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The Evaluation of Select Lifestyle Behavior Modification Following Participation in a Comprehensive Weight Management Clinic

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THE EVALUATION OF SELECT LIFESTYLE BEHAVIOR MODIFICATION FOLLOWING PARTICIPATION IN A COMPREHENSIVE WEIGHT MANAGEMENT CLINIC

Jennifer Lynn Bowling

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GRAND VALLEY STATE UNIVERSITY

In

Partial Fulfillment of the Requirements

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Dedication

For my husband and my children for their patience throughout this journey. For my father who instilled in me determination and drive.
Acknowledgments

I would like to express great gratitude to Dr. Brinntall for her ongoing support, shared knowledge, and her confidence in me. I would also like to thank Dr. Lown and Dr. Burritt for their guidance, encouragement, and assistance throughout the dissertation process. I would also like to give great thanks to Mary Kay Williams, FNP for acting as my mentor during this project and for sharing her bariatric knowledge that served as an underlying foundation for this project.
Abstract

Over the last decades, obesity in the United States has reached epidemic proportion. Obesity rates have nearly doubled since 1960 when 43% of the United States population was overweight or obese and 1% was extremely obese. In 2012, approximately 69% of the US population was overweight or obese while 6.3% were extremely obese. Obesity rates are expected to progressively increase; therefore, interventions and guidelines are imperative in order to reduce the long term health risks of the Nation and to reduce overall health care costs (National Institute of Health [NIH], 2012).

Obesity increases morbidity resulting from associated hypertension, cardiovascular disease, diabetes, stroke, sleep apnea as well as other comorbidities. Moreover, obesity and its related disorders substantially increase the Nation’s health care costs (Jensen et al., 2013). Although comprehensive weight management clinics and bariatric surgery remain viable options for the treatment of obesity, variability among weight management programs is problematic. Ultimately, a better awareness of contributing factors for successful lifestyle change is called for in order to support sustained weight loss, promote weight maintenance, and sustain healthy lifestyle choices.

This project evaluated select lifestyle behavior modification following participation in a comprehensive weight management program. Specifically, dietary and exercise habits were evaluated. Donabedian’s theoretical framework of structure, process, and outcome was utilized to evaluate a current institutional system, monitor end results of
patient care, and evaluate structures and/or processes in a comprehensive weight management clinic. Bandura’s self-efficacy theory was utilized to support and augment participant’s perception of their abilities to change behaviors, support behavior change, gain confidence, and influence health related goals and thoughts.

Seventeen participants were recruited from a small community weight management clinic in the Midwest. Participant informed consent was obtained after a full review of the project. Two established instruments, the Paffenbarger Physical Activity Questionnaire and the Three Factor Eating Questionnaire-R18V2, were used to gather data relative to physical activity and eating behavior. Instruments were repeated at six weeks and again at three months. Descriptive statistics were reported relative to select lifestyle behavior and changes while engaged in a weight management clinic using Statistical Packages for the Social Sciences (SPSS®) and Statistical Analysis System (SAS®).

Participants demonstrated weight loss and decreased BMI during the study period. Trends in improved eating behaviors were seen in a small portion of participants. Physical activity showed some increase but was inconsistent in the study population. Attrition and compliance with instrument completion in this small sample precluded further statistical analysis. Further exploration into the rationale for minimal physical activity among some participants, the evaluation of barriers to physical activity, continued evaluation of physical activity, and education regarding time management for physical activity should be considered.
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CHAPTER 1
INTRODUCTION

Obesity has become an epidemic that is at the forefront of concern for the American population. Obesity rates have nearly doubled since 1960 when 32% of the United States population was overweight, 13% were obese, and %1 were extremely obese. Currently, 33.1% of the US population is overweight, 35.7% are obese, and 6.3% are extremely obese. Given these statistics, nearly two-thirds of the US population is overweight or obese. Obesity rates in the US peaked between 1980 and 2000 and have continued to increase (National Institute of Health [NIH], 2012). Obesity is now viewed as more damaging to health than smoking, excessive alcohol consumption, or poverty (Alvarado et al., 2005). Obesity is a treatable disease when appropriate interventions are implemented (Jensen et al., 2013).

Obesity is a multifactorial disease that is thought to rise from an environmental influence of social, behavioral, cultural, physiological, and metabolic factors coupled with genetic predisposition. An overweight state is defined as a body mass index (BMI) of 25.0-29.9 kg/m². Class I obesity is diagnosed with a BMI of 30.0-34.9 kg/m² while Class II obesity is diagnosed with a BMI of 35.0-39.9 kg/m². Class III obesity, formerly identified as morbid obesity, is associated with a BMI greater than 40 kg/m² (Jensen et al., 2013).

**Obesity Significance**

According to the most recent guidelines by the American Heart Association (AHA), the American College of Cardiology (ACC), and The Obesity Society (TOS) in conjunction with the National Heart Lung and Blood Institute (NHLBI), multiple comorbidities are associated with obesity and profoundly increased mortality risk and
health care expenses (Jensen et al., 2013). Comorbidities associated with obesity include hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, and restrictive lung disease. The risk of endometrial, breast, prostate, and colon cancer increases substantially in the presence of obesity (NHLBI, 2000). Those with a BMI greater than 25 kg/m², a waist circumference greater than 40 inches (males), or waist circumference greater than 30 inches (females) are at risk of developing these comorbidities. While there is no evidence that mortality is reversed with weight loss, comorbid conditions can be improved or reversed (NHLBI). As they exist, the estimated annual costs in the United States for the treatment of obesity and its comorbidities are in excess of $200 billion dollars. This figure is approximately 6% of total health care costs in the United States (Ochner, Puma, Raevuori, Teixeira, & Geliebter, 2010). According to Jensen et al., obese patients incur 46% higher inpatient medical expenses, have 26% increase in primary care visits, and spend 80% more on prescription medications compared to normal-weight patients.

Treatment modalities for obesity include lifestyle modification in the form of physical activity and dietary changes, pharmacotherapy, and bariatric surgery (Papalazarou et al., 2010). Surgical intervention is recommended for patients with a BMI greater than 40 kg/m² or a BMI greater than 35 kg/m² (Class II obesity) when at least two comorbidities exist (Ochner, Puma, Raevuori, Teixeira, & Geliebter, 2010). While the most effective treatment has been found to be surgical intervention, maintaining optimal weight loss is unlikely to be achieved or maintained without lifestyle modification (Papalazarou et al.).
Currently, many insurance companies are requiring bariatric surgery candidates with a BMI less than 50 kg/m\(^2\) to participate in a medically supervised weight management clinic prior to authorization of surgical services (American Society of Medical and Bariatric Surgeons [ASMBS], 2013). However, the length, focus, type, and duration, as well as the multidisciplinary participation among these programs vary significantly. While some programs focus exclusively on weight loss, others are educating patients preoperatively regarding physical activity, behavior modification, eating behavior modification, and cognitive behavioral therapy (NHLBI, 2000). Surprisingly, there are currently no standard recommendations for preoperative weight management for the bariatric population (Ochner, 2012). The ultimate goal is not to simply promote preoperative weight loss, rather to engage participants in the necessary lifestyle changes to promote postoperative weight loss and the maintenance of such (NHLBI).

**Treatment Guidelines**

According to the AHA/ACC/TOS guidelines for obesity, treatment for obesity should include high-intensity comprehensive lifestyle intervention that utilizes a trained interventionist or nutrition professional/dietitian; however, the guidelines lack specific interventions. A trained interventionist may include registered dietitians, psychologists, exercise specialists, or health counselors. In-person sessions of greater than 14 sessions in six months are recommended either in group or individual format. The components of the intervention should include a program of increased physical activity, moderately reduced-calorie diet, and behavioral therapy to promote adherence. Where in-person sessions are not feasible, they may be delivered electronically via telephone or internet in a fashion that allows for expert feedback. The guidelines further provide an algorithm for chronic
disease management for primary care of patients who are overweight and obese (Jensen et al., 2013).

The most recent published NHLBI (2000) guidelines note that the goals of any weight loss intervention are: to prevent further weight gain, reduce total body weight, and maintain a lower body weight over an extended period of time. The NHLBI goal of 10% weight loss over six months of therapy is the desired goal. It is further recommended that those choosing to undergo surgical intervention be followed by a multidisciplinary team that includes a dietary, medical, physical activity, and behavioral interventions, with lifelong follow up postoperatively NHLBI.

According to the NHLBI (2000), overweight and obese patients are not receiving adequate care from primary care providers attributed to the previous lack of clear guidelines. In the absence of an authoritative source, the NHLBI developed these guidelines for assessment and treatment of overweight and obese in patients with a BMI between 25 kg/m² and 29.0 kg/m² or BMI >30 kg/m² in the primary care setting. In response to this void, guidelines are now provided in the form of an Expert Panel’s Treatment Algorithm to provide a step-by-step approach to patient treatment and education with multiple tools related to diet, physical activity, and behavioral modification for patient education. A brief behavioral assessment, information relative to diet prescription, and physical activity suggestions are included. Further recommendations include utilization of a “team” approach that consists of nutritionists, dietitians, psychologists, and exercise physiologists to create an individualized cohesive plan of care. Guidelines to promote weight loss and maintenance, long-term monitoring, regular clinic visits, group meetings and/or telephone/e-mail communication are also
considered. Additionally, patients are encouraged to stop by for unscheduled follow up weight checks, diet and exercise log review, or to receive educational materials; yet, no guidelines for required follow up care are provided (NHLBI).

Guidelines for weight loss therapy and weight loss maintenance programs include diet therapy with calorie, fat, and carbohydrate reduction and daily physical activity with the expenditure of at least 100-200 excess kilocalories per day. The goal of increasing physical activity is trifold: to contribute to weight loss, to decrease abdominal fat, and to increase cardiorespiratory fitness. Behavior therapy is further recommended to focus on self-monitoring strategies, problem solving, cognitive restructuring, and social support (NHLBI, 2000). The NHLBI further recommends that the above interventions be maintained for at least six months prior to considering pharmacotherapy or surgical weight loss.

Ideally, those individuals in a well-designed program focusing on lifestyle modification can achieve the goal of maintained weight loss for an extended period of time. Indefinite participation can result in life-long sustained weight loss. Approximately 80% of those who lose weight will regain it, unless lifestyle modification techniques in the form of dietary modification, physical activity, and behavior therapy are continued (NHLBI, 2000).

The potential outcome of a comprehensive preoperative weight management clinic includes successful postoperative weight loss, defined as a loss of 50-75% of excess weight, and the long-term maintenance of this weight loss for a period of at least five years (Alvarado et al., 2005; Stoklossa & Atwal, 2013). Currently, 20-30% of those undergoing bariatric surgery do not achieve this outcome (Stoklossa & Atwal). The
ultimate goal of a comprehensive weight management clinic is continued lifestyle modification in the form of healthy eating behavior and physical activity, thus enhancing postoperative patient outcomes.

Government agencies such as the World Health Organization (WHO), the NHLBI, and the National Institute of Health (NIH) acknowledge the critical need for further research and intervention in an attempt to address the obesity epidemic and concurring comorbidities (NHLBI, 2000). Guidelines to aid practitioners in the treatment of overweight and obese individuals are now available via the NHLBI Obesity Education Initiative in cooperation with the National Institute of Diabetes (NID), and the National Institute of Digestive and Kidney Diseases (NIDDK). These guidelines for the treatment of overweight and obese individuals are further endorsed by the National Cholesterol Education Program (NCEP), the National High Blood Pressure Education Program (NHBPEP), and the North American Association for the Study of Obesity (NAASO) (NHLBI).

Conclusion

Comprehensive weight management clinics hold potential to best manage obesity thus reducing health care costs. However, outcomes related to eating behaviors and exercise habits in existing weight management clinics are understudied. Comprehension of these behaviors has the potential to optimize outcomes by providing change and insight into select lifestyle modification interventions. Effective interventions will assist in reducing health care costs incurred as a result of obesity and its comorbidities. Further, they may improve the health of American citizens and promote positive lifestyle changes while potentially affecting the obesity rate in the United States. To date, literature pertaining to assessment and evaluation of weight management clinic outcomes focusing
on behavior modification in the form of physical activity and eating behavior is lacking and represents a gap in literature.
CHAPTER 2
LITERATURE REVIEW

The aim of this literature review is to critically examine existing literature relative to select lifestyle modification following participation in a comprehensive weight management program. The specific objectives of the review are to identify credible studies in existing weight management clinics; conduct a critical appraisal of these studies; describe various types of clinics offering lifestyle interventions prior to bariatric surgery; and identify themes in existing research. Further, findings from this literature review were examined and compared with the outcomes of this project.

The integrative review model developed by Whittemore and Knafl (2005) served as the overarching framework for the literature review. Five distinct steps described in the utilized model include clear identification of the problem; performance of a well-defined literature search; performance of a systematic assessment of the literature; analysis of data for existing themes, plausibility, variability themes; and presentation of data to portray the process of integration (Whittemore & Knafl). All retrieved literature was examined with respect to quality, design, sample size, results, type of interventions, and year of publication.

A comprehensive literature search was performed to examine current literature relative to the evaluation of physical activity and eating behaviors following participation in a comprehensive weight management clinic. Multiple databases were queried including PubMed, Ebsco, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Library, Science Direct, Health Reference Center, MEDLINE, ProQuest, and Wiley Online Library. Databases were searched from 2003 to 2015 to reflect the most relevant literature. Due to the diversity of the types of weight
management programs, various search terms were utilized. Final search terms included preoperative weight loss; preoperative bariatric surgery weight loss; preoperative weight loss clinic; preoperative bariatric surgery weight management clinic; improving bariatric surgery outcomes; comprehensive weight loss clinic; comprehensive weight management clinic; and improving bariatric surgical compliance. All retrieved literature was evaluated using the Whittemore and Knafl model (2005) and included if established criteria was met. To assure completeness of the search, a medical librarian was consulted.

The initial search resulted in multiple duplicate citations and non-applicable results. Studies were eliminated if the focus of the study was a surgical procedure overview; related to weight management in the primary care setting; reported only economic benefits of surgery; described the preoperative psychosocial assessment or complications of bariatric surgery; identified post-bariatric nutritional deficits; evaluated effects of bariatric surgery on body systems; or reported bariatric surgery among pediatric and/or pregnant populations. To that end, six of the publications were eliminated based on the fact that they evaluated preoperative weight loss without a definitive intervention. Two were excluded as they addressed individual psychosocial and behavioral aspects (using specific measurement tools) of bariatric surgery candidates as predictors of outcomes. Lastly, one publication was eliminated as it related to insurance mandated where patient satisfaction with the intervention rather than the efficacy of the intervention.

Ultimately, of the 17 studies retrieved, only ten publications met the established inclusion criteria and were included in the review. Studies were included if the purpose was to examine preoperative lifestyle modification interventions among individuals contemplating bariatric surgery and/or reported the potential impact of lifestyle
modification on weight loss and behavior change, weight loss, and/or weight maintenance. Of the ten studies selected for review, one explored self-efficacy as related to diet and exercise habits between two intervention groups, one of which was provided an incentive; two described the evaluation of insurance mandated weight loss clinics; five studies reported the evaluation of lifestyle modification and its effects on postoperative weight loss; and one was a systematic review regarding pre-bariatric surgery and weight loss requirements. Using the established model, the literature was reported in two general themes and four sub-themes as follows: insurance mandated weight loss program and preoperative weight loss programs. The sub-themes were reported according to surgical approach. Studies with clear methodology and an analysis of results were reported. Finally, a detailed matrix was created to summarize findings of the studies and support easy retrieval of data (Appendix A).

**Lifestyle Intervention and Exercise/Dietary Self-Efficacy**

Utilizing a randomized controlled trial, Byrne, Barry, and Petry (2012) evaluated the effects of a pre-treatment self-efficacy intervention on weight loss and dietary/habits utilizing formal measurement instruments. Eligible participants were referred by a primary care provider if their ages were between the age of 18 and 55; had a BMI between 25.0 kg/m² and 39.9 kg/m²; a resting systolic blood pressure between 90 and 140 and a diastolic blood pressure between 60 and 90; were able to speak and read English at the 6th grade level; and agreed to participate and be randomly assigned to a treatment group. Those with uncontrolled psychiatric conditions; those who were pregnant; those with chronic conditions that would affect their ability to adhere to dietary and exercise interventions; those who met criteria for substance abuse or a history of an eating
disorder; and those who had participated in a weight management program within the last three months, or had lost more than 10% of excess weight in the last six months were excluded (Byrne, Barry, & Petry).

Participants (N=30) were randomly assigned to two groups: the control group and the incentive group. Both groups received the Diabetes Prevention Program manual and participated in the weight loss program focusing on long-term dietary changes, exercise habits, and cognition and emotions that may impede weight loss. Those in the incentive group were eligible to win prizes if they met weekly weight loss and exercise goals. Participants completed the Paffenbarger Physical Activity Questionnaire (PPAQ), The Self-Efficacy for Exercise Scale (SEE), and the Weight Efficacy Lifestyle Questionnaire (WEL) prior to and upon completion of the intervention (Byrne, Barry, & Petry, 2012). During the 12 week intervention, all participants were instructed to read one or two chapters from the manual weekly and complete the suggested activities; weigh in weekly; utilize a pedometer with a goal of 10,000 steps per day; maintain a food diary two days per week; maintain individually prescribed calorie restrictions; and meet weekly with a counselor weekly to review topics from the manual, receive advice and encouragement, and have any questions answered (Byrne, Barry, & Petry, 2012).

Researchers reported an average weight loss of 4.9-7.5 pounds with no variation between groups. Of interest, no change in physical activity (p=0.278), average daily calorie intake (p=0.251), or diet self-efficacy (p=0.148) were noted. However, there was a significant change in exercise self-efficacy (p=0.008) (Byrne, Barry, & Petry).

In summary, researchers concluded that improved exercise self-efficacy may enhance weight loss, despite the lack of change in physical activity. They further noted a
positive correlation between the numbers of sessions attended and weight loss. On average, patients attended 4.6-6.4 of the 12 treatments. The authors attribute the lack of participation to a frustration related to lack of weight loss and conclude that improved self-efficacy may ultimately improve treatment compliance (Byrne, Barry, & Petry, 2012).

**Insurance Mandated Weight Management Clinic Studies**

Two studies explored mandated weight management clinic participation prior to bariatric surgery (Jamal et al., 2006; Ochner, Puma, Raevuori, Teixeira, & Geliebter, 2010). The aim of both studies reported participation in insurance mandated weight management clinics and the evaluation of their effectiveness as measured by weight loss and the reduction in BMI.

Ochner et al. (2010) used a retrospective design to evaluate the effectiveness of a six month, physician supervised, presurgical weight loss regime required by insurance companies to determine whether presurgical weight change predicted short-term postsurgical weight loss outcomes. Inclusion criteria included a medical diagnosis of obesity (Body Mass Index >35kg/m²) and required participants to be preparing for any type of bariatric surgery. In the two-group design, the intervention group (n=94) was followed by their primary care physicians and submitted monthly weight measurements. In contrast, the control group (n=59) was not followed medically and was not required to adhere to a formal weight management program. No formal weight management education was provided to the participants in either group and no formal measurement tools were utilized. In both groups, a weight gain of 3.7 kg/m² ± 5.9 kg/m² (p< 0.0005) was noted upon program completion. Three months post-surgery, both groups lost 23.6 ±
8kg ($p<0.0005$) with no variation between groups again noted. Based upon three month consecutive evaluation, the researchers reported that those participants with weight gain during the preoperative period lost more weight postoperatively ($p<0.0001$) (Ochner et al).

Jamal et al. (2006) performed a prospective study comparing outcomes of bariatric patients undergoing 13 weeks of preoperative dietary counseling ($n=101$) to participants with no such requirement ($n=252$). All participants previously underwent bariatric surgery and were selected from a database at Virginia Commonwealth University. Those participating in the preoperative dietary counseling were required to meet monthly or weekly. Participants met with a registered dietitian where they received education regarding dietary lifestyle changes and an exercise regime. Weight loss was measured one year postoperatively. No other formal measurement was utilized to evaluate follow up measures and the conclusions of the study. Twenty-eight percent of those undergoing preoperative counseling did not complete the program as they ultimately chose not to have bariatric surgery. The attrition rate of the dietary counseling group was 50% higher than that of the control group. When comparing groups, the authors concluded that preoperative counseling may be a barrier to surgical treatment based upon the attrition rate, however, those barriers were not identified. At one year follow-up, those not requiring dietary counseling had a greater excess weight loss ($p<0.01$), lower BMI ($p<0.015$), and lower body weight ($p<0.01$). The authors further surmised that insurance mandated preoperative counseling had no impact on weight loss outcomes or postsurgical dietary compliance (Jamal et al.).
In both studies, authors reported that preoperative weight loss influenced postoperative weight loss, while participation in the clinic did not appear to affect postsurgical weight loss and compliance. Barriers assumed to be related include low income status may have impeded participation in clinics. However, the lack of formal measures is a concern in both studies. Also, of interest is the fact that Ochner et al. (2010) evaluated preoperative weight loss rather than the impact of lifestyle changes raising concern for study outcomes relative to study aims.

**Research Based Upon Surgical Approach**

Five studies, based upon surgical approach, evaluated the effectiveness of preoperative lifestyle modification on the effects of postoperative weight loss. Relative to design, four of the studies used randomized controlled trial design and one utilized a retrospective approach. All trials were performed at major medical centers, and authors acknowledged financial support from their prospective institutions. All were performed between 2005 and 2013.

**Roux-en-Y Gastric Bypass**

A retrospective study by Alvarado et al. (2005) evaluated whether preoperative weight loss was associated with positive outcomes in patients undergoing laparoscopic Roux-en-Y gastric bypass surgery. All participants \((N=90)\) had to demonstrate that they had made serious attempts to lose weight and were required to meet the 1991 NIH guidelines for bariatric surgery. Guidelines included a BMI >40 kg/m² or a BMI >35 kg/m² associated with a serious obesity related health problem such as diabetes, obstructive sleep apnea, or coronary artery disease; those willing to accept the surgical risk; those willing to participate in treatment and long term follow up; and those who
acknowledged the surgical procedure and lifestyles necessary to promote successful weight loss and maintenance of that weight loss (National Institute of Health [NIH], 2009). All were instructed to lose 10% of their excess body weight using any means desired and were counseled to concentrate on diets with proven efficacy. Participants were offered, but not required, to engage in nutritional counseling to assist with the weight loss. Postoperatively, they were instructed to start exercising; however, no formal education or program was provided (Alvarado et al.).

Through follow up and analysis, the researchers concluded that laparoscopic Roux-en-Y gastric bypass patients who had greater weight loss (≥5%) preoperatively had shorter operative times (average 36.2 minutes) and higher postoperative weight loss at one year than the group without weight loss (63% vs. 56% collectively). Outcome measures at one year included the collective percent of weight loss and correction or improvement of postoperative comorbidities. Improvement in comorbidities (hypercholesterolemia, depression, hypertension, obstructive sleep apnea, gastroesophageal reflux disease, and diabetes) between both groups was reported as 86.9%. However, researchers do not identify the method of measurement for improvement of comorbidities or provide other supporting data. Collective preoperative weight loss of 1% of initial excess body weight reportedly correlated with an increase of 1.8% loss of excessive body weight at one year postoperatively ($p<0.05$) (Alvarado et al., 2006). In summary, the authors concluded that participation in the preoperative weight management clinic may impact postsurgical weight loss by supporting continued lifestyle modification.
Vertical Banded Gastroplasty

Papalazarou et al. (2009) conducted a randomized controlled trial to evaluate the three-year effect of a postoperative lifestyle intervention on weight loss and the maintenance of weight loss after vertical banded gastroplasty. Women with a BMI greater than 40 kg/m$^2$ ($N=30$) who were anticipating vertical banded gastroplasty were recruited for this study. In this two group study, the sample size for the lifestyle group versus the usual treatment group is not reported. The lifestyle intervention group met postoperatively with a dietitian weekly for three months, every other week for the next three months, monthly for the following six months, every three months for the second postoperative year, and every six months for the third postoperative year. Education was provided and focused on nutrition, dietary intake, and physical activity. Dietary counseling encouraged high consumption of fruits, vegetables, whole grains, legumes, fish, olive oil, and low fat dairy products and low intake of meat and poultry. Avoidance of fast foods, sweets, and sauces was emphasized. One hundred and fifty minutes of moderate intensity exercise per week, in any form, was encouraged. Postoperative outcome measures included weight loss, dietary habits, physical activity level, and eating behavior changes. Measurement tools included the Dutch Eating Behavior Questionnaire, the Restraint Eating and External Eating Scales, and the Horokopio Physical Activity Questionnaire (Papalazarou et al.).

A strength of this study is the researchers evaluated the effectiveness of this intervention postoperatively and sequentially for three years. The researchers also concluded that patients undergoing vertical banded gastroplasty had an increase in postoperative weight loss and a change in lifestyle behaviors when participating in the
preoperative weight management clinic (Papalazarou et al., 2010). The researchers evaluated the effectiveness of the intervention utilizing the Dutch Eating Behavior Questionnaire (DBEQ), Restraint Eating Scale (RES), and External Eating Scale (EES), and the Harokopio Physical Activity Questionnaire (HPAQ). Reliability and validity for the instruments was not provided.

The lifestyle intervention group had significantly more weight loss at 12 months postoperatively (84.4 ± 3.9 kg vs 98.4 ± 4.4kg, p<0.05), at 24 months postoperatively (83.0kg ± 3.3kg vs 101.9kg, p<.0.05), and at 36 months postoperatively (84.4kg ± 3.3kg vs 102.5 ± 3.5 kg, p<0.05). The lifestyle group showed improved total DBEQ, RES, and EES over time postoperatively (p<0.001). The lifestyle group also reported an increase in fruit and vegetable intake (p<0.05) and a decrease in sweet consumption (p<0.05) in comparison to the usual care group. The lifestyle group also showed an increase in physical activity (p<0.001) and a decrease in television viewing (p<0.039) in comparison to the usual care group. Researchers concluded that the preoperative clinic may promote lifestyle changes postoperative, thus promoting sustained postoperative weight loss.

**Laparoscopic Gastric Banding**

Parikh et al. (2011) conducted a pilot randomized controlled trial evaluating the hypothesis that participating in a medically supervised weight management program does not predict outcomes after laparoscopic adjustable gastric banding. Participants met the NIH consensus criteria for bariatric surgery and had a medical diagnosis of severe obesity (BMI >35 kg/m²). Twenty-nine of the participants were assigned to one of two intervention groups and twenty-five were assigned to a usual care group. Intervention group one participated in monthly visits in which individualized behavior modification
counseling and goal setting was evaluated. Intervention group two participated in monthly visits with classes lead by a registered dietitian. The usual care group participated in one visit with a nutritionist. Outcomes were measured in all three groups at baseline, six months after baseline, and six months postoperatively using anthropometric measurements, a one-item eating behavior question, the Patient Activation/Health Measure, and the Paffenbarger Physical Activity questionnaire (Parikh et al.).

Researchers reported no significant difference in weight loss or patient lifestyle behaviors in either population and concluded that preoperative, medically supervised weight management did not offer any additional benefits. However, participants were only obligated to participate in two preoperative sessions, raising question about the sustained potential of a relatively brief intervention. By design, follow up was marginal in this Medicaid population who all earned less than $40,000 per year, and may have experienced additional burdens because of low income. Specifically, follow up was a concern in this study as of the 55 participants; complete follow up was only made on 23 patients. Only 34% of intervention group one complied with the study requirements while 50% of those in intervention group two complied with the study. The researchers note that reasons for the high attrition rate included the decision to not have surgery; social/insurance issues; medical issues; and lack of psychiatric clearance (Parikh et al., 2012).

From baseline to six months pre-surgery, there was no significant difference in BMI ($p=0.077$), adherence ($p=0.67$), eating behavior ($p=0.75$), patient activation ($p=0.40$), and/or physical activity level ($p=0.19$) between groups completing the study. Moreover,
no further statistical difference from baseline to six months postoperatively in BMI ($p=0.32$), adherence ($p=0.55$), patient activation ($p=0.87$) was noted between groups. However, physical activity ($p=0.031$) was increased in the intervention group. The researchers surmised that the participation in a preoperative weight management clinic is not beneficial in promoting postoperative lifestyle changes and weight loss outcomes (Parikh et al., 2012). In order to fully develop the intention of this study attention to sampling and a more detailed description of the educational offerings may need to be expanded in order to improve attrition.

**All Methods of Surgical Intervention**

Lier, Biringer, Stubhaug, and Tangen (2011) conducted a randomized controlled trial to assess whether attendance in a preoperative counseling program improved weight loss or adherence in postoperative bariatric surgery patients. The intervention group ($n=49$) participated in six weekly preoperative cognitive-behavioral sessions and three postoperative sessions. The focus of the sessions included problem solving, cognitive restructuring, mindfulness training, physical activity, and eating behavior. The aim of therapy was to improve coping skills that would enhance weight loss and support maintenance of postoperative lifestyles. The control group ($n=50$) received treatment as usual which consisted of two four hour educational seminars in which education pertaining to surgical approach and dietary strategies were provided. Outcomes were measured in both groups one year postoperatively using a researcher created three question survey assessing food intake volumes, vitamin use, and minutes of exercise performed each week. At one year postoperatively, the researchers noted that there were no significant differences in weight loss ($p=0.540$), eating habits ($p=0.580$), or physical
activity ($p=0.654$) between the groups and that preoperative group counseling did not increase treatment adherence to lifestyle changes, however, no specific results were reported (Lier, Biringer, Stubhaug, & Tangen).

In a multi-stage study, Kalarchian, Marcus, Courcoulas, Cheng, and Levine (2013) report a randomized controlled trial to evaluate the benefits of a six month behavioral lifestyle intervention prior to bariatric surgery. The initial stage of this ongoing study evaluated the impact of lifestyle interventions on preoperative weight loss in order to identify factors associated with preoperative weight loss. The second stage, currently in process, will examine the impact of the intervention on postoperative outcomes (Kalarchian, et al.).

All participants in the intervention group ($n=121$) were required to comply with a physician supervised diet and exercise program, with documentation of weight loss and maintenance of weight loss in order to obtain insurance approval for bariatric surgery. Those participants in the control group ($n=119$) were required to arrange a supervised diet with their primary care provider. Outcomes were measured in both groups at the end of the six month period utilizing the Beck Depression Inventory (BDI), the Eating Disorder Examination (EDI), and the Eating Behavior Inventory (EBI) (Kalarchian et al., 2013). The authors noted presence of documented reliability and validity for the instruments; however, scores were not supported.

The results suggest that those participating in the intervention group lost significantly more weight ($7.8 \pm 8.3 \text{ kg vs } 3.3 \pm 5.5 \text{ kg}, p<0.0001$). The researchers noted that EBI score was a significant predictor of weight loss ($p<0.02$), while BDI ($p<0.08$), and EDE ($p<0.22$) were not significant predictors of weight loss. The authors concluded
that the major finding of this study is that an evidence-based six months, behavioral lifestyle intervention is associated with significantly greater preoperative weight loss than in those participating in an independent physician diet and exercise program. Authors concluded that in future reports they will examine the impact of this program on postoperative behavioral lifestyle modification.

The studies Kalarchian, et al. (2013) and Lier, et al. (2012) both noted that preoperative lifestyle modification may enhance lifestyle choices. Lier, et al. concluded that the preoperative intervention of lifestyle modification enhances postoperative lifestyle choices, enhancing weight loss its maintenance. Kalarchian, et al. concluded that the preoperative weight management clinic can enhance preoperative weight loss and improve immediate surgical outcomes though this study is ongoing as researchers continue to evaluate the impact on postoperative lifestyle modification and weight loss. However, findings of these studies should be viewed cautiously considering the limitations to the studies and lack of formal measurement. The evidence regarding the benefit of a preoperative weight loss intervention suggests lack of clear support.

**Systematic Review**

Ochner et al. (2012) performed a systematic review of available literature regarding pre-bariatric surgery and weight loss requirements relative to postoperative weight loss and postoperative outcomes. Similar to this study, search terms of “insurance-mandated preoperative requirements” were utilized. In contrast, search terms pertaining to the effects of preoperative weight loss and perioperative complications; preoperative weight loss effects on postoperative weight loss; and contingency of surgery based on preoperative weight loss were also utilized. Literature was included if it was less than 20
years old, published in English, and body weight was self-reported. In total, 25 eligible articles met criteria and were assessed and categorized. Of note, one of the studies included in the review were performed by the lead author. Utilizing the United States Preventative Services Task Force criteria (USPSTF), each study was rated as good, fair, or poor (Ochner, et al., 2012). The USPSTF grades are classified as good if the results are from a well-designed, well-conducted study that directly assesses the effects on health outcomes and includes a well-represented population. Fair evidence sufficiently determines the effects on health outcomes but lacks generalizability, number, quality, or consistency. Poor evidence does not sufficiently assess the effects on health outcomes due to limited power, flaws in design, gaps in evidence, or results indicating effects on health outcomes (Retrieved from www.uspreventiveservicestaskforce.org). Of interest, the author noted that only one study in the review was well-designed and conducted and directly affected health outcomes in a well-represented population (Ochner, et al., 2012).

Authors reported three main conclusions from this literature: insurance mandated preoperative requirements offer no appreciable benefit to bariatric surgery patients; those programs requiring weight loss prior to surgery result in greater weight loss; and preoperative weight loss may lead to improved postoperative outcomes, including weight loss. The researchers further conclude that there is insufficient evidence to support preoperative weight loss. Additionally, the authors challenge the ethics of requiring preoperative weight reduction in bariatric surgical candidates (Ochner, et al., 2012).
Conclusion

In conclusion, a striking finding of this review is the limited amount of research regarding comprehensive weight management clinics, including those serving the preoperative bariatric surgery population. Additionally, the lack of rigor and clear outcome measures are lacking in multiple studies. Specifically lacking are those studies evaluating select lifestyle behavior modification following participating in comprehensive weight management clinics. Few studies suggest that an intervention focused on select lifestyle behaviors may contribute to weight loss and weight maintenance.

Four of the noted studies were randomized controlled trials, two were retrospective, one was prospective, and one was a systematic review. Funding for the above studies was provided by the medical institutes in which they were performed. The overall lack of measureable outcomes in existing studies suggests that further research is needed to comprehend the full influence of select lifestyle behaviors as a contributing factor to weight loss.
CHAPTER 3
CONCEPTUAL FRAMEWORK

The purpose of this chapter is to describe Donabedian’s theoretical model utilizing structure, process and outcomes and to discuss how the model will frame the exploration of inclusion/integration of select dietary and exercise behaviors in a comprehensive weight management program. Utilizing this framework, the structure of the organization will be outlined; the usual rendered patient care described; and formal measures of the evaluation will be iterated. Additionally, Donabedian’s framework and staged evaluation process will be explored and linked to Bandura’s self-efficacy theory in order to optimize understanding and enhance outcomes for clinic participants.

Donabedian Theoretical Model

For the past three decades, the Donabedian theoretical model has been the gold standard for determining quality standards, monitoring the end result of patient care, and improving structures and/or processes (Moran, Burson, & Conrad, 2014). According to Donabedian (1968), the first issue is choosing the project outcome or component to be evaluated. For this project, select lifestyle contributors that may impact obesity among participants in a weight management program were selected as they have not been previously studied within the chosen organization as outcome measurements were deemed to be a priority by the medical and surgical centers of the target institution.

Donabedian further suggests that “a complete system evaluation should include much more information concerning client behaviors than is now available” (1968, p. 184). Contrary to Donabedian’s carefully staged method, most existing studies describing weight management clinics lack careful design. Those few that do exist show mixed
results relative to the behaviors in obesity, specifically eating behavior and physical activity, suggesting that further evaluation could contribute to the science of weight loss in comprehensive clinics. For this project, an additional impetus is the recent insurance mandate to participate in a six month comprehensive weight management clinic despite the equivocal research to date regarding its contribution to pre-bariatric lifestyle modification.

The evaluation of health care methods ascribed to Donabedian’s framework includes the three dimensions of structure, process, and outcomes. This framework provides the underpinnings necessary to understand the potentially contributing behavioral components in populations seeking weight loss and provides a mechanism for a systematic evaluation (Donabedian, 1966). Because of its well-defined methodology, Donabedian’s stages will be utilized to determine the presence and variability of select lifestyle behaviors among those participating in a comprehensive weight management clinic.

**Structure**

According to Donabedian, *structure* evaluates the environment and the instruments which make up the process, as well as “administrative and related processes that support and direct the provision of care” (Donabedian, 1966, p. 694). The *structure* of the setting includes: materials that are utilized, human resources, leadership, and safety of the culture. Donabedian’s *structure* further incorporates adequacy of facilities and equipment; leadership qualifications; program operations and *structure*; and economic outcomes (Donabedian, 1966). In addition to the above, evaluation specific to the needs of the bariatric patient will include: the physical environment; access to specialized
equipment such as large blood pressure cuffs, scales for weighing, and weight appropriate furniture; qualifications of trained staff; and bariatric sensitive education provided to staff members. Other considerations are patient accessibility to care which includes the cost of program, location of the program, and the availability of insurance reimbursement. The premise of structure is that given the right setting, efficacious interventions can exist, along with high-quality medical care (Donabedian, 1966).

**Process**

The second dimension of process refers to the method of care delivery; a description of the process of care; how the evaluation of interventions will be performed; and the quality of the intervention. Process additionally incorporates the patient’s initiation of care and participation throughout the healthcare process (Donabedian, 1988). Naranjo and Viswanatha (2011) further interpret this process as “the intervention or service that provides patients with an improved outcome” (2011, p. 34). As part of the process to be rendered, the intervention includes education pertaining to lifestyle modification. Specifically, participants will receive counseling and education regarding physical activity, dietary changes, as well as individual behavioral and emotional counseling.

**Outcome**

The final dimension, outcome, is defined as the change in health status that occurs in a patient or populations health status. Donabedian (1988) further notes that a positive outcome can be seen as a change in patient knowledge and the patient’s satisfaction with a given program. Outcome is an indicator of the quality of the intervention and it allows
for performance measurement and benchmarking of quality performance, evaluating the
effectiveness of the intervention.

Evaluating outcomes can assess for potential areas of risk, non-compliance, and
underachievement. An essential component of this dimension is the dissemination of the
results relative to the outcomes of the intervention. Results can act as a catalyst for
change within the current organization as well as potential organizations and programs
(Naranjo, & Viswanatha, 2011). For this project, outcomes pertaining to a change
(lifestyle modification) during the participation in the six month comprehensive weight
management clinic will be measured utilizing the Paffenbarger Physical Activity
Questionnaire (PPAQ) and the Three-Factor Eating Questionnaire (TFEQ-R18V2).

Donabedian (1990) summarizes that health care is influenced by a “need” within
the community. Needs for care may relate to a certain state of ill health, prevention of
illness, therapy, or rehabilitation. For this project, care sought to manage obesity may be
initiated by a patient who recognizes the need for care, has access to the care, and
engages as a participant in this change. Further, organizations and programs maintain the
services needed while health care professionals implement the needed service to the full
extent. Specifically, organizations must maintain the capacity to produce care, produce
goods and services used in care, and select appropriate clinical strategies and maintain
skill in execution (Donabedian, 1990). As a result, Donabedian concludes that health care
in itself is not the goal, but rather a means to improve health status of those participating
in the program. Thus, the Donabedian model of *structure, process, and outcome* can offer
a framework to improve both the health status of a participant and population.
By using this approach, healthcare is transformed from a disease management approach to disease prevention and health maintenance approach. The methodology of this approach is premised on collaboration between health care providers and individuals with shared focus on self-care management, where by individuals are encouraged to manage their health habits. Providers are encouraged to reduce health care costs by
modifying the risk factors for chronic diseases. By altering health habits, individuals can live longer and healthier lives by reducing risks associated with comorbid conditions. Because psychosocial factors may affect lifestyle choices, improving self-efficacy of the individual contributes to a change in behavior, increases health risk awareness, and contributes to an increase in compliance (Bandura, 2004).

**Self-Efficacy Theory**

Bandura introduced his social cognitive theory in the 1970’s. His work has been used as a means to better understand and measure a person’s beliefs in their abilities to achieve certain tasks and their influence on task performance (Bandura, 1989). According to Bandura’s social cognitive theory (2004), there are four constructs in which an individual translates knowledge into health practices: knowledge, self-efficacy, outcome expectations, and perceived facilitators. Knowledge refers to a person’s awareness of risks and benefits various health practices. Outcome expectations pertain to the person’s health goals and plans and the strategies for achieving them. Perceived facilitators promote achievement of the goal and also includes the social and structural impediments inhibiting those health changes that are desired (Bandura, 2004).

Self-efficacy is defined as an individual’s confidence in their ability to succeed in behavior change. As the self-efficacy improves, individuals tend to set higher goals for themselves further promoting success and self-efficacy. However, in order to invoke behavior change people need to be educated regarding the rationale for the change, be provided adequate resources, and be aware of effective skills for obtaining that change. Most importantly, people must hold the belief they are capable of that change. Those who do not believe the change is possible will give up attempt early while those who believe
the change is possible will persist with the behavior change. Perceived self-efficacy influences the contemplation of behavior change, the effort made to change the behavior, the degree of change, and how the change is maintained (Bandura, 1990). Self-efficacy related to eating and physical activity behavior can be improved with participation in a weight management clinic that provides nutritional education, physical activity guidance, positive reinforcement, goal setting, and dietary monitoring (Bandura, 2004).

While participation in the multidisciplinary clinic may enhance a person’s knowledge and outcome expectations, improve perceived facilitators, and alleviate social and structural impediments, this project will focus on self-efficacy (Roach et al., 2003). Bandura’s self-efficacy theory can be postulated as a facilitator for the intervention in a comprehensive weight management clinic prior to bariatric surgery based upon select constructs that follow.

Bandura states that self-efficacy influences a person’s perceptions of their abilities to fulfill different levels of tasks (Bandura, 1989). Self-efficacy strongly influences an individual’s ability to change by providing motivation and action. Self-efficacy is derived from an individual’s belief that they hold the power to change the behavior. If an individual does not believe they have the power or ability to change a behavior, there will be little motivation change (Batsis et al., 2009). Self-efficacy theory proposes that as an individual’s confidence in their ability to change or carry out a behavior will increase the direction, intensity, and persistence of their ability to change that given behavior (Dishman et al., 2005).

Self-efficacy has been shown in select studies to predict long-term eating behavior after bariatric surgery (Batsis et al., 2009). It is postulated that those with low eating self-efficacy have difficulty resisting the temptation to overeat and tend to engage in emotional eating and binge eating behaviors. It is also proposed that low eating self-efficacy may lead to failure to implement appropriate eating behavior modifications during weight loss attempts and after weight loss interventions. Thus, self-efficacy can be a predictor of successful long-term weight loss (Batsis et al.).

Self-efficacy theory also proposes that those who feel confident with their ability to perform physical activity perceive fewer barriers to exercise and state a greater enjoyment derived from exercise. Self-efficacy may positively influence an individual’s thoughts, goals, and actions related to exercise (Dishman et al., 2005). When assessing self-efficacy for exercise and eating habits in relation to lifestyle, Annesi and Gorjala (2010) concluded that formal exercise training and eating behavior counseling may benefit self-efficacy in the treatment of obesity.
Participation in a multidisciplinary weight management clinic was shown to improve self-efficacy scores in a study by Batsis et al. (2009). Batsis et al. also reported that ongoing participation in a weight management clinic can enhance postoperative eating self-efficacy and assist with the attainment of long-term weight loss. Interventions that supported enhanced self-efficacy eating behaviors leading to weight loss include nutritional counseling and education with focus on healthy eating behaviors and keeping a food diary (Roach, et al. 2003). Additionally, Warziski, Sereika, Styn, Music, & Burke (2008) reported that verbal encouragement, self-monitoring of calories, physical activity, goal setting, and positive feedback improved self-efficacy of eating behaviors and promoted weight loss.

Bandura’s self-efficacy model can be used in tandem with Donabedian’s model using structure, process, and outcome framework as a mechanism to further enhance the quality of care. Donabedian’s concept of structure can be seen as a two-way relationship with Bandura’s Self-Efficacy concepts. For example, Bandura’s constructs of goals and behavior can directly affect outcomes by providing a comprehensive assessment of factors within settings that may impact outcomes. At the same time, self-efficacy can impact outcomes with an enhanced understanding of personal factors within the individual that impact change. By improving self-efficacy through multidisciplinary interventions; process may be improved leading to more efficacious outcomes.
Conclusion

Interventions in this project can potentially be augmented when Donabedian’s model and Bandura’s self-efficacy theory are used in tandem. Specific interventions include those that relate to select lifestyle modification in a targeted comprehensive weight management clinic. Project quality was enhanced by incorporating Bandura’s self-efficacy model into the interventions. The final steps at the Northern Michigan clinic are to re-evaluate project outcomes and to disseminate knowledge gained from this project to the comprehensive weight management clinic in order to contribute to the knowledge database and for benchmarking. Utilizing Bandura’s theory to increase self-
efficacy may increase confidence and reduce perceived barriers related to physical activity and healthy eating behaviors, thus promoting weight loss and maintenance of this weight loss.
CHAPTER 4

METHODOLOGY

The purpose of this chapter is to describe the methodology used to evaluate select lifestyle behaviors following participation in a comprehensive weight management clinic. This project was developed in collaboration with an established comprehensive weight management clinic associated with a regional medical center in Northern Michigan. This chapter will report unique regional and local factors. Further, the project design will be discussed including the protocol for project implementation; the Institutional Review Board approval including the time line; the selection and recruitment process for participants; and the instruments of measure. Lastly, perceived facilitators and barriers to the project will be presented along with the data management plan.

Relevant Local and Regional Factors

This project was conducted in the Greater Grand Traverse Region of Northern Michigan which includes Grand Traverse, Leelanau, Benzie, Kalkaska, and Antrim Counties. Overall, this region has experienced greater population growth than other regions in Michigan over the last five years. In fact, it is one of the only growing regions in Michigan. In 2011 the total population expanded to 173,063 and the growth rate is expected to increase yet another 2.6% in 2015 (Traverse City Area Chamber of Commerce, 2011).

Obesity rates in the Greater Grand Traverse Region mirror most obesity rates in Michigan and are recorded as: Leelanau County-31.5%; Grand Traverse County-23.9% (Anderson et al., 2009); Antrim County-30%; Kalkaska County 28.8%; and Benzie County-29% (National Institute for Children’s Health Quality [NICHQ], 2011). In
comparison, the obesity rate in Michigan is 31.4% while the rate of those who are overweight is 35%. According to the NICHQ (2011), a national organization who records obesity data, 19% of Grand Traverse and Antrim County residents state that they do not engage in leisure-time physical activity while 25% overall do not participate in any physical activity (Keeslar et al., 2012). The NICHQ speculates the projected health related cost of obesity for the state of Michigan in 2018 is 12,490 million dollars annually.

When compared with previous rates of obesity, the obesity rates in Michigan have risen more than 21.8% between 2001 and 2008 (Anderson, Lyon-Callo, Monje, Boivin, & Imes, 2009). Michigan now has the eleventh highest obesity rate in the United States with a current rate of 31.4% (Trust for America’s Health/Robert Wood Johnson Foundation, 2014). Recent data shows that Michigan males have a significantly higher prevalence of obesity as do those with higher income levels. Yet, there is no difference in obesity rate by race or educational levels. Interestingly, those in Michigan with college degrees are less likely to be obese than those without (Anderson, et al.).

**Project Design**

This project utilized a feasibility design to explore select lifestyle modification following participation in a comprehensive weight management clinic. The objectives of this feasibility study were to explore the participant recruitment process and the utility of measurement instruments in this setting. Additional objectives were to evaluate the sustainability of such a study in a larger sample of participants. Donabedian’s framework of structure, process, and outcomes was implemented in order to perform a systematic assessment of the clinic and this project. Anticipated expenditure for this project included
copying costs of the instruments and other documents. Unanticipated additional costs
included postage for mailing instruments and unreturned self-addressed, stamped
envelopes. All expenses were tracked and recorded.

**Institutional Review Board**

Approval was sought from Grand Valley State University’s (GVSU) Human
Research Review Committee (HRRC) and the participating organizations Institutional
Review Board on December 1, 2014. Two organizational applications together with the
protocol; the consent; data collection instruments; an expedited checklist; the DNP
students proof of the Collaborative Institutional Review Board Training Initiative
Program (CITI); Survey Monkey® templates; and the measurement instruments along
with proof of permission to utilize were submitted for approval.

Approval was received from the participating organization pending placement of
a company logo on the consent (Appendix C and Appendix D). Final approval was
received from the GVSU HRRC on January 23, 2015.

**Selection of Participants**

Participants for this project were recruited from a healthy weight center at the first
medical, dietary, counseling, or exercise consultation appointment after formal entry into
the comprehensive weight management clinic. All participants who sought enrollment in
the clinic between February 1, 2015 and March 1, 2015 were eligible if inclusion criteria
were met. Thus, the timeline for recruitment was one month. Data collection was
completed by June 1, 2015 allowing three months for instrument administration and
collection.
Inclusion and Exclusion Criteria

The target inclusion sought for this project consisted of persons who were recently enrolled in the clinic; individuals over the age of 18; individuals with a BMI greater than 30 kg/m²; and those who were voluntarily participating in the comprehensive weight management clinic regardless of interest in bariatric surgery. All participants who met inclusion criteria, agreed to the study criteria, and completed the consent process were invited to participate. Those with the inability to speak English or with a cognitive disability, including the inability to read, comprehend, or complete the required documents, were excluded. The DNP student met with each participant individually to assure informed consent and gain a formal signature for enrollment in the study.

Thus, participants interested in the Roux-en-y gastric bypass, laparoscopic banding, duodenal switch, gastric sleeve, and bariatric conversion procedures were also sought. Insurance criteria allow those individuals participating in the clinic as a requirement for bariatric surgery to attend such a clinic for up to two years prior to surgical date. However, no individuals seeking bariatric surgery were enrolled during the recruitment process. Those voluntarily participating, regardless of interest in bariatric surgery, were included in the sample. Ultimately, 17 participants were recruited and 17 were accepted.

Instruments

Measurement of lifestyle behavior changes included the Three Factor Eating Questionnaire (TFEQ-R18V2) and the Paffenbarger Physical Activity questionnaire (PPAQ). Both were used with permission received from the authors (See Appendix E and
Appendix F). Initial instructions for completion were provided by the DNP student. Subsequent instruments were placed in the patient chart for self-completion at designated intervals with instructions to place completed instruments in an envelope located at the desk of the department secretary. The purpose of the project, along with the rationale for participant completion of the instruments at the time of service, was discussed with the members of each discipline in order to enhance instrument completion and return. Completed instruments were retrieved twice weekly from the clinic.

**TFEQ-R18V2.** The TFEQ-R18V2 is a self-assessment scale developed and intended to measure three components of eating behavior: cognitive restraint, emotional eating, and uncontrolled eating (Appendix H). Uncontrolled eating refers to the loss of control over eating as a result of hunger or exposure to external stimuli. Cognitive restraint indicates the ability to control dietary intake in order to influence weight or body shape. Emotional eating assesses influence of eating habits in relation to negative mood states such as loneliness, anxiety, or depression. The TFEQ has since been revised to the shortened to the TFEQ-R18V2 (Cappelleri et al., 2009). The use of this revised instrument was recommended by the developer. Both instruments have been validated in multiple studies and have well established readability and validity. The TFEQ-R18V2 has shown robust factor structure and reliability with a Chronbach’s coefficient of $\alpha=0.89$ for uncontrolled eating, $\alpha=0.78$ for cognitive restraint, and $\alpha=0.94$ for emotional eating (Cappelleri et al.). De Lauzon, et al. (2004) also evaluated the efficacy of the TFEQ with applicability to the general population and noted Chronbach’s $\alpha$ of $\alpha=0.84$ for cognitive restraint, $\alpha=0.83$ for uncontrolled eating, and $\alpha=0.87$ for emotional eating.
**PPAQ.** The PPAQ, previously known as the Harvard Alumni Physical Activity Survey, is an eight question, self-report instrument developed by Paffenbarger, Wing, and Hyde in 1978 (Appendix G). The instrument was initially designed for a study investigating the association of physical activity and heart disease in an at-risk Harvard Alumni population (Dishman, Washburn, & Schoeller, 2001). This instrument has been utilized in multiple studies and has sustained reliability and validity in more than eleven studies. The PPAQ was chosen as it shows high reliability and validity with measurement of physical and allows for the monitoring of serial changes in physical activity with approximate excess kilocalorie expenditure (Erickson et al., 2013).

**Facilitators and Barriers for this Project**

Potential facilitators to the project included the multidisciplinary approach used by the clinic and existence of an integrated professional staff including a registered dietitian, exercise specialist, social worker, nurse practitioner, and bariatrician. Additionally, the staff appeared motivated to provide high quality, efficacious care. In fact, many incorporated aspects of the national guidelines and recommendations.

Potential barriers to this project included the fact that clinic participation is mandated for those considering bariatric surgery while others may elect to participate.

Other potential barriers for this project included the limited use of outcome measurement; affordability of the clinic given minimal insurance coverage; lack of formal recording of attrition rates and patient rationale for ceasing participation; potential transportation issues given the large service area; and the fact that participation may be insurance mandated for those considering bariatric surgery potentially influencing motivation and participation. Still, other barriers may exist and be unknown.
Data Management

A data management plan was established and shared with the clinic. Participants were coded in order to enhance identity protection and assure confidentiality. Additionally, a plan for data management was completed and approved by GVSU HRRC and the participating facility IRB allowing storage of the data in a locked drawer in the secure office of the clinic nurse practitioner. All coded data and demographic information was stored on a secure, coded flash drive. Provisions were made for storage of participant consents, completed measurement instruments, and the coded flash drive for a minimum of six years per Federal regulations. A plan for data analysis was created in conjunction with the support of GVSU’s Statistical Consulting Center. Analysis utilizing SPSS® was planned dependent upon the quality and amount of data received.

Conclusion

In summary, this chapter described the plan for conducting a feasibility study of the evaluation of select lifestyle modification following a comprehensive weight management clinic. Instruments for the study were introduced and reviewed. The multidisciplinary staff of the clinic was informed of the plan in order to encourage enrollment and support the project as it unfolded. Clinic staff was informed that the DNP student would consent all participants and facilitate the completion of further instruments. At their initial clinic visit, potential participants were approached to enter the study by the DNP student. The participants were selected, informed, and recruited based upon the pre-recruitment inclusion/exclusion criteria. Potential facilitators and barriers to the project were identified. Lastly, a plan for data management and analysis were performed.
CHAPTER 5

RESULTS

This chapter will report results of this scholarly project which examined select lifestyle behavior modification following participation in a comprehensive weight management clinic. The results will reflect the select lifestyle behaviors of physical activity and eating behaviors as well as weight and BMI changes. First, the chapter will present the clinical setting and usual care relative to the comprehensive weight management clinic in Northern Michigan and discuss similarities/differences in current guidelines and recommendations. Then, participant recruitment and consenting process will be presented. Next, the data of those who completed the project will be reviewed and reported. Finally, data will be interpreted and presented in charts in order to enhance understanding.

Clinical Setting and Usual Care

The Munson Healthy Weight Center is a weight management clinic that serves as a resource to the public, including those persons mandated to participate in such a clinic prior to bariatric surgery. It is an off-site, freestanding affiliated with a regional medical center. Present at the clinic are classrooms for group education and exercise classes, a full gym a wide variety of equipment, two exam rooms, and a shared office. Other resources at this site include a pharmacy, out patient radiology services, laboratory services, home care services, and an urgent care.

A board-certified bariatric physician who works in collaboration with a bariatric certified nurse practitioner, a registered dietitian, exercise specialists, and behavior health specialists supervises the clinic. The clinic has been in operation for approximately ten
years, with continued evolution since inception. Approximately 1000 patients participate in the clinic per year; however, to date the clinic has not implemented formal monitoring of the number of individuals who enroll. The ultimate goal of the clinic is to provide education for lifestyle modification in order to promote and sustain healthier lifestyles and at the same time, promote weight loss and weight maintenance. Within the clinic, a personalized and unique plan of care for each patient is developed that includes meal plans, exercise regimes, and counseling services (Munson Healthy Weight Center, n.d.).

A 60 minute mandatory orientation and a $20.00 fee are expected when entering the program. The intention of the orientation is to introduce the participant to the services and design the treatment plan. Other required documentation for the enrollment includes a signed physician referral form; registration and data enrollment forms; and recent laboratory profiles (dated within the last six months) that include a comprehensive metabolic profile, lipid panel, thyroid stimulating hormone level, and hemoglobin A1c (Appendix I). At the time of the orientation, and prior to appointments with other clinicians, cost and payment options are discussed. Currently, some insurance companies are reimbursing expenses for components of this clinic. Insurance requirements prior to bariatric surgery mandate monthly meetings with a health related discipline (Munson Healthy Weight Center, n.d.).

Following orientation, the participants attend a meal plan appointment to discuss the meal plan options of hypocaloric, partial meal replacement, or total meal replacement. Meetings with a dietitian are not required and are based on participant need. All participants meet with a behavioral health specialist to determine how many sessions are necessary. Typically, five to eight behavioral health sessions are available to the
participant throughout the program. Participants have an initial appointment with an exercise specialist followed by 30 minute sessions preceded by 30 minutes of independent cardio exercise. Other exercise options include supervised exercise and circuit training. Group education on variable topics is available one day per week led by the behavioral health specialist or the registered dietitian. It is suggested that participants meet with at least one discipline every month (Munson Healthy Weight Center, n.d.).

There are no specific requirements regarding participation, rather participation is encouraged by suggestions and offering options.

A strengths, weakness, opportunities and threats (SWOT) analysis of this comprehensive weight management clinic illustrated strengths of affiliation with a regional medical center, a multidisciplinary approach, and accessibility of exercise equipment. Weakness included the distance of travel required of outlying participants, lack of insurance funding, and variability of clinic hours. Noted opportunities are expanded clinic via telehealth, implementation of electronic sessions, and formal measurement of outcomes. The threats are the ability to participate in a weight management program through a personal primary care provider and the mentioned weaknesses that may prohibit participation in the clinic.

**Weight Management Guidelines Compared With Usual Care**

**Centers for Medicare and Medicaid Services**

According to the Centers for Medicare and Medicaid Services (CMS), the United States Preventative Services Task Force (USPSTF, 2012) has adopted the 5A’s (Assess, Advise, Agree, Assist, and Arrange) approach for obesity treatment. These include assessing behavioral risks and barriers to changing behaviors and meeting goals; advising
persons about personal health harms and benefits; giving clear, specific personalized advice regarding health behavior change; agreeing on collaboratively managed goals and methods; assisting in the achievement of goals by providing skills, confidence, and social support for health change; and arranging follow up contacts to provide ongoing assistance and to allow for treatment modification when necessary (Department of Health and Human Services [DHHS]: Centers for Medicare and Medicaid Services [CMS], 2012).

The multidisciplinary approach of the comprehensive weight management clinic adheres to much of the CMS criteria and incorporates the 5 A’s into usual care.

The CMS is currently reimbursing providers for Intensive Behavioral Therapy (IBT) for obesity, however, only in the primary care setting. The CMS defines a primary care setting as one “in which there is a provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community” (DHHS: CSM, p. 4, 2012). Unfortunately, this definition does not include formal weight management centers and as a result, services at the comprehensive weight loss clinic do not qualify for this reimbursement.

National Heart, Lung, and Blood Institute

While these components are not a current part of clinic services, recent updated recommendations from the NHLBI (2013) delineate a “comprehensive lifestyle modification” in order to create a daily calorie deficit. The preferred intervention is an onsite, high intensity interventions either individual or group by a trained interventionist with either individual or group meetings greater than or equal to 14 sessions in 6 months and a treatment that lasts for a period of at least one year. The guidelines further call for a
prescribed calorie reduction diet and exercise regime based upon individual tolerance, comorbidities, and personal preference. Weight maintenance recommendations include a prescribed, individualized, calorie reduction diet and an exercise program of 200-300 minutes per week. Weight maintenance programs and follow up may be offered via telephone or internet on a basis of at least once per month (Kushner & Ryan, 2014).

**Participant Recruitment and Selection**

All individuals who sought enrollment at the comprehensive weight management clinic who met inclusion criteria during the enrollment period of February 1, 2015 through March 1, 2015 were approached as possible participants. Potential participants were given complete information regarding the project as well as a review of their role utilizing an established protocol. Participants were informed of their right to decline participation and/or withdraw from the project at any time and were given contact information in order to do so. All participants were assured of confidentiality and were informed that likely a coded data collection would include age, gender, weight, height, and BMI. Additionally, potential participants were introduced to the TFEQ-R18V2 and the PPAQ instruments and were informed of the repeated measures at six weeks and three months. The DNP student who was available Monday through Friday during normal business hours performed consenting and instruction.

**Consenting Process**

All participation consents (Appendix B) and instruments were reviewed with potential participants by the DNP student. Participants were given ample time for questions regarding this project and their participation. A copy of the signed consent was provided to each participant for their personal records following enrollment.
Additionally, all participants were reminded that there was no financial or other incentive available for participation in this study. The DNP student was available for administration of instruments and consent two days per week during clinic hours. Participants also had the opportunity to contact the DNP student with questions during business hours throughout their participation in the program. The DNP student performed administration of the initial PPAQ and TFEQ-R18V2 at the initial visit to the comprehensive weight management clinic. All data was collected and stored by the DNP student on a coded flash drive and stored in a locked drawer in the office of the collaborating nurse practitioner, together with the hard copies of the completed instruments.

Seventeen participants signed a formal consent to participate in the project. Participants included 14 females and 3 males ranging in age from 34 years to 75 years of age. Sixteen participants returned the initial instruments as instructed. Two additional participants chose not to continue in the comprehensive weight management clinic and intended to pursue weight loss and exercise independently. Additionally, no instruments were returned from one participant. These three were lost from the study. Eight completed the initial measurement as well as the six week measures. An additional four participants were reminded to complete and return the six week instruments but failed to do so. Instruments were mailed to the four participants with a self-addressed, stamped envelope but none were returned. Five completed the three month instruments, however, only two completed instruments at all three intervals. Final analysis included two male and seven female participants. Despite the return rate on the instruments, 14 participants continued activity in the clinic at the six week measurement and seven participants
continued activity in the clinic for three months allowing for weight and BMI data to be collected (Appendix J). No formal participant withdrawal from the project was received.

Figure 4. Participant summary of instrument completion and data collection.

**Data Analysis**

The DNP student, in collaboration with the Grand Valley State University Statistical Consulting Center, performed data analysis. Demographic data and data from the formal measurement instruments were manually entered into a Survey Monkey® template for ease of merging into the statistical software. Data was analyzed utilizing
SPSS 20® SAS 9.4®. Findings reported descriptive data and compared change in the PPAQ and the TFEQ-R18V2 over time. Specifically, a change in the instrument outcomes of physical activity, emotional eating, cognitive restraint, and uncontrolled eating were assessed. Results also reported the demographic variables of weight and BMI. Results were reported in aggregates and disseminated to the organization.

No missing data was noted in the completed TFEQ-R18V2 instruments. Question four on the PPAQ was modified from “how many times per year” to read “how many times per week” in order to calculate the weekly excess kilocalorie expenditure, rather than annual kilocalorie expenditure. Question four, listing sports and recreational activities, were not completed on four instruments. Two of these instruments, completed by the same participant, further indicated no vigorous or moderate intensity activity on question eight. The other participant indicated minimal vigorous or moderate intensity activity on both instruments for question eight. Missing data in question four were imputed as no sports or recreational physical activity. All other responses relative to excess kilocalorie expenditure were appropriately answered on the PPAQ.

**Initial Analysis**

Initial analysis of the TFEQ-R18V2 and the PPAQ included the nine participants who completed instruments on at least two occasions. Changes in weight and BMI were calculated for the 14 participants who remained in program attendance. Of these fourteen participants, the mean age was 49.64 years. Initial analysis included the 3 male and 11 participants who completed the initial and the 6 week instruments.
Table 1

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**TFEQ-R18V2**

Possible scores for all scales ranged between 0-100 with higher scores indicating a higher propensity for emotional eating (EE), uncontrolled restraint, and cognitive restraint. Initial analysis of EE scores depicted a range of 5.6 to 72.77 with a mean score of 49.38. Scores for males ranged between 38.89 and 72.22 and scores for females ranged between 5.56 and 66.77. While there appeared to be no clinically significant variation in scores among males and females, it was noted that one male received an initial score of 72.22 which was the most notable EE score identified.

Uncontrolled eating (UE) scores range between 14.81 and 62.96 with a mean score of 41.97. Possible scores range between 0-100 with higher scores indicating greater probability of uncontrolled eating behaviors. Scores for males ranged between 40.74 and 62.96 and scores for females between14.81 and 59.26 with no clinically significant
differences noted between males and females. Again, the male scoring highest for EE scored highest for UE, but the score was not clinically significant using the suggested scoring system. Again, no clinically significant UE score was noted.

In contrast, higher scores for controlled restraint (CR) indicate a positive attribute. Possible scores again range from 0-100. Controlled restraint scores ranged between 22.22 and 66.77 with a mean score of 48.81. Both male scores were 33.33. Two female and two male participants presented scores less than 55.56 perhaps indicating lower mastery of CR behavior.

**PPAQ**

The analysis of weekly excess kilocalorie expenditure of nine participants resulted in a range of 251.50 kilocalories and 3629.00 kilocalories. Mean excess weekly kilocalorie expenditure was 1251.88 kilocalories. Mean was again calculated without two extreme of 251.50 kilocalories and 3629 kilocalories to reduce the risk of skewed data, indicating a new mean excess weekly kilocalorie expenditure of 785.66 kilocalories. No difference was noted between male and female participants.

**Weight/BMI**

Initial weight for 14 participants ranged from 186 pounds to 390 pounds with a mean weight of 236.78 pounds. BMI ranged between 32 kg/m² and 50 kg/m² with a mean BMI of 38.5 kg/m². No variation between sexes was noted.

**Six Week Analysis**

Three factor eating questionnaire-R18V2 and PPAQ results are reported for the seven participants who completed the initial and 6-week measurement instruments. The six-week analysis of weight and BMI change is then reported for 14 participants.
TFEQ-R18V2

Emotional Eating scores at the 6-week interval indicate a range of 5.56-77.78 with a mean score of 46.03. Two participants showed a slight improvement (11.11); one indicated no change; two indicated higher EE scores (5.56). One indicated an emotional eating score of 0.00 with an initial score of 38.89 indicating to tendency for EE. With this exception, no notable changes in EE scores were noted and there was no difference by sex.

Uncontrolled eating scores at the 6-week interval produced a range between 11.11 and 51.85 with a mean of 37.04. Four participants showed slight improvement in UE scores (-2.70 and -11.11) while one showed slight increase (37.04 to 40.74), although none were substantial. One participant showed a decrease in UE scores of 18.52 (40.74 to 22.22) and one showed an increase of 14.81 (33.33 to 28.15), again not indicating substantial changes.

Controlled restraint scores at the 6-week interval ranged between 22.22 and 100.00 with a mean of 42.85. One participant showed improvement in CR with a score change from 66.67 to 100.00, indicating superior CR eating behavior. No notable changes were detected in the remaining participants.

PPAQ

The 6 week range of excess kilocalorie expenditure indicates a range of 151-2,422.50 kilocalories and a mean of 1279 kilocalories. Mean weekly excess kilocalorie expenditure is similar to that noted at the initial measurement. Change in weekly excess kilocalorie expenditure is reported as follows: -656.50, -100.50, +281.00, +318.50, +490.50, +799.50, +973.50 kilocalories.
Weight/BMI

Weight ranged from 172 pounds to 285 pounds with mean of 216.57 pounds. Total weight loss equaled 283 pounds collectively. The greatest weight change was 105 pounds. Of interest, the greatest loss was noted in the participant with the highest weight at initiation.

Body mass index showed a range of 30 kg/m² to 49 kg/m² (overweight BMI >25 kg/m²) with a mean BMI of 36.14 kg/m² indicating an average reduction of 2.36 kg/m² from initial measurement. Greatest BMI reduction was noted to be 8 kg/m² (40 kg/m² to 32 kg/m²).

Three month Analysis

Analysis of data from the TFEQ-R18V2 and the PPAQ was performed from two participants who completed instruments at all three measurements. Possible eating behavior scores ranged between 0 and 100. Analysis was performed utilizing two participants who had completed the instruments at initiation and at three months. Weight and BMI changes were compared utilizing data from the seven participants who had been seen at the clinic at all 3 intervals and whose weight had been recorded.

TFEQ-R18V2

Emotional eating scores for those two participants completing three interval instruments indicate score changes of 0.00 and 5.56. Scores of one participant completing the initial and three month instruments showed an EE score change of +22.22 (5.56 to 27.78). While the other indicated a change of -60.00 in the EE score from 38.89 to 0.00 indicating no tendency for EE. This was the only notable change in EE noted throughout the project.
Uncontrolled eating scores including those participants who completed instruments at all three intervals indicated no substantial changes (+3.70 and -11.11) utilizing the scoring guidelines. Of those two completing instruments at the initial and the three month interval, one showed significant improvement (-51.85), improving the UE score to 7.41. This score was the only notable UE change throughout the project. No notable change was noted in the other (+14.81) participant.

Controlled Restraint scores between the six week and three month intervals among those completing instruments at all three intervals indicate a change of 0.00. Among the two participants completing the initial and three month instruments, a change of and 22.22 and 77.78 was noted. One participant now showed a score of 100.00 for CR; representing the only marked change in UE (-51.85). This was the only significant change in CR scores throughout the project. It should be noted that this is not the participant showing a final EE score of 0.00. While the second showed improvement in the CR score, the change did not increase the score to a clinically significant level.

**PPAQ**

Excess weekly kilocalorie expenditure was calculated utilizing two participants who completed the instruments at three intervals resulting in an increase in weekly excess kilocalorie expenditure of 676.00 and 832.20 kilocalories per week respectively. Excess kilocalorie expenditure was further calculated utilizing two participants who had completed the initial and three month instruments showing one participant with a decrease in weekly excess kilocalorie expenditure of 1330. This decrease was noted in the participant with the weekly excess kilocalorie expenditure of 3629 at initiation. One participant showed an increase in kilocalorie expenditure of 997.70 kilocalories per week.
Weight/BMI

Weight loss change from the six week and three month interval among the seven participants with weights recorded at three intervals ranged between +1 pound and -24 pounds with an average weight loss of 7.71 pounds. Analysis of change BMI noted a decrease of 1 kg/m² to 5 kg/m². The average BMI decrease was 1.71 kg/m².

Collectively, a total weight loss among the 7 consistently participating in the clinic is 249 pounds with an average BMI decrease of 3.86 kg/m². Total weight loss ranged between 6 and 113 pounds with an average total weight loss of 36 pounds. Continued increase in weekly excess kilocalorie expenditure was noted among the majority of the participants. Eating behavior change was minimal for all but one participant.

Comparison Graphs

Comparison charts depicting the weight loss and change in BMI, EE, UE, CR and excess weekly kilocalorie expenditure illustrate findings of the project graphically.
Table 2

*Emotional Eating Score Changes*

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Possible Scores range between 0-100

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Possible scores 0 and 100

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Weight Change

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Weight measured in pounds
Table 7

**BMI Change**

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**Conclusion**

In summary, participants showed consistent weight loss and decline in BMI throughout the project interval. While most participants continued to show increased weekly excess kilocalorie expenditure, two indicated a marked decrease. Only one participant indicated notable changes in CR scores and a second participant indicated a substantial change in EE and UE scores using the suggested scoring method. One participant showed a CR score of 100 (maximum score) at the six week interval and a second participant indicated a score of 100 at the three month interval perhaps misunderstanding the instrument instructions. Regarding EE, one participant indicated a
score of 0.0000 (a minimum score) at the six week interval and one participant indicated a score of 0.00 at the three month interval.

Overall, the recruitment and consenting process proceeded without difficulty and according to the protocol. One measurement instrument required very modest adaptation in order to better serve the length of the study. The instruments were well suited to the study and served to measure influential eating behaviors and physical activity. However, a larger sample size and follow up for unaccounted for instruments would add strength to the study. As is, limitations in the instrument completion limit conclusions of the study.
CHAPTER 6
DISCUSSION

The purpose of this chapter is to describe and discuss the results of the project. First, the findings of the project will be linked to the current literature review and discussed. Next, findings relative to the conceptual framework will be reported. Further, potential benefits and barriers of this project will be reviewed. Then, the DNP roles in relation to the project will be presented and discussed in reference to advanced practice nursing roles as well as the limitations and recommendations; implications for the advanced practice nurse; and implications for the clinic, practice, research will be presented.

Findings Relative to Literature

Participants

Sufficient participants were recruited for this feasibility study over a period of four weeks. Consistent with previously reported literature, attrition rates were high and compromised the amount and consistency of data. Previously, Byrne, Barry, & Petry (2012) and Parikh, et al. (2012) reported troublesome attrition and rates of 50% and 60%. Considerate attrition was also noted by Jamal et al. (2006) suggesting that dedicated attention to participant recruitment, retention and engagement are imperative.

Relative to activity level, Byrne, Barry, & Petry (2012) reported no change in physical activity in a study similar to this project. Changes in physical activity were also assessed utilizing the PPAQ in a study by Parikh et al. (2012). Likewise, Parikh et al. (2012) also reported no significant changes in physical activity. Papalazarou et al. (2010) reported positive changes in diet and exercise lifestyle behaviors at 12, 24, and 36 months postoperatively utilizing a self-report physical activity questionnaire. When using the
TVEQ-R18V2, no substantial changes in EE, UE, and CR were noted in this project, however, measurement at varying intervals may indicate otherwise. Alvarado et al. (2006) reported that participation in a preoperative weight management clinic may influence lifestyle modification; however, formal measurement of lifestyle behaviors was limited in this study of insurance mandated weight loss.

**Weight Loss**

Bryne, Barry, & Petry (2012) reported a mean weight loss of 4.9-7.5 kg/m². Kalarchian, et al. (2013) and Jamal et al. (2006) reported similar weight loss results. Both studied populations at university medical centers. Ochner et al. (2010) noted weight gain among participants when exploring presurgical weight change. Findings of this project noted an average weight loss at six weeks of 20.29 pounds and an average total weight loss among remaining participants of 36.43 pounds at three months.

**Findings Related to Conceptual Framework**

**Donabedian Framework**

Donabedian’s model of structure, process, and outcomes served as a framework to assess standards, monitor results of patient care and improve processes as they presented. Incorporating this model into practice also supported the health status of those participating as a secondary gain. The results of this evaluation and the Donabedian model will be shared with the participating organization. The results of the project can be utilized to illustrate, improve, and change in other organizations.

**Self-Efficacy**

While concepts from Bandura’s self-efficacy theory were incorporated into the medical visit by the DNP student, the framework is not formally implemented by the disciplines of the clinic. For this reason, measurements of changes in self-efficacy were
not obtained. Specific interventions for improving self-efficacy include verbal encouragement, self-monitoring of calories/physical activity, goal setting, and positive feedback. All of these strategies are provided by this multidisciplinary clinic in some form; however, efforts to increase awareness of the benefits of self-efficacy may improve engagement of participants and ultimately, lifestyle modification.

Bandura describes self-efficacy as a person’s confidence to change behaviors (Bandura, 2004). The above interventions of verbal encouragement, goal setting, the encouraged use of a pedometer and/or an electronic activity tracker for self-monitoring of physical activity, and positive feedback are currently implemented at the clinic. While the framework was not formally applied as relates to physical activity, it is feasible that the continued increase in excess weekly kilocalorie expenditure may be related to an increase in self-efficacy.

According to Batsis et al. (2009), those with low eating self-efficacy have difficulty resisting the temptation to overeat and tend to engage in overeating and binge eating. However, the tendency for these behaviors (EE, UE, and CR) was not apparent in this project. Assessing for these tendencies at initial entry to the clinic may allow for the identification of participants who may benefit from enhanced self-efficacy. The effects of self-efficacy relative to diet and exercise habits are an area for further development in similar DNP projects.

**Benefits**

Potential benefits of this project include that the design and instruments allowed for formal measurement of physical activity and eating behaviors in the comprehensive weight management clinic population. These measurements are lacking in this current
setting and are also lacking in current weight management clinic literature. This gap in current literature pertaining to comprehensive weight management clinic was further reported by Ochner et al. (2012). An additional benefit of this project is that it builds a foundation for enhanced evaluation of select behavior lifestyle modification within the weight management clinic of interest and that may be applied to similar clinics.

**Limitations**

There were several limitations to this project. First, the sample size limits the conclusions of this feasibility project. Time constraints of this project limited the recruitment time to four weeks. Ideally, a larger sample may have added greater depth into the understanding of the influence of the comprehensive weight management clinic on select lifestyle behaviors. Consistent with prior studies in weight management clinics, attrition was an issue and the project suffered from a high attrition rate and a lower than anticipated yield of instruments. Two participants chose not to participate in the program equating to a 12% attrition rate. While no participants formally withdrew from the study, many did not return the instruments despite personal mailings with a self-addressed, stamped envelope. A table summarizing completion of instruments is included (Appendix J).

Lastly, the inconsistency in the administration of instruments at the six week and three month intervals could have been improved. Participant appointments with multiple disciplines occurred during business hours or evening hours with frequent cancellation and “no-show” for these appointments creating difficulty capturing participants. While some were retrieved at the time of appointments, many instruments were placed in participant charts for self-administration and lost to the project. Despite much
communication with the individual disciplines regarding the project and the suggested approach to instrument completion, some disciplines appeared to be more supportive and thus had a greater return of instruments. Moreover, the fact that the PPAQ and the TFEQ-R18V2 are both self-reported instrument should also be considered. As self-reported instruments, both are subject to measurement errors such as personal bias, which may limit accuracy of the findings.

Finally, the ultimate goal of the project was to capture the population anticipating bariatric surgery. However, this population was not available during the recruitment time frame. In fact, participation in the clinic by this population now appears limited. Factors that may contribute to the decline in enrollment include the fact that surgical candidates now have the option to participate in a weight management clinic using their primary care provider. This typically involves a monthly office visit that is often covered by health insurance. In comparison, the healthy weight center costs may exceed $2000 for six month participation.

**Roles of the DNP Relative to the Project**

The American Association of Colleges of Nursing (AACN) reports that nursing scholarship includes five activities critical to DNP work. These include activities “that systematically advance the teaching, research, and practice of nursing through rigorous inquiry that 1) is significant to the profession, 2) creative, 3) can be documented, 4) can be replicated or elaborated, and 5) can be peer reviewed through various methods” (Waldrop, Caruso, Fuchs, & Hypes, 1999, p.373). This project covers the AACN components of scholarship that include development of clinical knowledge and the application of research skills. While DNP scholarship is a skill that is developed
gradually, this project demonstrates the knowledge and skill set recommended for scholar
development.

The DNP student assumed the role of project coordinator for this feasibility study. While enacting this role, the project proposal was developed and a vast literature review of current studies and of the incorporated measurement instruments. Also conducted was the IRB process with approval received from the participating facilities. The project coordinator recruited the participants, obtained informed consent, and collected measurement instruments. Lastly, data obtained from the study was analyzed by the coordinator in conjunction with the GVSU Statistical Consulting Center.

The DNP project author was responsible for assessing anthropometrics, performing physical assessment, providing encouragement, education, and evaluating progress towards goals in conjunction with the nurse practitioner at monthly medical visits. Throughout this project the DNP student portrayed many DNP roles including that of clinician by performing monthly medical visits for the participants. Throughout this project, the DNP author also portrayed the role of advocate for the obese population. Leadership and innovation was demonstrated by providing suggested systems change within the organization, specifically outcome measurement within the new electronic health record. The role of educator was demonstrated at each participant interaction and included providing education pertaining to diet, exercise, health maintenance, and obesity related comorbidities. Additional DNP characteristics employed throughout this project include interdisciplinary collaboration between the multiple health disciplines within the clinic (Chism, 2013).
Five criteria are characteristic of a DNP project including: evaluating health outcomes; becoming an expert relative to a specific problem or population; collaborating with multiple disciplines; translating and applying of evidence; and evaluating health outcomes (Waldrop, Caruso, Fuchs, & Hypes, 2014). This project demonstrated these five characteristics. While the DNP student is not yet an expert in the area of obesity and bariatric surgery, a great foundation was developed. While the DNP author is evolving in the role of the DNP, common characteristics of DNP projects were successfully developed and incorporated as the project ensued.

The Eight Essentials of the DNP were largely incorporated into this project by the DNP student. Most significantly incorporated was Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes. This was accomplished via ensuring effective communication and leadership skills within the multiple disciplines relative to the purpose of the project. Essential VII relates to the Clinical Prevention and Population Health for Improving the Nation’s health. This was accomplished through analyzing the environment and scientific data specific to obesity and comprehensive weight management clinics. Lastly, Essential VIII (Advanced Nursing Practice) was largely incorporated by conducting a comprehensive assessment of health and illness parameters in complex health situations utilizing a culturally sensitive approach; evaluating therapeutic interventions based on science; developing therapeutic relationships and partnerships with patients; demonstrating advanced levels of clinical judgement; evaluating evidence-based care to improve patient outcomes; educating and guiding individuals through complex health situations; and evaluating the links among practice and populations.
Essential I (Scientific Underpinnings for Practice) was incorporated through use of science-based theories and concepts and through developing and evaluating practice approaches based on theory. Organizational and Systems Leadership for Quality Improvement and Systems Thinking (Essential II) was incorporated in the evaluation of care deliver, ensuring accountability for quality of health care and for patients, and employing cultural sensitivity. The use of analytical methods to critically appraise existing literature, evaluating outcomes, applying relevant findings to practice and utilizing information technology to collect data demonstrates the incorporation of Clinical Scholarship and Analytical Methods for Evidence-Based Practice (Essential III). Essential IV was incorporated by providing input for the measurement of health care outcomes (weight loss and comorbidity improvement) in the new electronic health record. Health Care Policy for Advocacy in Health Care was incorporated by attending an Obesity Advocacy webinar.

**Implications for the Advanced Practice Nurse**

With the growing demand for quality health care, the NHLBI (2000) identifies advanced practice nurses (APNs) as a resource for multiple roles in health care settings to help achieve the Triple Aim of improved health care quality, improved access to care, and affordable health care. The DNP could contribute to weight loss and weight management education through the promotion of dietary counseling, physical activity, and behavior modification. Approaching weight loss with a positive attitude with support and encouragement supports patient compliance and success (NHLBI). Moreover, APNs in weight loss centers could play an integral role in treatment and follow up of the comorbid conditions of obesity such as hypertension, dyslipidemia, diabetes, coronary
artery disease, stroke, cancer, gallbladder disease, respiratory issues, and obstructive sleep apnea as well as contribute to the referral process as needed.

**Implications for Science, Research, and Policy**

This feasibility study lays the foundation for expanded research evaluating select lifestyle modification following participation in a comprehensive weight management clinic. Results of such studies may influence the insurance mandated participation in such a clinic. Further policy implications include national or state funding as well as expanded insurance coverage for participation in a comprehensive weight management clinic. Awareness of barriers and facilitators noted within this project and in the literature review will enhance participant recruitment, improve instrument administration, and enhance follow up. The implementation of the TFEQ-R18V2 and the PPAQ within this project may encourage similar clinics to incorporate the formal measurement of diet and exercise habits in order to document changes in behavior.

**Implications for the Comprehensive Weight Management Clinic**

Based upon the findings of this project, recommendations include the monitoring of weekly excess physical activity throughout the program. This will allow participants to visualize the progress in activity and may improve self-efficacy. Administration of an eating behavior scale such as the TFEQ-R18V2 can identify those with the propensity towards EE, UE, and CR allowing for further intervention. A formal system to track participation and attrition and a protocol for stepwise follow-up of patients should be developed. Finally, adopting the guidelines of the AHA/ACC/TOS (Jensen et al., 2013) and the NHLBI (2013) that allows for electronic sessions may remove patient barriers as many participants reside in outlying areas.
Conclusion

Due to the type of study and small sample size, results are limited to the clinic in which it was conducted but may prove beneficial for future studies regarding select lifestyle changes and weight loss thus reducing the gap in current literature. The study intended to include those insurance mandated to participate in consideration for bariatric surgery. However, this population is now lacking this comprehensive weight management clinic. For this reason, all persons seeking participation at the clinic and meeting project inclusion criteria were also considered for the sample.

This DNP project examined select lifestyle behavior modification in a comprehensive weight management clinic in Northern Michigan utilizing an early feasibility design. Although participants were successfully recruited, the project was troubled by attrition and compliance and lack of the return of measurement instruments. As a result, conclusions of the study were limited. Trends suggest eating behaviors and physical activity data could be retrieved utilizing the selected instruments.

This project introduced organizational assessment, formal metrics, and conceptual frameworks to the weight management clinic and staff. Formal measurement of excess weekly kilocalorie expenditure throughout participation in the clinic has the potential to increase self-efficacy of the participants and may prove to be self-empowering. Formal assessment of the tendency for EE, UE, and CR may aide in the reversal of these behaviors by the nutritional counselor. To further enhance this query, dietary journals could have been reviewed for additional insights into care. Areas for further study and development include evaluation of the consistently high attrition rate in weight...
management clinics as well as the lack of disciplined studies addressing optimal approaches to lifestyle modification in clinics employing existing national guidelines.

Obesity, as a disease, continues to exist as a national health concern creating challenges to current health care systems. Guidelines and recommendations pertaining to weight loss, weight management, and co-morbidity management are crucial as the prevalence of obesity continues to rise. Utilizing a feasibility design, his project explored select lifestyle modification following participation in a comprehensive weight management clinic. The DNP scholar has the potential to improve the quality of health care, reduce barriers to health care, and reduce health care costs when completing similar projects.
## APPENDIX A

### Literature Review Results

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<th>Authors</th>
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<th>Type of Surg.</th>
<th>Inclusion criteria</th>
<th>Sample Size</th>
<th>Intervention/ Measurement</th>
<th>Stat. Analysis</th>
<th>Results</th>
<th>Conclusion</th>
<th>Comments</th>
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<td>Retrospective Level IV C</td>
<td>Roux-en-Y</td>
<td>NIH Criteria</td>
<td>N=90</td>
<td>Preop WL without interventions. No formal measurement</td>
<td>MLR ( p &lt; 0.05 )</td>
<td>Weight loss stated ( p &lt; 0.05 ) no data provided</td>
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<td>Evaluated WL only. Not BM or PA</td>
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<td>Jamal, et al. (2006)</td>
<td>Prospective Level IV C</td>
<td>All</td>
<td>Dxs of obesity</td>
<td>Interv. n=72 control n=252</td>
<td>PDC-13 weeks No formal Measurement</td>
<td>ANOVA, Fisher’s exact t-test ( p &lt; 0.05 )</td>
<td>WL ( p &lt; 0.0001 ), lower BMI ( p &lt; 0.015 ), lower wt ( p &lt; 0.01 ) in no PDC group</td>
<td>PDC not effective</td>
<td>Unequal sample size. Intervention group 28% attrition Intervention =19%</td>
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<td>RCT Level IV C</td>
<td>All</td>
<td>NIH Criteria</td>
<td>Intervention n=121 Control n=119</td>
<td>Lifestyle modification, dietary/exercise . BDI, EDE, EBI</td>
<td>Linear regress; 2 tail t-test, wilcoxon, chi-square</td>
<td>Wt loss &gt; interv. group. ( p &lt; 0.0001 )</td>
<td>Lifestyle changes increase preop wt loss</td>
<td>First part of study. To assess postop effectiveness</td>
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<td>All</td>
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<td>Control=50 intervention=49 reference=39</td>
<td>Counseling (CBT) q week for 6w Self-report measurement</td>
<td>ANOVA ( p &lt; 0.05 )</td>
<td>Measure changes post op PA ( p &lt; 0.540 ), WL ( p &lt; 0.975 )</td>
<td>Counseling not effect, but PA &amp; EB intervention. are. Identified need to individualized .</td>
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<td>RM ANOVA LR Chi square</td>
<td>( p = 0.001 )</td>
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<td>Short evaluation period</td>
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<td>ANOVA</td>
<td>Wt lower in int group p&lt;0.05 at 12, 24 &amp; 36 mo</td>
<td>Intervention effective</td>
<td>Used DEBQ, RE, EE, EE &amp; HPAS. Female only</td>
</tr>
<tr>
<td>Parikh, et al. (2011)</td>
<td>Pilot RCT Level II C</td>
<td>Lap Band</td>
<td>NIH Criteria/Low income/Medicaid only</td>
<td>N=55 Intervention =15; individual intervention n=15 control=30</td>
<td>MSWM for only required 2 sessions but stated 6 mo program. MGS, PAM</td>
<td>Fisher's exact</td>
<td>Measure adherence p&lt;.31 p=.88, EB, PA p=.60</td>
<td>Measured EB &amp; PA</td>
<td>&gt;50% attrition Sample limits.</td>
</tr>
<tr>
<td>Ochner, et al. (2012)</td>
<td>Systematic review</td>
<td>All types</td>
<td>n/a</td>
<td>Various methods of interventions</td>
<td>Various throughout studies</td>
<td>One article “good”. Note poor quality of data</td>
<td>Note a further need for “good” quality research.</td>
<td>Noted high attrition rate</td>
<td></td>
</tr>
</tbody>
</table>

BM- Behavior modification; EB-eating behavior; FU-follow up ; LR-Linear regression ; LS-lifestyle ; LSC-lifestyle choices ; MLR-Multiple Linear Regression ; MSWM-medically supervised weight management ; PDC-preoperative dietary counseling ; PA-physical activity ; RCT-randomized controlled trial ; RM-repeated measures; VSG-vertical sleeve gastroplasty
APPENDIX B

Consent

Consent to Act as a Participant in a Research Project and HIPPA Authorization for Release of Health Information for Research Purposes

Title of the Project: Evaluation of Select Lifestyle Behavior Modification Following a Comprehensive Weight Management Clinic

Principle Investigator: Jennifer Bowling, RN, BSN,
Doctor of Nursing Practice Student

Faculty Advisor: Ruth Ann Brinntall, PhD, ACON, CHPN, APRN-BC

PURPOSE OF THE PROJECT

The purpose of this project is to evaluate the contribution between select behavioral components of a comprehensive weight management program and actual lifestyle change following participation in a comprehensive weight management clinic. Specifically diet and exercise habits will be evaluated and reported. The goal of the clinic is to educate people about healthy lifestyle changes that can help with weight loss and help maintain weight loss. The results of this project will help understand the contribution of select lifestyle behaviors to weight loss. There is no charge for being a part of this project. The decision to be part of this project is voluntary and will not affect your care. All information about participation will be
available for your review before you agree to join. The purpose of this study is NOT to see how much weight you lose during this project.

RISKS OF JOINING

There are no known risks of harm linked with this project. The project does involve the possible risk that others may see your health information. There is a small risk that your health information may be lost, but multiple steps for preventing this are listed below.

BENEFITS OF JOINING

There may be no direct benefits of being part of this project. There are no financial incentives for participation in this project. Your decision to be part of the project may help health care providers better understand the benefits of the weight management clinic. Results of this project will be shared with you personally. You may also contact the researcher for results.

PRIVACY OF INFORMATION

As part of the project, your health information will be gathered and used. Your name will not appear on any of the information. The information you will give may include your name, height, weight, body mass index, age, sex, and race. Your name and other information will remain private and your name will be coded to help prevent anyone from recognizing you. Your name will only be known by this Doctor of Nursing Practice (DNP) student. Other information may be shared with the research team.

All paper and electronic data will be stored in a locked area at Grand Traverse Surgery on a coded computer drive. According to federal law, your information will be kept for six years and then it will be destroyed.

JOINING THE PROJECT

You are being asked to join this project because you have decided to be part of a weight management clinic.

Being part of this project is voluntary. You do not have to be part of this project. You may choose to stop at any time. You will receive the same care whether you choose to join or not. You will not be paid to join this project. If you choose to be part of this project and have chosen to join the weight management clinic, you will fill out two surveys about your diet and exercise habits three times during the project.
AGREEMENT TO JOIN

By signing below you state that you have read all of the above and that you agree to participate in this project and have your health information used. You have been informed and given the opportunity to ask questions. You are aware that you may choose not to be part of the project at any time and have your health information removed from the files. You may ask questions about the project at any time.

By signing below, I am agreeing to have my health information submitted to the database that will gather information about the weight management program and the impact it may have on the outcome of weight loss and lifestyle changes.

______________________________________________                                    Printed
Name

_______________________________________________
Signed Name

Date_______________

___________ Initial stating that you have received a copy of this consent

I state that I have provided the details of the project, including the procedures and risk. I have answered any questions. I believe the participant has understood the information provided.

______________________________________________                                    Date
Jennifer Bowling, DNP Student

Contact Information

If you have any questions about this project you may contact the project leader at

Jennifer Bowling, DNP Student, Grand Valley State University
If you have any questions about your rights as a participant, please contact the Research Protections Office at Grand Valley State University, Grand Rapids MI
Email: HRRC@GVSU.EDU                     Phone: 616-331-3197

This project has been approved by the Munson Medical Center Institutional Review Board. This research protocol has also been approved by the Human Research Review Committee at Grand Valley State University, file number 15-078-H, expires on January 23, 2016.
APPENDIX C

Grand Valley State University Human Research Review Committee Approval

DATE: January 23, 2015

TO: Jennifer Bowling, DNP
FROM: Grand Valley State University Human Research Review Committee
STUDY TITLE: [685022-1] Evaluation of lifestyle behaviors following a comprehensive weight management clinic
REFERENCE #: 15-078-H
SUBMISSION TYPE: New Project
ACTION: APPROVED
APPROVAL DATE: January 23, 2015
APPROVAL: January 23, 2016
EXPIRATION: 
REVIEW TYPE: Expedited Review

Thank you for your submission of materials for this research study. The Human Research Review Committee has approved your research plan application as compliant with all applicable sections of the federal regulations, Michigan law, GVSU policies and HRRC procedures. All research must be conducted in accordance with this approved submission.

Please insert the following sentence into your information/consent documents as appropriate. All project materials produced for participants or the public must contain this information.

This research protocol has been approved by the Human Research Review Committee at Grand Valley State University. File No. 15-078-H Expiration: January 23, 2016.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require that each participant receive a copy of the signed consent document.

The following information is required in order to maintain current approval with the HRRC. Failure to submit within 30 days, unless otherwise noted, constitutes non-compliance with HRRC procedures and may result in a suspension of approval.

- An official letter documenting permission to conduct research at the research site.

This approval is based on the HRRC determination that no greater than minimal risk is posed to research participants. This study has received expedited review, 45 CFR 46.110 category [enter category], based on the Office of Human Research Protections 1998 Guidance on Expedited Review Categories.

Please note the following in order to comply with federal regulations and HRRC policy:
1. Any change to previously approved materials must be approved by this office prior to initiation. Please use the Change in Approved Protocol form for this submission. This includes, but is not limited to, changes in key personnel, study location, participant selection process, etc. See HRRC policy 1010, Modifications to approved protocols.

2. All UNANTICIPATED PROBLEMS and SERIOUS ADVERSE EVENTS to participants or other parties affected by the research must be reported to this office within 7 days of the event occurrence, using the UP/SAE Report form. If the adverse event includes a fatality, hospitalization, or security breach of sensitive information immediately notify the Human Research Review Committee Chair, Dr. Paul J. Reitemeier, 331-3417 AND Human Research Protections Administrator, Mr. Jon Jellisma, in the Office of the Provost, 331-2400. See HRRC policy 1020, Unanticipated problems and adverse events.

3. All instances of non-compliance or complaints regarding this study must be reported to this office in a timely manner. There are no specific forms for this report type. See HRRC policy 1030, Research non-compliance.

4. All required research records must be securely retained in either paper or electronic format for a minimum of 3 years following the closure of the approved study. This includes original or digitized copies of signed consent documents. Research studies subject to the privacy protections under HIPAA are required to maintain selected research records for a period of at least 6 years after the close of the study.

5. At least 60 days prior to current approval expiration, please submit a Continuing Review form:
   - Protocols that are active and open for enrollment require both the Primary Investigator and Authorizing Official to electronically sign the Continuing Review submission in IRBNet.
   - Protocols that are active for data analysis or long term follow-up ONLY require the Principal Investigator’s signature but do not need to be further authorized.
   - A copy of the informed consent/assent form currently in use in the study must accompany the submission unless the study has been closed to enrollment, and active only for data analysis, for more than 1 year.

If you have any questions, please contact the Research Protections Program, Monday through Thursday, at (616) 331-3197 or rpp@gvsu.edu. The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.
APPENDIX D

Participating Facility IRB Approval

Institutional Review Board

FVA #0002923
Registration #00002961

Certificate of Approval by Expedited Review

DATE: January 15, 2015
TO: Jennifer Bowling, DNP

Project Title: Evaluation of lifestyle behaviors following a comprehensive weight management clinic
IRBNet ID #: 685022-1
IRB #: 14.036
Sponsor: Kirkhof College of Nursing

List of study documents:
- Application Form RB New Research Study Application form (Updated 01/15/2015)
- Application Form - Application (UPDATED: 01/13/2015)
- Consent Form - consent (UPDATED: 01/13/2015)
- Data Collection - data collection instrument (UPDATED: 01/13/2015)
- Letter - Letter to IRB (UPDATED: 01/13/2015)
- Other - Appendix E (UPDATED: 01/13/2015)
- Other - Appendix D (UPDATED: 01/13/2015)
- Other - Appendix C (UPDATED: 01/13/2015)
- Other - Appendix B (UPDATED: 01/13/2015)
- Other - Appendix A (UPDATED: 01/13/2015)
- Other - expedited checklist.doc (UPDATED: 11/16/2014)
- Other - student research protocol checklist.doc (UPDATED: 11/16/2014)
- Other - permission.docx (UPDATED: 11/15/2014)
- Protocol - protocol (UPDATED: 01/13/2015)
- Training/Certification - CITI (UPDATED: 11/21/2014)

Action: Final Approval
Effective Date: January 15, 2015
Site Status Reporting: Open
Project Status: Active-speak to enrollment
Study Expiration Date: December 14, 2015
Project Risk Level: Minimal Risk

[Redacted text] acknowledges submission of the revised documents with the requested modifications made on January 13, 2015 for above-referenced study. After review [redacted text] gives final approval of this study and all changes in the revised documents noted above effective as of January 15, 2015.

In accordance with good clinical practice guidelines and federal regulations continuing review of this study will be required annually. Any protocol amendments or revisions to the study should be brought before the IRB as soon as possible and prior to implementation of the changes. You will be notified in advance to complete, sign and submit the [redacted text] Continuing Study Renewal form, available on IRBNet at www.irbnet.org within 30 days prior to the annual review expiration date noted above.

Sites must have active on-going IRB approval in order to enroll subjects, perform any study interventions, collect/report data, and/or, if under an FWA, analyze identified data at the site.

Please notify [redacted text] if the above-referenced study becomes closed to patient enrollment or becomes permanently closed. Note, sites that have only completed enrollment (i.e., closed to accrual) cannot be closed if data relating to subjects is still being collected.

Call the IRB office at [redacted text] if you have any questions or concerns regarding your submission to the IRB. This letter is in accordance with all applicable regulations, and a copy is retained within [redacted text] IRB records.
APPENDIX E

TFEQ-R18V2 Permission to Utilize

Från: Jennifer Bowling [bowlijen@mail.gvsu.edu](mailto:bowlijen@mail.gvsu.edu)
Skickat: den 10 september 2013 19:52
Till: Jan Karlsson
Ämne: TFEQ-R21

I am a graduate student at Grand Valley State University in Grand Rapids, Michigan. Your email address was forwarded to me by Dr. Cappelleri. For the completion of the Doctor of Nursing Practice, I will be performing an intervention analysis. Because I have great interest in the bariatric population, I will be analyzing the effectiveness of a six month, pre-operative, comprehensive weight-loss clinic. I will also measure the effectiveness when used in surgical patients.

I would like to utilize the TFEQ-R21 as noted in Psychometric analysis of the Three-Factor Eating Questionnaire-R21: results from a large diverse sample of obese and non-obese participants. Measurements will be taken pre-participation and three and six months post participation and/or post surgery.

I have attached a copy of my prospectus should you wish to review this first. I look forward to hearing from you soon.

Thank you for your consideration,

Jennifer Bowling
Bowlijen@mail.gvsu.edu

Yes, you have permission to use the TFEQ-R18v2 in your study.
Best,
Jan

Från: Jennifer Bowling [bowlijen@mail.gvsu.edu](mailto:bowlijen@mail.gvsu.edu)
Skickat: den 12 september 2013 00:05
Till: Jan Karlsson
Ämne: Re: TFEQ-R21

Great!! Thank you!! Will this allow me permission to utilize this tool?

Thank you for your help!!

Jennifer Bowling
Hi Jennifer,

I suggest you use the TFEQ-R18V2, which is the latest version, and it has been validated in North American obese and non-obese samples.

I enclose the questionnaire and scoring instructions

Best regards,
Jan Karlsson, psychologist, associate professor

Obesity Unit
Medical Department
Örebro University Hospital
701 85 Örebro
Sweden

Centre for Health Care Sciences
Örebro University Hospital
Box 1324
701 13 Örebro
Sweden
Hi Jennifer,

Thanks for your email. The Paffenbarger physical activity questionnaire is published in many outlets, along with descriptions of reliability/validity, and scoring algorithms, including:

- JAMA 1995;273:1179-1184;

There is no charge for using the questionnaire; however, please acknowledge the source.

Best,
Howard

~~~~~~~~~~~~~~~~~~~~~~
Howard D. Sesso, ScD, MPH
Associate Professor of Medicine, Harvard Medical School
Associate Epidemiologist, Brigham and Women's Hospital
Division of Preventive Medicine
900 Commonwealth Avenue East - 3rd Floor
Boston, MA 02215

From: Jennifer Bowling [mailto:bowljen@mail.gvsu.edu]
Sent: Tuesday, October 15, 2013 5:05 PM
To: Sesso, Howard D.
Subject: Paffenbarger Physical Activity Questionnaire
Paffenbargar Physical Activity Questionnaire

1. How many city blocks or their equivalent do you normally walk each day? _____ blocks/day  
   (Let 12 blocks = 1 mile)
2. What is your usual pace of walking? (Please check one)
   a. ___ Casual or strolling (less than 2 mph)  
   b. ___ Average or normal (2 to 3 mph)  
   c. ___ Fairly brisk (3 to 4 mph)  
   d. ___ Brisk or striding (4 mph or faster)
3. How many flights or stairs to you climb up each day? _____ flights/day (Let 1 flight = 10 steps)
4. List any sports or recreation you have actively participated in during the past year.
   Please remember seasonal sports or events.

<table>
<thead>
<tr>
<th>Sport, Recreation, or Other Physical Activity</th>
<th>Number of Times/year</th>
<th>Average Time/Episode</th>
<th>Years Participation</th>
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</tbody>
</table>

5. Which of these statements best expresses your view? (Please check one)
   a. ___ I take enough exercise to keep healthy.  
   b. ___ I ought to take more exercise.  
   c. ___ Don’t know
6. At least once a week, do you engage in regular activity akin to brisk walking, jogging, bicycling, swimming, etc. long enough to work up a sweat, get your heart thumping, or get out of breath?
   ___ No  Why not? ___________________  ___ Yes  How many times per week? ___ Activity: ___________________
7. When you are exercising in your usual fashion, how would you rate your level of exertion (degree of effort)? (Please circle one number.)
   Normal  Very very weak (just noticeable)  Very weak  Weak  Moderate  Somewhat strong  Strong (heavy)  Very strong  Very very strong (almost maximal)  Maximal

85
8. On a usual weekday and a weekend day, how much time do you spend on the following activities? Total for each day should add to 24 hours.

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>Usual Weekday Hours/Day</th>
<th>Usual Weekend Day Hours/Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Vigorous activity (digging in the garden, strenuous sports, jogging, aerobic dancing, sustained swimming, brisk walking, heavy carpentry, bicycling on hills, etc.)</td>
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<tr>
<td>b. Moderate activity (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)</td>
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<tr>
<td>c. Light activity (office work, driving car, strolling, personal care, standing with little motion, etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Sitting activity (eating, reading, desk work, watching TV, listening to radio, etc.)</td>
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<td></td>
</tr>
<tr>
<td>e. Sleeping or reclining</td>
<td></td>
<td></td>
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</tbody>
</table>
INSTRUCTIONS

Administering or completing the Paffenbarger questionnaire is self-explanatory. The individual is asked explicitly about walking and stair climbing, which are modes of "getting about" required of almost everyone. In addition, information on recreation and sports play is requested through open-ended questions concerning frequency of times played annually and years of participation together with duration of play/episode.

CALCULATIONS

The kilocalorie scores for city blocks walked and flights of stairs climbed were defined by Paffenbarger and colleagues in 1978 (11). The original source of the kilocalorie scores used for sports play and recreation is Passmore and Darwin (13).

Kilocalories

Walking
1 city block = 8 kcal
12 city blocks = 1 mile = 96 kcal

Climbing stairs
1 flight of stairs = 10 steps = 4 kcal

Sports and recreational activities

Light intensity = 5 kcal/min
Vigorous intensity = 10 kcal/min
Mixed intensity = 7.5 kcal/min

Kilocalories per week

\[(\text{blocks/day} \times 7 \text{ days/wk} \times 8 \text{ kcal/block}) + (\text{Flights of stairs/d} \times 7 \text{ d/wk} \times 4 \text{ kcal/flight})\]

\[(\text{activity MET intensity} \times \text{occasions/wk} \times \text{duration(min/occasion)}) \div (\text{wk/yr} \div 52 \text{ wk/yr})\]

Physical Activities Ranked by MET Value


MET value = 2.5: boating, sailing; croquet, trail bike riding

MET value = 3.0: bocci ball, lawn ball; bowling; candlepin bowling; duckpin bowling; carpentry in workshop; do-it-yourself projects; diving; horseshoes; Indian clubs; shuffleboard; surfing and wind surfing

MET value = 3.5: archery; catch, frisbee, games with children; coaching sports; fishing from riverbank or boat; surf casting; home maintenance; housekeeping; hunting; swimming, working dogs in the field; mowing lawn with power mower

MET value = 4.0: boat maintenance; curling; gardening; golf; raking lawn; walking

MET value = 4.5: badminton; body building, Nautilus, weight lifting; canoeing for pleasure; kayaking; white water rafting; farming; ranching, horseback riding, fox hunting; painting; paper hanging; platform tennis; table tennis; snowshoeing; spear fishing; squash

MET value = 5.0: baseball, cricket, kickball, softball, track ball, whiffleball; basketball; dancing; digging, spading; gymnastics, trampoline; skateboarding

MET value = 5.5: aerobics, calisthenics, home exercise, tai chi chuan; bicycling; cardiac rehabilitation therapy, health club

MET value = 6.0: bayonet, fencing, kendo, two-handed sword; body surfing, swimming; cross-country hiking; cycling machine, rowing machine treadmill walking; fishing in stream with wading boots; mowing lawn with hand mower; water skiing

MET value = 6.5: carpentry outside, roof repair, shingling; cutting wood, splitting wood; heavy work around home and yard; paddleball, paddle tennis; sledding, tobogganing; snow shoveling; snow skiing, downhill skiing

MET value = 7.0: back packing, cold hockey, football, lacrosse, rugby; forestry and trail maintenance; ice hockey, ice skating, roller skating; jogging; racquetball; scuba diving; soccer; tennis (lawn and court)

MET value = 8.0: boxing; judo, martial arts; wrestling; mountain climbing; polo; snowshoeing; snow skiing, crosscountry

MET value = 10.0: handball; logging, lumbering; water polo

MET value = 12.0: canoeing or rowing in competition, racing crew, sculls; competition running, track and field; squash
EXAMPLE

These hypothetical data are used to demonstrate the kilocalorie scoring method.

1. How many flights of stairs do you usually climb up each day (let 1 flight = 10 steps)?
   7 flights per day

2. How many city blocks or their equivalent do you regularly walk each day (let 12 blocks = 1 mile)?
   12 blocks per day

3. List any sports or recreational activity you have participated in during the past week. Please include only the time you were physically active (i.e., actual playing time in jogging, bicycling, swimming, brisk walking, gardening, carpentry, calisthenics, etc.).

Racquetball: 2 times/wk. 45 min/time (coded as vigorous)

7 flights/d × 4 kcal/flight = 28 kcal/d × 7 d/wk = 196 kcal/wk

12 blocks/d × 8 kcal/block = 96 kcal/d × 7 d/wk = 672 kcal/wk

Racquetball = (10 kcal/min × 90 min/wk) = 900 kcal/wk

Total = 196 kcal/wk + 672 kcal/wk + 900 kcal/wk = 1768 kcal/wk

OTHER STUDIES USING THE QUESTIONNAIRE

In addition to the references cited, other studies have used the Paffenbarger Questionnaire (2,4,5,8,10,12).

REFERENCES


APPENDIX H

TFEQ-R18V2

This section contains statements and questions about eating habits and feelings of hunger.
Read each statement carefully and answer by ticking the alternative that best applies to you.

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<tbody>
<tr>
<td>1. I deliberately take small helpings to control my weight</td>
<td>6. Being with someone who is eating often makes me want to also eat</td>
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<tr>
<td>a. Definitely true</td>
<td>a. Definitely true</td>
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<tr>
<td>b. Mostly true</td>
<td>b. Mostly true</td>
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<tr>
<td>c. Mostly false</td>
<td>c. Mostly false</td>
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<td>d. Definitely false</td>
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<tr>
<td>2. I start to eat when I feel anxious</td>
<td>7. When I feel tense or &quot;wound up&quot;, I often feel I need to eat</td>
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<tr>
<td>a. Definitely true</td>
<td>a. Definitely true</td>
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<td>b. Mostly true</td>
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<td>c. Mostly false</td>
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<tr>
<td>3. Sometimes when I start eating, I just can't seem to stop</td>
<td>8. I often get so hungry that my stomach feels like a bottomless pit</td>
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<td></td>
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<tr>
<td>a. Definitely true</td>
<td>a. Definitely true</td>
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<tr>
<td>b. Mostly true</td>
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<td>c. Mostly false</td>
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<td>d. Definitely false</td>
<td>d. Definitely false</td>
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<tr>
<td>4. When I feel sad, I often eat too much</td>
<td>9. I'm always so hungry that it's hard for me to stop eating before I finish the food on my plate</td>
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<tr>
<td>a. Definitely true</td>
<td>a. Definitely true</td>
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<td>b. Mostly true</td>
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<tbody>
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<td>5. I don't eat some foods because they make me fat</td>
<td>10. When I feel lonely, I console myself by eating</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Definitely true</td>
<td>a. Definitely true</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Mostly true</td>
<td>b. Mostly true</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Mostly false</td>
<td>c. Mostly false</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Definitely false</td>
<td>d. Definitely false</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This section contains statements and questions about eating habits and feelings of hunger. Read each statement carefully and answer by ticking the alternative that best applies to you.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Options</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. I consciously hold back at meals to keep from gaining weight</td>
<td>1. Definitely true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Mostly true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mostly false</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Definitely false</td>
<td></td>
</tr>
<tr>
<td>15. When I see something that looks very delicious, I often get so hungry</td>
<td>1. Definitely true</td>
<td></td>
</tr>
<tr>
<td>that I have to eat right away</td>
<td>2. Mostly true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mostly false</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Definitely false</td>
<td></td>
</tr>
<tr>
<td>12. When I smell appetizing food or see a delicious dish, I find it very</td>
<td>1. Definitely true</td>
<td></td>
</tr>
<tr>
<td>difficult to keep from eating - even if I’ve just finished a meal</td>
<td>2. Mostly true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mostly false</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Definitely false</td>
<td></td>
</tr>
<tr>
<td>16. When I feel depressed, I want to eat</td>
<td>1. Definitely true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Mostly true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mostly false</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Definitely false</td>
<td></td>
</tr>
<tr>
<td>13. I’m always hungry enough to eat at any time</td>
<td>1. Definitely true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Mostly true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mostly false</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Definitely false</td>
<td></td>
</tr>
<tr>
<td>17. Do you go on eating binges even though you’re not hungry?</td>
<td>1. Never</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Rarely</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Sometimes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. At least once a week</td>
<td></td>
</tr>
<tr>
<td>14. If I feel nervous, I try to calm down by eating</td>
<td>1. Definitely true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Mostly true</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Mostly false</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Definitely false</td>
<td></td>
</tr>
<tr>
<td>18. How often do you feel hungry?</td>
<td>1. Only at mealtimes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Sometimes between meals</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Often between meals</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Almost always</td>
<td></td>
</tr>
</tbody>
</table>
TFEQ-R18V2 Scoring Instructions

• **Items**
  TFEQ-R18V2 comprises 18 items, which are aggregated to three separate scale scores.

• **Response format**
  A 4-point response format is used.

• **Data entry**
  Items should be entered as coded in the questionnaire (number beside the response box). After data entry, out-of-range values should be checked for.

• **Item recoding**
  Items 1-16 need recoding (as shown below) before computing scale scores. No recoding is required for item 17-18.

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Precoded item value</th>
<th>Final item value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-16</td>
<td>1 → 2 → 3 → 4</td>
<td>4 3 2 1</td>
</tr>
</tbody>
</table>
The TFEQ-R18V2 covers three eating behavior scales:

- The **Uncontrolled eating** scale assesses the tendency to lose control over eating when feeling hungry or when exposed to external stimuli.

- The **Cognitive restraint** scale assesses the tendency to control food intake in order to influence body weight and body shape.

- The **Emotional eating** scale measures the propensity to overeat in relation to negative mood states, e.g., when feeling lonely, anxious, or depressed.

<table>
<thead>
<tr>
<th>Scale</th>
<th>Number of items in scale</th>
<th>Item no. in questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncontrolled eating (UE)</td>
<td>9</td>
<td>3, 6, 8, 9, 12, 13, 15, 17, 18</td>
</tr>
<tr>
<td>Cognitive restraint (CR)</td>
<td>3</td>
<td>1, 5, 11</td>
</tr>
<tr>
<td>Emotional eating (EE)</td>
<td>6</td>
<td>2, 4, 7, 10, 14, 16</td>
</tr>
</tbody>
</table>
Computing scale scores

A. Raw scale scores

After recoding items a raw scale score is obtained by calculating the mean of all items included in the scale multiplied with the number of items in the scale.

Missing data

Sometimes respondents leave one or more of the items blank. We recommend that a scale score be calculated according to the ‘half-scale’ method, i.e. a scale score is computed if at least half of the items in a scale are answered (or half plus one in the case of scales with an odd number of items).

<table>
<thead>
<tr>
<th>Scale</th>
<th>Scoring formulas for computing raw scale scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncontrolled eating (UE)</td>
<td>If the number of(^1) (item 3, 6, 8, 9, 12, 13, 15, 17, 18) ≥ 5 then (UE_{raw}^2 = \text{Mean of (item 3, 6, 8, 9, 12, 13, 15, 17, 18)} \times 9)</td>
</tr>
<tr>
<td>Cognitive restraint (CR)</td>
<td>If the number of(^1) (item 1, 5, 11) ≥ 2 then (CR_{raw}^2 = \text{Mean of (item 1, 5, 11)} \times 3)</td>
</tr>
<tr>
<td>Emotional eating (EE)</td>
<td>If the number of(^1) (item 2, 4, 7, 10, 14, 16) ≥ 3 then (EE_{raw}^2 = \text{Mean of (item 2, 4, 7, 10, 14, 16)} \times 6)</td>
</tr>
</tbody>
</table>

\(^1\) Computes the number of items that are answered in each scale by each respondent

\(^2\) Raw scale score
B. Transformed scale scores (range 0-100)

The next step involves transforming the raw scale score to a 0-to-100 scale. Transformed scale scores represent the percentage of the total possible raw scale score. We recommend that transformed scale scores be used in presenting results since they are easily understood and facilitate comparisons.

Scoring formulas for transformed scale scores

Transformed scale score = 
\[
\left( \frac{\text{Raw scale score} - \text{lowest possible raw score}}{\text{possible raw score range}} \right) \times \text{100}
\]

<table>
<thead>
<tr>
<th>Scale</th>
<th>Lowest and highest possible raw scores</th>
<th>Possible raw score range</th>
<th>Scoring formulas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncontrolled eating</td>
<td>9-36</td>
<td>27</td>
<td>( UM = \left( \frac{UE_{\text{raw}} - 9}{27} \right) \times 100 )</td>
</tr>
<tr>
<td>Cognitive restraint</td>
<td>3-12</td>
<td>9</td>
<td>( CR = \left( \frac{CR_{\text{raw}} - 3}{9} \right) \times 100 )</td>
</tr>
<tr>
<td>Emotional eating</td>
<td>6-24</td>
<td>18</td>
<td>( EE = \left( \frac{EE_{\text{raw}} - 6}{18} \right) \times 100 )</td>
</tr>
</tbody>
</table>

- Interpreting scores

Higher scores indicate more Uncontrolled, Restraint and Emotional eating.
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Hello,

Welcome to the Healthy Weight Center, a physician supervised weight management clinic. We are committed to helping you live a healthier lifestyle, and will assist you in selecting the most appropriate path for you to achieve your goals. Our dedicated staff of Registered Dieticians, Exercise Specialists, and Behavior Health Specialists will provide you the information and tools necessary to develop a healthier lifestyle. You will have the opportunity to help create a plan of care to change your behaviors that will allow you to achieve your goals.

You will be scheduled for an orientation with an Exercise Specialist and together will build a plan of care that is appropriate for you. Meal plans, exercise and behavior modifications will be discussed to develop a path to live a healthier lifestyle.

Prior to your Orientation, please complete the following checklist:

- Call to schedule (orientation fee $20)
- Obtain signed physician referral form
- Complete pages 2-5 of the enclosed Registration and Enrollment Forms
  Obtain or bring a copy of your latest chemistry profile, lipid panel, TSH and HbA1c. If you have not had these lab values checked in the past six months, please do so with your primary care provider.

In order to build the most appropriate plan for you, it is important to be accurate and honest with all the information.

Cost and payment options will be discussed before we schedule further appointments. To be eligible for our services to be covered by insurance it may be required that you be medically monitored by a physician at least once a month for as long as 6 months.

We are located on the ground level of:

Our mailing address is:

Thank you for your interest. We are looking forward to helping you achieve
Enrollment Form

**Physical Exam Worksheet**

Patient Name of Record: ________________________________

EMR Identification Number: ____________________________

Height: ________ inches Weight: ________ lbs. Waist Circumference: ________ inches

Hip Circumference: ________ inches BP: ________ / ________ Heart Rate: ________ bpm.

Lab values: □ Labs recorded below (drawn on: ________ / ________ / ________) □ Labs requested □ Labs not required

Tot Cholesterol: ________ LDL: ________ HDL: ________ Triglycerides: ________

Hgb A1c: ________ Fasting Glucose: ________ Thyroid (TSH): ________

Healthy Weight Center program

Visit setting: □ Individual session □ Group session

These GOAL Weight entries require body mass measurements - DO NOT record weight LOSS goals

Initial weight goal: I want to weigh ________ lbs. in 4 weeks

Long-term weight goal: I want to weigh ________ lbs. eventually

Motivations to lose weight (choose two)
□ improve health □ improve appearance □ feel better □ live longer
□ wishes of family members □ wishes of friends or others

OTHER (not listed): ________________________________

Barriers to success (choose two)
□ exercise □ lack of motivation □ poor food preparation □ poor food choices
□ inability to control eating/portion sizes □ lack of time □ money
□ lack of support from family or others

OTHER (not listed): ________________________________
Enrollment Form

In order for us to process your enrollment form quickly and accurately, please print legibly and be sure to complete the entire form prior to the orientation meeting. If you are unsure of what to do please ask for assistance from a staff member at the orientation.

First Name: ___________________________ Last Name: ___________________________ DOB: ____/____/____

What was your weight at age 18? ______ Highest adult weight? ______ Lowest adult weight? ______

If you could weigh whatever you wanted, what would your “dream weight” be? ______

At what weight do you feel you would be happy? ______ What weight would be “acceptable” to you? ______

At what weight (less than your current weight) would you still be disappointed? ______

What weight do you have in mind to achieve as your “goal weight” through this program? ______

Please indicate which weight loss medications you have used in the past (check all that apply):

□ Phentermine  □ Meridia®  □ None
□ Fenfluramine  □ Xenical®
□ Dexfenfluramine  □ Wellbutrin
□ Phen/Fen combination  □ Other (list): ________________________

Are you pregnant? □ Yes  □ No  □ NA  Are you planning a pregnancy in the near future? □ Yes  □ No  □ NA

Are you currently breast feeding (lactating)? □ Yes  □ No  □ NA

Indicate which of the following conditions you have suffered or currently suffer from (choose all that apply):

□ Heart Attack  □ High Blood Pressure  □ PCOS
□ Heart Failure  □ Osteoarthritis  □ GERD (acid reflux)
□ Heart Valvular Disease  □ Sleep Apnea  □ Fibromyalgia
□ Neurological Disease  □ Type 1 Diabetes  □ Other (list types below)
□ Bowel Disease  □ Type 2 Diabetes  □ None
□ Kidney Disease  □ Thyroid Disease
□ NASH (fatty liver)  □ Depression
□ Liver Disease (severe)  □ Anemia
□ Cancer (list types below)  □ Gout

Other diseases or illnesses: ___________________________________________________________

Types of cancer: _________________________________________________________________

Smoking? (choose one):
□ Never smoked  □ Quit smoking  □ Less than pack/day  □ Up to 2 packs/day  □ More than 2 packs/day

If you smoke or used to smoke, How long? ______ years. If you quit smoking, when? (date) ______

Do you use alcohol? (choose one):
□ Never  □ Quit drinking  □ Less than 3 drinks/week  □ Up to 14 drinks/week  □ More than 14 drinks/week
Enrollment Form

Indicate what symptoms you are currently experiencing (choose all that apply):

- Vision problems
- Hearing problems
- Swallowing problems
- Shortness of breath
- Chest pain
- Palpitations
- Wheezing
- Indigestion/Nausea
- Lactose intolerance
- Abdominal pain
- Diarrhea
- Constipation
- Vomiting
- Rectal Bleeding
- None
- Other (list)

Do you have a history of: (choose all that apply)

- Anorexia
- Bulimia
- Binge eating
- Incest/sexual abuse
- Suicide attempt or plans

- Never
- Past
- Present

Once you have completed page two through page five of this enrollment form, be sure to sign and date below. Page six and seven will be completed by a staff member at the conclusion of your Orientation meeting.

Important Note – You must hand in your registration and enrollment forms, as well as your physician’s authorization before your program start appointment will be scheduled. If you have any questions, please contact one of the Healthy Weight Center staff members.

Hint – To use xxxxxx, please disable any pop-up blockers and change your email/spam filter settings to accept important email from xxxxxx and xxxxxx staff messages. Contact us if you need help with this.

In accordance with the NOTICE OF PRIVACY PRACTICES that you previously read and signed at XXXXXXXXX, this notice informs you that the XXXX will share the information contained in this document and other information gathered during your participation in the Weight Management Program with the company XXXXXXX. By signing below you are indicating that you previously read the above stated notice and are fully aware of, and will allow, the sharing of your weight management related information with XXXXX.

Signature: __________________________ Date: __________________________
Enrollment Form

Has any member of your immediate family (parents, brothers, sisters) ever had: (choose all that apply):

<table>
<thead>
<tr>
<th>Disease Type</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular disease</td>
<td></td>
</tr>
<tr>
<td>Diabetes (type 1 or type 2)</td>
<td></td>
</tr>
<tr>
<td>Gout</td>
<td></td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td></td>
</tr>
<tr>
<td>Sleep Apnea</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
</tr>
<tr>
<td>Breast Cancer</td>
<td></td>
</tr>
<tr>
<td>Colon Cancer</td>
<td></td>
</tr>
<tr>
<td>Lung Cancer</td>
<td></td>
</tr>
<tr>
<td>Ovarian Cancer</td>
<td></td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td></td>
</tr>
<tr>
<td>Other Cancer</td>
<td></td>
</tr>
<tr>
<td>Alcoholism</td>
<td></td>
</tr>
</tbody>
</table>

Indicate what types of medication you are currently taking (prescription and over the counter - choose all that apply):

<table>
<thead>
<tr>
<th>Type of Medication</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>for Weight Loss</td>
<td></td>
</tr>
<tr>
<td>for High Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>for Heart Disease</td>
<td></td>
</tr>
<tr>
<td>for Birth Control</td>
<td></td>
</tr>
<tr>
<td>for Hormone Replacement</td>
<td></td>
</tr>
<tr>
<td>for Diabetes</td>
<td></td>
</tr>
<tr>
<td>for Depression</td>
<td></td>
</tr>
<tr>
<td>for Anxiety</td>
<td></td>
</tr>
<tr>
<td>for Sleep</td>
<td></td>
</tr>
<tr>
<td>for Hypothyroidism</td>
<td></td>
</tr>
<tr>
<td>for Gout</td>
<td></td>
</tr>
<tr>
<td>for Allergies</td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
</tr>
</tbody>
</table>

List ALL medication you are currently taking in the box below (prescription and over the counter, including vitamins – include the name of the medication, dosage, and frequency for each medicine): \[ I am not taking any prescription medications \]

List any medication allergies: \[ None \]

List any food allergies: \[ None \]

List any hospitalizations for surgery, major illness or injury that required an overnight stay (include date): \[ None \]
Meal Plan Options

All diet plans are supported by medical research as effective means for losing weight.

<table>
<thead>
<tr>
<th>Meal Plan: Hypocaloric</th>
</tr>
</thead>
</table>
This plan has been designed to provide optimum nutrition that will help you lose or control your weight and maintain health. Along with regular exercise and lifestyle education, this plan is designed to help you lose 1-2 pounds per week, although results may vary from person to person. This plan includes the use of whole foods that are portion based on food groups and calorie content, but can also include the use of meal replacement supplements. The calorie range for this plan is 1,200 to 1,600 calories per day. Eating from a wide variety of foods provides better overall nutrition.

<table>
<thead>
<tr>
<th>Meal Plan: Partial Meal Replacement</th>
</tr>
</thead>
</table>
This plan uses a structured diet of pre-packaged entrees (purchased at the grocery store), dairy products, fruits and vegetables, plus approximately 4 packets of meal replacement supplements (purchased from our vendor) per day. This plan along with regular exercise and lifestyle education is designed to help you lose 2-3 pounds per week. The calorie range for this is 1,000-1,200 calories per day. This plan may be recommended for those who are 25 to 50 pounds overweight.

There is an additional cost of approximately $41-62 per week for supplements.

<table>
<thead>
<tr>
<th>Meal Plan: Total Meal Replacement</th>
</tr>
</thead>
</table>
This plan exclusively uses protein based meal replacement supplements. The typical plan equals 600-800 calories per day. For safe progress, patients on this plan may be required to make and attend follow up visits at the Healthy Weight Center Clinic with our program Medical Director, or with your own Primary Care Provider. These appointments are not included in the program fee. This plan along with regular exercise and lifestyle education is designed to help you lose 3-5 pounds per week, and is best for those who are 25 – 100+ pounds overweight.

There is an additional cost of approximately $65-88 per week for supplements.
Menu

**Orientation**

A 60-minute appointment used to introduce you to our services and design your individual plan of care.

**Meal Plan Start Appointment**

A 60-minute appointment to teach you everything you need to know about your meal plan.

**Registered Dietitian**  
*Appointment duration: 30 or 60 minutes*

Depending on need, schedule half-hour or hour long sessions based on the registered dietitian’s recommendations. Priority Health participants may attend a maximum of 5 sessions in a contract year.

**Behavioral Health**  
*Appointment duration: 50 minutes*

At your first appointment, the behavioral health specialist will determine how many sessions are necessary. Five to eight sessions are available to you throughout your time in the program.

**Exercise Specialist**  
*Appointment duration: 30 minutes of 1 on 1, 60 minutes*

Your first session will be one hour in duration; the remaining ones will be half-hour in duration. You must plan for half-hour of cardio (on your own) before your individual sessions with the exercise specialist.

**Supervised Exercise**  
*Appointment duration: 60 minutes*

Come at your scheduled time for this small group exercise session; staff to participant ratio is 1:8. Time allotted for these appointments allows for both cardiovascular exercise and resistance training.

**Group Education**  
*Appointment duration: 60 minutes*

Class is held on Thursdays at 5:30 p.m. Speakers for the classes will rotate between the Behavioral Health Specialist and the Registered Dietitian. You will be given a schedule of class topics and dates.

**Circuit Training**  
*Appointment duration: 60 minutes*

This class follows the Group Education class on Thursday evenings. Circuit training begins at 6:30 p.m. and is located in the Physical Therapy Gym.

*We do have a 24-hour cancellation policy. If you need to make any changes in your schedule, please do so at least 24 actual hours in advance by calling. Messages left are time/date stamped. Cancellations with less than 24 actual hours advanced notice or no-shows cannot be made up. A total of 3 missed appointments may lead to dismissal from the program.*
Enrollment Form

Treatment Plan Protocol

- **BMI < 19**: Counseling against weight loss, evaluation for eating disorder
- **19 < BMI < 25**: Maintenance Diet
- **25 < BMI < 30**: Hypo-caloric Diet
- **30 < BMI < 35**: Partial Meal Replacement Diet
- **35 < BMI < 40**: Total Meal Replacement Diet
- **BMI > 40**: Bariatric Surgery Referral following failure in medically-supervised weight loss program

Primary Risk Factors

- Lack of Primary Risk Factors
- Primary Risk Factors Present and/or Waist Exceeds Limit

**Treatment Plan** (choose one):

- **Total Meal Replacement** (full supplements – estimated rate of loss 3-5 lbs/wk)
- **Partial Meal Replacement** (partial supplements with food plan – estimated rate of loss 2-3 lbs/wk)
- **Hypo-caloric** (no supplements with 700 cal deficit whole food plan – estimated rate of loss 1-2 lbs/wk)

If the Treatment plan is not selected according to this protocol, please indicate the reason for your choice:

- PCP Preference
- Patient Preference
- Comorbidity
- Financial Considerations
- Supplement Intolerance
- Other:

Physician consent received?  □ Yes  □ No  □ n/a (non-supplemented plan)

Has a start date appointment been scheduled?  □ Yes  □ No  Date of the appointment: ___/___/____

Other comments:

Staff member (signature): ____________________________

Staff member (please print): ____________________________ Date of service: ___/___/____
### Participation Summary

<table>
<thead>
<tr>
<th>ID</th>
<th>Initial</th>
<th>6-Week</th>
<th>3 Month</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Complete</td>
<td>Complete</td>
<td>Survey missing from chart-not returned</td>
<td>Not seen in May. No 3rd survey</td>
</tr>
<tr>
<td>101</td>
<td>Complete</td>
<td>Not returned</td>
<td></td>
<td>Not seen since February. No return of last two surveys</td>
</tr>
<tr>
<td>102</td>
<td>Complete</td>
<td>Complete</td>
<td>Survey missing from chart-not returned</td>
<td>Seen in May. No third survey</td>
</tr>
<tr>
<td>103</td>
<td>Complete</td>
<td></td>
<td></td>
<td>Dropped program in Feb-Will do at home. Drop from study</td>
</tr>
<tr>
<td>104</td>
<td>Complete</td>
<td>Survey missing from chart-Mailed with no return</td>
<td>Survey missing from chart-not returned</td>
<td>Seen monthly at clinic</td>
</tr>
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<td>Survey Left in chart</td>
<td>Last seen in April. No return of last two surveys</td>
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<td>Survey missing from chart-not returned</td>
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</tr>
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</tr>
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<td>Not seen since March</td>
</tr>
<tr>
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<td>Description</td>
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<td>------------------------------------------</td>
<td>----------------</td>
<td>-------------------------------</td>
</tr>
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<tr>
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References


