## WHAT DRIVES INDIVIDUALS TO CHOOSE BARIATRIC SURGERY? AN IN-DEPTH REVIEW OF DIETARY AND NUTRITIONAL VARIABLES

#### A THESIS

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BY

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#### ABSTRACT

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### WHAT DRIVES INDIVIDUALS TO CHOOSE BARIATRIC SURGERY? AN IN-DEPTH REVIEW OF DIETARY AND NUTRITIONAL VARIABLES

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The motivations, eating habits, and behavioral characteristics of African American and Caucasian obese females (n=200) seeking bariatric surgery were described in this study. Heads Up is a study that examined surgical and nonsurgical approaches to weight management of obese adults. The present study collected and analyzed data from the Heads Up pre-surgical dietary assessment interview questionnaire. Differences between groups were assessed using two-way ANOVA and Pearson's correlation coefficients were used to examine associations between variables. Participants reported consuming fast food 2.9 ± 2.6 times per week and fried foods 2.1 ± 1.8 times per week. Approximately 27% reported regular consumption of sugar-sweetened sodas and 23% reported regular consumption of sugar-sweetened tea beverages. Over half (59%) of females indicated that health concerns were the primary reason for seeking surgery. Findings suggest that foods low in nutrient value are commonly consumed among females seeking bariatric surgery. Addressing usual dietary intake and level of motivation prior to bariatric surgery may improve long term surgical success.

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#### LIST OF ABBREVIATIONS

AGB Adjustable Gastric Band

ASMBS American Society for Metabolic and Bariatric Surgery

BMI Body Mass Index

CDC Centers for Disease Control and Prevention

HRQoL Health-related Quality of Life

LCD Low-calorie Diet

NHANES National Health and Nutrition Examination Survey

NIH National Institutes of Health

OGB Office of Group Benefits

PBRC Pennington Biomedical Research Center

RYGB Roux-en-Y Gastric Bypass

SSB Sugar-sweetened Beverage

SV1 Screening Visit One

SV2 Screening Visit Two

VSG Vertical Sleeve Gastrectomy

WHO World Health Organization

#### CHAPTER I

#### INTRODUCTION

Obesity is a serious concern in the United States with profound effects on physical and psychological health (Centers for Disease Control and Prevention [CDC], 2012). In 2014, an estimated 7.7% of adults in the United States were morbidly obese (body mass index [BMI] ≥ 40 kg/m²) (Flegal, Kruszon-Moran, Carroll, Fryar, & Ogden, 2016). Surgical interventions for the treatment of morbid obesity may be more effective in reducing weight and improving or resolving obesity-related medical conditions compared to non-surgical interventions (Buchwald & Consensus Conference Panel, 2005). While many achieve significant weight loss following bariatric surgery, there are some who do not successfully achieve or maintain weight loss (O'Brien, McPhail, Chaston, & Dixon, 2006).

An individual's success following weight loss surgery is largely dependent on the implementation of several dietary changes (McGrice & Don Paul, 2015). Therefore, a dietary assessment conducted prior to bariatric surgery may be beneficial to evaluate usual dietary intake patterns and to identify the need for short term intervention prior to surgery. Assessment of the individual's readiness to change and elucidating any potential dietary issues that may occur following surgery may contribute to improved long term outcomes (Aills, Blankenship, Buffington, Furtado, & Parrott, 2008). Pre-surgical dietary assessments generally collect information regarding behaviors such as weight loss attempts, self-weighing frequency, weight loss goals, dietary intake, and physical activity. Furthermore, a pre-surgical assessment can identify motivations for seeking surgical treatment and future plans that may indicate willingness to implement post-surgery lifestyle changes.

#### **Purpose of the Study**

There is little known about the factors that contribute to an individual's decision to seek bariatric surgery as opposed to behavioral intervention. This study utilized responses from a presurgical dietary assessment interview questionnaire to describe the motivations for surgery, self-perceptions of weight gain, dietary habits, and various behaviors (e.g. weight loss history, exercise habits, self-weighing frequency, etc.) of 200 obese females seeking bariatric surgery. An in-depth examination of these factors may provide insight into the shared behaviors, perceptions, motivations, and other dietary characteristics of obese females who are seeking to undergo bariatric surgery.

#### **Objectives**

- To identify the reason(s) females seek bariatric surgery as opposed to behavioral intervention.
- To identify the self-perceived cause(s) of weight gain in females seeking bariatric surgery.
- To identify current dietary patterns and frequency of consumption of various meals and food and beverage groups prior to seeking surgery.
- To examine possible associations between dietary intake and certain behaviors in females seeking bariatric surgery.

#### **Hypotheses**

The decision to seek bariatric surgery for treatment of obesity is associated with the
following dietary characteristics: high consumption of energy-dense foods, fast food,
sugar-sweetened beverages, and desserts as well as the tendency to skip meals during the
day.

- Health reasons are the primary motivation for seeking bariatric surgery.
- Females seeking bariatric surgery attribute their weight gain to overeating and choosing foods low in nutrient value.

#### CHAPTER II

#### REVIEW OF LITERATURE

#### **Obesity**

#### **Definition**

The Centers for Disease Control and Prevention (CDC) defines obesity as "weight that is higher than what is considered as a healthy weight for a given height" (CDC, 2012). Body mass index (BMI) is a common measure used to classify an individual as overweight or obese. An individual's BMI is determined by calculating weight in kilograms divided by the individual's height in meters squared (kg/m²) (CDC, 2012). For adults, obesity is defined as a BMI greater than or equal to  $30 \text{ kg/m}^2$ . Obesity is further divided into the following grades: grade I ( $30 - 34 \text{ kg/m}^2$ ), grade II ( $35 - 39 \text{ kg/m}^2$ ), and grade III ( $\ge 40 \text{ kg/m}^2$ ) (CDC, 2012).

#### Prevalence

Obesity rates have been rapidly rising over the past decades in the United States (Flegal, Carroll, Ogden, & Curtin, 2010). Data from the National Health and Nutrition Examination Survey (NHANES) indicated that from 2013 to 2014, more than one-third (37.7%) of adults in the United States were considered obese (Flegal, Kruszon-Moran, Carroll, Fryar, & Ogden, 2016). As of 2014, individuals with grade III obesity, also referred to as "extreme obesity" or "morbid obesity", represented approximately 7.7% of adults in the U.S. (Flegal et al., 2016). Moreover, grade III obesity was predominately higher in females (9.9%) compared to males (5.5%) (Flegal et al., 2016).

#### **Etiology**

Obesity is a complex disease that has many interrelated etiologies. While the precise cause of obesity remains unclear, research has suggested that obesity develops as a result of the interaction between several behavioral, psychological, genetic, and environmental factors (McAllister et al., 2009; Wright & Aronne, 2012). A report updated in 2016 by the World Health Organization (WHO) stated that obesity generally develops as a result of an energy imbalance between calories consumed and calories expended (WHO, 2016). A major factor influencing the development of obesity is the environment. An individual's dietary and/or physical activity behaviors are greatly impacted by the environment. Over the past few years, environmental and societal changes have influenced the prevalence of obesity, specifically, an unhealthy diet pattern and decreased physical activity (WHO, 2016).

In general, poor dietary habits are recognized as potential determinants of obesity and comorbid conditions. In 2003, WHO suggested the rising obesity rates were a result of the increased consumption of energy-dense foods low in nutrients but high in fat and sugar (WHO, 2003). Other types of foods low in nutrient value that potentially contribute to weight gain include fast foods and sugar-sweetened beverages (SSB). Specifically, the influence of fast food on weight gain and obesity has been studied extensively (Bowman & Vineyard, 2004; Jeffery & French, 1998; Pereira et al., 2005). In a cross-sectional study of 1,059 adults, fast food consumption was positively associated with BMI, but this effect was observed only in females (Jeffrey & French, 1998). Key findings from the NHANES 2007 – 2010 survey revealed that adults consumed 11.3% of their total daily caloric intake from fast food (Fryar & Ervin, 2013). The researchers also reported the consumption of calories from fast food was significantly higher in African American adults compared to Caucasian and Hispanic adults. Moreover, the

percentage of calories consumed from fast food was associated with increasing weight status (normal  $\rightarrow$  overweight  $\rightarrow$  obese). In each age group (20-39, 40-59, 60 and older), obese adults consumed the highest percentage of their total daily calories from fast food (18.0%, 11.2%, 7.7%, respectively) (Fryar & Ervin, 2013).

SSBs and their contribution to weight gain and obesity have been widely researched. SSBs include sodas, soft drinks, fruit drinks, energy drinks, and vitamin water beverages containing added sugars. Several large studies have consistently reported positive associations between SSB consumption and weight gain (Hu & Malik, 2010). The excessive consumption of SSBs may lead to weight gain due to their high sugar content and low satiety value (Hu & Malik, 2010).

In addition to the consumption of certain foods and beverages, eating habits such as skipping meals and the frequency of eating meals away from the home have been identified as possible contributors to obesity. Several studies have reported that skipping meals is associated with a significantly greater risk of obesity (Goyal & Julka, 2014; Ma et al., 2003). Ma and colleagues found that participants who skipped breakfast regularly (i.e. 75 percent of days measured by a 24-hour recall) were 4.5 times more at risk for obesity compared to those who regularly consumed breakfast (95% CI: 1.57, 12.90). A higher frequency of consuming breakfast or dinner meals away from the home was also significantly associated with an increased risk of obesity (Ma et al., 2003).

#### Consequences

The increasing prevalence of obesity is of major health concern because of the serious medical, psychological, and economic consequences (National Heart, Lung, and Blood Institute [NHLBI], 2013). Obese individuals have a considerably greater risk of developing chronic

diseases and health conditions such as Type 2 diabetes, cardiovascular diseases, and certain types of cancer (Finer, 2015; Hruby et al., 2016). Other medical conditions associated with obesity include sleep apnea, osteoarthritis, nonalcoholic fatty liver disease, gallbladder disease, and stroke (Shamseddeen, Getty, Hamdallah, & Ali, 2011). Furthermore, obese individuals have an increased risk of death compared to healthy individuals (Adams et al., 2006).

In addition to the health effects, obesity may have a detrimental impact on quality of life and psychological well-being. Health-related quality of life (HRQoL) is frequently mentioned in the literature and is defined as an individual's self perceived increase or decrease in their quality of life due to health problems (Fabricatore, Wadden, Sarwer, & Faith, 2005; Pan et al., 2014). Fabricatore and colleagues studied HRQoL symptoms in 306 extremely obese individuals. They concluded that a decrease in participants' HRQoL was due to several factors including the following: physical functioning (decreases in the ability to complete daily living activities) (72%), bodily pain (52%), and physical role limitations (decreases in the ability to fulfill social and occupational roles) (45%). Research also indicates that a decreased HRQoL is associated with an increasing BMI with the relationship more pronounced in females than in males (Pan et al., 2014). In a study examining HRQoL in obese individuals seeking various treatment methods for weight loss, impairments in HRQoL were highest among bariatric surgery patients (Koloktin, Crosby, & Williams, 2002).

Obesity may also have a negative influence on psychological health. In a study of 600 obese adults by Heras, Kritikos, Hatzopoulos, Kritikos, and Mitsibounas (2010), participants reported several psychological consequences of obesity including depression, low self-esteem, and relationship issues. A systematic literature review by van Hout, van Oudheusden, and van

Heck (2004) suggested that morbidly obese individuals tend to be "depressed, anxious, have poor impulse control, low self-esteem, and impaired quality of life."

Additionally, the alarming rates of obesity in the United States have created public health concern and an increasing financial burden (Spieker & Pyzocha, 2016). Spieker and Pyzocha (2016) estimated that total obesity-related healthcare costs (indirect and direct) may be greater than \$275 billion per year in the United States. A meta-analysis reported that the annual medical spending of an obese person in the year 2014 was \$1,910 (USD) (Kim & Basu, 2016).

#### **Treatment Methods**

Today, many treatment options are available for weight loss, including lifestyle modifications (e.g. diet and/or exercise), pharmacological treatments, behavior modification therapies (e.g. self-monitoring, nutrition education, and/or cognitive therapy), and surgical interventions. Conventional methods, such as diet and exercise regimens and behavior modification strategies, may be ineffective in sustaining long term weight loss in obese individuals (Anderson, Konz, Frederich, & Wood, 2001; Kramer, Jeffery, Forster, & Snell, 1989). Behavior modification and pharmacological treatment methods typically result in only an 8 to 10 percent initial weight loss, and weight regain after cessation of treatment is likely (Sarwer, Wadden, & Fabricatore, 2005). The surgical intervention for the treatment of severe obesity, referred to as bariatric surgery, is therefore considered to be superior in reducing weight (Habib, Samamé, & Galvani, 2013; Picot et al., 2009). Consequently, bariatric surgery has gained popularity with 468,409 bariatric surgeries performed worldwide in 2013 (Angrisani et al., 2015).

#### **Bariatric Surgery**

Bariatric surgery involves a surgical alteration of the gastrointestinal tract to reduce food intake, leading to weight loss. Common bariatric surgery procedures include the Adjustable

Gastric Band (AGB), Roux-en-Y Gastric Bypass (RYGB), and Vertical Sleeve Gastrectomy (VSG). According to the National Institutes of Health (NIH), in order for an individual to be considered a candidate for bariatric surgery, the BMI must be greater than 40 kg/m² or greater than 35 kg/m² with at least two obesity-related co-morbidities (NIH, 1998). In addition, the individual's prior weight loss attempts must have resulted in an inability to maintain a healthy weight (NIH, 1998). The cost of bariatric surgery ranges from \$15,000 to \$25,000 (USD) and varies based on the type of surgery and location (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016).

Bariatric surgery is considered the most effective method for treating morbid obesity since it achieves substantial weight loss and either improves or completely resolves obesity-related medical conditions (Buchwald & Consensus Conference Panel, 2005). Buchwald and colleagues (2004) published a meta-analysis of 136 studies to determine the impact of bariatric surgery on weight outcomes and obesity-related comorbidities. They reported that the average weight loss in the total population (n=7588) was approximately 39.7 kilograms among surgical participants. Patients experienced improvement or complete resolution of medical conditions such as diabetes (85.4% of patients), hyperlipidemia (83% of patients), hypertension (78.5% of patients), and sleep apnea (83.6% of patients).

Despite the positive effects of bariatric surgery on reducing body weight, post-surgical complications and problems are possible. The post-surgical dietary requirements involve reducing portion sizes, chewing foods slowly and completely, eating and drinking separately, avoiding foods that are poorly tolerated, and taking prescribed vitamin supplements (Parkes, 2006). Non-compliance with post-surgical dietary requirements may lead to problems such as suboptimal weight loss, early weight regain, food intolerances, gastrointestinal issues, and/or

vitamin and mineral deficiencies (Harbottle, 2011; Sarwer, Dilks, & West-Smith, 2011). These issues may be prevented with dietary compliance; however, patient adherence to the post-surgery diet is generally low (Sarwer et al., 2011). On the contrary, individuals who do comply with the postoperative diet typically achieve significant weight loss and positive outcomes. For example, Sarwer and colleagues found that participants with high adherence to the post-surgery diet changes had 4.5 percent greater weight loss at post-operative week 92 than those with low adherence (Sarwer et al., 2008).

There is also concern regarding the potential risks and safety of such extensive and invasive procedures. However, experience has shown that the risks of obesity outweigh the risks associated with bariatric surgery (Christou et al., 2004). Specifically, a prospective, multi-center, observational study by Flum and colleagues (2009) indicated that adverse complications (e.g., deep-vein thrombosis or venous thromboembolism, operative re-intervention, failure to be discharged by 30 days, and/or death) following bariatric surgery occurred in only 4.1% of patients.

#### **Pre-Bariatric Surgery Dietary Assessment**

Overall, bariatric surgery appears to be a safe and successful approach to achieve significant weight loss, improve or resolve co-morbidities, and enhance quality of life in obese individuals. However, success following bariatric surgery relies heavily on the individual's ability to sustain lifestyle changes, especially changes in the diet (Richardson, Plaisance, Periou, Buquoi, & Tillery, 2009). Richardson and colleagues (2009) stated that nutrition is the most important factor involved in maximizing and maintaining weight loss following bariatric surgery. In 2008, the American Society for Metabolic and Bariatric Surgery (ASMBS) nutrition committee published nutritional guidelines for the bariatric surgery patient. They strongly

suggested that a comprehensive nutritional assessment be conducted prior to bariatric surgery since nutrition assessment and dietary management of bariatric surgery patients have been associated with weight loss success (Aills et al., 2008). According to the committee, the goal of the nutrition assessment is to "determine any pre-existing nutritional problems, develop appropriate dietary interventions for correction, and create a plan for postoperative dietary intake that will enhance the likelihood of success." They further emphasized the importance of assessing various factors that have the potential to affect nutritional status. This may include the individual's level of motivation or readiness to change current health behaviors, realistic weight loss goals, general nutrition knowledge, and current behavioral and/or psychosocial issues (Aills et al., 2008).

The ASMBS committee also provided several recommendations and suggestions on various components to include in the nutritional assessment. They advised the evaluation of weight history and previous weight loss attempts as well as the exploration of life events that may have caused weight gain. In addition to including the assessment of dietary intake and physical activity, the committee recommended exploring psychosocial factors such as the individual's motivation/reasons for seeking surgical intervention and emotional connection with food in order to possibly identify personal barriers to change (Aills et al., 2008).

#### **Motivation for Surgery**

Determining an individual's motivation for seeking bariatric surgery may be an important potential indicator of post-surgery weight loss success. Few studies have explored the reasons individuals choose bariatric surgery as opposed to behavioral intervention. A study by Munoz and colleagues (2007) surveyed 109 severely obese adults to determine reasons for seeking surgery. Several factors as to why people may desire bariatric surgery were identified: health

concerns such as the desire to treat or improve co-morbid conditions; quality of life improvements such as the ability to increase physical activity, improve appearance and relationships; and psychological motivations such as the improvement of self-esteem and body image. Participants' responses were grouped into psychological, medical, and quality of life categories. Results indicated that 73.5% of participants endorsed current medical conditions (e.g. to lose weight to control high blood pressure) as their primary reason for seeking surgery. The next most frequently reported primary reason was preventive medical reasons (e.g. to reduce the risk of developing diabetes or a history of heart disease in family) by 16.5% of participants. Only 3% of participants recognized quality of life or self-esteem (e.g. to lose weight for a social event) as a major influence in their motivation for selecting bariatric surgery (Munoz et al., 2007).

A study by Libeton, Dixon, Laurie, and O'Brien (2004) also examined individuals' motivations for choosing bariatric surgery. The researchers administered a questionnaire that asked participants to rank six statements that reflected their reason for seeking surgery, from most important to least important. The researchers reported 28.4% of participants ranked health concerns (e.g. the concern that health will deteriorate and life may be shortened) highest among the statements as the primary reason for participants selecting bariatric surgery. In contrast to the findings by Munoz and colleagues, Libeton et al. noted appearance (23.6%) and medical condition (23.6%) were both reported as the next most frequent appropriate motivational statement. They also recognized gender differences in responses: females were more likely to choose appearance than males (27.7% vs 0.0%, respectively) (p<0.001) and males were more likely to choose medical conditions than females (38.7% vs 20.9%, respectively) (p=0.032) as their most important factor. The researchers concluded that weight loss following the surgery

was not significantly associated with the individual's primary motivating factor leading him or her to seek surgery (Libeton et al., 2004).

#### Perceived Contributors to Weight Gain

As discussed previously, multiple factors are involved in the development of obesity (McAllister et al., 2009). Obese individuals may understand some of the factors contributing to their current weight status but may miss the more complex scope of the problem. Therefore, gaining insight into the factors individuals believe to be most responsible for causing their weight gain may be beneficial.

Befort, Thomas, Daley, Rhode, and Ahluwalia (2008) utilized focus groups to explore obese African American females' perceptions and beliefs about their body size. They determined that more participants recognized behavioral reasons as the cause of their weight gain compared to medical or genetic reasons. Specifically, most of the participants identified poor eating behaviors as the primary cause of their weight gain. Some participants further described these behaviors as "eating late, eating excessive portions, consuming too much soda and junk food, and eating at fast-food and all-you-can-eat restaurants."

In 2014, Fox and colleagues examined the self-perception of body weight and the contributing factors of weight gain in 79 British adults. Using a rating scale, participants ranked factors that contributed to their weight gain from one (no contribution) to four (great contribution). Results indicated that the highest rated factor was lack of physical activity (3.73  $\pm$  0.63) and next highest was excessive food consumption (3.34  $\pm$  1.01). Factors ranked lower included slow metabolism (2.85  $\pm$  1.05), stress/depression (2.82  $\pm$  1.01), and genetics (2.54  $\pm$  0.94) (Fox et al., 2014).

Temple Newhook, Gregory, and Twells (2013) interviewed 54 obese individuals regarding perspectives on their weight gain history, focusing on their explanations for weight gain and emotions involved in their weight gain experiences. Participants described factors that led to rapid weight gain or gradual weight gain during their lives. The researchers reported that major life events during childhood and pregnancy, lifestyle changes, illness, and/or injury were identified as causes of rapid weight gain. Participants explained gradual weight gain could be attributed to sporadic dieting, food consumption, physical inactivity, and sedentarism. In regards to of food consumption, participants reported "emotional eating, food addictions, cultural influences, irregular eating patterns, and food quality and quantity" as predictors of weight gain (Temple Newhook et al., 2013).

#### CHAPTER III

#### **METHODS**

#### **Recruitment of Participants**

Data extracted from the pre-surgical dietary assessment interview questionnaires of female participants enrolled in the surgical arm of the Heads Up study were utilized for this study. Heads Up was a five-year observational study that began in 2011. The study was sponsored by the Office of Group Benefits (OGB), a health insurance benefits management group in Louisiana. Heads Up examined both surgical and nonsurgical methods to achieve weight loss in obese individuals. The objective of the study was to determine how to best implement obesity health management provided to its enrollees. The program was directed by Pennington Biomedical Research Center (PBRC) in Baton Rouge, Louisiana and consisted of three components: a surgical demonstration project component, an intensive medical intervention project (behavioral nutrition sessions), and a translational component (web-based behavioral nutrition sessions). Both surgical and non-surgical treatment methods were covered by the participant's insurance company.

Program members were solicited for interest in either the surgical or non-surgical program and directed to a website that provided information on both programs. Individuals were required to meet the following eligibility criteria: be active members of the sponsoring insurance company; be 21 - 70 years of age, of any gender; and have a BMI 40 - 60 kg/m<sup>2</sup> or Type 2 diabetes and a BMI 35 - 60 kg/m<sup>2</sup>. Individuals who were deemed eligible following the web screening were then further screened via telephone interview and offered the opportunity to be placed in a lottery for the surgical program or non-surgical (behavioral intervention) program

depending on their choice of either surgery or behavioral intervention. Individuals were then placed in the lottery system after providing verbal consent and, if selected for the surgical intervention, were scheduled for their first screening visit (SV1).

The SV1 involved the collection of written consent, demographic information, and anthropometric measurements. The participants who met the requirements for surgery were provided a liquid, low-calorie diet (LCD) consisting of 800 - 900 kilocalories/day. During the pre-surgery period, participants were required to consume five Health One meal-replacement shakes daily for 14 days. Compliance to the LCD was assessed through daily food records and verified by dietitians. Following the 14 days, participants completed their second screening visit (SV2) at PBRC.

At SV2, participants were excluded from the study if they failed to lose at least four pounds and/or did not complete 10 out of the 14 food records. If the participants were compliant with the LCD, they then completed a psychological assessment interview and a dietary assessment interview to determine bariatric surgery suitability. Participants were excluded from the study for any of the following reason(s): unable to consent to randomization to one of the three surgical procedures; having no previous attempts to lose weight using conventional methods; having unrealistic weight loss goals; lack of a post-surgery diet and exercise plan; and/or lack of knowledge regarding post-surgery nutritional requirements. Case conferencing followed all SV2 visits by the intervention team (clinic, dietary, and behavior specialists) and some individuals were excluded based on study inclusion criteria at that point. Participants successfully completing SV2 and the subsequent case conferencing panel were presented to a surgical review panel, consisting of medical, psychological, and dietary experts, for approval and referral for surgery. Selected participants received RYGB, VSG, or AGB surgery.

#### **Study Design**

Participants included in the subset analyses consisted of African American (n=92) and Caucasian females (n=108). Initially, participants were randomly chosen from four groups: those selected for RYGB surgery (n=50), AGB surgery (n=50), VSG surgery (n=50), and those who were denied surgery/excluded from the study at the time of or following SV2 (n=50). The females were matched for age, BMI, and race from each of the three surgical types (RYGB, AGB, VSG) and the denied surgery group. After initial analyses were conducted, no differences were found between the three surgical type groups. Therefore, these three groups were collapsed into one. Data was then analyzed for two groups: females approved for surgery (n=150) and females denied surgery (n=50). Data was also analyzed by racial group. All participants in this study met inclusion criteria for SV1 and SV2 requirements (compliant with study protocol and LCD, and completed a pre-surgical dietary assessment). This present study was approved by the Institutional Review Boards of Pennington Biomedical Research Center and Texas Woman's University.

#### Instrumentation

This study utilized the Heads Up pre-surgical dietary assessment interview questionnaire (Appendix A). While the questionnaire had not been previously used in other studies, the questions were based on suggestions by the Bariatric Society. Some of the participant interviews utilized in this study were conducted by the author of this thesis (Appendix B) and others were conducted by registered dietitians involved in the Heads Up project. The interview consisted of 39 questions, including open-ended and closed-ended questions. The dietary assessment interview questionnaire collected information on weight history and weight loss attempts, weight loss goals, dietary intake, physical activity, and various psychosocial components. The dietary

intake-focused questions obtained information on the individual's eating patterns including both poor and healthful food choices and habits. The interview also gathered information regarding personal motivations for seeking surgery, self-perceived contributors to current weight, and future plans demonstrating willingness to make post-surgical lifestyle changes.

#### **Data Collection**

Age, race, weight, and BMI were collected from each participant's medical record. The remaining data utilized in the present study were collected from the pre-surgical dietary assessment interview questionnaire. The participants' responses to the close-ended questions were recorded as yes or no responses. The participants' responses to the open-ended questions were coded into logical fixed categories reviewed by several registered dietitians and based on similar participant responses (Table 1). For most questions, it was possible for the participant to report more than one response which was then placed into the appropriate categories.

The motivating factor(s) for seeking surgery were recorded into the following categories: improve health, improve obesity-related medical conditions, tool for weight loss, previous unsuccessful weight loss efforts, improve appearance, increase physical activity, and/or no cost. The self-perceived contributor(s) to weight gain were recorded as overeating, poor food choices, no physical activity/sedentary lifestyle, stress, pregnancy-associated weight gain, genetics/metabolism, social interactions/events, medical conditions/medications, and/or no answer/other. The role(s) of food in life were recorded as enjoyment, social interactions/events, comfort, essential to life/not a big role, boredom, convenience, and/or no answer/other. The relationship with food after surgery was categorized as changes in eating habits, changes in portion sizes, changes in meal preparation/cooking habits, changes in thoughts about food, and/or no answer/other.

Table 1

Open Ended Questions and Respective Category Designations

Question	Category Designation			
Why are you interested in bariatric surgery?	Improve health			
	Improve obesity-related medical conditions			
	Tool for weight loss			
	Previous unsuccessful weight loss efforts			
	Improve appearance			
	Increase physical activity			
	No cost			
What do you believe has contributed to your current	Overeating			
weight?	Poor food choices			
	No physical activity/sedentary lifestyle			
	Stress			
	Pregnancy-associated weight gain			
	Genetics/metabolism			
	Social interactions/events			
	Medical conditions/medications			
	No answer/other			
What role does food play in your life?	Enjoyment			
	Social interactions/events			
	Comfort			
	Essential to life/not a big role			
	Boredom			
	Convenience			
	No answer/other			
How do you think your relationship with food will	Changes in eating habits			
change after surgery?	Changes in portion sizes			
	Changes in meal preparation/cooking habits			
	Changes in thoughts about food			
	No answer/other			

The amount of desired weight loss was calculated by subtracting the desired goal weight from the current weight. The reported frequency of self-weighing was categorized as daily, weekly, monthly, and rarely. To record the participants' plans for exercise following surgery, responses were grouped into the following categories: continue current regimen, increase frequency/duration of current regimen, or begin a new type of exercise. The methods of previous weight loss were recorded as prescription medications, over the counter medications, dietary or herbal supplements, weight loss programs (e.g. Weight Watchers, Atkins, etc.), meal replacements (e.g. Slim Fast, Ideal Protein, etc.), or other (e.g. diet and exercise, low carbohydrate, starvation, etc.).

The reported frequency of consuming fast food, fried food, sweets/desserts (cookies, cakes, candy, ice cream, chocolate), fruit, and vegetables, and the frequency of dining out at non-fast food type restaurants were recorded as a weekly frequency or converted to a weekly frequency if necessary. If the participant reported regularly consuming one of the options of foods high in protein listed on the questionnaire (red meat, pork, chicken, turkey, fish, tofu, beans, eggs, and/or nuts), it was recorded as consuming protein. If the participant reported regularly adding any of fats or oils listed on the questionnaire to her foods (butter, margarine, salad dressing, oil, and/or mayonnaise), it was recorded as adding fat or oil to food.

The types of beverages regularly consumed were recorded as the following: water, sugar-sweetened soda, diet soda, coffee, sugar-sweetened tea, unsweetened tea, energy drink (e.g. Red Bull, Monster, etc.), milk, fruit juice, and/or fruit flavored beverage (e.g. Kool-Aid, Hawaiian Punch, etc.). The frequency of alcoholic beverage consumption was recorded as weekly, monthly, or yearly. The types of alcoholic beverages consumed were grouped into the following categories: beer, wine, liquor, mixed beverages, and/or frozen beverages. During the interview,

participants reported their typical consumption of breakfast, lunch, dinner, and snack food items.

For the purposes of this study, the meal responses were coded as dichotomous variables (whether or not the meal was consumed) to minimize variability.

Eating behaviors of the participants including a history of binge-eating, night-time eating, feeling of not being able to stop eating, and/or attempted to get rid of food after eating were recorded. These responses were based on self-perceived eating behaviors and not a clinical diagnosis of binge-eating or night eating syndrome.

#### **Statistical Analyses**

Pearson's correlations coefficients were used to examine associations between continuous variables. Differences between races and groups (i.e., approved for surgery vs. denied surgery) were tested using a two-way ANOVA. Differences in categorical variables were analyzed using chi-square tests. A P value < 0.05 was considered significant for all analyses unless otherwise specified. All analyses were performed using SAS® software (version 9.4, SAS Institute INC.)

#### CHAPTER IV

#### **RESULTS**

#### **Demographic Characteristics**

The study population consisted of females (n=200) screened for the surgical arm of the Heads Up study at PBRC and included 108 Caucasians (54%) and 92 African Americans (46%). All participants completed the pre-surgical dietary assessment interview at SV2. Participants were in one of two groups: those who were approved for surgery or those who were denied surgery. No significant differences were observed between groups or races for age, BMI, or weight (Table 2).

Table 2

Demographic Characteristics of Participants by Surgical Approval Status and Race

		Gro	oup	Race		
Characteristic	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	Caucasian (n=108)	African American (n=92)	
Age (years)	$46.3 \pm 8.5$	$46.5 \pm 8.6$	$45.7 \pm 8.6$	$46.9 \pm 8.1$	$45.5 \pm 9.0$	
BMI (kg/m <sup>2</sup> )	$48.9 \pm 5.8$	$48.7 \pm 5.8$	$49.6 \pm 5.8$	$49.0 \pm 5.8$	$48.8 \pm 5.8$	
Weight (lbs.)	$286.7 \pm 39.6$	$285.0 \pm 38.2$	$291.8 \pm 43.6$	$284.9 \pm 40.1$	$288.9 \pm 39.1$	

*Note.* BMI = body mass index. All values are reported as mean  $\pm$  standard deviation. There were no significant differences between groups or races.

#### **Participant Characteristics**

Characteristics of participants within groups and races included body weight information (amount of desired weight loss, lowest weight, weight loss on LCD, greatest amount of weight loss, weight loss attempts, methods of weight loss, self-weighing frequency), exercise frequency, and eating behaviors (binge-eating and nighttime eating habits). No significant differences were found in body weight between participants who were approved for surgery compared to those who were denied surgery (Table 3). Statistically significant differences between racial groups in regards to body weight were found (Table 3). The lowest weight (lbs.) during adulthood reported on the questionnaire was lower for Caucasians as compared to African Americans (172.7  $\pm$  41.6 vs. 187.8  $\pm$  51.5, respectively) (p<0.05). Weight loss (lbs.) on the LCD prior to the SV2 visit was greater in Caucasians compared to African Americans (11.7  $\pm$  4.3 vs. 10.5  $\pm$  3.2, respectively) (p<0.05). When asked about previous weight loss attempts, Caucasians reported greater weight loss (lbs.) when compared to African Americans (52.1  $\pm$  27.3 vs. 36.4  $\pm$  21.4, respectively) (p<0.0001).

Table 3

Body Weight Characteristics of Participants by Surgical Approval Status and Race

		Group		_	Race		
Characteristic	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Amount of desired weight loss (lbs.)	114.1 ± 31.3	112.0 ± 30.9	120.3 ± 32.4	0.125	116.0 ± 31.2	111.6 ± 31.6	0.338
Lowest weight (lbs.)	179.5 ± 46.8	179.6 ± 48.7	179.2 ± 41.0	0.951	172.7 ± 41.6	187.8 ± 51.5	0.023
Weight loss on LCD (lbs.)	11.2 ± 3.9	11.5 ± 4.0	10.3 ± 3.3	0.060	11.7 ± 4.3	10.5 ± 3.2	0.030
Weight loss attempts (no.)	12.6 ± 13.7	11.7 ± 10.0	15.5 ± 21.2	0.109	13.2 ± 13.0	12.0 ± 14.5	0.579
Greatest amount of weight loss (lbs.)	44.8 ± 3.0	45.8 ± 26.8	42.7 ± 22.9	0.463	52.1 ± 27.3	36.4 ± 21.4	<0.0001

*Note.* LCD = low-calorie diet. All values are reported as mean  $\pm$  standard deviation.

No significant differences were found between groups or races for reported self-weighing frequency (Table 4). Participants who weighed themselves more frequently tended to be approved for surgery compared to those denied surgery although differences were not significant

(9% vs. 6%, respectively) (p=0.443). A greater percentage of Caucasians weighed themselves daily compared to African Americans (11% vs. 4%, respectively) (p=0.051).

Table 4
Self-Weighing Frequency by Surgical Approval Status and Race

		Gro	up	<del>-</del>	Ra	ice	<del>-</del>
	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Self-Weighing Frequency <sup>a</sup>				0.443			0.051
Daily	8%	9%	6%		11%	4%	
Weekly	25%	26%	20%		30%	18%	
Monthly	18%	19%	14%		15%	21%	
Rarely	50%	47%	60%		44%	57%	

*Note.* All values are reported as percentages. There were no significant differences between groups or races at any frequency. The p values are derived from the Chi-squared statistic, which is an overall test for independence between groups and responses. If the statistic is significant, this indicates the responses are different between groups.

Overall, the most common previous weight loss method was weight loss programs (70%) and second was prescription medications (56%) (Table 5). Several significant differences were observed in the methods used in previous weight loss between groups and races (Table 5). Compared to those approved for surgery, a higher percentage of individuals denied surgery had previously used over the counter medications for weight loss (36% vs. 19%, respectively)

<sup>&</sup>lt;sup>a</sup>Self-weighing frequency had four, mutually exclusive responses (daily, weekly, monthly, or rarely).

(p<0.05) as well as meal replacements (64% vs. 46%, respectively) (p<0.05). Significantly more Caucasians had tried weight loss programs compared to African Americans (79% vs. 60%, respectively) (p<0.005).

Table 5

Methods of Weight Loss by Surgical Approval Status and Race

		Group		_	Ra	ice	
Method of Weight Loss	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Prescription medications	56%	55%	58%	0.742	52%	61%	0.200
Over the counter medications	23%	19%	36%	0.012	22%	24%	0.777
Dietary or herbal supplements	26%	25%	24%	0.779	23%	28%	0.408
Weight loss programs	70%	72%	64%	0.256	79%	60%	0.003
Meal replacements	51%	46%	64%	0.030	53%	48%	0.444
Other	39%	42%	28%	0.078	35%	42%	0.297

Note. All values are reported as percentages.

Fifty percent of participants reported that they were regularly exercising prior to the time of the interview (Table 6). African Americans reported exercising for a longer period of time compared to Caucasians ( $19.2 \pm 23.0$  vs.  $11.9 \pm 17.3$ , respectively) (p<0.05). A slight trend in currently exercising was noted for those approved for surgery compared to those denied surgery (53% vs. 42%, respectively) (p=0.191) (Table 6). No significant differences were observed when exercise plan was compared between groups (Table 6). Significantly more African Americans reported that they planned to continue their current exercise regimen following surgery compared to Caucasians (29% vs. 17%, respectively) (p<0.05). A higher percentage of individuals denied surgery had no plan for exercise post-surgery compared to those approved for surgery (8% vs. 2%, respectively) (p<0.05).

Table 6

Exercise Characteristics of Participants by Surgical Approval Status and Race

		Group		-	Race		
Characteristic	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Exercise time (minutes/day)	15.3 ± 20.4	15.7 ± 19.9	13.8 ± 22.1	0.576	11.9 ± 17.3	19.2 ± 23.0	0.011
Exercise prior to interview	50%	53%	42%	0.191	45%	55%	0.156
Plan to continue current exercise regimen	23%	24%	18%	0.379	17%	29%	0.032
Plan to increase frequency/duration of current regimen	18%	19%	12%	0.237	18%	17%	0.970
Plan to begin new type of exercise	27%	26%	30%	0.581	27%	27%	0.959
Plan to begin exercising post- surgery	46%	45%	46%	0.935	48%	42%	0.415
No plan for exercise post-surgery	4%	2%	8%	0.046	6%	1%	0.087

*Note.* Values are reported as percentage or mean  $\pm$  standard deviation.

#### **Dietary Characteristics**

The reported regular consumption of fast food, fried food, desserts, fruits, vegetables, foods high in protein, fats and oils, and frequency of dining out prior to the time of the interview was compared between groups and races (Table 7). On average, descriptive analyses indicated participants (n=200) reported consuming fast food  $2.9 \pm 2.6$  times per week and fried foods  $2.1 \pm 1.8$  times per week. All participants reported dining out at restaurants on average  $1.6 \pm 1.4$  times per week. Participants consumed desserts approximately  $3.4 \pm 3.2$  times per week, and fruits and vegetables  $5.1 \pm 2.8$  times per week and  $5.7 \pm 2.5$  times per week, respectively.

Those approved for surgery consumed vegetables more frequently during the week compared to those denied surgery  $(5.9 \pm 2.6 \text{ vs. } 4.9 \pm 2.3, \text{ respectively})$  (p<0.05) (Table 7). Significant differences were found between racial groups (Table 7). Compared to Caucasians, African Americans reported more frequent, weekly consumption of fast food  $(3.4 \pm 3.0 \text{ vs } 1.9 \pm 1.7, \text{ respectively})$  (p<0.01). In contrast, Caucasians reported more frequent weekly consumption of vegetables compared to African Americans  $(6.1 \pm 2.7 \text{ vs } 5.2 \pm 2.3, \text{ respectively})$  (p<0.01).

All participants reported regular consumption of foods high in protein (Table 7).

Approximately 98% reported consuming at least one serving of a food high in protein per day

(Table 7). When asked if they typically added fats or oils to their food, approximately 98% reported affirmatively (Table 7).

Table 7

Dietary Characteristics of Participants by Surgical Approval Status and Race

		Gro	oup		Ra	Race	
Dietary Characteristic	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Fast food consumption (no./week)	$2.9 \pm 2.6$	$2.7 \pm 2.1$	$3.4 \pm 3.7$	0.124	$2.4 \pm 2.0$	$3.4 \pm 3.1$	0.008
Dining out (no./week)	$1.6 \pm 1.4$	$1.6 \pm 1.5$	$1.5 \pm 1.2$	0.599	$1.7 \pm 1.5$	$1.5 \pm 1.3$	0.418
Fried food consumption (no./week)	$2.1 \pm 1.8$	$2.0 \pm 1.7$	$2.5 \pm 2.0$	0.090	$1.9 \pm 1.7$	$2.3 \pm 1.9$	0.154
Dessert consumption (no./week)	$3.4 \pm 3.2$	$3.3 \pm 3.1$	$3.5 \pm 3.5$	0.788	$3.3 \pm 3.0$	$3.4 \pm 3.4$	0.864
Fruit consumption (no./week)	$5.1 \pm 2.8$	$5.3 \pm 2.9$	$4.5 \pm 2.5$	0.075	$5.4 \pm 3.0$	$4.8 \pm 2.5$	0.153
Vegetable consumption (no./week)	$5.7 \pm 2.5$	$5.9 \pm 2.6$	$4.9 \pm 2.3$	0.015	$6.1 \pm 2.7$	$5.2 \pm 2.3$	0.009
Protein consumption (%)	100%	99%	96%	0.243	99%	100%	0.355
Consume a serving of protein per day (%)	98%	100%	98%	0.083	96%	100%	0.062
Fats and oils consumption (%)	98%	97%	100%	0.248	96%	100%	0.063

Note. Values reported as percentage or mean  $\pm$  standard deviation.

Approximately 27% of participants reported regular consumption of sugar-sweetened sodas and 23% reported regular consumption of sugar-sweetened tea beverages (Table 8). Significant differences were found between racial groups in terms of regular beverage consumption (Table 8). Compared to Caucasians, African Americans reported more frequent consumption of sugar-sweetened sodas (34.8% vs 19.4%, respectively) (p<0.05), sugar-sweetened tea (33% vs. 15%, respectively) (p<0.01), fruit juice (15% vs. 0%, respectively) (p<0.0001), and fruit-flavored beverages (17% vs. 3%, respectively) (p<0.001). When compared to African Americans, a greater percentage of Caucasians reported more frequent consumption of diet sodas (52% vs. 34%, respectively) (p<0.01) and unsweetened tea (33% vs. 11%, respectively) (p<0.001).

Table 8

Beverage Consumption by Surgical Approval Status and Race

		Gro	Group		Ra	ice	
Beverage Type	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Sugar- sweetened soda	27%	25%	32%	0.309	19%	35%	0.014
Diet soda	44%	45%	40%	0.563	52%	34%	0.010
Coffee	21%	23%	14%	0.161	22%	20%	0.6457
Sugar- sweetened tea	23%	23%	22%	0.846	15%	33%	0.003
Unsweetened tea	23%	26%	14%	0.081	33%	11%	0.0002
Milk	7%	4%	14%	0.020	6%	8%	0.557
Fruit juice	7%	5%	12%	0.119	0%	15%	<.0001
Fruit- flavored beverage	10%	10%	8%	0.787	3%	17%	0.0004

*Note.* All values are reported as percentages.

No significant differences were observed between groups or races for the reported regular consumption of breakfast, lunch, dinner, or snacks (Table 9). Compared to those approved for surgery, females denied surgery tended to report less frequent, regular consumption of breakfast (60% vs. 73%, respectively) (p=0.092).

Table 9

Meal Consumption by Surgical Approval Status and Race

		Gro	up	-	Ra		
Meal	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Breakfast	70%	73%	60%	0.092	70%	68%	0.772
Lunch	96%	97%	92%	0.109	95%	97%	0.728
Dinner	100%	100%	98%	0.250	99%	100%	1.000
Snacks	95%	93%	98%	0.298	93%	97%	0.199

*Note.* All values are reported as percentages. There were no significant differences between groups or races.

Approximately 59% of participants reported that they regularly consumed alcohol prior to the time of the interview (Table 10). A greater percentage of African Americans reported alcohol consumption compared to Caucasians (66% vs. 52%, respectively) (p<0.05) (Table 10). A larger percentage of those denied surgery reported consuming alcohol compared to those approved for surgery (74% vs. 53%, respectively) (p<0.01) (Table 10). The frequency of alcohol consumption was also higher in those denied surgery compared to those approved for surgery (14% vs. 7%, respectively) (p<0.05) (Table 10). Types of alcohol regularly consumed by the participants included: beer (9%), wine (30%), liquor (5%), mixed beverages (14%), and frozen beverages (14%).

Table 10

Alcohol Consumption by Surgical Approval Status and Race

		Gro	up	-	Ra	ice	-
Alcohol Consumption and Frequency	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Alcohol consumption <sup>a</sup>	59%	53%	74%	0.010	52%	66%	0.039
Alcohol consumption frequency <sup>b</sup>				0.010			0.211
Weekly alcohol consumption	9%	7%	14%		7%	10%	
Monthly alcohol consumption	22%	18%	34%		19%	26%	
Yearly alcohol consumption	19%	19%	20%		17%	22%	

*Note.* All values are reported as percentages. The p values are derived from the Chi-squared statistic, which is an overall test for independence between groups and responses. If the statistic is significant, this indicates the responses are different between groups.

Only 2% of all participants reported perceived binge-eating behaviors and 14% reported nighttime eating in past years (Table 11). Approximately 14% reported a time when they felt as if they could not stop eating and 1% stated that there was a time when they felt like purging food after eating (Table 11). A greater percentage of those denied surgery reported times where they

<sup>&</sup>lt;sup>a</sup>*Alcohol consumption* had two, mutually exclusive responses (yes or no); the given percentages reflect proportion of those who responded "yes"

<sup>&</sup>lt;sup>b</sup>Alcohol consumption frequency had three, mutually exclusive responses (weekly, monthly, or yearly).

felt as if they could not stop eating compared to those approved for surgery (22% vs. 11%, respectively) (p<0.05) (Table 11).

Table 11

Eating Behaviors of Participants by Surgical Approval Status and Race

		Gro	up	-	Ra	ce	
Behavior	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Binge-eating	2%	2%	0%	0.314	2%	1%	0.657
Night-time eating	14%	11%	20%	0.120	11%	16%	0.284
Feeling of not being able to stop eating	14%	11%	22%	0.042	17%	10%	0.156
Attempted to get rid of food after eating	1%	1%	0%	0.411	1%	1%	0.909

*Note.* All values are reported as percentages.

Pearson's correlation coefficients indicated that BMI was inversely associated with fruit consumption (r = -0.16, p < 0.05). Body weight was inversely associated with fruit consumption (r = -0.19, p < 0.05) and vegetable consumption (r = -0.19, p < 0.05). The amount of desired weight loss was inversely associated with fruit consumption (r = -0.22, p < 0.05) and vegetable consumption (r = -0.18, p < 0.05). Self-weighing frequency was inversely associated with fast

food consumption (r = -0.24, p<0.001), fried food consumption (r = -0.17, p<0.05), and consumption of desserts (r = -0.16, p<0.05).

#### **Motivation for Surgery**

Table 12 lists the possible sample participant responses to the question, "Why are you interested in bariatric surgery?" and respective categories. When reviewing the reasons that all participants were seeking surgery (including both those approved and those denied; n=200), the two major reasons cited were health concerns (59%) and the desire to treat or improve current medical issues (34%), such as Type 2 diabetes and/or hypertension (Table 13). Other reasons included: a tool for weight loss (28%), previously unsuccessful weight loss attempts (26%), to be more physically active (14%), and/or improved appearance (8%). Only three participants endorsed seeking the surgery because it was no cost (2%) (Table 13).

Of the 150 approved for surgery, 89 (59%) reported health concerns as a motivation for seeking surgery (Table 13). In this group, however, the second most reported reason was as a tool for weight loss (36%). In the 50 who were not chosen for surgery, 29 (58%) reported health concerns as a reason for wanting surgery. The second most frequent response in the denied surgery group was previously unsuccessful weight loss attempts (38%). When comparing groups, a greater percentage who were approved for surgery desired surgery as a tool for weight loss compared to those who were denied surgery (36% vs. 2%, respectively) (p<0.0001). In contrast, a higher percentage of those denied surgery identified unsuccessful weight loss efforts as a reason for seeking surgery compared to those approved for surgery (38% vs. 21%, respectively) (p<0.05). No significant differences were found when racial groups were compared (Table 13).

Table 12

Reasons for Seeking Surgery: Sample Participant Responses

Interview Question	Category	Participant Response	
"Why are you interested	Improve health	"I want a better quality of life."	
in bariatric surgery?		"I want to live longer."	
	Obesity-related medical conditions	"I want to improve my medical conditions and get off of my medications."	
	Unsuccessful weight	"I am tired of yo-yo dieting."	
	loss methods	"I have tried dieting in the past but I always gain the weight back."	
	Appearance	"I want to look better."	
	Physical activity	"I want to be more active."	
		"I want to have more energy."	
	No cost	"I do not have to pay for it."	

Table 13

Reasons for Seeking Surgery by Surgical Approval Status and Race

		Gro	up	-	Race		-	
Reason	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value	
Improve health	59%	59%	58%	0.868	56%	62%	0.433	
Obesity- related medical conditions	34%	35%	28%	0.341	33%	34%	0.057	
Tool for weight loss	28%	36%	2%	<0.0001	25%	30%	0.391	
Unsuccessful weight loss efforts	26%	21%	38%	0.019	28%	23%	0.423	
Appearance	8%	7%	10%	0.553	8%	8%	0.851	
Physical Activity	14%	15%	12%	0.638	16%	12%	0.442	
No cost	2%	1%	2%	1.000	1%	1%	0.657	

*Note.* All values are reported as percentages.

### **Perceived Contributors to Weight Gain**

Table 14 lists sample participant responses to the question, "What kinds of things do you think have contributed to your current weight?" with the respective categories. Overall (n=200), the most frequently reported contributing factor was poor food choices (57%) and the second was lack of physical activity (47%) (Table 15). Some participants attributed their weight gain to stress/emotions (33%) and/or overeating (25%). Infrequent responses included pregnancy-associated weight gain (11.5%), genetics/metabolism (9%), medical conditions/medications (6.5%), and/or social influences (4%) (Table 15).

Of the 150 participants selected for surgery, 83 (55%) reported poor food choices as the primary contributor to weight gain and secondarily, a lack of physical activity (48%) (Table 15). Other responses participants identified were stress (33%) and overeating (25%). Less frequent responses included pregnancy-associated weight gain (15%), genetics/metabolism (11%), medical reasons (7%), and social reasons (4%). There were few significant differences to the weight gain question when the approved for surgery and denied surgery groups were compared (Table 15). When compared to those that were denied surgery, a larger percentage of those approved for surgery identified pregnancy-associated weight gain (15% vs. 2%, respectively) (p<0.05) and genetics/metabolism (11% vs. 2%, respectively) (p<0.05) as contributing factors. No significant differences were found when racial groups were compared (Table 15).

Table 14
Self-Perception of Weight Gain: Sample Participant Responses

Interview Question	Category	Participant Response
"What kinds of things do you think have contributed to your current	Overeating	"Lack of portion control"
weight?"	Poor food choices	"Eating the wrong types of foods"
	No physical activity	"Not exercising enough"
		"Sedentary lifestyle"
	Stress/emotional reasons	"Stressful job"
		"Divorce, marriage, death of loved one, etc."
	Pregnancy-associated weight gain	"Having children"
	Genetics/Metabolism	"Always been overweight"
		"Slow metabolism"
	Social events/interactions	"Culture"
		"Social activities and celebrations"
	Medical conditions/medications	"Diabetes medications"

Table 15
Self-Perception of Weight Gain by Surgical Approval Status and Race

		Gro	oup	-	Race		
Cause	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Overeating	25%	25%	22%	0.635	25%	24%	0.859
Poor food choices	57%	55%	62%	0.410	57%	56%	0.899
No physical activity	47%	48%	44%	0.624	42%	53%	0.102
Stress	33%	32%	36%	0.520	33%	33%	0.936
Pregnancy- associated weight gain	12%	15%	2%	0.012	11%	11%	0.650
Genetics/ metabolism	9%	11%	2%	0.048	8%	10%	0.721
Social events/ interactions	4%	4%	2%	0.683	6%	2%	0.456
Medical	7%	7%	6%	1.000	4%	10%	0.155
No answer/ Other	1%	0%	2%	0.250	3%	0%	1.000

*Note.* All values are reported as percentages.

### Role of Food in Life

Table 16 lists sample participant responses to the question, "What role does food play in your life?" with the respective categories. Overall (n=200), the most frequently reported role by the participants was social events and interactions (42%) (Table 17). The next most frequent responses included comfort (36%), enjoyment (28%), and essential to life (19%) (Table 17). The less frequent responses were boredom (6%), convenience (4%), and no answer/other (4%) (Table 17).

The most frequently reported role in the females approved for surgery was social reasons (44%), whereas comfort (42%) was the most frequent response in those denied surgery (Table 17). In both groups, 28% indicated enjoyment as a role that food plays in their lives. Compared to those approved for surgery, a greater percentage of those denied surgery did not answer or report any of the other possible reasons identified by the approved group (10% vs. 1%, respectively) (p<0.05) (Table 17). Significant differences were found when the role of food was compared between racial groups (Table 17). Compared to African Americans, a higher percentage of Caucasians endorsed comfort (43% vs. 28%, respectively) (p<0.05) and boredom (7% vs. 4%, respectively) (p<0.05) as roles.

Table 16

Role of Food in Life: Sample Participant Responses

Interview Question	Category	Participant Response
"What role does food play in your life?"	Enjoyment	"I love to eat."
	Social events/interactions	"Everything revolves around food."
	Emotional/stress/comfort	"I turn to food when I am stressed."
	Essential to live	"Food is just a part of life."  "I do not live to eat."
	Boredom	"I eat when I am bored."
	Convenience	"Food is something quick and easy."

Table 17

Role of Food in Life by Surgical Approval Status and Race

		Gro	Group		Race		
Role	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Enjoyment	28%	28%	28%	1.000	29%	27%	0.810
Social	42%	44%	36%	0.321	44%	40%	0.637
Comfort	36%	34%	42%	0.307	43%	28%	0.035
Essential	19%	17%	22%	0.462	14%	24%	0.069
Boredom	6%	7%	4%	0.196	9%	2%	0.036
Convenience	4%	5%	0%	0.196	4%	3%	1.000
No answer/Other	4%	1%	10%	0.012	1%	7%	0.050

*Note.* All values are reported as percentages.

## **Relationship with Food After Surgery**

Table 18 lists sample participant responses to the question, "How do you think your relationship with food will change after surgery?" with the respective categories. Approximately half (47%) of all participants (n=200) reported surgery would require changing eating habits and 38% reported portion sizes would need to be reduced post-surgery. Participants (18%) also reported that thoughts about food would change. Only 10% indicated they planned to change

cooking/meal preparation habits. A greater percentage who were approved for surgery intended to change their eating habits after surgery compared to those who were denied surgery (52% vs. 32%, respectively) (p<0.05) (Table 19). No significant differences were found between racial groups (Table 19).

Table 18

Relationship with Food after Surgery: Sample Participant Responses

Interview Question	Category	Participant Response
"How do you think your relationship with food will	Changes in eating habits	"I will eat healthier."
change after surgery?"	Changes in portion size	"I will eat less."
	Changes in meal preparation/cooking	"I will prepare meals ahead of time."
		"I will cook more often."
	Changes in thoughts about food	"I will not live to eat; I will eat to live."
		"I will not see food as comfort but rather as fuel."

Table 19

Relationship with Food after Surgery by Surgical Approval Status and Race

		Group		-	Race		-
Change	Total (n=200)	Approved for Surgery (n=150)	Denied Surgery (n=50)	P value	Caucasian (n=108)	African American (n=92)	P value
Changes in eating habits	47%	52%	32%	0.014	48%	46%	0.073
Changes in portion sizes	38%	39%	36%	0.737	34%	42%	0.238
Changes in meal prep./cooking	10%	10%	10%	1.000	8%	12%	0.395
Changes in thoughts about food	18%	19%	14%	0.452	21%	13%	0.126
No answer/Other	17%	14%	26%	0.050	18%	16%	0.809

Note. All values are reported as percentages.

#### CHAPTER V

#### DISCUSSION

The results of this study indicate that foods and beverages low in nutrient value such as fast foods, fried foods and sugar-sweetened beverages are commonly consumed among females seeking bariatric surgery. There are few other studies that have explored the dietary habits of obese individuals prior to bariatric surgery. A study by Mitchell et al. (2015) documented that participants generally reported unhealthy or problematic eating habits prior to undergoing bariatric surgery, such as skipping meals and frequent fast food consumption. Mitchell and colleagues assessed the self-reported frequency of consuming breakfast, lunch and dinner meals per week and self-reported frequency of eating meals at fast-food and non-fast food restaurants before bariatric surgery in participants (n=2266) of the Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) study. They found that slightly more than half (54%) of participants reported eating breakfast regularly and half of participants reported eating meals at restaurants four times per week, two of which were at fast-food restaurants (Mitchell et al., 2015). In the present study, the majority of participants (70%) did report breakfast consumption; however, a larger percentage of individuals selected for surgery consumed breakfast compared to those denied surgery. This may indicate a more regular eating pattern in those approved for surgery rather than those who had a tendency to skip meals, which is a behavior that is not advisable after surgery. While the consumption of fast foods, fried foods, desserts, sugar-sweetened beverages, and alcoholic beverages was common in all participants, the individuals approved for surgery consumed these types of foods and beverages less often than those who were denied surgery. For those denied surgery, this observation is probably an indication of less healthy eating habits that may have continued if they received surgery. In addition, these individuals may have been denied surgery because they could not follow the initial protocol required for surgery. In contrast, the participants approved for surgery consumed foods high in nutrient value such as fruits and vegetables more frequently. Perhaps these individuals were already making healthful changes within their diet, which could have suggested a willingness to continue making positive dietary changes following surgery.

More frequent self-weighing influences weight loss and behavior changes (Butryn, Phelan, Hill, & Wing, 2007). In the present study, individuals who weighed themselves more often (daily, weekly, and monthly weighing compared to rarely weighing) tended to be approved for surgery. It is possible that these individuals demonstrated a greater self-awareness, which could have prompted positive behavioral changes following surgery. Also, as self-weighing frequency decreased, participants in this study tended to report more frequent consumption of foods low in nutrient value such as fast foods, fried foods and desserts. This finding is similar to the results of a study of overweight adults by Steinberg, Bennett, Askew, and Tate (2015) that showed males and females who weighed less often were less likely to participate in weight control behaviors associated with weight loss such as reduced caloric intake, decreased consumption of fast foods and reduced portion sizes of desserts.

Results from this study found that health reasons are the primary motivation for seeking bariatric surgery. This observation is consistent with findings of other studies suggesting that health reasons and current medical conditions are the main reasons individuals seek bariatric surgery (Munoz et al., 2007; Libeton et al., 2004). In addition, appearance was not a large motivating factor when compared to improved health and well-being. No previous studies were

identified examining whether previous unsuccessful weight loss efforts were a reason one seeks bariatric surgery. Previous unsuccessful weight loss efforts were reported by 26% of participants in this study as a reason for seeking bariatric surgery, possibly implying that these individuals desired to undergo surgery as a last resort.

Fox et al. (2014) found that the primary self-perception of females as the cause of weight gain was lack of physical activity. In contrast, the present study found that poor food choices were the most common factor among participants with the second being a lack of physical activity. These findings suggest that most individuals are generally aware of what has likely contributed to their current weight (poor diet and little/no exercise). However, some participants attributed their weight gain to factors such as stress, weight gain associated with pregnancy, genetics or slowed metabolism, and/or social events and interactions. Although these factors may play a role, it appears that some factors reported by participants may not realistically represent the scope of obesity's etiology. In addition, individuals may not delve deeply into the causes of their overweight condition which may potentially be multiple factors. Obesity is complex in nature and diet may be affected by many intrinsic and extrinsic factors.

The role of food in life was examined in an effort to determine the individual's personal connection to food. Among all participants, the most commonly reported role of food in their lives was social events and interactions. This is not surprising since food and eating often play a large part in one's social and/or family life. In contrast, participants did not frequently recognize a social influence as a contributing factor to their weight gain. This discrepancy between identifying social/family life as a major role but not recognizing that social events likely contribute to weight gain may in part be explained by the social modeling of food intake (using

others peoples' eating as a guide for what and how much to eat), which is consistently mentioned in the literature and is likely an unconscious process (Cruwys, Bevelander, & Hermans, 2015).

Surprisingly, only about half of the participants in this study reported that surgery would require them to change their eating habits and less than half indicated that they intended to change their portion sizes after surgery. Further, a greater percentage of those approved for surgery intended to change their eating habits after surgery compared those denied surgery. This finding was expected as participants had a greater likelihood of being approved for surgery if they had a specific plan to change nutrition behaviors following the surgery (if they had not started making any changes already). Therefore, the identification of plans for behavioral changes possibly demonstrates an intention to make lifestyle changes and perhaps greatly influences weight loss following surgery if their motivation is sustained. Future studies are warranted to determine if plans for dietary changes after surgery influences long term weight loss success.

#### **Strengths**

There were several strengths of this study that should be noted. First, a large sample size was used. While not all of the individuals in the main study were used, only females were included since that number was substantially higher from all three surgical type groups with African Americans and Caucasians equally represented in each group. The group of females that were denied surgery was initially regarded as a "control" group, but were also equally distributed by race. Each of the four groups were matched for age and BMI to control for variables during the data analyses. Second, this study examined several dietary, physical activity, psychological, and behavioral domains.

#### Limitations

One limitation to this study was that the approved for surgery and denied surgery groups were not equal. The number of participants in the approved for surgery group (n=150) was three times the number of the participants in the denied surgery group (n=50). This limitation was minor and did not compromise the integrity of the results. Initially, the intention was to show potential differences among the surgical types, but there were no significant differences found between variables of interest. Consequently, the three surgical type groups were collapsed into one larger group for subsequent analyses. Second, the pre-surgical dietary assessment interview questionnaire was not a validated instrument. Third, the categories for entering data were adapted based on similar responses to the questions and not based on prior studies. Finally, the data were collected solely on African American and Caucasian females from the state of Louisiana. Therefore, results may not be generalizable to males, various races, and other areas of the country.

#### CHAPTER VI

## CONCLUSIONS AND IMPLICATIONS FOR FUTURE RESEARCH

Based on the study results, the following hypotheses are either accepted or rejected:

- The decision to seek bariatric surgery for treatment of obesity is associated with the following dietary characteristics: high consumption of energy-dense foods, fast food, sugar-sweetened beverages, and desserts as well as the tendency to skip meals during the day. Accepted
- Health reasons are the primary motivation for seeking bariatric surgery. Accepted
- Females seeking bariatric surgery attribute their weight gain to overeating.
   Rejected
- Females seeking bariatric surgery attribute their weight gain to choosing foods low in nutrient value. Accepted

This study examined several dietary, behavioral, and motivational factors involved in a female's decision to seek bariatric surgery. It was hypothesized that the decision to seek bariatric surgery for treatment of obesity would be associated with poor eating habits such as high consumption of energy-dense foods, fast food, sugar-sweetened beverages, and desserts as well as the tendency to skip meals during the day. Findings of this study did suggest that poor dietary choices and eating behaviors are common among females seeking bariatric surgery. These factors likely contributed to the development of obesity. Therefore, it may be advantageous to address an individual's usual dietary intake during pre-surgical dietary assessments to subsequently promote greater dietary adherence and weight loss following surgery.

It was confirmed that the desire to improve health was the main reason females seek bariatric surgery. However, there were other psychological and lifestyle factors that appeared to be involved, such as an improvement in appearance and/or the ability to be more physically active. In addition to evaluating usual dietary intake, determining an individual's level of motivation or readiness to change prior to surgery is important since it may be an indicator of post-surgical weight loss success.

Follow-up studies will examine the eating habits, behaviors, and motivational factors of men seeking bariatric surgery. In the future, outcome data such as weight change, compliance to the post-surgical diet, etc. should be examined. This could determine the ability of the dietary interview instrument to predict dietary adherence and long-term weight loss following surgery. Exploring opportunities to improve this instrument may also increase the value of this type of assessment in the long term.

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## APPENDIX A

Pre-Surgical Dietary Assessment Interview Questionnaire

	Heads Up!	Acrostic
Participant ID (affix ID label here)		Staff Initials
		Date / / /

# **Pre-surgical Dietary Assessment**

Date:	Age:	Gender:	M	F	
BMI at SV1	Heightftin	Weight:	T	lbs	
Weight loss on LCD	Days on LCD				
So tell me why you are interested in bariatric surgery	7?				
Desired goal weight:lbs					
Heaviest Weightlbs at age	Lowest weight since a	ge 21:		_lbs	
What kinds of things do you think have contributed	to your current weight?				
Is there a family history of obesity?YesNo					
How often do you weigh yourself?					
Are you presently exercising?YesNo	If yes, what is your regimen'	?			
D 7 ( ) (D)					
Frequency, Intensity, Time, Type					
What is your plan for exercise after surgery?					
How many times have you attempted to lose weight	?				
Tell me about the time you lost the greatest amount of	of weight. lbs	S.			
How long were you able to keep it off?r	nonths				
People try lots of different ways to lose weight. Wha	t methods have you tried?				
Prescription drugs Over the					
Dietary or herbal supplements	Commercial weight loss pro	grams			
Meal replacements (such as slim fast, opti fast or other liquid or powdered meals)					
Other  How many times no week do you got foot foo do?					
How many times per week do you eat fast foods?					
How many times per week do you dine out?					
How many times per week do you eat fried food?					
now many times per week do you eat med food?					
Do you add butter, margarine, salad dressing, oil or	navonnaise to your food? (P	lease circle	(:)		

	Heads Up!	Acrostic
Participant ID (affix ID label here)	300	Staff Initials
		Date / / / /

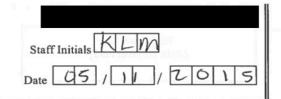
How often do you eat sweets (cookies, cakes, candy, ice cream, chocolate)? (times per week)			
What types of beverages do you drink throughout the day?			
How often do you consume alcohol? Which types?			
How many times per week do you eat fruits and vegetables?			
How many times per week do you eat cheese or yogurt?			
Do you eat red meat, pork, chicken, turkey, fish, tofu, beans, eggs or nuts? (please circle)			
Do you eat at least one serving of these every day? Yes No			
Which is your favorite?			
What is a typical breakfast for you?			
What is a typical lunch for you?			
What is a truinal dimon for you?			
What is a typical dinner for you?			
What do you like to snack on?			
Have you ever had a time when you ate more food than you typically would, in one sitting, in which you felt as if you couldn't stop?			
Have you ever had a time when you tried to get rid of the food after you ate?			
Has there been a time when a physician or friend made comments on your eating?			
History of binge eating:YesNo Night time eatingYesNo			
Tell me a little bit about the role that food has played in your life.			
Ten me a naie on about the fold that food has played in your me.			
How do you think your relationship with food is going to change after surgery?			

	Heads Up!	Acrostic	
Participant ID (affix ID label here)		Staff Initials	
		Date /	
You were given a sheet last visit that talked remember from that sheet.	d about your eating pa	atterns following surge	ry. Tell me what you
Review of Food Diary:			
Clinical Impression			
200 March 200 Mar (201 Jan 184 Mar)	150:20		
Recommendation for study: (to be do	ata entered) 🔲 🕻	Green Yello	w Red
Heads Up! QUALITY CONTROL (QC)	and DATA ENTRY:		
QC Staff Initials:	Dar	te://20	
Data Entry Staff Initials:	Da	ate://20	

## Appendix B

Completed Pre-Surgical Dietary Assessment Interview Questionnaire





# Pre-surgical Dietary Assessment

Date: 05/11/15	Age: 52	Gender: M (F)
BMI at SV1_41.3	Height 5 ft 5 in	Weight: 248 lbs
Weight loss on LCD   0.12   b	Days on LCD	
So tell me why you are interested in bariatric surger	y?	(2) Control car of the final fi
Tired of yo-yo dieting		
		and the second of the second
Desired goal weight: 180 lbs		A CARLO DE LA CINE DE CARLO
Heaviest Weight 270 lbs at age 52	Lowest weight since a	age 21: <u>150</u> lbs 23
What kinds of things do you think have contributed medical issues (Dm)	to your current weight?	1 60 000
poor diet, little to no physic	al activity	and a Primary and a second
Is there a family history of obesity? ✓YesNo	- B	Carana de la
How often do you weigh yourself? Ohce a	Neek	
Are you presently exercising?   Yes No	If yes, what is your regimen	1?
n a same management	1 da 20	ng stall maranis in Angla at an ing star.
Frequency, Intensity, Time, Type <u>Walking</u>	1 x day - 20 mir	[ [][a: 6][-1] Tul 1 & [
What is your plan for exercise after surgery?		
Continue walking		
How many times have you attempted to lose weight	? 10-15	
Tell me about the time you lost the greatest amount	of weight. 25 lb	s. Weight watcher
How long were you able to keep it off?	months	
People try lots of different ways to lose weight. Whi	at methods have you tried?	1150
Prescription drugs No Over the	e counter drugs 400 - De	xatrim, HCG
	_Commercial weight loss pro	ograms <u>WW</u>
Meal replacements (such as slim fast, opti fast or other liquid Other N D	uid or powdered meals) 100	
How many times per week do you eat fast foods?		The state of the s
2-5 x WL		makers, tenni arminal marit inna
How many times per week do you dine out?		
once		
How many times per week do you eat fried food?  At least once	10.11040 (F1.00.0)	В
Do you add butter, margarine, salad dressing, oil or	mayonnaise to your food? (l	Please circle)

Pre-Surgical Dietary Assessment V 2.0

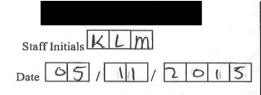
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5/20/13

H	eads	Up	!
		-	



How often do you eat sweets (cookies, cakes, candy, ice cream, chocolate)? 2 (times per week) (50mmy 600
What types of beverages do you drink throughout the day?
water, zero-calone sodas
How often do you consume alcohol? Once & months
Which types? (1) INL "WEY 3
How many times per week do you eat fruits and vegetables? Douly
How many times per week do you eat cheese or yogurt? 3 - 4 x wk
Do you eat red meat, pork, chicken, turkey, fish, tofu, beans, eggs of nuts? (please circle)
Do you eat at least one serving of these every day? (Yes) No
Which is your favorite? Chicken
What is a typical breakfast for you? Doesn't eat breakfast (not hungry)
Coffee - spienda, FF creamer
(12 02.)
W/L + 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 2
What is a typical lunch for you?
Smart oneo, Salad
What is a typical dinner for you?
chicken, turkey, salad, veg.
Weekends - may be fast food What do you like to snack on?
What do you like to snack on?
wavy lays chips, gummy bears
Have you ever had a time when you ate more food than you typically would, in one sitting, in which you felt
as if you couldn't stop? No
as if you couldn't stop. NO make a second continue and a second state
Have you ever had a time when you tried to get rid of the food after you ate? V 0
Has there been a time when a physician or friend made comments on your eating?
History of binge eating:YesNo Night time eatingYesNo



Tell me a little bit about the role that food has played in your life.  Doesn't live to eat  Cultural foods, southern eating
How do you think your relationship with food is going to change after surgery? Will learn the importance of eating well and how to Cook healthier
You were given a sheet last visit that talked about your eating patterns following surgery. Tell me what you remember from that sheet.  She was not given the sheet @ SV    We went over the info together
Clinical Impression -Good understanding of 3 surgenes of 15 ok with all 3 -Good plans for exercise after surgery (walking more of the longer periods of time) - Wants to continue with weight watchers post surgery of continue making changes in her diet (cooking)
healthrer & portion SIZED)  - She has support (Husband also does W.W. + she has a good group leader at w.W.)
Recommendation for study: (to be data entered) Green Yellow Red
Heads Up! QUALITY CONTROL (QC) and DATA ENTRY:  QC Staff Initials: Date: 05 19/20 15  Data Entry Staff Initials: Date: 5/20/20 5

Pre-Surgical Dietary Assessment V 2.0

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## APPENDIX C

IRB Exemption Letter



### **Institutional Review Board**

Office of Research 6700 Fannin, Houston, TX 77030 713-794-2480 irb-houston@twu.edu http://www.twu.edu/irb.html

DATE: April 29, 2016

TO: Ms. Kendall McLean

Nutrition & Food Sciences - Houston

FROM: Institutional Review Board (IRB) - Houston

Re: Exemption for What Drives Individuals to Choose Bariatric Surgery? An In-Depth Review of

Dietary and Nutritional Variables. (Protocol #: 19008)

The above referenced study has been reviewed by the TWU IRB (operating under FWA00000178) and was determined to be exempt from further review.

If applicable, agency approval letters must be submitted to the IRB upon receipt PRIOR to any data collection at that agency. Because a signed consent form is not required for exempt studies, the filing of signatures of participants with the TWU IRB is not necessary.

Although your protocol has been exempted from further IRB review and your protocol file has been closed, any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Ms. Rose Bush, Nutrition & Food Sciences - Houston
Dr. Carolyn Moore, Nutrition & Food Sciences - Houston
Graduate School