparison, and qualitative data regarding impact of the coaching program were analyzed. Results indicate favorable results for health behaviors: 81.4% would recommend the program to a friend; 79.7% of participants are continuing to follow the advice given to them by their wellness coach; 78.0% of participants reported adhering to the guidelines given to them by their dietitian; 71.2% are consuming calories that are "much less" compared to pre-weight loss; 47.5% are classified as having high levels of PA; and a mean of 4.15, SD = 1.12 on a five-point Likert scale was reported for "how beneficial was the coaching program." A qualitative analysis found positive results for several psychosocial factors, motivation, and new skills learned. A comprehensive, wellness approach encompassing evidence based strategies toward weight loss had positive results towards health related behaviors and emotional and social well-being.

Additionally, participants reported responses consistent with continued engagement in health behaviors and weight loss maintenance

Introduction

Although lifestyle and behavior modifications seem to be most effective for modest weight loss, bariatric surgery appears to be a more effective treatment for excessive weight loss (EWL) in the severe obese and obesity related comorbidities (Padwell, et al., 2011) However, questions still remain regarding long-term success of bariatric surgery and its effect on weight loss maintenance and prevention of, or return of, lifestyle diseases. It has been suggested that perhaps the combination of lifestyle and behavior modification, entailing changes in both eating behavior and physical activity levels in combination with bariatric surgery may be most effective for long-term weight loss success (Hsu, et al., 1998; Powell, Calvin, & Calvin, 2007; Burke & Wang, 2011) and sustained improvements in quality of life (Karlson, Taft, Ryden, Sjostorm, & Sullivan, 2007; Forbush, Nof, Esternach, & Hill, 2011; Romain, et al., 2012).

Successful modest weight loss (of 5-10% of body weight) in obese individuals can lead to substantial improvement in risk factors associated with heart disease and diabetes (Wing & Hill, 2001). Although a modest weight loss can improve comorbidities, bariatric patients lose on average 40-65% of their excess weight (%EWL) (Hsu, et al., 1998; Buchwald, et al., 2004); a change that may be more difficult to sustain without additional interventions regarding behavior modification. The most common successful strategies and behavioral factors identified by members of The National Weight Control Registry (NWCR) were eating a diet low in fat, high in carbohydrates, frequent self-monitoring of their weight and behavior related to weight (e.g. food intake), and regular physical activity, (Wing & Hill, 2001). Weight loss efficacy is

dependent on behavior modification (Colles, Dixon, & O'Brien, 2008) and lifestyle interventions may contribute to behavior modifications necessary for long-term weight management, such as decreases restraint eating patterns, increased physical activity and healthier dietary patterns (Papalazarou, et al., 2010).

Obesity is a chronic disease that has a multifactorial etiology, such as genetics, social factors, environmental factors, and psychological issues, affecting all areas of life, (Ensberger & Koletsky, 1999). Therefore, it is feasible a wellness approach may be effective in treating such a disease. A wellness approach toward obesity recognizes the whole person and treats the disease using a multidisciplinary approach. The wellness approach to health and/or disease is a holistic model, utilizing interactive, multiple dimensions (physical, emotional, social, spiritual, environmental, intellectual, occupational, financial, and aesthetic). A wellness approach emphasizes the integration of the individual dimensions as a way to address a certain health issue. This approach attempts to discover the underlying cause or source of the problem as well as potential barriers of various solutions. With respect to obesity, a wellness approach focuses on addressing the behaviors causing obesity, the barriers toward behavior change, a healthy lifestyle, and a positive attitude to health and self-care, thus improving the physical and mental well-being of obese patients, versus treating the symptoms of the disease and focusing on the body weight itself (Ensberger & Koletsky, 1999). Wellness coaching programs using an interdisciplinary approach are becoming popular for people wishing to make improvements in their lives and/or address various health issues. Wellness coaches are educated professionals and experts in assisting individuals in identifying their values and desires, transforming them into action, and maintaining lasting change over time. The wellness coach utilizes evidence-based

strategies to enhance motivation for behavior change and assists individuals to identify personal reasons for pursuing greater wellness, (Mayo School of Health Science, 2012). Wellness coaching programs have been implemented as worksite wellness programs, weight loss programs in clinics and hospitals, and as fitness programs in sports or fitness facilities, yet few are evaluated for their effectiveness, value, and as a method for program improvement. Therefore, the purpose of this study was to quantitatively and qualitatively evaluate a weight loss coaching program for its impact on health-related behaviors and psychosocial factors related to weight loss in a regional health facility.

Methods

A questionnaire containing measures of dietary and exercise behaviors, exercise motivation, and quality of life, along with questions evaluating the wellness program, was sent out to all participants who engaged in a weight wellness coaching program at a regional health clinic in the Midwest from 2009-2012 (n=392). Measures of exercise motivation and quality of life were not analyzed for the purpose of this study. Dietary behaviors assessed were dietary adherence, a pre-and post-weight loss estimated caloric consumption comparison. If participants answered "yes" to the question "Do you currently follow the nutrition guidelines as instructed by your dietitian, they were considered "adhering," whereas a "no" answer was considered "non-adhering." A comparison or pre-and post-caloric consumption was made based on the response to the question, "How would you classify your current caloric consumption compared to before your weight loss program" (much less, somewhat less, same, somewhat more, much more)?

Walking, moderate and vigorous physical activity (PA) was assessed via The International Physical Activity Questionnaire-Short (IPAQ-short). Weekly MET minutes of the

three types of PA were calculated by the following IPAQ scoring protocol and reported in units of metabolic equivalent (MET) minutes per week: Walking = (3.3 × walking minutes × walking days); Moderate Activity = (4.0 × moderate activity minutes × moderate activity days); and Vigorous Activity = (8.0 × vigorous activity minutes × vigorous activity days) (Hagströmer, Oja, & Sjöström, 2006). Participants were then either categorized as having low, moderate, on high physical activity based on the scoring protocol. High PA consists of meeting either one of the following two criteria: 1) engaged in vigorous-intensity activity on at least three days and accumulating at least 1500 MET-minutes per week, or 2) seven or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 3000 MET-minute per week. Moderate PA consists of meeting any one of the following three criteria: 1) three or more days of vigorous activity of at least 20 minutes per day, 2) five or more days of moderate-intensity activity or walking of at least 30 minutes per day, or 3) five or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min per week. Those individuals who not meet criteria for high or moderate categories are considered low or inactive.

Questions evaluating the wellness coaching program were analyzed. A five point Likert scale was used to determine how beneficial the program was: "On a scale of 1 to 5, 1 being not at all and 5 being extremely helpful, how beneficial was the coaching program?" Participants also responded "yes" or "no" to the questions "Would you recommend this coaching program to a friend?" and "Are your currently following the advice given to you by your coach for living a healthy lifestyle?" A qualitative analysis was conducted on the responses to the question "Please indicate how your participation in the coaching program has impacted your life. What areas of

your life have changed as a result of your weight loss?" Participant responses were coded and categorized based on established coding techniques and guidelines (Saldana, 2013). Responses were coded as eating behavioral (EB), physical activity behavioral (PAB) physical (P), emotional (E), social (S), educational (Ed), lifestyle change (LS) coaching related (C), program related (PR), or overall health (O). Once responses were coded, they were categorized as Overall well-being (O and LS), Physical (P), Behavioral (EB and PAB), Psychosocial (E and S), or Program related (Ed, C and PR). Participants were also asked if they used any computer applications to assist them with their physical habits and/or nutrition habits.

Frequency data and chi square analysis were conducted using Statistical Package for the Social Sciences (SPSS – version 21.0, Armonk, NY). The study was approved by the North Dakota State University Institutional Review Board (IRB) and Sanford Health Institutional Review Board.

Results

Of the 392 surveys sent out, 59 (15.0%) were returned and analyzed. Frequencies and Chi Square results are presented in Table 8. Results from Chi square goodness of fit indicate the sample was not evenly distributed in their responses for dietary adherence (X^2=18.46, p=.00), caloric consumption (X^2=101.25, p=.00), app usage (X^2=100.53, p=.00), recommending the program to a friend (X^2=32, p=.00), and continuing the advice of their wellness coach (X^2=29.63, p=.00). Although almost half (47.5%) were placed in one of the three physical activity categories (high), Chi square goodness of fit results indicate a fairly even distribution (X2 = 5.93, p = .052) regarding PA levels.

Table 8

Chi Square Goodness of Fit for Participant Responses

Category	N	Percent	
Dietary Adherence			
Yes	46	78.0%	
No	13	22.0%	X^2 (1, n=59) = 18.46*
Caloric Consumption			
Much less	42	71.2%	
Somewhat less	10	16.9%	
Same	5	8.5%	
Somewhat more	1	1.7%	
Much More	1	1.7%	X^2 (4, n=59) = 101.25*
Physical Activity			
Low	13	22.0%	
Moderate	18	30.5%	
High	28	47.5%	X^2 (2, n=59) = 5.93
App usage			
Yes, both	6	10.2%	
Yes, PA only	3	5.1%	
Yes, Nutrition only	2	3.4%	
No	48	81.4%	X^2 (3, n= 59) = 100.53*
Recommend Program to a friend			
Yes	48	81.4%	
No	6	10.2%	X^2 (1, n=54) = 32.67*
Continue Using Advice of Coach			
Yes	47	79.7%	
No	7	11.9%	X^2 (1, n=54) = 29.63*

Note. $p < .05$*

Overall, quantitative results were favorable for the wellness coaching program. The mean score, out of 5, for "how beneficial was the coaching program," was 4.15, SD = 1.12; 81.4% would recommend the program to a friend; and 79.7% of participants are continuing to follow the advice given to them by their wellness coach. Additionally, results indicate participants are engaging in health behaviors; 78.0% of participants reported adhering to the guidelines given to them by their dietitian, 71.2% are consuming calories that are "much less" compared to pre-weight loss, and 47.5% are classified as having high levels of PA. However, despite wellness coaching intervention, only 18.6% of participants used any kind of computer application to track

caloric intake or PA. In addition to participation in the wellness coaching program, 43 of the 59 participants (72.8%) elected to undergo in bariatric surgery. However, participation in surgery did not appear to have an effect on the variables analyzed. Chi Square results are presented in Table 9. The only factor in which bariatric surgery election had an effect was caloric consumption ($X^2 = 24.07$, p = .00, Φ = .64).

Table 9

Chi Square Results of Variables of Wellness Coaching Participants

	Surgery Election			
Variable	Wellness, no Surgery N=43	Wellness plus surgery N=16	X^2	Φ
Dietary Adherence				
Yes	10	36		
No	6	7	3.06	.23
Caloric Consumption				
Much less	5	37		
Somewhat less	5	5		
Same	5	0		
Somewhat more	1	0		
Much More	0	1	24.07*	.64
Physical Activity				
Low	5	8		
Moderate	6	12		
High	5	23	2.41	.20
App usage				
Yes, both	3	3		
Yes, PA only	1	2		
Yes, Nutrition only	1	1		
No	11	37	2.61	.21
Recommend Program to a friend				
Yes	12	36		
No	3	3	1.66	.18
Continue Using Advice of Coach				
Yes	13	34		
No	2	5	.00	.01

Note. p < .05*

Results of a qualitative analysis on how the program has impacted participant's lives and what areas of changed are presented in Table 10. The most common personal responses were "able to do more" (O), having "healthier eating habits" (EB), having "more energy," being more physically active (walking, going to the gym and wearing pedometer) (PAB), "more confident" and "more self-esteem" (E), and feelings of social support (S). The most common responses regarding what participants learned from the program were "more awareness" of how to eat and exercise; "I learned it was a lifestyle change;" "good tips, "good ideas," and "good advice" for eating (e.g. food choices, what and how to eat) and exercising; "gave me the tools needed" for successful weight loss; and "prepared me for what to expect" following surgery.

Three of the participants reported negatively about the program. Those comments were coaching specific including, "she set unrealistic goals," "preached about what to eat, how to exercise," "coach did not understand about overweight people or bariatric surgery," and "there was no difference.

Table 10

Coded Responses for Participant Responses on Coaching Program

Category		
Overall well-being	O	LS
	• *"Generally healthier"* • *"Helped me look at the whole picture besides the weight"* • *"I can do so many more things for myself and my family"* • *"Everything has changed in my life as a result (of the weight loss)"* • *"Better health overall"* • *"I look great"* • *"I have my life back"* • *"Everyday things are easier to complete"* • *"Generally easier to move around"*	• *"Prepared me for how my life would change"* • *"watch and reflect on behaviors"* • *"focus on life not food"* • *"more enjoyable lifestyle"*
Physical	P	
	• *More fit, look better* • *Better sex life* • *Better sleep* • *More energy/more ambition* • *Fewer migraines* • *Improved mobility* • *Rarely sick* • *Physical health improved* • *Decreased BP, reduce insulin, improved lipids* • *Maintained weight loss* • *Increase exercise tolerance* • *Less back pain, less pain, less joint pain* • *Improved arthritis*	

Category		
Behavioral	EB	PAB
	• *Eat less, smaller amounts* • *Aware of eating routines* • *Eat more frequently* • *Eat more regularly* • *Eat better/healthier eating habits (more vegetables and fruits, less bread, less sweets).* • *Keep track of what I eat* • *Eat differently* • *Track food* • *Enjoy eating*	• *Wear pedometer* • *Walk a lot/increased walking, walk faster, walk more distances, walk the golf course* • *Trying new types of exercise* • *More well-rounded exercise program* • *Exercise more/regularly, go to gym, more active, move more* • *Try to use exercise ball daily* • *Keep up/play with children/grandchildren* • *Run with dog* • *Walk faster*
Psychosocial	E	S
	• *Feel better/mentally feel better* • *Control depression* • *Happier, happier with self* • *More sense of control* • *Self-esteem* • *Better outlook on future* • *Improved self-image* • *More confident* • *Kept me focused* • *More motivated* • *More pride* • *"I am comfortable in my clothes"*	• *Felt Support (of coach and others)* • *"Good to hear stories of other people"* • *"By not going through it by myself, I didn't feel singled out"* • *Received encouragement* • *"Relationships have changed (some gained, some lost)"* • *More active socially*

Category			
Program Related	Ed	Pr	C
	• *Awareness of components of food, eating routines, calories, portion sizes, alcohol intake* • *"Helped me set realistic goals"* • *"Helped to realize importance and* • *consistency of exercise"* • *"Gave more ideas and methods (of weight loss)"* • *"Taught me choice matters"* • *"I learned to it was a lifestyle change; not just when you are in the program"* • *"You have to use what you learned and incorporate it into your daily life (to be successful)"* • *"Learned about how to eat"* • *"Gave me more ideas on what to look for and what to eat"* • *"Learning about food has helped me make better decisions"*	• *"Good tips on eating habits, food choices"* • *"Provided good tips for getting the most out of workout, where to start and how to progress"* • *"Gave good ideas for new exercises (e.g. exercise ball)"* • *"Reinforced working out and tracking food"* • *"Helped me focus on overall health and not just my weight (LS)"* • *"Great program"* • *"Gave me great tools to work on weight loss"* • *"Gave me tools to use when I didn't know what else to do"* • *"I really enjoyed it"* • *"Cognitive behavior therapy gave me the tools to be successful"* • *"Great advice and easy to follow"* • *"It was challenging"* • *"Gave me specific work out plans and exercises for my target areas"* • *"Prepared me for what to expect after surgery"* • *'It was very informative"* • *"It was excellent"* • *"Wonderful program"*	*"They got me started (being active)"* *"Impressed when she called me at home"* *"Coach was amazing"* *"Explained it well"* *"Coach was terrific"* *"Good attitude of wellness coach; loved her"*

Discussion

Overall, the wellness coaching program evaluated in this study showed positive results for health behaviors and psychosocial factors relating to weight loss and maintenance. The majority of participants in this study reported adhering to their dietitian's guidelines, consuming calories that are "much less" than they were eating prior to their weight loss, and regularly participating in physical activity and/or exercise. These are similar to the behaviors reported by Colles, et al., (2008) in which participants who were successful in weight loss had better dietary restraint, ate more frequently, had fewer episodes of eating in response to anxiety, and infrequent recurrence of "old eating patterns," and better physical activity levels, compared to their non-successful counterparts. Factors that may have contributed to these behaviors were the "tools," "tips" ideas," and "advice" provided by the wellness coaches for weight loss, including exercise ideas and guidelines, specific workout plans, food choices, eating practices, tracking food intake and physical activity, and goal setting.

Since eating behaviors after bariatric surgery play an important role in bariatric postoperative outcomes (Zunker, Karr, Saunders, & Mitchell, 2012) it is important that patients and clients understand what "healthy eating" entails. Clients may have a number of interpretations of certain terminology with respect to eating behaviors. Results from the Zunker, et al., (2012) study exemplify this concept as participants identified the term "grazing" in various ways. Some characterized it as mindful food choices that are consumed in small amounts frequently throughout the day, while others viewed it as an unhealthy eating pattern and perceived it as unplanned, mindless, continuous food consumption. Additionally, clients may not be aware of current PA or exercise guidelines.

Snuggs, McIntyre & Chowdry (2010) discovered the overweight and obese adult participants in their study were unfamiliar with any ACSM recommendations, and when asked to guess what they were, participants underestimated the current guidelines. Other studies reported weight loss participants lacked the information and ability to properly use exercise equipment or design a workout plan (Snuggs, et al., 2010). Wellness programs can assist in clarifying such terminology and guidelines, and educating clients on healthful eating habits and physical activity guidelines. Responses from the current study, such as: "I learned about how to eat," [the program] "gave me more ideas on what to look for and what to eat," "learning about food has helped me make better decisions," [the program] "helped to realize importance and consistency of exercise," "I exercise more/regularly/go to gym/ I'm more active, I move more," and [the program] "gave me specific work out plans and exercises for my target areas," allude to the educational concepts learned from the program.

Other positive results associated with the program refer to various psychosocial factors such as self-esteem, self-confidence, social support, happiness, and well-being. One participant reported "exercise helped control my depression," consistent to the results of Colles, et al, (2008) in which fewer symptoms of depression were associated with increases in weight loss. Several participants reported the program helped "prepare me for what to expect after surgery". Expectations the patient or client have regarding their weight loss is another potential factor contributing to successful weight loss (Crawford & Glover, 2012), although their review of qualitative findings is ambiguous.

Several responses included "more self-esteem" and "more confidence." Self-esteem and self-efficacy have been identified as barriers to PA and relating weight

loss/maintenance (Snuggs, et al., 2010). Therefore, improvements in these factors can assist in maintaining a regular PA routine. Additionally, participants in weight loss studies also longed to be happy with their size, and wanted more self-esteem (Snuggs, et al., 2010). Responses from the present study participants, such as "I am comfortable in my clothes, and [I have an] "improved self-image" add to the positive qualities offered by the wellness program. These factors are also associated with improvements in health-related quality of life (HRQoL) (Kolotkin, et al., 2003; vanNunen, Wouters, Vingerhoets, Hox & Geenen, 2007). Osei-Assiby, Kyrou, Kumar, Saravan, and Matyka, (2010) suggest improvements in psychosocial variables can be seen in patients attending a weight loss service that provides psychological counseling in addition to weight loss interventions.

Motivation is another key factor for behavior change associated with weight loss and maintenance, yet often lack of motivation is cited as a barrier to initiate or sustain regular physical activity (Snuggs, et al., 2010). Persons who have more autonomous motivation for weight loss tend to actively participate in a program more regularly, lose more weight during the program, and maintain their weight loss (Williams, Grow, Freedman, Ryan & Deci, 1996). The present study found responses supporting autonomy and motivation, such as "more sense of control," kept me focused," and "kept me motivated." Some of the strongest motivators for physical activity cited have been to feel good, lose weight, and be able to do activities with family or friends (Snuggs, et al., 2010). Participants in the Snuggs, et al., (2010) study reported wanting other people to motivate them, to be more active, and expressed a need for a social network involving motivation, friendly competition, and social norms for physical activity. Responses from the present study support this behavior: "I feel better/mentally feel better," "I've maintained my weight

loss," "I can keep up/play with my children/grandchildren," "I am more active socially," and "it [the program] brought out my competitiveness."

Lastly, a collaborative, lifestyle approach to weight loss has been shown to be effective (Donnelly, et al., 2009) by helping patients overcome barriers, incorporate behavior modification techniques, such as self- monitoring, self-evaluation, goal setting, reinforcement, stimulus control, and relapse prevention and regulate their body weight by adopting healthier eating habits and a less sedentary lifestyle (Papalazarou, et al., 2010). Weight loss success requires significant behavioral changes and is largely dependent on an individual's ability to implement permanent lifestyle changes as well as acquiring new coping skills to decrease reliance on food for addressing emotional needs (Bauchowitz, et al., 2005). Participant responses such as [the program] "helped me set realistic goals," "I learned it was a lifestyle change; not just when you are in the program," [I have a] "more enjoyable lifestyle," and "you have to use what you learned and incorporate it into your daily life (to be successful)" from the present study display support for a lifestyle approach toward weight loss.

Limitations

Limitations of this study include a small rate of return on the questionnaires, lack of baseline data to compare pre- and post-weight loss measures, and generalizability of the data, as the particular geographical area in which the study was conducted lacks ethnical diversity. Additionally, the majority of the respondents also underwent bariatric surgery, it is difficult to assess if the improvement in physical and psychosocial well-being were the result of the coaching program or the weight loss itself due to surgery; despite the nature of the questionnaire asking participants to discuss the impact of the coaching program.

Conclusions

A comprehensive, wellness approach encompassing evidence-based strategies toward weight loss had positive results towards health related behaviors and emotional and social well-being. Participants from this study reported behaviors consistent with a healthy lifestyle including adhering to nutritional guidelines given to them by their dietitian and/or wellness coach, and engaging in moderate to high levels of physical activity. Additionally, participants in this study reported new skills and lessons learned, such as methods of exercise and dietary patterns that will assist them in continued engagement of healthy behaviors. Lastly, participants reported responses consistent with improved confidence, improved self-esteem, improved emotional well-being, feelings of social support, and encouragement and motivation; all factors associated with continued engagement in health behaviors and weight loss maintenance. Future research should include baseline measures of dietary and exercise behaviors, quality of life factors, and motivation in order to compare results pre- and post- weight loss.

References

Bauchowitz, A., Gonder - Fredrick, L., Olbrisch, M., Azarbad, L., Ryee, M., Woodson, M., …., & Schirmer, B. (2005). Psychosocial evaluation of bariatric surgery candidates: A survey or present practices. *Pschyosomatic Medicine, 67*, 825-832.

Buchwald, H., Avidor, Y., Braunwald, E. Jensen, M.D., Pories, W., Fahrbach, K., & Schoelles, K., (2004). Bariatric surgery, a systematic review. *Journal of American Medical Association, 29,* 1724-1737. Retrieved from www.jama.ama-assn.org.

Burke, L. E., & Wang, J. (2011). Treatment strategies for overweight and obesity. *Journal of Nursing Scholarship, 43,* 368-375. doi:10.1111/j.1547-5069.2011.01424.x.

Colles, S., Dixon, J., & O'Brien, P. (2012). Hunger control and regular physical activity facilitate weight loss after laparoscopic adjustable gastric banding. *Obesity Surgery*, (Preprints), 1-8.

Crawford, R., & Glover, L. (2012). The impact of pre-treatment weight-loss expectations on weight loss, weight regain, and attrition in people who are overweight and obese: a systematic review of the literature. *British Journal of Health Psychology, 17,* 609-630. doi:10.1111/j.2044-8287.2011.02059.x.

Donnelly, J., Blair, S., Jakicic, J., Manore, M., Rankin, J., & Smith, B. (2009). American College of Sports Medicine position stand. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. *Medicine and Science in Sports and Exercise, 41,* 459-471.

Ernsberger, P. & Koletsky, R.J. (1999). Biomedical rationale for a wellness approach to obesity: An alternative to a focus on weight loss. *Journal of Social Issues, 55,* 221-260. DOI: 10.1111/0022-4537.00114.

Hagströmer, M., Oja, P., & Sjöström, M. (2006). The International Physical Activity Questionnaire (IPAQ): A study of concurrent and construct validity. *Public Health Nutrition, 9,* 755-762.

Hsu, L., Benotti, P., Dwyer, J., Roberts, S., Saltzman, E., Shikora, S., & Rand, W. (1998). Nonsurgical factors that influence the outcome of bariatric surgery: A review. *Psychosomatic Medicine, 60,* 338-346.

IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.

Forbush, S., Nof, L., Echternach, J., & Hill, C. (2011). Influence of activity on quality of life scores after RYGBP. *Obesity Surgery, 21,* 1296-1304. DOI: 10.1007/s11695-010-0184-1.

Kolotkin, R., Crosby, R., Pendleton, R., Strong, M., Gress, R., & Adams, T. (2003). Health-related quality of life in patients seeking gastric bypass surgery vs. non-treatment-seeking controls. *Obesity Surgery, 13,* 371-377.

Mayo School of Health Sciences (2011). http://www.mayoclinic.com/health/weight-loss/NU00266.

Osei-Assibey, G., Kyrou, I., Kumar, S., Saravanan, P., & Matyka, K. (2010). Self-reported psychosocial health in obese patients before and after weight loss. *Journal of Obesity*, 2010. 1-6. DOI: 1155/2010/372463.

Padwell, R., Klarenbach,S., Weibe, N., Birch, D., Karmali, S., Manns, B., Hazel, M., Sharma, A.M., & Tonelli, M. (2011). Bariatric surgery: A systematic review and network meta-analysis of randomized trials. *Obesity Reviews, 12*, 602-621.

Papalazarou, A., Yannakoulia, M., Kavouras, S., Komesidou, V., Dimitriadis, Papakonstantinou, A., & Sidossis, L. (2010). Lifestyle intervention favorably affects weight loss and maintenance following obesity surgery. *Obesity (Silver Spring, Md.), 18,* 1348-1353.

Powell, L., Calvin, J., & Calvin, J. (2007). Effective obesity treatments. *The American Psychologist, 62,* 234-246.

Romain, A.J., Bernard, P., Attalin, C., Gernigon, G., Ninot, A., and Avignon, (2012). Health-related quality of life and stages of behavioural change for exercise in overweight/obese individuals. *Diabetes and Metabolism, 38,* 352-358. Retrieved from Science Direct, http://dx.doi.org/10.1016/j.diabet.2012.03.003.

Saldana, J. (2013). A Coding Manual for Qualitative Researchers. Retrieved from http://www.sagepub.com/upm-data/24614_01_Saldana_Ch_01.pdf.

Snuggs, L. S. McIntyre, C., & Cowdery, J.E. (2010). Overweight and obese sedentary adults' physical activity beliefs and preferences. *American Journal of Health Studies 25,* 685-701.

Van Nunen A.M., Wouters E.J., Vingerhoets A.J., Hox J.J., & Geenen, R. (2007). The health-related quality of life of obese persons seeking or not seeking surgical or non-surgical treatment: a meta-analysis. *Obesity Surgery, 17*: 1357-66.

Williams, G. C., Grow, V. M., Freedman, Z. R., Ryan, R. M., & Deci, E. L. (1996). Motivational predictors of weight loss and weight-loss maintenance. *Journal of Personality and Social Psychology, 70,* 115-126. doi:10.1037/0022-3514.70.1.115.

Wing, R.R., & Hill, J.O. (2001). Successful weight loss maintenance. *Annual Review of Nutrition 21*, 323-341. DOI: 10.1146/annurev.nutr.21.1.323.

Zunker, C., Karr, T., Saunders, R., & Mitchell, J. (2012). Eating behaviors post-bariatric surgery: a qualitative study of grazing. *Obesity Surgery, 22*, 1225-1231.

CHAPTER V: CONCLUSIONS AND RECCOMENDATIONS

Results from both papers indicate positive results for a comprehensive, wellness approach toward weight loss. Participation in the wellness coaching program had positive effects on both health behaviors and psychosocial factors associated with weight loss maintenance. In the first study, measures of physical activity, exercise motivation, and vitality were found statistically significantly different between groups. Those participants who completed the 12-week wellness coaching program, had more minutes of weekly MVPA, engaged in more vigorous PA minutes per week and had more total PA METs compared to those who did not participate in the program. Additionally, those who participated in the coaching program had higher intrinsic motivation, higher identified regulation, and higher vitality scores compared to those who did not participate. These results suggest wellness coaching had a positive effect on motivation to exercise by improving an inherent interest in PA and feeling of personal importance. It is suggested that higher vitality scores may be the result of increased energy levels due to higher amounts of PA. Results of the second study support these finding as qualitative analysis revealed the coaching program assisted with participant's motivation to exercise and eat healthy. Participants also reported having more energy as a result of the weight loss and related coaching program. Participants in the second study also reported they engaged more in exercise and PA behaviors as a result of having learned new skills enabling them to do so.

Another important finding was the wellness coaching program had positive results towards emotional and social well-being. Qualitative analysis revealed improved confidence, improved self-esteem, improved emotional well-being, feelings of social

support, and encouragement and motivation. Overall, wellness coaching participants are engaged in behaviors consistent with a healthy lifestyle and have gained favorable psychosocial factors associated with continue engagement those behaviors and for weight loss maintenance. In general, positive effects were found for individuals participating in the wellness coaching program for weight loss and improvement in overall well-being. Future research should include baseline measures of dietary and exercise behaviors, quality of life factors, and motivation in order to compare results pre- and post- weight loss. Objective measures of PA should also be included in future research involving this population. Further research should also include more complex, multivariate analysis to identify possible confounding variables affecting post-surgical health-related behaviors, as the present study used simple, descriptive analysis to explore the nature and effectiveness of wellness coaching. Since obesity, weight loss, health-related behaviors are multifactorial, future research should examine those related variables such as demographics (e.g. age, gender, and amount of weight lost), pre-surgical behaviors, pre-surgical attitudes and expectations, socioeconomic status, and available social support.

REFERENCES

American Diabetes Association. Economic costs of diabetes in the U.S. in 2007. *Diabetes Care. 2008, 31,*596-615.

American Society for Metabolic and Bariatric Surgery, (2012). http://www.asmbs.org/.

Anderson, J., Conley, S., & Nicholas, A. (2007). One hundred pound weight losses with an intensive behavioral program: changes in risk factors in 118 patients with long-term follow-up. *American Journal of Clinical Nutrition, 86,* 301-307.

Anderson, J., Grant, L., Gotthelf, L., & Stifler, L. (2007). Weight loss and long-term follow-up of severely obese individuals treated with an intense behavioral program. *International Journal of Obesity (2005), 31,* 488-493.

Bandura, 1977. *Social Learning Theory*. Englewood Cliffs, NJ: Prentice Hall.

Bauchowitz, A., Gonder - Fredrick, L., Olbrisch, M., Azarbad, L., Ryee, M., Woodson, M., … & Schirmer, B. (2005). Psychosocial evaluation of bariatric surgery candidates: A survey or present practices. *Pschyosomatic Medicine, 67,* 825-832.

Boeka A, and Lokken K. (2008) Neuropsychological performance of a clinical sample of extremely obese individuals. *Archives Clinical Neuropsychology, 23,* 467-74.

Bond, D. S., Evans, R. K., DeMaria, E., Wolfe, L., Meador, J., Kellum, J., & Warren, B. J. (2006). Physical activity and quality of life improvements before obesity surgery. *American Journal of Health Behavior, 30,* 422-434.

Bond, D. S., Phelan, S. S., Leahey, T. M., Hill, J. O., & Wing, R. R. (2009). Weight-loss maintenance in successful weight losers: Surgical vs. non-surgical methods. *International Journal of Obesity, 33,* 173-180. doi:10.1038/ijo.2008.256

Bond, D., Jakicic, J., Vithiananthan, S., Thomas, J., Leahey, T., Sax, H., …& Wing, R. (2010). Objective quantification of physical activity in bariatric surgery candidates and normal-weight controls. *Surgery for Obesity and Related Diseases: Journal of the American Society for Bariatric Surgery, 6,* 72-78.

Bond, D., Unick, J., Jakicic, J., Vithiananthan, S., Pohl, D., Roye, G. G., & Wing, R. (2011). Objective assessment of time spent being sedentary in bariatric surgery candidates. *Obesity Surgery, 21,* 811-814.

Bond, D., Jakicic, J., Unick, J.L., Vithiananthan, S., Pohl, D., Roye, G. G., …& Wing, R. (2012). Pre- to postoperative physical activity changes in bariatric surgery patients: self-report vs. objective measures. *Obesity, 18,* 2395-2397. Retrieved from: http://onlinelibrary.wiley.com/doi/10.1038/oby.2010.88/.

Bouchard, C., Blair, S., & Haskell, W.L.,(2007). *Physical Activity and Health*. Champaign IL: Human Kinetics.

Brandenburg, D., & Kotlowski, R. (2005). Practice makes perfect? Patient response to a prebariatric surgery behavior modification program. *Obesity Surgery, 15,* 125-132.

Buchwald, H., & Oien, D. (2009). Metabolic/bariatric surgery, Worldwide 2008. *Obesity Surgery, 19,* 1605-1611.

Buchwald, H., Avidor, Y., Braunwald, E. Jensen, M.D., Pories, W., Fahrbach, K., & Schoelles, K., (2004). Bariatric surgery, a systematic review. *Journal of American Medical Association, 292.* 1724-1737. Retrieved January 14, 2012 from www.jama.ama-assn.org.

Burke, L. E., & Wang, J. (2011). Treatment strategies for overweight and obesity. *Journal of Nursing Scholarship, 43,* 368-375. doi:10.1111/j.1547-5069.2011.01424.x.

Center for Disease Control and Prevention, 2012. http://www.cdc.gov/h1n1flu/in_the_news/obesity_qa.htm.

Center for Nutrition and Weight Management, 2007. http://www.geisinger.org/services/gastro/nut_wgt_mgt.html.

Cheak-Zamora, N. C., Wyrwich, K. W., & McBride, T. D. (2009). Reliability and validity of the SF-12v2 in the medical expenditure panel survey. *Quality of Life Research, 18*, 727-735. doi:10.1007/s11136-009-9483

Cherala, SS (2012). Gastric bypass surgeries in New Hampshire, 1996-2007. *Prevention of Chronic Diseases, 9*:110089.

Colles, S., Dixon, J., & O'Brien, P. (2012). Hunger control and regular physical activity facilitate weight loss after laparoscopic adjustable gastric banding. *Obesity Surgery, 18*, 1-8.

Crawford, R., & Glover, L. (2012). The impact of pre-treatment weight-loss expectations on weight loss, weight regain, and attrition in people who are overweight and obese: A systematic review of the literature. *British Journal of Health Psychology, 17*, 609-630. doi:10.1111/j.2044-8287.2011.02059.x.

de Zwaan, M., Mitchell, J., Howell, L., Monson, N., Swan-Kremeier, L., Crosby, R., & Seim, H. (2003). Characteristics of morbidly obese patients before gastric bypass surgery. *Comprehensive Psychiatry, 44*, 428-434.

Deci, E. & Ryan R. (2002). Handbook of self-determination research. Rochester, NY, University of Rochester Press.

DM/wellness companies looking at health coaching programs' effectiveness. (2008). *Disease Management Advisor, 14*, 9. DOI: http://dx.doi.org/10.5888/pcd9.110089.

Donnelly, J., Blair, S., Jakicic, J., Manore, M., Rankin, J., & Smith, B. (2009). American College of Sports Medicine position stand. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. *Medicine and Science in Sports and Exercise, 41,* 459-471.

Douketis, J. D., Macie, C. C., Thabane, L. L., & Williamson, D. F. (2005). Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice. *International Journal of Obesity, 29,* 1153-1167. doi:10.1038/sj.ijo.0802982.

Edlin & Golanty, (2012). *Health and Wellness,* Tenth edition. Jones and Bartlett, Sadbury, MA.

Ernsberger, P. & Koletsky, R.J. (1999). Biomedical rationale for a wellness approach to obesity: An alternative to a focus on weight loss. *Journal of Social Issues*, *55*. 221-260. DOI: 10.1111/0022-4537.00114.

Evans, R., Bond, D., Wolfe, L., Meador, J., Herrick, J., Kellum, J., & Maher, J. (2007). Participation in 150 min/week of moderate or higher intensity physical activity yields greater weight loss after gastric bypass surgery. *Surgery for Obesity and Related Diseases: Journal of the American Society for Bariatric Surgery, 3,* 526-530.

Forbush, S., Nof, L., Echternach, J., & Hill, C. (2011). Influence of activity on quality of life scores after RYGBP. *Obesity Surgery, 21,* 1296-1304. DOI: 10.1007/s11695-010-0184-1.

Gould, J. C., Beverstein, G., Reinhardt, S., & Garren, M. J. (2007). Impact of routine and long-term follow-up on weight loss after laparoscopic gastric bypass. *Surgery for Obesity and Related Diseases, 3,* 627-630.

Green, A., Dymek-Valentine, M., Pytluk, S., Grange, D., & Alverdy, J. (2004). Psychosocial outcome of gastric bypass surgery for patients with and without binge eating. *Obesity Surgery, 14,* 975-985.

Hagströmer, M., Oja, P., & Sjöström, M. (2006). The International Physical Activity Questionnaire (IPAQ): A study of concurrent and construct validity. *Public Health Nutrition, 9,* 755-762.

Hofsø, D., Aasheim, E., Søvik, T., Jakobsen, G., Johnson, L., Sandbu, R., & Hjelmesæth, J. (2011). [Follow-up after bariatric surgery]. *Norwegian Medical Journal: Tidsskrift for Praktisk Medicin, Ny Række, 131,* 1887-1892.

Hsu, L., Benotti, P., Dwyer, J., Roberts, S., Saltzman, E., Shikora, S., & Rand, W. (1998). Nonsurgical factors that influence the outcome of bariatric surgery: A review. *Psychosomatic Medicine, 60,* 338-346.

IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.

Josbeno, D., Kalarchian, M., Sparto, P., Otto, A., & Jakicic, J. (2011). Physical activity and physical function in individuals post-bariatric surgery. *Obesity Surgery, 21,* 1243-1249. DOI:10.1007/s11695-010-0327-4.

Karlsson, J. J., Taft, C. C., Rydén, A. A., Sjöström, L. L., & Sullivan, M. M. (2007). Ten-year trends in health-related quality of life after surgical and conventional treatment

for severe obesity: The SOS intervention study. *International Journal of Obesity, 31,* 1248-1261. doi:10.1038/sj.ijo.0803573.

King, W. C., Hsu, J. Y., Belle, S. H., Courcoulas, A. P., Eid, G. M., Flum, D. R., & Wolfe, B. M. (2012). Pre- to postoperative changes in physical activity: report from the longitudinal assessment of bariatric surgery-2 (LABS-2). *Surgery for Obesity and Related Diseases, 8,* 469-496.

Kolotkin, R., Crosby, R., Pendleton, R., Strong, M., Gress, R., & Adams, T. (2003). Health-related quality of life in patients seeking gastric bypass surgery vs. non-treatment-seeking controls. *Obesity Surgery, 13,* 371-377.

Kolotkin, R., LaMonte, M., Litwin, S., Crosby, R., Gress, R., Yanowitz, F., & Adams,T. (2011). Cardiorespiratory fitness and health-related quality of life in bariatric surgery patients. *Obesity Surgery, 21,* 457-464.

Kushner, R. F., & Noble, C. A. (2006). Long-term outcome of bariatric surgery: An interim analysis. *Mayo Clinic Proceedings, 81,* S46-S51.

Leahey, T., Bond, D., Irwin, S., Crowther, J., & Wing, R. (2009). When is the best time to deliver behavioral intervention to bariatric surgery patients: before or after surgery? *Surgery for Obesity and Related Diseases,, 5,* 99-102.

Levy, R. L., Finch, E. A., Crowell, M. D., Talley, N. J., & Jeffery, R. W. (2007). Behavioral intervention for the treatment of obesity: Strategies and effectiveness data. *American Journal of Gastroenterology, 102,* 2314-2321. doi:10.1111/j.1572-0241.2007.01342.x.

Lokken,, K. L., Boeka, A.G., Yellumahanthi, K., Wesley, M., & Clements, R.H. (2010). Cognitive performance of morbidly obese patients seeking bariatric surgery. *The American Surgeon, 76*, 55-59.

Lutfi, R., Torquati, A., Sekhar, N., & Richards, W. (2006). Predictors of success after laparoscopic gastric bypass: A multivariate analysis of socioeconomic factors. *Surgical Endoscopy, 20(6),* 864-867.

MacLean, L., Rhode, B., Forse, R., & Nohr, C. (1995). Surgery for obesity - an update of a randomized trial. *Obesity Surgery*, *5*, 145-150.

Markland, D., & Tobin, V. (2004). A modification to the behavioral regulation in exercise questionnaire to include an assessment of amotivation. *Journal of Sport & Exercise Psychology, 26*, 191-196.

Mayo School of Health Sciences (2011). http://www.mayoclinic.com/health/weight-loss/NU00266.

Menon, J, Paulet, M., &Thomas, J.,III (2012). Wellness coaching and health-related quality of life, a case controlled difference-in-difference analysis. *Journal of Occupational and Environmental Medicine, 54*, 1259-1266.

Mitchell, J., Lancaster, K., Burgard, M., Howell, L., Krahn, D., …., & Gosnell, B. (2001). Long-term follow-up of patients' status after gastric bypass. *Obesity Surgery*, *11*, 464-468.

Moustaka, F. C., Vlachopoulos, S. P., Vazou, S., Kaperoni, M., & Markland, D. A. (2010). Initial validity evidence for the behavioral regulation in exercise questionnaire-2 among Greek exercise participants. *European Journal of Psychological Assessment*, 26, 269-276. doi:10.1027/1015-5759/a000036.

Mullan, E., Markland, D., & Ingledew, D.K., (1997). A graded conceptualization of self-determination in the regulation of exercise behavior: Development of a measure using confirmatory factor analytic procedures. *Personality and Individual Differences, 23,* 745-752.

Mullan, E., & Markland, D. (1997). Variations in self-determination across the stages of change for exercise in adults. *Motivation & Emotion, 21,* 349-362.

National Heart, Lung and Blood Institute (2012). http://www.nhlbi.nih.gov/meetings/workshops/bariatric-surgery.htm.

National Institute of Health, (2012). http://www.nih.gov.

Ovbiosa, O.E., & Long, D.A. (2012). Wellness program satisfaction, sustained coaching participation, and achievement of health goals. *Journal of Occupational and Environmental Medicine, 54,* 592-597.

Ochner, C., Dambkowski, C., Yeomans, B., Teixeira, J., & Xavier Pi-Sunyer, F. (2012). Pre-bariatric surgery weight loss requirements and the effect of preoperative weight loss on postoperative outcome. *International Journal of Obesity, 36,* 1380-1387. doi:10.1038/ijo.2012.60.

Ortega, E., Morínigo, R., Flores, L., Moize, V., Rios, M., Lacy, A., & Vidal, J. (2012). Predictive factors of excess body weight loss 1 year after laparoscopic bariatric surgery. *Surgical Endoscopy, 26,* 1744-1750.

Osei-Assibey, G., Kyrou, I., Kumar, S., Saravanan, P., & Matyka, K. (2010). Self-Reported Psychosocial Health in Obese Patients before and after Weight Loss. *Journal of Obesity*, 2010. 1-6. DOI: 1155/2010/372463.

Padwell, R., Klarenbach,S., Weibe, N., Birch, D., Karmali, S., Manns, B., Hazel, M., Sharma, A.M., & Tonelli, M. (2011). Bariatric Surgery: A systematic review and network meta-analysis of randomized trials. *Obesity Reviews, 12*, 602-621.

Papalazarou, A., Yannakoulia, M., Kavouras, S., Komesidou, V., Dimitriadis, Papakonstantinou, A., & Sidossis, L. (2010). Lifestyle intervention favorably affects weight loss and maintenance following obesity surgery. *Obesity (Silver Spring, Md.), 18*, 1348-1353.

Pories, W., MacDonald, K., Morgan, E., Sinha, M., Dohm, G., Swanson, M., …& Caro, J.F. (1992). Surgical treatment of obesity and its effect on diabetes: 10-y follow-up. *American Journal of Clinical Nutrition, 55,* 582S-585S.

Pories, W., Swanson, M., MacDonald, K., Long, S., Morris, P., Brown, B., …& Dolezal, J.M. (1995). Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. *Annals of Surgery*, *222*, 339-350.

Powell, L., Calvin, J., & Calvin, J. (2007). Effective obesity treatments. *The American Psychologist, 62*, 234-246.

Prochaska, J.O., DiClemente, C.C., & Norcross, J. (1992). In search of how people change: Applications to addictive behaviors. *American Psychologist , 47*, 1102-1114.

Prochaska, J.O., Butterworth, S., Redding, Butterworth Redding C.A. Burdenb, V. Perrinb, N., Leob, M., Flaherty-Robbb, M. & Prochaskac, J.A. (2008). Initial efficacy of MI, TTM tailoring and HRI's with multiple behaviors for employee health promotion. *Preventative Medicine, 46*, 226-231.

Romain, A.J., Bernard, P., Attalin, C., Gernigon, G., Ninot, A., & Avignon, (2012). Health-related quality of life and stages of behavioural change for exercise in overweight/obese individuals. *Diabetes and Metabolism, 38,* 352-358. Retrieved from Science Direct, http://dx.doi.org/10.1016/j.diabet.2012.03.003.

Ryan, R. M., & Deci, E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist, 55,* 68-78. doi:10.1037/0003-066X.55.1.68.

Sanford Health (2012). Obesity overview. http://www.sanfordhealth.org/healthinformation/healthwise/topic/hw252864.

Sarwer, D., Wadden, T., & Fabricatore, A. (2005). Psychosocial and behavioral aspects of bariatric surgery. *Obesity Research, 13(4),* 639-648.

Schouten, R., Wiryasaputra, D., van Dielen, F., van Gemert, W., & Greve, J. (2010). Long-term results of bariatric restrictive procedures: a prospective study. *Obesity Surgery, 20,* 1617-1626.

Smith, B. K., Walleghen, E., Cook-Wiens, G., Martin, R. N., Curry, C. R., Sullivan, D. K., & Donnelly, J. E. (2009). Comparison of two self-directed weight loss interventions: Limited weekly support vs. no outside support. *Obesity Research & Clinical Practice,* 3(3), 149-157.

Snuggs, L. S. McIntyre, C., & Cowdery, J.E. (2010) Overweight and obese sedentary adults' physical activity beliefs and preferences. *American Journal of Health Studies, 2,* 25-31.

Still, C., Benotti, P., Wood, G., Gerhard, G., Petrick, A., Reed, M., & Strodel, W. (2007). Outcomes of preoperative weight loss in high-risk patients undergoing gastric bypass surgery. *Archives of Surgery, 142,* 994-998.

Sutton, D., & Raines, D. (2010). Health-related quality of life following a surgical weight loss intervention. *Applied Nursing Research*: 23, 52-56.

Tindle, H. A., Omalu, B., Courcoulas, A., Marcus, M., Hammers, J., & Kuller, L. H. (2010). Risk of suicide after long-term follow-up from bariatric surgery. *American Journal of Medicine*, *123*, 1036-1042. doi:10.1016/j.amjmed.2010.06.016.

Van Nunen A.M., Wouters E.J., Vingerhoets A.J., Hox J.J., & Geenen R. (2007). The health-related quality of life of obese persons seeking or not seeking surgical or non-surgical treatment: a meta-analysis. *Obesity Surgery, 17,* 1357-66.

Waddington, C. & Bailiff, M. (2009). Wellness coaching and cancer care. *Oncology Nursing Forum, 36,* 44.

Ware, J. E.. (2004). SF-36 Health Survey Update. In M. E. Maruish (Ed.). *The use of psychological testing for treatment planning and outcomes assessment: Volume 3: Instruments for adults (3rd ed.)* (pp. 693-718). Mahwah, NJ US: Lawrence Erlbaum Associates Publishers.

Williams, G. C., Grow, V. M., Freedman, Z. R., Ryan, R. M., & Deci, E. L. (1996). Motivational predictors of weight loss and weight-loss maintenance. *Journal of Personality and Social Psychology, 70,* 115-126. doi:10.1037/0022-3514.70.1.115.

Wilson, P. M., Mack, D. E., & Grattan, K. P. (2008). Understanding motivation for exercise: A self-determination theory perspective. *Canadian Psychology, 49,* 250-256. doi:10.1037/a0012762.

Wilson, P. M., Rodgers, W. M., & Fraser, S. N. (2002). Examining the psychometric properties of the behavioral regulation in exercise questionnaire. *Measurement in Physical Education & Exercise Science, 6,* 1-21.

Wilson, P. M., Sabiston, C. M., Mack, D. E., & Blanchard, C. M. (2012). On the nature and function of scoring protocols used in exercise motivation research: An empirical study of the behavioral regulation in exercise questionnaire. *Psychology of Sport & Exercise, 13,* 614-622.

Wing, R.R., & Hill, J.O. (2001) Successful weight loss maintenance. *Annual Review of Nutrition, 21,* 323-341. DOI: 10.1146/annurev.nutr.21.1.323.

Wolf A.M., Conaway M.R., Crowther, J.Q, Hazen, K.Y., Nadler, J.L., Oneida, B, & Bovbjerg, V.E.(2004). Translating lifestyle intervention to practice in obese patients with type 2 diabetes: Improving control with activity and nutrition (ICAN). *Diabetes Care. 27,* 1570-1576.

Zunker, C., Karr, T., Saunders, R., & Mitchell, J. (2012). Eating behaviors post-bariatric surgery: a qualitative study of grazing. *Obesity Surgery, 22,* 1225-1231.

APPENDIX A: SANFORD BARIATRIC WELLNESS QUESTIONNAIRE

Age_____Height_____Current Weight_____

1. Did you complete Sanford's Weight loss coaching program (12 weeks) **Yes** **No**

    a. If so, when: _____ (mm/yy thru mm/yy)

2. Did you have surgery? **Yes** **No** **(If no, skip to question 8)**

3. What was your weight prior to surgery: _____

4. How much weight did you lose as a result of your surgery? _____ (max wt. loss)

5. How long has it been since your weight loss surgery?_____**years**_____**months**

6. What type of surgery did you have? **Bypass** **lap band**
   Other:_____

7. On average, how often do/did you follow up with members of Sanford's health care team? (please indicate either specific number or times, monthly, annually, etc.)

    Your bariatric surgeon? _____

    Your regular physician? _____

    Your dietitian?_____

8. Do you currently follow the nutrition guidelines as instructed by your dietitian?

    YES **NO**

   8a) How much protein on average, do you consume on a daily basis?_____

   8b) Do you consume a protein supplement? **YES** **NO**

9. How would you classify your current caloric consumption compared to before surgery or weight loss program?

   Much less **Somewhat less** **Same** **Somewhat more** **Much more**

10. In your own words, how have your eating habits changed (if any)?

11. Do you use any computer apps to log your physical activity and/or food intake?

Yes, both **Yes, physical activity** **Yes, nutrition** **No**

The following questions refer to Sanford's Wellness Coaching Program. If you did not participate in the Wellness Coaching program, please leave blank (skip to question #17)

12) On a 1 to 5 scale, 1 being not at all and 5 being extremely helpful, how beneficial was the coaching program?

Not beneficial		**Somewhat beneficial**		**Extremely beneficial**
1	**2**	**3**	**4**	**5**

13) Would you recommend this coaching program to a friend? **YES** **NO**

14) Are you continuing to use the advice given to you by your coach for living a healthy lifestyle? **YES** **NO**

15) Please indicate how your participation in Sanford's coaching program has impacted your life? What areas of your life have changed as a result of your weight loss? *(feel free to share as much or as little as you wish)*

16) How can Sanford's wellness coaching program be improved?

*The following questions will ask you about the time you spent being physically active in the past **7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise, or sport. Think only about those physical activities that you did for at least **10 minutes at a time.***

*Think about all the **vigorous** activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal.*

17) During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling? _____ days per week

17a) How much time did you usually spend doing vigorous physical activities on one of those days?

_____hours per day _____ minutes per day _____ Don't know/Not sure

*Think about all the **moderate** activities that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.*

18) During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.
_____ days per week

18a) How much time did you usually spend doing moderate physical activities on one of those days?
_____ hours per day _____ minutes per day_____ Don't know/Not sure

*Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure*

19) During the last 7 days, on how many days did you walk for at least 10 minutes at a time? _____ days per week

19a) How much time did you usually spend walking on one of those days?

_____ hours per day _____minutes per day _____Don't know/Not sure

*Now think about the time you spent **sitting** on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may*

include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

20) During the last 7 days, how much time did you spend sitting on a week day?

_____ hours per day _____minutes per day_____ Don't know/Not sure

The next few questions ask for your views about your health.

21) In general, would you say your health is:

Excellent **Very good** **Good** **Fair** **Poor**

22) During a typical day, does your health limit you in the following activities?

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, playing golf?

Yes, limited a lot **Yes, limited a little** **No, not limited at all**

Climbing several flights of stairs?

Yes, limited a lot **Yes, limited a little** **No, not limited at all**

23) During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Accomplished less than you would like?	☐	☐	☐	☐	☐
b) Were limited in the kind of work or other activities?	☐	☐	☐	☐	☐

24) During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time

a) Accomplished less than you would like
☐……..☐……..☐……☐…….....☐

b) Did work or other activities less carefully than usual
☐……..☐……..☐……☐……☐

25) During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all **A little bit** **Moderately** **Quite a bit** **Extremely**

26) These questions are about how you feel and how things have been with you during the Past 4 weeks.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time

a) Have you felt calm and peaceful?
☐……..☐…….☐……☐……..☐

b) Did you have a lot of energy?
☐……..☐……☐……☐……☐

c) Have you felt down-hearted and depressed?
☐…….☐……☐……☐……☐

27) During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time

☐…….☐…….☐……..☐……☐

Using the scale below, please indicate to what extent each of the following items is true for you. Please note that there are no right or wrong answers and no trick questions. We simply want to know how you personally feel about exercise.

	Not true for me		**Sometimes true for me**		**Very true for me**
28) I exercise because other people say I should	0	1	2	3	4
29) I feel guilty when I don't exercise	0	1	2	3	4
30) I value the benefits of exercise	0	1	2	3	4
31) I exercise because it's fun	0	1	2	3	4
32) I don't see why I should have to exercise	0	1	2	3	4
33) I take part in exercise because my friends/family/partner say I should	0	1	2	3	4
34) I feel ashamed when I miss an exercise session	0	1	2	3	4
35) It's important to me to exercise regularly	0	1	2	3	4
36) I can't see why I should bother exercising	0	1	2	3	4
37) I enjoy my exercise sessions	0	1	2	3	4
38) I exercise because others will not be pleased with me if I don't	0	1	2	3	4
39) I don't see the point in exercising	0	1	2	3	4
40) I feel like a failure when I haven't exercised in a while	0	1	2	3	4
41) I think it is important to make the effort to exercise regularly	0	1	2	3	4
42) I find exercise a pleasurable activity	0	1	2	3	4
43) I feel under pressure from my friends/family to exercise	0	1	2	3	4

	Not true for me		Sometimes true for me		Very true for me
44) I get restless if I don't exercise regularly	0	1	2	3	4
45) I get pleasure and satisfaction from participating in exercise	0	1	2	3	4
46) I think exercising is a waste of time	0	1	2	3	4

Thank you for participating in our research and program evaluation!

APPENDIX B: NDSU IRB

NDSU NORTH DAKOTA STATE UNIVERSITY

Wednesday, March 13, 2013
FederalWide Assurance FWA00002439

Bradford Strand
Health, Nutrition & Exercise Sciences
EML351

Re: Certification of Exempt Human Subjects Research:
Protocol #HE13175, "Effect of Method of Weight Loss on Health Behaviors and Quality of Life"

Co-investigator(s) and research team: Anita Gust. M.S.

Certification Date: 3/13/13
Study site(s): varied
Funding: n/a
Expiration Date: 3/12/16

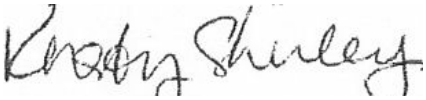
The above referenced human subjects research project has been certified as exempt (category # :f) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, *Protection of Human Subjects).* This determination is based on the protocol (received 2/22/13) and consent, survey, and request for contact information (received 3/12/13).

Please also note the following:

- If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
- Conduct the study as described in the approved protocol. If you wish to make changes, obtain approval from the IRB prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
- Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Report any significant new findings that may affect the risks and benefits to the participants and the IRB

- Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study. Sincerely,



Kristy Shirley, CIP, Research Compliance Administrator

INSTITUIONAL REVIEW BOARD
NDSU Dept 4000 I PO Box 6050 I Fargo ND 58108-6050 I 701-23t8995 I Fax 70123t8098 I ndsu_edu/irb
Shipping address: Research 1, 1735 NDSU Research Park Drive. Fargo, ND 58102

APPENDIX C: SANFORD STUDY ORDER

This Study Order, effective as of the date of the last signature below written (the "Effective Date"), is made by and between Sanford Research, USD ("SRUSD") and North Dakota State University ("NDSU") and is hereby made subject to and governed by the Research Affiliation Agreement between Sanford and NDSU which became effective March 12, 2012 (the "Research Agreement").

The terms and conditions of this Study Order shall prevail over any conflicting or inconsistent terms in the Research Agreement when there is expressly stated an intent to supersede the Research Agreement, but then only with respect to the services performed under this Study Order. Defined terms in this Study Order have the meanings assigned to them in the Research Agreement, unless otherwise expressly provided in this Study Order.

ARTICLE I STUDY INFORMATON

A. Sanford lead investigator:	Holly Boub, Manager of Cardiac Rehab
B. NDSU lead investigator:	Bradford Strand, Professor
C. Protocol:	"Effect of Method of Weight Loss on Health Behaviors and Quality of Life"
D. Projected No. of Study subjects:	400 Sanford bariatric procedure patients; 400 Sanford weight Loss coaching program participants
E. Sanford Performance Site:	Sanford Medical Center Fargo, Department of Cardiac Rehab

ARTICLE II
SCOPE OF WORK

A. Services provided by NDSU:

i. NDSU shall conduct the Study as described in the Sanford Institutional Review Board ("IRB") application attached hereto and incorporated herein as Exhibit A.

ii. NDSU shall consent participants using the IRB approved Adult Consent to Participate in a Research Study which will be sent with the survey, attached hereto and incorporated herein as Exhibit D.

iii. NDSU shall be permitted to maintain de-identified copies of the returned surveys in accordance with NDSU policy.

B. Services provided by Sanford:

i. Sanford Medical Center Fargo, Department of Cardiac Rehab, under the direction of SRUSD, will identify potential participants and mail out the study questionnaires.

ARTICLE III
COMPENSATION

There will be no compensation received by either patty under this Study Order.

ARTICLE IV
TERM AND TERMINATION

The Study shall commence at the performance site located at 736 Broadway North, Fargo, North Dakota, 58122 upon the Effective Date of this Study Order and approval of the Study by the IRB and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Study Order is earlier terminated. This Study Order may be terminated by either party, with or without cause, upon thirty (30) days prior written notice to the other party.

ARTICLE V
NOTICE

Any notice required or permitted by this Study Order shall be in writing and delivered by hand or sent by registered or cet1ified mail, postage prepaid, return receipt requested, or by nationally recognized overnight delivery service, delivery charges prepaid, in each case addressed to the pa11y to receive such notice at the address set forth below or such other address as is subsequently specified in writing in accordance with this Article. Such notice shall be deemed given or provided as of the date of receipt.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Study Order.

SANFORD RESEARCH/USD

By: _____

Name: David Pearce, PhD

Title: VP of Research

Date: 6/21/13

NDSU

By: _____

Name: Valrey V. Kettner

Title: Associate Vice President
Office of Sponsored Programs Administration

Date: 06/17/13

READ AND ACKNOWLEDGED:

By: _____

Name: Holly Boub

Title: Sanford Cardiac Rehab Manager

Date: June 18, 2013

READ AND ACKNOWLEDGED:

By: _____

Name: Bradford Strand

Title: NDSU Professor

Date: June 17, 13

Study Order Addendum
for
NDSU and Sanford Clinical Research Project Collaboration

PI: Bradford Strand

Project Title: The Effect of Method of Weight Loss on Health Behaviors and Quality of Life

This Addendum to the Study Order for the above-noted project sets forth certain terms that will control the conduct of the Study Order over any inconsistencies with the terms and conditions of the Master Research Affiliation Agreement.

1. IRB review for this Study is covered by:

O IRB Authorization Agreement, in which IRB of Record is NDSU or Sanford. (Circle)

xxD Joint review by both Sanford and NDSU

2. The following federal requirements will not apply to the conduct of this Study:

xxD Food and Drug Administration (FDA) regulations xxD FDA Good Clinical Practice Guidelines

xxD Privacy Rule (HIPPA)

3. A Study Subject, signed consent is necessary for this Study? DYes xx D No

If yes, signed consent shall be obtained and maintained by NDSU or Sanford. (Circle)

4. A Study Subject, HIPPA Authorization is necessary for this Study? O Yes xx D No

If yes, HIPPA Auth. shall be obtained and maintained by NDSU or Sanford. (Circle)

5. Will any NDSU personnel assist with the performance of Study within a Sanford Facility?

DYes XX O No

If yes, such personnel have acquired the necessary privileges at the facility.

O Yes O No O Not applicable

NORTH DAKOTA STATE UNIVERSITY

By: Valrey V. Kettner

Name: Valrey Kettner

Title: Assoc. VP Sponsored Programs

Date: 06/17/13

SANFORD RESEARCH/USD

By:

Name: Davda Pearce, PhD

Title: COO | VP Research

Date: 6/24/13