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The Association between Depression and Adherence to the Post-operative Regimen, and Subsequent Weight Loss after Laparoscopic Adjustable Gastric Banding

A dissertation submitted to the Graduate School of the University of Cincinnati in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Nursing by

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Abstract

Adherence to a regimen that includes follow-up appointments, diet, and physical activity after laparoscopic adjustable gastric banding, (LAGB) was recognized as a contributor to weight loss. Research suggested a positive association between adherence to this regimen and weight loss after LAGB. Research also suggested an inverse association between depression and adherence. It was hypothesized that subjects with depression would be less adherent to the post-operative regimen and would lose less weight after LAGB when compared with those without depression.

This study was a retrospective review of 246 LAGB subjects from a bariatric surgery practice in the Midwest who met the National Institutes of Health (NIH) criteria for bariatric surgery. The purpose of the study was to examine the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB. The independent variables were depression and adherence to the post-operative regimen. The dependent variables were adherence to the post-operative regimen and weight loss after LAGB. Subjects were categorized as depressed or non-depressed and adherent or non-adherent to the post-operative regimen.

The results did not support the hypotheses. Confounding factors (e.g., the effect of depression on self-reporting of adherence and changes in the state of depression) may have influenced the results. In addition, study limitations, such as self-reporting of depression and adherence to the post-operative regimen may have impacted the findings. The study’s findings raise questions about current protocols that delay or deny LAGB due to depression. Well designed studies on the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB are lacking. Evidence is insufficient to support
the use of the pre-operative mental health evaluation to determine LAGB candidacy. Future investigations of factors that may affect adherence to the post-operative regimen and subsequent weight loss after LAGB are warranted.
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Chapter 1: Problem and Significance

Traditional weight loss regimens, such as dietary and physical activity changes were often ineffective for the treatment of severe obesity. Bariatric (weight loss) surgery was an option for individuals with class III obesity or class II obesity with obesity-related comorbidities. Poorly sustained or sub-optimal weight loss after bariatric surgery had been assumed to be due to non-adherence to the recommended lifestyle behaviors that helped to achieve the initial weight loss (Mun, Blackburn, & Matthews, 2001). Difficulty adhering to the recommended dietary and physical activity behaviors may have been due in part to depression. Studies showed poor adherence among subjects with depression (Benner et al., 2001; Molassiotis et al., 2002; Wing, Phelan, & Tate, 2002; & Mackin & Arean, 2007).

Results from the National Health and Nutrition Examination Survey (NHANES) from 2005 to 2006 showed that in any 2-week period, 5.4% of Americans 12 years of age and older experienced depression (Pratt & Brody, 2008). In 2009, the National Institutes of Mental Health (NIMH) reported that depression affected approximately 17 million American adults annually, with a higher incidence than cancer, acquired immune deficiency syndrome, or heart disease (NIMH, 2009). Obesity was the most common chronic physical illness. Overweight and obesity affected approximately 65% of adult Americans (Ogden et al., 2006). Due to the high prevalence of both depression and obesity in adults, it was likely that depression and obesity were comorbid conditions. Indeed, studies showed that lifetime prevalence rates of depression among obese subjects ranged from 29% to 56% (Glinski, Wetzler, & Goodiabetesan, 2001; Kolotkin et al., 2003). These rates were higher than the U.S. national average of 6.7% (Kessler, Chiu, Demler, & Walters, 2005). Multiple studies showed that depression was common among bariatric surgery candidates (Clark et al., 2003; Averburkh et al., 2003; Buddeberg-Fischer, Klaghofer, Sigrist, & Buddeburg, 2004; Sogg & Mori, 2004).
Treatments for obesity were guided by obesity classification. Obesity was separated into three classes according to the increased health risks associated with increasing body mass index (BMI) levels: class I (BMI of 30–34.9), class II (BMI of 35–39.9) and class III (BMI ≥40). Therapeutic lifestyle changes (e.g., increased physical activity and reduced energy intake) were considered for all obese individuals. More aggressive approaches, such as pharmacotherapy and bariatric surgery, were generally reserved for individuals with class III obesity or class II obesity with high-risk obesity-related comorbidities (Katzmarzyk & Maison, 2006).

The National Institutes of Health (NIH, 1992) Consensus Development Conference Panel for Gastrointestinal Surgery for Severe Obesity recommended bariatric surgery for well-informed, motivated individuals with class III obesity with acceptable operative risks and those with class II obesity and high-risk obesity-related comorbidities, such as type 2 diabetes, hypertension, obstructive sleep apnea syndrome, cardiopulmonary disease, and hypercholesterolemia. The conference panel also reported the superiority of bariatric surgery over non-surgical approaches for the treatment of severe obesity.

Although bariatric surgery was the treatment of choice for individuals with class III obesity or class II obesity with comorbidities, it did not produce the same outcomes in every person (Van Hout, Verschure, & van Heck, 2005). Weight loss with bariatric procedures required adherence to a post-operative regimen of follow-up appointments, diet, and physical activity (Pessina, Andrioli, & Vassallo, 2001; Busetto et al., 2002; Ray, Nickels, Sayeed, & Sax, 2003; Burgmer et al., 2005; Lara et al., 2005).

It was inherently important to identify factors that were associated with adherence to the post-operative regimen and weight loss because up to 30% of bariatric subjects failed to achieve significant weight loss and may have experienced weight regain (Benotti & Forse, 1995;
Puzziferri, 2005; & Kalarchian et al., 2007). No known studies have examined the association between depression and adherence to the post-operative regimen, and subsequent weight loss after laparoscopic adjustable gastric banding (LAGB), a type of bariatric surgery.

**Study Purpose and Research Questions**

The purpose of this study was to examine the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB. It was hypothesized that subjects with depression, based on the Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision [DSM-IV-TR; (APA, 2000)] criteria for a major depressive episode, would be less adherent to the post-operative regimen, and subsequently lose less weight after LAGB, when compared with those without depression (see Figure 1).

![Model of the association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased weight loss after LAGB.](image_url)

**Figure 1.** Model of the association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased weight loss after LAGB.
The hypotheses were as follows:

Hypothesis 1: Subjects with depression would be less adherent to the 6-month and 12-month post-operative regimens than those without depression.

Hypothesis 2: Subjects who were adherent to the 6-month and 12-month post-operative regimens would lose more weight at 6 months and 12 months after LAGB than those who were non-adherent.

Hypothesis 3: Subjects with depression would lose less weight at 6 months and 12 months after LAGB than those without depression.

Hypothesis 4: Depression and adherence to the 6-month and 12-month post-operative regimens interacted in their effects on the percentage of excess weight loss (%EWL) loss at 6 months and 12 months after LAGB.

Secondarily, among subjects with depression, the association between the individual symptoms of a major depressive episode and each component of the post-operative regimen was considered. The association between depression and adherence to the post-operative regimen was explored after adjusting for confounders. In addition, the association between depression and adherence to the post-operative regimen, and subsequent weight loss was explored after adjusting for confounders. Finally, adherence to the post-operative regimen and weight loss was compared among subjects with current depression, those with a history of prior depression, and those without depression.
Chapter 2: Review of Pertinent Literature

Obesity

The prevalence of obesity doubled among American adults between 1980 and 2004 (Flegal, 2002; Ogden et al., 2006). From 2005 to 2006, over 72 million Americans were obese (Centers for Disease Control & Prevention [CDC], 2007). Obesity was predicted to be the leading health problem globally by the year 2025 (Vaidya, 2006).

Obesity was associated with increased morbidity. Certain cancers (breast, colon, and uterine), hypertension, diabetes, obstructive sleep apnea syndrome, dyslipidemias, atherosclerosis, and osteoarthritis increased in prevalence among obese individuals (Fisher & Schauer, 2002; Crookes, 2006). Annually, comorbidities of obesity accounted for approximately $147 billion of all medical spending. Obese patients spent 40% more per year on health care costs than non-obese patients (CDC, 2009).

Individuals with class III obesity or class II obesity with comorbidities had the greatest need for weight loss therapy. However, weight loss programs, diets, and drug therapies had not shown long-term effectiveness in treating individuals that fit these criteria (Fisher & Schauer, 2002). Bariatric surgery provided the greatest degree of sustained weight loss and improvement or resolution of comorbidities when patients adhered to the post-operative regimen (Livingston, 2002; Kinzl et al., 2007).

Bariatric Surgery

The major objectives of bariatric surgery were to reduce weight and maintain weight reduction. There were three bariatric surgical techniques. The first technique primarily restricted stomach size, such as LAGB. The second technique caused maldigestion and malabsorption, such as biliopancreatic diversion. The third technique combined restriction of the
stomach size, maldigestion, and malabsorption, such as gastric bypass surgery. The technique that was the focus of this study was LAGB.

Individuals seeking bariatric surgery were typically required to complete a mental health evaluation to assist in determining their appropriateness and approval for surgery (Devlin et al., 2004; Bauchowitz, et al., 2005). Insurance companies required a mental health evaluation prior to bariatric surgery to approve coverage for these procedures (Bauchowitz, et al. 2005). The practice of the pre-operative mental health evaluation resulted from recommendations from the NIH Consensus Development Conference Panel for Gastrointestinal Surgery for Severe Obesity (NIH, 1992). The panel concluded that patients be selected for surgery after evaluation by a multidisciplinary team with medical, surgical, psychiatric, and nutritional expertise. The panel also noted the need to consider changes in mood and quality of life that could occur with surgery and weight loss. They recommended a discussion of the probable outcome of the surgery, the need for post-operative regimen compliance, and the potential post-operative complications. However, the panel did not identify any specific mental illnesses or behaviors that it believed contraindicated surgery. Also, the panel did not offer guidelines for the multidisciplinary evaluation.

Results of a study on the level of involvement of mental health professionals in the evaluation of bariatric surgery candidates showed that 3% of candidates were disqualified from surgery due to psychosocial reasons, such as depression. A history of a suicide attempt, a symptom of a major depressive episode, was among the top three mental health issues that concerned providers of bariatric surgery. Among bariatric program staff members, 88.8% considered current symptoms of depression as a definite contraindication to bariatric surgery. Current symptoms of depression were considered by 95.1% of staff members to be a possible
contraindication to bariatric surgery. Most staff members found the pre-operative mental health evaluation to be “very valuable” or “valuable.” However, it was unknown how the results of the pre-operative mental health evaluation were used by bariatric surgery program staff members or how the results affected the decision making about a candidate’s suitability for bariatric surgery (Bauchowitz et al., 2005). Moreover, despite the increased demand for bariatric surgery and the involvement of mental health professionals in the patient selection process, minimal data existed on the predictors of weight loss after bariatric surgery or how to best evaluate bariatric surgery candidates (Bauchowitz et al., 2005).

With any type of bariatric procedure, successful outcomes required adherence to post-operative follow-up appointments and behavioral changes (Pessina, Andrioli, & Vassallo, 2001; Busetto et al., 2002; Ray, Nickels, Sayeed, & Sax, 2003; Burgmer et al., 2005; Lara et al., 2005). The American Society for Bariatric Surgery (ASBS) recommended regular post-operative follow-up appointments for a minimum of five years. Numerous changes in diet were prescribed, such as eating foods high in protein and low in saturated fats, avoiding calorie-dense liquids and foods, and eating three meals a day and one snack that was low in fat and calories (i.e. 200 calories or less). Bariatric surgery patients were also instructed to participate in a minimum of 30 minutes of calorie-burning physical activity daily.

The importance of adherence to follow-up appointments, diet, and physical activity in determining success and weight loss after bariatric surgery was suggested in one study (Burgmer et al., 2005). Another study showed that failure to adhere to the post-operative regimen predicted unsatisfactory weight loss and complications (Pessina, Andrioli, & Vassallo, 2001). While non-adherence to the post-operative regimen affected outcomes after surgery, little published data were available about the factors that influenced adherence to the post-operative
regimen of follow-up appointments, diet, and physical activity, and subsequent weight loss (Lara et al., 2005).

**Laparoscopic Adjustable Gastric Banding**

Laparoscopic adjustable gastric banding was one of the most popular restrictive bariatric surgical procedures worldwide (Buchwald et al., 2004). Adjustable gastric banding was performed laparoscopically by subcutaneous insertion of a hollow gastric band with an inflatable pouch around the upper part of the stomach. A small gastric pouch was created with a narrow access to the larger, more distal stomach. Inflation of the band with saline via a port allowed for adjustment on the constriction. Constriction was based on the patient’s weight loss and nutritional status (Karmali & Shaffer, 2005). Over a period of time, constriction increased until the “sweet spot” was reached. The “sweet spot” was the point where optimal weight loss was reached with minimal fluid required for band restriction. The “sweet spot” was an individual experience and the timing could not be predetermined. The amount of saline required and total content varied among patients. Weight loss after LAGB was gradual, which reflected the gradual constriction of the stoma at follow-up appointments.

Typically follow-up appointments occurred at 6 months and 12 months after LAGB. By 6 months, patients usually reached their “sweet spot” and lost an average of 25% to 36% of their excess body weight (Holloway, Forney, & Gould, 2004; T. Curry, personal communication, April 7, 2010). Weight loss continued if patients adhered to the regimen of follow-up appointments, diet, and physical activity. By 12 months, most patients lost 40% to 60% of their excess weight (Dixon, Dixon, & O’Brien, 2001; Rubenstein, Ferraro, & Raffel, 2002; Shen et al., 2004; T. Curry, personal communication, April 7, 2010).
As with other surgical procedures, specifically those performed with the obese population, complications were possible. The most frequent complications of LAGB included gastric prolapse, stoma obstruction, esophageal and gastric pouch dilation, erosion, gastric necrosis, and port problems, such as infection, tube breakage, or leaks. Complications may have been related to non-adherence to the post-operative regimen, specifically to diet. In addition, complications may have led to continued non-adherence to the post-operative regimen and subsequently suboptimal or poorly sustained weight loss.

Despite the potential complications, LAGB was considered safe and this minimally invasive bariatric surgical procedure was offered to patients with class III obesity or class II obesity with comorbidities. The LAGB produced sustained weight loss when combined with adherence to follow-up appointments, decreased energy intake, and increased physical activity (Busetto et al., 2002). However, LAGB did not produce the same weight loss outcomes in all patients. A possible reason for weight loss variability after LAGB may have been depression. Depression may have impacted patients’ ability to adhere to the post-operative regimen which may have led to variability in weight loss.

Adherence to the Post-operative Regimen

Lasting weight loss after bariatric surgery involved anatomical alterations and adherence to the post-operative regimen of follow-up appointments, diet, and physical activity (Delin, Watts, & Bassett, 1995; Ray, Nickels, Sayeed, & Sax, 2003). Adherence to the post-operative regimen was critical for success with all types of bariatric surgeries (Ray, Nickels, Sayeed, & Sax, 2003; Friedman, Applegate, & Grant, 2007). Non-adherence to follow-up appointments, persistent consumption of calorie-dense and high-fat foods and liquids, and physical inactivity were associated with poor weight loss and complications after LAGB (Poole et al., 2005). In a
previous study, LAGB subjects who were non-adherent to follow-up appointments lost less weight and regained more weight when compared to those who were adherent (Shen, et al., 2004).

**Adherence and the Self-Regulatory Theory**

Adherence was based on the patient’s ability to participate in and abide by the agreed upon treatment recommendations made with his or her health care professional (Gearing & Mian, 2005). However, despite the ability to adhere to treatment recommendations, patients may have chosen not to follow them.

Adherence to the post-operative regimen was conceptualized in this study with the Self-Regulatory Theory (SRT). Within the SRT, self-regulation was the individual’s ability to flexibly activate, monitor, inhibit, persevere, and adapt behaviors, attention, emotions, and cognitive strategies in response to direction from internal cues, environmental stimuli, and feedback from others, in an attempt to attain personally relevant goals (Zimmerman, 2000; Novak & Clayton, 2001; Lengua, 2003; & Finkenhauer, Engels, & Baumeister, 2005). Core components of the SRT involved self-efficacy, self-monitoring and adapting behaviors, goal-setting, and planning, which may have been impacted by depression. For instance, a LAGB patient who avoided high-fat foods and participated in calorie-burning physical activity for at least 30 minutes daily knew if progress was being made toward the weight loss goal by self-regulation of behaviors, such as monitoring changes in weight and waist circumference. If progress was not made, as evidenced by weight gain or sub-optimal weight loss, strategies were adjusted via self-regulation to meet the goal. When the appropriate individualized strategies were formulated and the goal was met, the patient continued to adhere to the post-operative regimen in order to maintain weight loss.
The SRT was a system of conscious personal health management strategies. With the necessary knowledge, skills, and confidence, self-regulation allowed an individual to make changes, even when faced with less than ideal circumstances (Bandura, 1997). Self-regulatory behavior, specifically goal setting, was associated with healthier eating habits and more appropriate consumption of fat, fiber, fruits, and vegetables (Schnoll & Zimmerman, 2001; Ammerman, Lindquist, Lohr, & Hersey, 2002; Pelletier, Dion, Slovinec-D’Angelo, & Reid, 2004; Vartanian, Herman, & Polivey, 2006, & Anderson, Winnett, & Wojcik, 2007). In one study, data were collected on various daily behaviors that required self-regulation, such as dietary habits and keeping appointments. Results showed that obese and overweight subjects who participated in a physical activity program demonstrated better self-regulation of other related behaviors, such as missing fewer appointments (Oaten & Cheng, 2006).

Self-regulation strategies such as planning and goal setting were utilized in studies to facilitate improvement in negative health behaviors, such as over-consumption of unhealthy foods, lack of physical activity, and non-adherence to prescription medications (Dombrowski & Luszczynska, 2009; Baumeister, Heatherton, & Tice, 1994). As experience was gained from the process of self-regulation, the ability to make informed choices was acquired. Therefore, the goal behavior was executed correctly to reach the target goal. Adherence to the regimen then became easier and habitual (Zimmerman, 2000; Novak & Clayton, 2001; Lengua, 2003; & Finkenhauer, Engels, & Baumeister, 2005). However, it was possible that self-regulation was adversely impacted by depression which led to the inability to self-regulate adherence behaviors and subsequently less weight loss after LAGB.
Depression

Depression was the largest determinant of disability worldwide (Andrews, 2001). Depression was a recurrent illness akin to other chronic illnesses, such as obesity and diabetes (Andrews, Sanderson, Slade, & Issakidis, 2000). Depression was episodic, as well as a lifelong condition that affected volition, energy, and appetite (Andrews, 2001). The U.S. National Comorbidity Survey showed that among people aged 15 to 54 years who had ever met diagnostic criteria for depression, 75% had more than one episode (Kessler, Zhao, Blazer, & Swartz, 1997).

Most national guidelines for the treatment of depression recommended adequate treatment for the current episode, as well as six months of continued treatment after remission (National Institute for Clinical Excellence, 2004). Investigators found that approximately half of a community sample who recovered from depression relapsed within one year. Also, it was predicted that the majority of subjects would relapse within two years (Andrews, 2001). In another study, 42% of subjects became non-adherent with their antidepressant medications within the first 30 days and 72% stopped taking the medication within 90 days (Olfsen, Marcus, Tedeschi, & Wan, 2006). It was unclear why depressed patients had difficulty adhering to treatment regimens. Based on the SRT, it was assumed that the primary cause of non-adherence to treatment regimens was directly related to depression (Mitchell, 2006). It was possible that depressed patients were non-adherent to treatment regimens, which led to poorer health outcomes.

The Association between Depression and Adherence

Subjects in previous studies who were non-adherent to treatment regimens tended to be more depressed than subjects who were adherent (Bosley, Fosbury, & Cochrane, 1995; Di Matteo, Lepper, & Crogham, 2000; Benner et al. 2001, Molassiotis et al., 2002; Wing, Phelan, &
Tate, 2002; Leserman, 2003; Corvera-Tindel, Doering, Gomex, & Dracup, 2004; Kaplan, Bhadlokar, Brown, White, & Brown, 2004; Mackin & Arean, 2007). Across a variety of medical settings, nearly half of all American subjects were non-adherent to the regimen prescribed by their healthcare providers for the prevention and treatment of acute or chronic conditions (DiMatteo & DiNiccola, 1982; Epstein & Cluss, 1982; DiMatteo, 1994; Bosley, Fosbury, & Cochrane, 1995, Lin et al., 1995; DiMatteo, Lepper, & Crogham, 2000; Lin et al, 2004). Depending on the illness, adherence rates to medication and behavioral regimens ranged from 33% to 94% (Meichenbaum & Turk, 1987). Clinically significant levels of depression were associated with poorer self-care behaviors, including adherence to diet, physical activity, and medication regimens (Ciechanowski, Katon, & Russo, 2000; Ciechanowski, Katon, Russo, & Hirsch, 2003; Lin et al., 2004; Park, Hong, Lee, Ha, & Sung, 2004; Kilbourne et al., 2005; Kaselkar et al., 2006). Estimates of non-adherence to follow-up appointments varied widely, with a range of 5% to 55% in U.S. primary care settings (George & Rubin, 2003). Subjects with depression missed more appointments than those without depression in a primary care setting. Depression may have affected adherence to follow-up appointments, diet, and physical activity because of its association with impaired memory and concentration, decreased energy and motivation, and feelings of hopelessness (Ciechanowski et al., 2006). Severity of depression was also an important factor in non-adherence to follow-up appointments (Mackin & Arean, 2007).

Many studies have been conducted on the association between depression and adherence to diabetes treatment regimens. Depression among subjects with diabetes was associated with poorer adherence to blood glucose monitoring, hypoglycemic medications, diet, and physical activity regimens (Venturinin et al., 1999; Freedland, Clouse, & Lustman, 2000; Anderson, Freedland, Clouse, & Lustman, 2001; Ciechanowski, Katon, & Russo, 2001; Lin et al., 2004, de
Groot, Anderson, Gilmer et al., 2005; Kalsekor et al., 2006; Kyrios, Nankeris, Reddy, & Sorbello, 2006; Gonzalez et al., 2007). Another study showed that depression was the sole predictor of overall non-adherence to the diabetic treatment regimen (Kyrios, Nankeris, Reddy, & Sorbello, 2006).

Studies were conducted on the association between depression and adherence among subjects with heart disease (Januzzi, Stern, Pasternak, DeSanctis, 2000 & Gehi, Haas, Pipkin, & Whooley, 2005). For instance, subjects with depression and recent myocardial infarctions were less adherent to behavioral recommendations, such as increased physical activity and dietary changes, when compared with subjects without depression (Ziegelstein et al., 2000). Subjects with depression in another study were less likely to adhere to recommendations to quit smoking, take prescribed medications, engage in physical activity, and attend cardiac rehabilitation for the treatment of acute coronary syndromes (Kronish et al., 2006).

Long-term success after surgery required strict adherence to medical regimens in the post-operative phase, especially after transplantation. Non-adherence to the post-operative regimen was one of the main causes of organ rejection (Gremigni et al., 2007). Despite the importance of strict post-operative adherence, research in many countries demonstrated that non-adherence was commonplace among transplant recipients (Butler, Roderick, Mullee, Mason, & Peveler, 2004). Depression was identified as a risk factor for non-adherence to treatment after kidney transplantation (Kiley, Lam, & Pollack, 1993).

Results of one study showed that higher levels of depression increased the likelihood for non-adherence to medication and dietary regimens. Also, the level of depression was inversely related to the level of adherence. Moreover, higher levels of depression were predictive of early treatment discontinuation (Kim, Han, Hill, Rose, & Roary, 2003).
When patients were non-adherent to medical regimens, they may have taken their medications incorrectly, forgotten or refused to follow diet and physical activity recommendations, cancelled or missed appointments, and continued behaviors that endangered their health. Non-adherence may have resulted in the exacerbation of previously stable illnesses (DiMatteo, Lepper, & Crogham, 2000). Depression among subjects with chronic illnesses showed increased symptom burden, functional impairment, healthcare costs, and impaired self-care and adherence (Katon & Ciechanowski, 2002).

**Effect of Depression on Health Outcomes**

The positive association between depression and chronic physical illnesses in both clinical and epidemiological studies was well documented (Dew, 1998; Venturinin et al., 1999; Freedland, Clouse, & Lustman, 2000; Anderson, Freedland, Cluse, & Lustman, 2001; Ciechanowski, Katon, & Russo, 2001; Kim, Han, Hill, Rose, & Roary, 2003; Lin et al., 2004, de Groot, Anderson, Gilmer et al., 2005; Kalsekor et al., 2006, Kyrios, Nankeris, Reddy, & Sorbello, 2006; Gonzalez et al., 2007). Depression was associated with adverse health outcomes (Ciechanowski, Katon, & Russo, 2001; Kalarchian et al., 2007). Comorbid depression negatively affected health outcomes, such as weight loss, health care utilization, and overall functioning in patients with chronic illnesses (Egede, Zheng, & Simpson, 2002). Some researchers speculated direct effects of depression on physiological outcomes, such as weight loss (Covinsky, Fortinsky, Palmer, Kresevic, & Landefeld, 1997; Ford et al., 1998; & Abramson, Berger, Krumholz, & Vaccarino, 2001). Other researchers surmised that behavioral factors mediated the association between depression and health outcomes. Depression negatively impacted subjects’ management of their chronic illnesses by its adverse effects on memory, energy, sense of self-efficacy, and interpersonal interactions (Katz, 1996). Depression
also adversely affected subjects’ satisfaction with care, which in turn predicted poorer adherence to medical regimens (Katon et al., 1995). Non-adherence to medical regimens was one of the major obstacles in the management of chronic illnesses (Bane, Hughes, & McElnay, 2006).

The Relationship between Depression and Obesity

A positive association between depression and obesity was documented (Dong, Sanchez, & Price, 2004; Jorm et al., 2003; Roberts, Deleger, Strawbridge, & Kaplan, 2003; Stunkard, Faith, & Allison, 2003; McElroy, Kotwal, Malhotra, Nelson, & Keck, 2004; Rosmond, 2004). Studies showed that subjects with class III obesity were at increased risk of depression (Doll, Peterson, & Stewart-Brown, 2000; Wadden et al., 2001; Kolotkin, Crosby, & Williams, 2002; Herpetz et al., 2003; Sarwer, Wadden, & Fabricatore, 2005; Wadden et al., 2006). Also, among obese subjects, rates of depression were as high as 80% (Black, Goldstein, & Mason, 1992; Carpenter, Hasin, Allison, & Faith, 2000; Robert, Kaplan, Shema, & Strawbridge, 2000; Glinski, Wetzler, & Goodman, 2001; Kolotkin et al., 2003). It was suggested that the association between depression and obesity was stronger among subjects with class III obesity or class II obesity with comorbidities, than subjects with class I obesity (Ray, Nickels, Sayeed, & Sax, 2003).

Depression and Weight Loss

Success after obesity treatment required learning behaviors, invoking dietary rules that governed eating and engaging in elevated levels of physical activity. Although behavioral programs to modify lifestyle were the cornerstones of obesity treatments (Panfilis et al., 2007), these programs were rarely effective in the treatment of class III obesity or class II obesity with comorbidities. Even if weight loss was achieved, it was rarely maintained for periods longer
than a year (Jeffery et al., 2000). Depression may have led to difficulty in engaging in lifestyle changes which resulted in poorer weight loss.

Depression affected volition, cognition, motivation, appetite, and energy which may have impacted one’s ability to self-regulate adherence to the post-operative regimen. If the ability to self-regulate was impaired, poorer weight loss may have resulted. Studies showed that depression was a risk factor for less weight loss among obese subjects with depression (Wadden & Stunkard, 1987; Spitzer et al., 1992; Linde et al., 2004; Bonnet et al., 2005; Panfilis et al., 2007). It was also suggested that the severity of depression negatively impacted weight loss (Linde et al., 2004).

Subjects seeking obesity treatment reported more depression than obese individuals in the community who did not seek treatment (Friedman & Brownwell, 1995). In another study, depression was associated with a higher caloric intake and less physical activity when compared with those without depression. The investigators concluded that modifications in lifestyle habits were more challenging among depressed subjects (Bonnett et al., 2005). Perhaps, dietary and physical activity changes were more difficult among subjects with depression due to the impact of depression on self-regulation.

Depression was often assessed at the start of both non-surgical and surgical weight loss programs (NIH, 1991; Black, Goldstein, & Mason, 1992; Powers, Rosemurgy, Perez, & Boyd, 1999; Glinski, Wetzler, & Goldman, 2001; Busetto et al., 2002; National Institute of Clinical Excellence, 2002; Averburkh et al., 2003; Stunkard & Allison, 2003; Cohn, 2003; Sarwer et al., 2004; Bonnett et al., 2005; Richardson, Avripas, Neal, & Marcus, 2005; de Panfilis et al., 2007; Pontiroli et al., 2007). Depression diagnosed at the start of a non-surgical weight loss program
was associated with early termination of obesity treatment in one study (Wing, Phelan, & Tate, 2002).

**Bariatric Surgery Candidates with Depression**

Bariatric surgery candidates with depression were assumed to be at greater risk for non-adherence to the post-operative regimen and complications after surgery (Powers, Rosemurgy, Coover, & Boyd, 1988; Sullivan et al., 1993; Adami, Gandolfo, Bauer, & Scopinaro, 1995; Kalarchian, Wilson, Brolin, & Bradley, 1998; Powers, Perez, Boyd, & Rosemurgy, 1999; Doll, Peterson, & Stewart-Brown, 2000; Wadden, et al., 2001; Kolotkin, Crosby, & Williams, 2002; Papageorgiou, Papakonstantinou, Memplekou, Terzis, & Melissas, 2002; Averburkh, et al., 2003; de Zwaan et al., 2003; Herpetz et al., 2003; Greenburg, Perna, Kaplan, & Sullivan, 2005; Fabricatore, Wadden, Sarwer, & Faith, 2005; Sarwer, Wadden, & Fabricatore, 2005; Wadden et al., 2006). Among gastric bypass candidates, depressive disorders were the most common current mental illness (Glinski, Wetzler, & Goldman, 2001). Lifetime prevalence of depression among bariatric surgery patients ranged from 20% to 40% (Black, Goldstein, & Mason, 1992; Kalarchian et al., 2007). Rates of pre-operative depression ranged from 41% to 45% (Cohn, 2003 & Sarwer et al., 2004). Female bariatric surgery candidates with class III obesity were more depressed than female subjects with other classes of obesity (Wadden et al., 2006). After the pre-operative mental health evaluations, 42.6% of subjects were advised to seek individual cognitive-behavioral psychotherapy and 29.4% were recommended to seek an evaluation for psychotropic medication. Depression was among the primary reasons for therapy and medication referrals (Friedman, Applegate, & Grant, 2007).

The influence of depression on obesity treatment outcomes reinforced the need to identify bariatric surgery candidates who were at higher risk for decreased adherence to the post-
operative regimen, and subsequently poorer post-operative outcomes (Ray, Nickel, Sayeed, & Sax, 2003). Furthermore, depression tended to be chronic and recurrent, and thereby more amenable to repeated episodes after surgery which may have contributed to non-adherence to the post-operative regimen and weight regain over time (Kalarchian et al., 2007).

**Association between Depression and Adherence after Bariatric Surgery**

After bariatric surgery, subjects were instructed to adhere to a post-operative regimen, which included follow-up appointments, diet, and physical activity. The association between depression and adherence to the post-operative regimen was mixed. For instance, the inability to adjust to the small pouch after restrictive bariatric procedures, due to psychiatric symptoms, such as depression, was associated with non-adherence to the post-operative diet (Pessina, Andreoli, & Vassallo, 2001). In another study, high levels of depression among gastric bypass patients were associated with non-adherence to the post-operative diet and physical activity (Ray, Nickels, Sayeed, & Sax, 2003; Bond, Phelan, Leahy, Hill, & Wing, 2009). Therefore, it was unknown if depression impacted subjects’ ability to self-regulate adherence to the post-operative regimen which led to decreased weight loss after bariatric surgery.

**Association between Adherence and Weight Loss after Bariatric Surgery**

Weight loss after bariatric surgery was associated with anatomical changes and adherence to the post-operative regimen (Hsu et al., 1998). For instance, weight loss with all bariatric procedures occurred because the narrowed outlet from the small gastric pouch slowed gastric emptying which limited caloric intake. Additionally, with gastric bypass, dumping syndrome aided in adherence to components of the post-operative diet, such as avoidance of caloric-dense sweet foods (Brolin et al., 1994; Hsu et al., 1998). Gastric bypass also caused nutrient malabsorption which enhanced weight loss (Brolin et al., 1994). However, some patients learned
to overcome the constriction and dumping sensation which led to non-adherence to the post-operative diet, and subsequently sub-optimal weight loss and weight regain over time (Yale & Weiler, 1991; Sugerman et al., 1992; Kral et al., 1993; Brolin et al., 1994). It was unclear why some patients were non-adherent to the post-operative regimen which led to decreased weight loss.

**Association between Depression and Weight Loss after Bariatric Surgery**

The association between depression and weight loss after bariatric surgery was also unclear (Kalarchian & Marcus, 2005; Lin & Perna, 2006). Most studies demonstrated that bariatric surgery had a positive short-term impact on mood. However, this positive effect may have dissipated over time and subjects may have experienced the onset or recurrence of a mental illness, such as depression (Kodama et al., 1998). In one study depressive disorders were predictive of poor weight loss (Zyden, Hedenbro, & Frederiksen, 1994). Other researchers found that failure to lose weight after restrictive bariatric surgeries was related to motivational or psychological factors, such as depression (Grace, 1992). However, other investigators concluded that depression was not predictive of weight loss after gastric bypass surgery (Delin, Watts, & Bassett, 1995, Dymek, le Grange, Neven, & Alverdy, 2001; Averburkh et al., 2003; Ma et al., 2006; Alger-Mayer, Rosati, Polimeni & Malone, 2008).

**Association among Depression, Adherence, and Weight Loss after LAGB**

Weight loss after LAGB required strict adherence to the post-operative regimen. The difference in weight loss between an adherent and non-adherent patient was tremendous. An adherent patient typically lost 40% to 60% of their excess body weight. On the other hand, a non-adherent patient often lost 0-5% excess body weight and may have regained weight (Shen et al., 2004; Langer et al., 2008; T.Curry, personal communication, May 3, 2010). Non-adherence
to follow-up appointments, persistent consumption of calorie-dense and high-fat foods and liquids, and lack of physical activity were associated with poor weight loss and complications after LAGB (Poole et al., 2005). Non-adherence among depressed LAGB patients may have been due to factors such as the disbelief in the efficacy of treatment, inadequate social support, and financial and time constraints which may have impaired their abilities to self-regulate adherence behaviors.

Two studies examined adherence to post-operative regimens of follow-up appointments and diet after LAGB. The first study compared the impact of adherence to follow-up appointments on weight loss between subjects who had LAGB and those who had gastric bypass (Shen et al., 2004). Results showed that adherence to post-operative follow-up appointments was a significant factor in the amount of weight lost after LAGB, but not after gastric bypass. Subjects who were adherent to follow-up appointments lost more weight than those who were non-adherent after LAGB. The investigators concluded that both consistent adherence to follow-up appointments and band adjustments that occurred at these appointments were important to achieve clinically significant weight loss after LAGB (Shen et al., 2004).

In the second study, the investigators concluded that adherence to follow-up appointments and dietary “rules” were predictive of weight loss up to four years after LAGB. However, follow-up appointments and “rules” were not defined (Pontiroli et al., 2007).

**Conclusion and Summary of the Literature**

There were two purposes of the review of the literature. The first purpose was to synthesize what was known about the relationships among obesity, depression, adherence, and weight loss, as well as the associations between depression and adherence, depression and health outcomes, and depression and weight loss among bariatric surgery subjects. The second purpose
was to explore the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB. Based on the review of the literature, depression was an important factor associated with non-adherence to medical, surgical, and weight loss regimens (DiMatteo, Lepper, & Crogham, 2000; Benner et al., 2001; Wing, Phelan, & Tate, 2002; Leserman, 2003; Ray, Nickels, Sayeed, & Sax, 2003; Lin et al. 2004; Linde et al., 2004; Shen et al., 2004; Bonnet et al., 2005; Gilmer et al., 2005; Kalsekar et al. 2006; Gonzalez et al., 2007; Pontiroli et al., 2007). It was possible that symptoms of depression, such as decreased motivation, cognitive impairments, fatigue, and decrements in memory and attention (DiMatteo, Lepper, & Crogham, 2000; Rubin, 2005) impacted subjects’ ability to self-regulate adherence behaviors which led to variability in weight loss after LAGB.

Results of previous studies on the association among depression, adherence to the post-operative regimen, and weight loss after LAGB were inconsistent and had numerous limitations. Although some studies showed that various physiological factors were associated with decreased adherence and poor weight loss after bariatric surgery, no investigator had specifically examined the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB. Furthermore, the strength and direction of any relationship among depression, adherence to the post-operative regimen, and subsequent weight loss after LAGB, had yet to be fully elucidated.

**Theoretical Framework**

The theoretical model (see Figure 1) was used as the framework to guide data collection of variables to be measured and to depict the hypothesized associations of this study. Based on the model, it was hypothesized that increased depression would lead to decreased adherence to the post-operative regimen and subsequently decreased weight loss. The theoretical mechanism
for the hypothesized associations was conceptualized via the SRT. It was hypothesized that depression would decrease subjects’ ability to self-regulate adherence to the post-operative regimen, and subsequently lead to less weight loss after LAGB.

It was hypothesized that weight loss after LAGB was dependent on the degree to which subjects adhered to the post-operative regimen. Adherence to the post-operative regimen was recommended to lose optimal weight and prevent weight regain. Adherence to the post-operative regimen was conceptualized via the SRT. Self-regulation espoused the individuals’ beliefs in their ability to regulate health behaviors and influence the course of their illnesses (Leventhal & Leventhal, 1998). Therefore, in this study, it was assumed that LAGB subjects would adhere to the post-operative regimen if they were confident in their abilities to do so in order to achieve their weight loss goals.

Self-regulation involved five cognitions about an illness: (1) identity: the label of the threat (obesity) and its symptoms; (2) time-line: the prognosis and changeability of the illness (obesity); (3) cause: the putative cause of the illness, such as genetics, unhealthy eating habits, or physical inactivity; (4) consequences: the effects of the illness, such as poor quality of life or sudden death; and (5) cure-control: the degree to which the illness could be prevented, cured, and kept from progressing (Leventhal, Nerenz, & Steele, 1984, Weinman, Petrie, Moss-Morris, & Horne, 1996 Leventhal & Leventhal, 1998).

A previous study showed that depression negatively impacted subjects’ management of their chronic illnesses by its adverse effects on memory, sense of self-efficacy, and interpersonal interactions (Katz, 1996). In the present study, it was expected that subjects with depression had symptoms such as apathy; impaired ability to plan and set goals; sleep and appetite disturbances; low energy and motivation; and/or feelings of hopelessness and helplessness which led to
impaired self-regulation of adherence to the post-operative regimen, and subsequently less weight loss after LAGB.
Chapter 3: Methods

Design

This study was a retrospective cohort design that examined the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB. Previous studies had not examined these associations. Also, very little was known about factors that impacted adherence to the post-operative regimen and weight loss after LAGB. Therefore, a retrospective design, which posed minimal risk to subjects, was appropriate to initially explore the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB.

Sample.

The sample included all subjects who had LAGB from July 17, 2006 to one year before Institutional Review Board approval on November 25, 2008. This period was selected to maintain consistency of the pre-operative mental health evaluation by one psychiatric nurse practitioner (psych-CNP) and to ensure that subjects had the opportunity to attend the 12-month follow-up appointment prior to data collection. Subjects were categorized based on depression (with or without) and adherence to the post-operative regimen (adherent or non-adherent). Because of the chronic nature of depression, it was anticipated that there would be minimal differences in adherence to the post-operative regimen and subsequent weight loss after LAGB between subjects with current depression and those with a history of prior depression. Therefore, in the primary analyses, the category of subjects with depression included subjects with current depression and those with a history of prior depression.
Setting.

Subjects’ medical records were obtained from a bariatric surgery practice in the Midwest. The practice employed two bariatric surgeons who specialized in LAGB and who had performed more than 600 LAGB procedures between them prior to the study. The practice also employed two registered nurses (RNs) who assessed subjects both before and after surgery. The surgeons and RNs provided education and support to subjects both before and after LAGB at post-operative follow-up appointments and via monthly support groups and online (see Appendix A). Subjects were advised to attend monthly support groups and utilize online support because an association between support group attendance and greater weight loss after bariatric surgery was found in a previous study (Orth, Madan, Taddeucci, Coday, & Tichansky, 2008). Support groups were provided free of charge on the second Monday of each month in a community room at a medical office building and on the second Tuesday of each month at a church. Support groups were led by a RN or surgeon and lasted 30 to 60 minutes. These sessions addressed ways to manage weight loss plateaus, physical, emotional, relationship, and social changes after LAGB, and adherence to the post-operative regimen.

The surgeon referred all subjects to the consulting psych-CNP for the pre-operative mental health evaluation. The psych-CNP had a Master of Science degree in nursing with a specialization in adult psychiatric and mental health nursing. She was certified as an advanced practice registered nurse in psychiatric and mental health nursing by the American Nurses Credentialing Center. She had worked in the area of psychiatric nursing for over 15 years and had performed pre-operative mental health evaluations since 2003. The pre-operative mental health evaluation included a mental status examination (see Appendix B), psychiatric review of systems (see Appendix C), and history of psychiatric treatment, weight, substance abuse, and
family psychiatric history, as well as current stressors, social support, coping skills, weight loss goals, possible barriers to adherence to the post-operative regimen and weight loss, and solutions to overcome these barriers. The principal investigator (PI) and the psych-CNP were the same individual.

**Inclusion and exclusion criteria.**

Subjects were included in the study if the following criteria were met:

- aged 18 years or older.
- had surgery from July 17, 2006 to one year before Institutional Review Board (IRB) approval (November 25, 2008).
- met NIH criteria for bariatric surgery: (1) BMI ≥ 40; (2) BMI of 35 to 39.9 with one or more high-risk comorbidities, such as obstructive sleep apnea syndrome, hypertension, obesity-related cardiomyopathy, diabetes, obesity-associated hypoventilation, glucose intolerance, cardiac disease, cardiopulmonary disease, renal disease, and serum lipid abnormalities; or (3) BMI of 35 to 39.9 with obesity-induced physical problems interfering with lifestyle, precluding or severely interfering with employment, family functioning, or ambulation, such as severe joint pain and back pain.

Subjects were excluded from the study if they became pregnant within twelve months after surgery.

**Definitions**

**Depression.**

The category of depression included subjects with current depression and a history of prior depression. Subjects were defined as having current depression if it was documented in the pre-operative mental health evaluation that they met the DSM-IV-TR criteria for major
depressive episodes. Subjects were defined as having a history of prior depression if they met the DSM-IV-TR criteria for major depressive episodes prior to the pre-operative mental health evaluation.

Subjects were defined as depressed if five or more of the following symptoms were present during the same two-week period of time which represented a change from previous functioning. At least one of the symptoms was either depressed mood or a loss of interest or pleasure (anhedonia).

1. Depressed mood for most of the day, nearly every day, as indicated by either subjective report (e.g., felt sad or empty) or observed by others (e.g., appeared tearful)
2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day, as indicated by either subjective account or observed by others
3. Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decreased or increased appetite nearly every day
4. Insomnia or hypersomnia nearly every day
5. Psychomotor agitation or psychomotor retardation nearly every day that was observed by others
6. Fatigue or a loss of energy (anergia) nearly every day
7. Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day which was not merely self-reproach or guilt about being sick
8. Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or observed by others)
9. Recurrent thoughts of death (not just fear of dying), or recurrent suicidal ideation with or without a specific plan for committing suicide, or a suicide attempt.
The symptoms must have caused clinically significant distress or impairment in social, occupational, or other important areas of functioning. The symptoms could not have been due to the direct physiological effects of a substance (e.g., illicit drug, prescription medication) or a general medical condition (e.g., hypothyroidism). The symptoms could not be better accounted for by bereavement. The symptoms must have been characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation. If subjects did not meet these criteria, they were considered negative for depression.

**Adherence to the 6-month and 12-month post-operative regimens.**

The post-operative regimen included three components: (a) follow-up appointments; (b) diet; and (c) physical activity.

*a) Follow-up appointments:* Subjects were defined as adherent to the 6-month post-operative follow-up appointment if they attended an appointment with a surgeon or RN between five and seven months after LAGB and had a minimum of three follow-up appointments within 6 months of LAGB. If subjects attended more than one follow-up appointment that occurred between five and seven months after LAGB, the progress note closest to the 6-month time point was reviewed for data collection. Subjects were defined as adherent to the 12-month follow-up appointment if they attended a follow-up appointment with a surgeon or RN between 11 and 13 months after LAGB and had a minimum of four follow-up appointments within 12 months of LAGB. If subjects attended more than one follow-up appointment that occurred between 11 months and 13 months after LAGB, the progress note closest to the 12-month time point was reviewed for data collection. Subjects were also defined as non-adherent to the 6-month or 12-month post-operative follow-up appointment(s) if they missed or cancelled more than two appointments.
Evidence of adherence to the post-operative diet and physical activity was assessed by a surgeon or RN at follow-up appointments and was documented in subjects’ medical records. Adherence was defined as a binary variable for each component at 6 months and 12 months after LAGB.

b) Diet: Subjects were defined as adherent to the 6-month and 12-month post-operative diets if the following criteria were documented in the medical records:

- consumed adequate fluids, protein, fruits, vegetables, and fiber.
- did not consume bread, soft foods, or foods high in fat and calories.
- did not consume beverages high in fat and calories.
- took a multivitamin daily by mouth.
- ate slowly and chewed adequately (approximately 15 chews per bite).
- did not eat large volumes of food (greater than 50 cc).
- did not eat past the first hint of fullness.
- did not drink 30 minutes prior to meals, during meals, or one hour after meals.
- ate three meals and one low-fat snack that contained no more than 200 calories daily.

c) Physical Activity: Subjects were defined as adherent to the 6-month and 12-month post-operative physical activity if it was documented in the medical record that subjects participated in a minimum of 30 minutes daily of physical activity (or the equivalent of 210 minutes over 168 hours).

Percentage of Excess Weight Loss.

The %EWL was used in this study and in previous bariatric surgery studies to assess post-operative weight loss outcomes (Dixon, Dixon, & O’Brien, 2001; Busetto et al., 2002;
Dixon, Dixon, O’Brien, 2003; Ray, Nickels, Sayeed, & Sax, 2003; Ma et al., 2006). Weight was measured in pounds. The %EWL loss was defined as:

\[
\text{\%EWL} = \left( \frac{\text{initial weight} - \text{post-operative weight}}{\text{initial weight} - \text{ideal body weight}} \right) \times 100.
\]

Initial and post-operative weights were measured via electronic scale by a RN or surgeon. Ideal body weight was defined as the weight appropriate for the subject’s height based on the 1983 Metropolitan Height and Weight Tables for medium-framed individuals (ASBS, 2000). The medium frame category was typically used, regardless of the subject’s actual frame size (Oria, 2005). The %EWL at 6 months and 12 months after LAGB was calculated by the PI. The %EWL was unable to be calculated for subjects who were non-adherent to the 6-month and 12-month post-operative follow-up appointments because they were not present for weight measurements; therefore, these subjects were excluded from all analyses involving excess weight loss.

**Instruments**

The Data Collection Form (DCF) was designed by the PI to gather study data (see Appendix D). Data collected included the subjects’ weight at the initial visit with the surgeon and at the 6-month and 12-month post-operative follow-up appointments, pre-operative BMI, sex, age at the pre-operative mental health evaluation, number and types of comorbidities, adherence to the post-operative regimen, depression status (current, depression, history of prior depression, or none), %EWL at 6 months and 12 months after surgery, support group attendance, and antidepressant medication use.

**Human Subjects**

A request for a waiver of informed consent was approved by the University of Cincinnati’s IRB. A retrospective medical record audit posed minimal risk to the subjects and
did not adversely affect their rights or welfare. It was not practicable to conduct this study without the waiver.

Procedures

The University’s IRB granted approval for the study protocol. The bariatric practice’s administrator granted permission for review of the subjects’ medical records. Medical records were located inside the main administrative office of the practice on chart shelves. A small area of the office was available for the PI to collect data from the medical records. The PI compiled a list of all possible subjects. From the list, five charts were retrieved from the shelves at a time. After the data were collected, medical records were returned to the main administrative office chart shelves and five more were retrieved until all data were collected.

Collected data were compiled on the DCF by the PI. Data were obtained from the subjects’ history and physical, self-history and review of systems, and the initial nursing and surgical assessments in the medical records. The pre-operative mental health evaluation, psychiatric review of systems (see Appendices B & C) and medical history within the medical records were reviewed for documentation of depression. If the DSM-IV-TR criteria for a major depressive episode were documented in the pre-operative mental health evaluation, a check mark was placed on the DCF next to the box that corresponded to the appropriate depression category. Medical record progress notes were reviewed for documentation of adherence to the 6-month and 12-month post-operative regimens and the %EWL at 6 months and 12 months after LAGB.

Data Management

The major risk of this study was the breach of confidentiality; therefore, strict confidentiality was maintained at all times. The PI recorded data manually on the DCF. When data collection was completed, the PI transferred the data to the Statistical Package for the Social
The electronic data were linked to identifiers by one master list compiled by the PI. Subjects included in the study were assigned an unique study identification number. All identifiable data, including the master list were secured in the Institute of Nursing Research and Scholarship (INRS) in the College of Nursing at the University of Cincinnati. The master list and transferred data were not stored in the same place. All identifiable computer records were stored in a password-protected computer.

**Statistical Analysis**

The PI conducted the statistical analyses with SPSS version 11.5 (SPSS Inc., Chicago, IL). For Hypothesis 1, chi-squared ($\chi^2$) tests were used to determine if adherence to the 6-month and 12-month post-operative regimens was independent of depression. For Hypothesis 2, $t$-tests were used to compare the differences in the %EWL between subjects who were adherent and non-adherent to the 6-month and 12-month post-operative regimens. For Hypothesis 3, $t$-tests were used to compare the %EWL between subjects with depression and those without depression. For Hypothesis 4, Analysis of Variance (ANOVA) was used to assess if the effects of depression and adherence to the 6-month and 12-month post-operative regimens interacted such that the combined effects on weight loss at 6 months and 12 months after LAGB would be greater than the sum of the independent effects of depression and adherence to the 6-month and 12-month post-operative regimens.

**Secondary Analyses**

To assess the independence of categorical variables (e.g. sex, antidepressant medication use, comorbidities, and social support), $\chi^2$ tests were used. To compare continuous variables (e.g. age and number of comorbidities) between groups, $t$-tests were used. Logistic regression was used to test for factors affecting binary outcomes. Linear regression was used to test for
factors affecting continuous outcomes. Pearson product-moment correlation coefficient (Pearson’s $r$) was used to determine the association between two continuous variables. For all sets of statistical tests, a Bonferroni correction was made to adjust for the increased risk of Type I error. The adjusted critical $p$ value was obtained with the following formula: $\left((1-(1-\alpha)^{1/n})\right)$, where $\alpha$ equaled 0.05 and $n$ equaled the number of comparisons.

**Power Analyses**

For Hypothesis 1, $\chi^2$ tests were planned to examine if adherence to the 6-month and 12-month post-operative regimens was independent of depression. Based on the review of the literature, it was assumed that 40% of the subjects would be positive for depression. Therefore, adherence to the 6-month and 12-month post-operative regimens was assumed to be approximately 40% among subjects with depression. It was also assumed that subjects without depression would be adherent to the 6-month and 12-month post-operative regimens approximately 60% of the time. Therefore, the expected odds ratio of adherence to the post-operative regimen was 2.25. Using a two-group $\chi^2$ test, the odds ratio would be detected if the sample size was 202 (81 subjects with depression and 122 subjects without depression). It was assumed that the critical $p$ value was $\leq 0.05$, and the required power was 80%.

For Hypothesis 2, $t$-tests were planned to compare the %EWL between subjects who were adherent and non-adherent to the 6-month and 12-month post-operative regimens. For Hypothesis 3, $t$-tests were also planned to compare the %EWL between subjects with depression (group 1, estimated mean of 30%EWL) and those without depression (group 2, estimated mean of 50%EWL). The mean difference in %EWL between subjects with depression and those without depression was expected to be 20%EWL. It was assumed that the common standard deviation ($sd$) would be 15. For 80% power and a critical $p$ of $\leq 0.05$, a sample size of 23
subjects was needed with two groups (e.g., group 1 = 9 subjects; group 2 = 14 subjects). This estimate was based on the assumption that 60% of the subjects would be negative for depression and 40% of the subjects would be positive for depression.

Based on the a priori power analyses, to answer the research question, 202 subjects were required (i.e., the largest estimated sample size for any primary analyses) to accept the outcomes of the statistical analyses with confidence.
Chapter 4: Findings

Sampling

A total of 375 subjects were screened to determine study inclusion. One-hundred and twenty-nine subjects were excluded. The final sample consisted of 246 subjects (see Figure 2).

Figure 2. Flowchart of inclusion and exclusion of subjects.

Description of the Sample

The cohort was described in Table 1. The sample included 246 subjects, most being females without depression. Subjects’ ages covered a wide range from 18 years to 72 years. Pre-operative BMIs varied from 35 to 74. Pre-operative weights ranged from 172.8 lbs to 536.0 lbs. One-hundred and ninety-five subjects (79.3%) were adherent to the 6-month post-operative follow-up appointment. The range of BMIs 6 months after LAGB was 25.7 to 65. Weights ranged from 108.4 lbs to 466.2 lbs 6 months after LAGB. The %EWL 6 months after surgery also covered a wide range from 1.4% to 74.2%. One-hundred and sixty-four subjects (66.7%)
were adherent to the 12-month post-operative follow-up appointment. Twelve months after surgery, post-operative BMIs ranged from 17.5 to 71.8 and weights ranged from 126.2 lbs to 472.5 lbs. The %EWL 12 months after LAGB ranged from 4.3% to 79.4%. Twenty subjects (8.1%) were non-adherent to both the 6-month and 12-month post-operative follow-up appointments. Therefore, adherence to the post-operative diet and physical activity and %EWL were unable to be assessed for those subjects.
Table 1

*Characteristics of the Sample, N=246*

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>42 (17.1)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>204 (82.9)</td>
<td></td>
</tr>
<tr>
<td>Depressed (current and history of)</td>
<td>112 (45.5)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td>42.5 (10.9)</td>
</tr>
<tr>
<td>Pre-operative body mass index</td>
<td></td>
<td>44.7 (8.2)</td>
</tr>
<tr>
<td>Pre-operative weight (lbs)</td>
<td></td>
<td>275.4 (67.0)</td>
</tr>
<tr>
<td>Adherent to the 6-month post-operative follow-up appointment</td>
<td>195 (79.3)</td>
<td></td>
</tr>
<tr>
<td>6-month post-operative weight (lbs)</td>
<td></td>
<td>236.1 (58.5)</td>
</tr>
<tr>
<td>6-month %EWL</td>
<td></td>
<td>25.7 (13.1)</td>
</tr>
<tr>
<td>Adherent to the 12-month post-operative follow-up appointment</td>
<td>164 (66.7)</td>
<td></td>
</tr>
<tr>
<td>12-month post-operative weight (lbs)</td>
<td></td>
<td>219.4 (57.7)</td>
</tr>
<tr>
<td>12-month %EWL</td>
<td></td>
<td>37.1 (16.8)</td>
</tr>
</tbody>
</table>

*Note. SD = standard deviation; %EWL = percentage of excess weight loss*

**Primary Analyses**

**Depression and adherence.**

Hypothesis 1. It was hypothesized that subjects with depression would be less adherent to the 6-month and 12-month post-operative regimens than those without depression.

Chi-squared tests were used to determine if adherence to the 6-month and 12-month post-operative regimens was independent of depression. One hundred and ninety-five subjects were
adherent to the 6-month post-operative follow-up appointment (87 subjects with depression and 108 subjects without depression). One hundred and sixty-four subjects were adherent to the 12-month post-operative follow-up appointment (77 subjects with depression and 87 subjects without depression). Subjects who were adherent to the 6-month and/or 12-month post-operative follow-up appointments were assessed for adherence to the post-operative diet and physical activity. It was possible for subjects to be non-adherent to the 6-month post-operative follow-up appointment, but adherent to the 12-month post-operative follow-up appointment and vice versa. Based on the results, adherence to the 6-month and 12-month post-operative regimens was independent of depression (see Tables 2 & 3). Therefore, hypothesis 1 was not supported.

Table 2

Comparison of Adherence to the 6-month Post-operative Regimen between Subjects with Depression and Those without Depression

<table>
<thead>
<tr>
<th>Post-operative regimen component</th>
<th>With depression</th>
<th>Without depression</th>
<th>$\chi^2$</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherent to follow-up appointment</td>
<td>87/112 (77.7%)</td>
<td>108/134 (80.6%)</td>
<td>0.316</td>
<td>0.574</td>
</tr>
<tr>
<td>Adherent to diet</td>
<td>25/87 (28.7%)</td>
<td>29/108 (26.9%)</td>
<td>0.016</td>
<td>0.898</td>
</tr>
<tr>
<td>Adherent to physical activity</td>
<td>45/87 (51.7%)</td>
<td>69/108 (63.9%)</td>
<td>3.141</td>
<td>0.076</td>
</tr>
</tbody>
</table>

*Note. $\chi^2$ = chi-squared*
Table 3

Comparison of Adherence to the 12-month Post-operative Regimen between Subjects with Depression and Those without Depression

<table>
<thead>
<tr>
<th>Post-operative regimen component</th>
<th>With depression</th>
<th>Without depression</th>
<th>$\chi^2$</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherent to follow-up appointment,</td>
<td>77/112 (68.8%)</td>
<td>87/134 (64.9%)</td>
<td>0.402</td>
<td>0.526</td>
</tr>
<tr>
<td>Adherent to diet</td>
<td>23/77 (29.9%)</td>
<td>19/87 (21.8%)</td>
<td>1.741</td>
<td>0.187</td>
</tr>
<tr>
<td>Adherent to physical activity</td>
<td>38/77 (49.4%)</td>
<td>49/87 (56.3%)</td>
<td>0.186</td>
<td>0.666</td>
</tr>
</tbody>
</table>

Note. $\chi^2 = \text{chi-squared}$

Adherence and %EWL.

Hypothesis 2: It was hypothesized that subjects who were adherent to the 6-month and 12-month post-operative regimens would lose more weight than those who were non-adherent.

T-tests were used to compare the %EWL between subjects who were adherent and non-adherent to the 6-month and 12-month post-operative regimens. Only subjects who were adherent to the 6-month and/or 12-month post-operative follow-up appointments had their weights measured and %EWL calculated. Results were mixed (see Tables 4 & 5). Subjects who were adherent to the 6-month post-operative physical activity lost a greater %EWL (27.3%EWL) than those who were non-adherent (23.4%EWL; $p = 0.045$). Subjects who were adherent to the 12-month post-operative diet lost a greater %EWL (43.4%EWL) than those who were non-adherent (34.8%EWL; $p = 0.006$). There was no difference in the %EWL at 6 months after LAGB based on adherence to the 6-month post-operative diet. There was also no difference in the %EWL 12 months after LAGB based on adherence to the 12-month post-operative physical activity. Based on the mixed results, Hypothesis 2 could not be supported or rejected.
Table 4

*Comparison of the %EWL between Subjects who were Adherent and Non-adherent to the 6-month Post-operative Diet and Physical Activity*

<table>
<thead>
<tr>
<th>Component</th>
<th>Adherent</th>
<th>N</th>
<th>%EWL Mean (SD)</th>
<th>F</th>
<th>t</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>Yes</td>
<td>54</td>
<td>25.3 (13.4)</td>
<td>0.005</td>
<td>-0.242</td>
<td>0.809</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>141</td>
<td>25.8 (13.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td>Yes</td>
<td>114</td>
<td>27.3 (14.3)</td>
<td>4.110</td>
<td>2.016</td>
<td>0.045</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>81</td>
<td>23.4 (11.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* %EWL = percentage of excess weight loss; F = F statistic; t = Student’s t-test

Table 5

*Comparison of the %EWL between Subjects Who Were Adherent and Non-Adherent to the 12-month Post-operative Diet and Physical Activity*

<table>
<thead>
<tr>
<th>Component</th>
<th>Adherent</th>
<th>N</th>
<th>%EWL Mean (SD)</th>
<th>F</th>
<th>t</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>Yes</td>
<td>42</td>
<td>43.4 (17.3)</td>
<td>0.518</td>
<td>2.779</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>122</td>
<td>34.8 (16.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td>Yes</td>
<td>87</td>
<td>38.9 (16.8)</td>
<td>0.036</td>
<td>1.547</td>
<td>0.124</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>77</td>
<td>34.8 (16.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* %EWL = percentage of excess weight loss; F = F statistic; t = Student’s t-test

**Depression and %EWL.**

**Hypothesis 3:** It was hypothesized that subjects with depression would lose less weight than those without depression.

To examine if there was a difference in the %EWL at 6 months and 12 months after LAGB based on depression, t-tests were used. Based on the results, there was no difference in
the %EWL at 6 months and 12 months after LAGB between subjects with depression and those without depression (see Table 6). Therefore, Hypothesis 3 was not supported.

Table 6

Effects of Depression on the %EWL among Subjects who were Adherent to the 6-month and 12-month Follow-up Appointments

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Depression</th>
<th>N</th>
<th>%EWL Mean (SD)</th>
<th>F</th>
<th>t</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months after LAGB,</td>
<td>Yes</td>
<td>87</td>
<td>25.1 (13.8)</td>
<td>0.261</td>
<td>-0.525</td>
<td>0.610</td>
</tr>
<tr>
<td>N=195</td>
<td>No</td>
<td>108</td>
<td>26.1 (12.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months after LAGB,</td>
<td>Yes</td>
<td>77</td>
<td>35.6 (16.8)</td>
<td>0.256</td>
<td>-1.031</td>
<td>0.613</td>
</tr>
<tr>
<td>N=164</td>
<td>No</td>
<td>87</td>
<td>38.3 (16.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; SD = standard deviation; F = F statistic; t = Student’s t-test

**Interaction between depression and adherence.**

**Hypothesis 4:** It was hypothesized that there was an interaction between depression and adherence to the 6-month and 12-month post-operative regimens such that the combined effects on the %EWL at 6 months and 12 months after LAGB would be different from the sum of the independent effects of depression and adherence to the 6-month and 12-month post-operative regimens.

To test if there was an interaction of depression and adherence to the 6-month and 12-month post-operative regimens in their effects on %EWL at 6 months and 12 months after LAGB, ANOVA was used. Only subjects who were adherent to the 6-month and/or 12-month post-operative follow-up appointments were included in the analyses because adherence to the post-operative diet and physical activity and %EWL were able to be assessed. Results showed no interactions between depression and adherence to the 6-month and 12-month post-operative
diets and physical activity in their effects on the %EWL (see Tables 7-10). There was a main
effect of adherence to the 6-month post-operative physical activity on the %EWL at 6 months
after LAGB ($F = 4.248, p = 0.041$). There was also a main effect of adherence to the 12-month
post-operative diet on the %EWL at 12 months after LAGB ($F = 8.271, p = 0.005$). Therefore,
Hypothesis 4 was not supported.

Table 7

*Effects of Depression and Adherence to the 6-month Post-operative Diet and Physical Activity
on the %EWL. Interaction Effects Shown.*

<table>
<thead>
<tr>
<th>Variables</th>
<th>$F$</th>
<th>$p$ value</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>1.072</td>
<td>0.302</td>
<td>-1.083</td>
</tr>
<tr>
<td>6-month post-operative diet</td>
<td>0.058</td>
<td>0.809</td>
<td>0.615</td>
</tr>
<tr>
<td>Depression x 6-month post-operative diet</td>
<td>0.280</td>
<td>0.598</td>
<td>-1.648</td>
</tr>
<tr>
<td>Depression</td>
<td>0.626</td>
<td>0.430</td>
<td>-4.000</td>
</tr>
<tr>
<td>6-month post-operative physical activity</td>
<td>4.248</td>
<td>0.041</td>
<td>1.529</td>
</tr>
<tr>
<td>Depression x 6-month post-operative physical activity</td>
<td>1.618</td>
<td>0.205</td>
<td>4.933</td>
</tr>
</tbody>
</table>

*Note.* %EWL = percentage of excess weight loss; $F = F$-statistic; B = the value for the regression
equation predicting the dependent variable from the independent variable;
$x = interaction.
Table 8

Effects of Depression and Adherence to the 12-month Diet and Physical Activity on the %EWL. Interaction Effects Shown.

<table>
<thead>
<tr>
<th>Variables</th>
<th>F</th>
<th>p value</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>3.021</td>
<td>0.084</td>
<td>-0.705</td>
</tr>
<tr>
<td>12-month post-operative diet</td>
<td>8.271</td>
<td>0.005</td>
<td>12.877</td>
</tr>
<tr>
<td>Depression x 12-month post-operative diet</td>
<td>2.246</td>
<td>0.136</td>
<td>-8.823</td>
</tr>
<tr>
<td>Depression</td>
<td>0.530</td>
<td>0.468</td>
<td>-1.268</td>
</tr>
<tr>
<td>12-month post-operative physical activity</td>
<td>2.099</td>
<td>0.149</td>
<td>4.505</td>
</tr>
<tr>
<td>Depression x 12-month post-operative physical activity</td>
<td>0.062</td>
<td>0.803</td>
<td>-1.325</td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; \( F \) = F statistic; B = the value for the regression equation predicting the dependent variable from the independent variable; \( x \) = interaction
Table 9

The %EWL for Subjects with and without Depression who were Adherent and Non-adherent to the 6-month Diet and Physical Activity

<table>
<thead>
<tr>
<th>Depression</th>
<th>Adherent to 6-month diet</th>
<th>N</th>
<th>%EWL Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>25</td>
<td>23.5 (13.7)</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>86</td>
<td>26.2 (13.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>55</td>
<td>25.1 (13.4)</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>29</td>
<td>26.8 (13.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Depression</th>
<th>Adherent to 6-month physical activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Note. %EWL = percentage of excess weight loss; SD = standard deviation*
Table 10

The %EWL for Subjects with and without Depression who were Adherent and Non-adherent to the 12-month Diet and Physical Activity

<table>
<thead>
<tr>
<th>Depression</th>
<th>Adherent to 12-month diet</th>
<th>N</th>
<th>%EWL Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>22</td>
<td>38.5 (13.5)</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>74</td>
<td>35.2 (15.3)</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>48</td>
<td>34.5 (17.4)</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>20</td>
<td>48.1 (19.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Depression</th>
<th>Adherent to 12-month physical activity</th>
<th>N</th>
<th>%EWL Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>35</td>
<td>37.3 (17.9)</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>42</td>
<td>35.4 (18.1)</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>35</td>
<td>34.2 (14.6)</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>52</td>
<td>39.9 (16.1)</td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; SD = standard deviation

Secondary Analyses

Confounders.

Logistic regression was used to model the association between depression and adherence to the 6-month and 12-month post-operative regimens after adjusting for the effects of age at the time of the pre-operative mental health evaluation, sex, antidepressant medication use, number of comorbidities (0-13), and social support. Comorbidities included hypertension, polycystic ovarian syndrome, heart disease, dyslipidemia, asthma, gastroesophageal reflux disease or acid reflux, arthralgias (included rheumatoid arthritis and osteoarthritis), diabetes (included non-insulin dependent and insulin dependent), sleep disorders (included primary insomnia, sleep disorders not otherwise specified, and obstructive sleep apnea), cancers, stress urinary
incontinence, hypercholesterolonemia, and other diseases and disorders. The effect of each comorbidity on the association between depression and adherence to the 6-month and 12-month post-operative regimens was also assessed by including it in a model with age at the time of the pre-operative mental health evaluation, sex, antidepressant medication use, and social support. Adherence to the post-operative diet and physical activity was assessed at the 6-month and 12-month post-operative follow-up appointments. Therefore, only subjects who were adherent to the 6-month and/or 12-month post-operative follow-up appointments were included in the analyses. The critical $p$ values were adjusted because multiple models were estimated. The Bonferroni correction yielded a critical $p$ value of $\leq 0.0006$. Results suggested that the association between depression and adherence to the 6-month and 12-month post-operative regimens was not affected by sex, age, antidepressant medication use, number of comorbidities, or social support (see Tables 11-16). The association between depression and adherence to the 6-month and 12-month post-operative regimens was also not affected by age, sex, antidepressant medication use, individual comorbidities, or social support (results not shown). However, caution was warranted when interpreting the models with small samples.

Linear regression was used to assess if the %EWL at 6 months and 12 months after LAGB was associated with depression and adherence to the 6-month and 12-month post-operative regimens after adjusting for the same confounders used in the logistic regression models. Weights were obtained at post-operative follow-up appointments. Therefore, only subjects who were adherent to the 6-month and/or 12-month post-operative follow-up appointments were included in the models. Bonferroni corrections for multiple comparisons yielded an adjusted critical $p$ value of $\leq 0.0001$. Results suggested that the %EWL at 6 months and 12 months after LAGB was not affected by the association between depression and
adherence to the 6-month and 12-month post-operative diets and physical activity after adjusting for age, sex, antidepressant medication use, number of comorbidities, and social support (see Tables 17-20). However, due to small sample sizes, caution was required when interpreting Tables 19 and 20. Also, the %EWL at 6 months and 12 months after LAGB was not affected by the association between depression and adherence to the 6-month and 12-month post-operative regimens after adjusting for age, sex, antidepressant medication use, each comorbidity, and social support (results not shown). However, many models with small group sizes required caution with interpretation.

Table 11

The Association between Depression and Adherence to the 6-month Follow-up Appointment after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>p value</th>
<th>Exp B</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.470</td>
<td>1.455</td>
<td>0.526</td>
<td>4.026</td>
</tr>
<tr>
<td>Sex</td>
<td>0.575</td>
<td>1.257</td>
<td>0.565</td>
<td>2.799</td>
</tr>
<tr>
<td>Age</td>
<td>0.170</td>
<td>1.022</td>
<td>0.991</td>
<td>1.053</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>0.978</td>
<td>1.013</td>
<td>0.404</td>
<td>2.537</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.995</td>
<td>1.001</td>
<td>0.790</td>
<td>1.268</td>
</tr>
<tr>
<td>Social support</td>
<td>0.004</td>
<td>0.232</td>
<td>0.086</td>
<td>0.624</td>
</tr>
</tbody>
</table>

Note. Exp B = odds ratio; CI = confidence interval; LL = lower limit, UL = upper limit
Table 12

The Association between Depression and Adherence to the 6-month Diet after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>p value</th>
<th>Exp B</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.433</td>
<td>0.681</td>
<td>0.260</td>
<td>1.779</td>
</tr>
<tr>
<td>Sex</td>
<td>0.437</td>
<td>0.722</td>
<td>0.317</td>
<td>1.642</td>
</tr>
<tr>
<td>Age</td>
<td>0.880</td>
<td>0.998</td>
<td>0.967</td>
<td>1.029</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>0.496</td>
<td>0.726</td>
<td>0.288</td>
<td>1.827</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.144</td>
<td>1.200</td>
<td>0.940</td>
<td>1.533</td>
</tr>
<tr>
<td>Social support</td>
<td>0.033</td>
<td>0.484</td>
<td>0.248</td>
<td>0.943</td>
</tr>
</tbody>
</table>

Note. Exp B = odds ratio; CI = confidence interval; LL = lower limit, UL = upper limit
Table 13

*The Association between Depression and Adherence to the 6-month Physical Activity after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support*

<table>
<thead>
<tr>
<th>Variable</th>
<th>P value</th>
<th>Exp B</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.048</td>
<td>2.252</td>
<td>1.007</td>
<td>5.039</td>
</tr>
<tr>
<td>Sex</td>
<td>0.290</td>
<td>0.685</td>
<td>0.340</td>
<td>1.381</td>
</tr>
<tr>
<td>Age</td>
<td>0.026</td>
<td>1.030</td>
<td>1.003</td>
<td>1.057</td>
</tr>
<tr>
<td>Antidepressant Medication use</td>
<td>0.807</td>
<td>1.098</td>
<td>0.517</td>
<td>2.332</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.779</td>
<td>1.028</td>
<td>0.845</td>
<td>1.252</td>
</tr>
<tr>
<td>Social support</td>
<td>0.009</td>
<td>0.444</td>
<td>0.242</td>
<td>0.814</td>
</tr>
</tbody>
</table>

*Note.* Exp B = odds ratio; CI = confidence interval; LL = lower limit, UL = upper limit
Table 14

The Association between Depression and Adherence to the 12-month Follow-up Appointment after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>p value</th>
<th>Exp B</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.861</td>
<td>1.080</td>
<td>0.457</td>
<td>2.555</td>
</tr>
<tr>
<td>Sex</td>
<td>0.305</td>
<td>1.448</td>
<td>0.713</td>
<td>2.940</td>
</tr>
<tr>
<td>Age</td>
<td>0.198</td>
<td>0.983</td>
<td>0.957</td>
<td>1.009</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>0.782</td>
<td>0.888</td>
<td>0.383</td>
<td>2.059</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.867</td>
<td>0.982</td>
<td>0.798</td>
<td>1.210</td>
</tr>
<tr>
<td>Social support</td>
<td>0.001</td>
<td>3.609</td>
<td>1.701</td>
<td>7.656</td>
</tr>
</tbody>
</table>

Note. Exp B = odds ratio; CI = confidence interval; LL = lower limit, UL = upper limit
Table 15

The Association between Depression and Adherence to the 12-month Diet after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>p value</th>
<th>Exp B</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.563</td>
<td>1.353</td>
<td>0.485</td>
<td>3.770</td>
</tr>
<tr>
<td>Sex</td>
<td>0.851</td>
<td>1.097</td>
<td>0.418</td>
<td>2.877</td>
</tr>
<tr>
<td>Age</td>
<td>0.516</td>
<td>0.989</td>
<td>0.957</td>
<td>1.022</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>0.491</td>
<td>1.432</td>
<td>0.515</td>
<td>3.978</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.385</td>
<td>1.122</td>
<td>0.866</td>
<td>1.453</td>
</tr>
<tr>
<td>Social support</td>
<td>0.961</td>
<td>1.019</td>
<td>0.475</td>
<td>2.189</td>
</tr>
</tbody>
</table>

*Note.* Exp B = odds ratio; CI = confidence interval; LL = lower limit, UL = upper limit
Table 16

The Association between Depression and Adherence to the 12-month Physical Activity after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>p value</th>
<th>Exp B</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.668</td>
<td>0.835</td>
<td>0.365</td>
<td>1.906</td>
</tr>
<tr>
<td>Sex</td>
<td>0.475</td>
<td>1.320</td>
<td>0.617</td>
<td>2.826</td>
</tr>
<tr>
<td>Age</td>
<td>0.197</td>
<td>1.018</td>
<td>0.991</td>
<td>1.045</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>0.791</td>
<td>0.896</td>
<td>0.399</td>
<td>2.012</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.660</td>
<td>0.995</td>
<td>0.779</td>
<td>1.171</td>
</tr>
<tr>
<td>Social support</td>
<td>0.001</td>
<td>2.833</td>
<td>1.551</td>
<td>5.173</td>
</tr>
</tbody>
</table>

Note. Exp B = odds ratio; CI = confidence interval; LL = lower limit, UL = upper limit
Table 17

The Association between Depression and Adherence to the 6-month Diet on %EWL after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>p value</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.021</td>
<td>0.648</td>
<td>-7.052</td>
<td>4.400</td>
</tr>
<tr>
<td>Sex</td>
<td>-0.129</td>
<td>0.962</td>
<td>-5.400</td>
<td>5.143</td>
</tr>
<tr>
<td>Age</td>
<td>0.018</td>
<td>0.842</td>
<td>-0.159</td>
<td>0.194</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>-0.577</td>
<td>0.850</td>
<td>-6.599</td>
<td>5.446</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.882</td>
<td>0.235</td>
<td>-0.577</td>
<td>2.342</td>
</tr>
<tr>
<td>Social support</td>
<td>-0.974</td>
<td>0.645</td>
<td>-5.134</td>
<td>3.186</td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; B = indicates the contributions of each independent variable to explaining the total variance in the dependent variable; CI = confidence interval; LL = lower limit, UL = upper limit
Table 18

The Association between Depression and Adherence to the 6-month Physical Activity on %EWL after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>p value</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.039</td>
<td>0.612</td>
<td>-0.131</td>
<td>0.221</td>
</tr>
<tr>
<td>Sex</td>
<td>0.402</td>
<td>0.880</td>
<td>-4.829</td>
<td>5.633</td>
</tr>
<tr>
<td>Age</td>
<td>0.038</td>
<td>0.670</td>
<td>-0.138</td>
<td>0.214</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>-0.279</td>
<td>0.927</td>
<td>-6.243</td>
<td>5.685</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>0.926</td>
<td>0.205</td>
<td>-0.511</td>
<td>2.363</td>
</tr>
<tr>
<td>Social support</td>
<td>-0.574</td>
<td>0.784</td>
<td>-4.690</td>
<td>3.543</td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; B = indicates the contributions of each independent variable to explaining the total variance in the dependent variable; CI = confidence interval; LL = lower limit, UL = upper limit
Table 19

The Association between Depression and Adherence to the 12-month Diet on %EWL after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>p value</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.032</td>
<td>0.669</td>
<td>-0.208</td>
<td>0.309</td>
</tr>
<tr>
<td>Sex</td>
<td>-2.846</td>
<td>0.454</td>
<td>-10.329</td>
<td>4.637</td>
</tr>
<tr>
<td>Age</td>
<td>0.053</td>
<td>0.686</td>
<td>-0.207</td>
<td>0.314</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>4.044</td>
<td>0.326</td>
<td>-4.056</td>
<td>12.145</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>-0.559</td>
<td>0.562</td>
<td>-2.457</td>
<td>1.339</td>
</tr>
<tr>
<td>Social support</td>
<td>0.657</td>
<td>0.816</td>
<td>-4.903</td>
<td>6.218</td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; B = indicates the contributions of each independent variable to explaining the total variance in the dependent variable; CI = confidence interval; LL = lower limit, UL = upper limit
Table 20

*The Association between Depression and Adherence to the 12-month Physical Activity on %EWL after Adjusting for Sex, Age, Antidepressant Medication Use, Number of Comorbidities, and Social Support*

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>p value</th>
<th>LL</th>
<th>UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>0.060</td>
<td>0.477</td>
<td>-0.171</td>
<td>0.363</td>
</tr>
<tr>
<td>Sex</td>
<td>-3.069</td>
<td>0.427</td>
<td>-10.677</td>
<td>4.539</td>
</tr>
<tr>
<td>Age</td>
<td>0.104</td>
<td>0.448</td>
<td>-0.165</td>
<td>0.373</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>3.177</td>
<td>0.446</td>
<td>-5.040</td>
<td>11.393</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>-0.795</td>
<td>0.416</td>
<td>-2.720</td>
<td>1.131</td>
</tr>
<tr>
<td>Social support</td>
<td>1.903</td>
<td>0.510</td>
<td>-3.784</td>
<td>7.590</td>
</tr>
</tbody>
</table>

*Note.* %EWL = percentage of excess weight loss; B = indicates the contributions of each independent variable to explaining the total variance in the dependent variable; CI = confidence interval; LL = lower limit, UL = upper limit

**Comparison of confounders between depressed and non-depressed subjects.**

Age, sex, antidepressant medication use, number of comorbidities, and social support between subjects with depression and those without depression were compared. There was no difference in age between depressed and non-depressed subjects. However, there were differences in sex, antidepressant medication use, number of comorbidities, and social support between subjects with depression and those without depression (see Table 21).
Table 21

Comparison of Confounders between Subjects with Depression (N=112) and Those without Depression (N=134)

<table>
<thead>
<tr>
<th>Confounder</th>
<th>Depressed N (%) or Mean (SD)</th>
<th>Non-depressed N (%) or Mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>42.8 (10.6)</td>
<td>42.4 (10.9)</td>
<td>0.649</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>90/112 (80.4)</td>
<td>114/134 (85.1)</td>
<td>0.037</td>
</tr>
<tr>
<td>Antidepressant medication use</td>
<td>90/112 (80.4)</td>
<td>10/134 (7.5)</td>
<td>0.000</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td>2 (1.2)</td>
<td>1.7 (1.4)</td>
<td>0.017</td>
</tr>
<tr>
<td>(range 0-13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social support</td>
<td>37/112 (33.0)</td>
<td>29/134 (21.6)</td>
<td>0.045</td>
</tr>
</tbody>
</table>

Note. SD = standard deviation

Association among the number of post-operative regimen components to which subjects with and without depression adhered and %EWL.

T-tests were used to examine if there was a difference in the number of 6-month and 12-month post-operative regimen components to which subjects with and without depression adhered. Results showed no difference in the number of post-operative regimen components to which subjects with and without depression adhered (see Table 22). Results of the Pearson’s r showed no correlation between the %EWL at 6 months and 12 months after LAGB and the number of 6-month and 12-month post-operative regimen components to which subjects adhered (p = 0.681; p = 0.290, respectively).
Table 22

Comparison of the Number of Post-operative Regimen Components to which Subjects with and without Depression Adhered

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Depression</th>
<th>Number of subjects N (%)</th>
<th>Number of components Mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>Yes</td>
<td>87/195 (44.6)</td>
<td>10.8 (1.9)</td>
<td>0.850</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>108/195 (55.4)</td>
<td>10.8 (1.6)</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>Yes</td>
<td>77/164 (47.0)</td>
<td>10.9 (1.9)</td>
<td>0.269</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>87/164 (53.0)</td>
<td>11.1 (1.8)</td>
<td></td>
</tr>
</tbody>
</table>

Note. SD = standard deviation

*Association between the symptoms of depression and each component of adherence to the post-operative regimen.*

Chi-squared analyses were used to consider the association between the symptoms of a major depressive episode and each component of adherence to the 6-month and 12-month post-operative regimens among subjects with and without depression. Results showed that each component of adherence to the 6-month and 12-month post-operative regimens was independent of the symptoms of a major depressive episode (results not shown).

*Adherence to the post-operative regimen and the %EWL among subjects with a history of prior depression.*

Chi-squared tests were used to examine if adherence to the 6-month and 12-month post-operative regimens was independent of a history of prior depression. *T*-tests were used to compare the %EWL between subjects with a history of prior depression and those with current depression. *T*-tests were also used to compare the %EWL between subjects with a history of prior depression and those without depression. Results showed that adherence to the 6-month
and 12-month post-operative regimens were independent of a history of prior depression (see Tables 23 & 24). There was no difference in the %EWL at 6 months and 12 months after LAGB between subjects with a history of prior depression and those with current depression (see Table 25). There was also no difference in the %EWL at 6 months and 12 months after LAGB between subjects with a history of prior depression and those without depression (see Table 26).

Table 23

Comparison of Adherence to the Post-operative Regimen between Subjects with a History of Prior Depression (N=11) and Those with Current Depression (N=101)

<table>
<thead>
<tr>
<th>Post-operative adherence component</th>
<th>Adherent subjects with a history of prior depression N (%)</th>
<th>Adherent subjects with current depression N (%)</th>
<th>( \chi^2 )</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-month follow-up</td>
<td>7/11 (63.6)</td>
<td>80/101 (79.2)</td>
<td>2.318</td>
<td>0.314</td>
</tr>
<tr>
<td>6-month diet</td>
<td>0/7 (0.0)</td>
<td>25/80 (31.3)</td>
<td>3.418</td>
<td>0.181</td>
</tr>
<tr>
<td>6-month physical activity</td>
<td>5/7 (71.4)</td>
<td>40/80 (50.0)</td>
<td>4.205</td>
<td>0.122</td>
</tr>
<tr>
<td>12-month follow-up</td>
<td>7/11 (63.6)</td>
<td>70/101 (69.3)</td>
<td>0.157</td>
<td>0.924</td>
</tr>
<tr>
<td>12-month diet</td>
<td>1/7 (14.3)</td>
<td>22/70 (31.4)</td>
<td>2.501</td>
<td>0.286</td>
</tr>
<tr>
<td>12-month physical activity</td>
<td>3/7 (42.9)</td>
<td>35/70 (50.0)</td>
<td>0.580</td>
<td>0.748</td>
</tr>
</tbody>
</table>

*Note. \( \chi^2 \)= chi-squared*
Table 24

*Comparison of Adherence to the Post-operative Regimen between Subjects with a History of Prior Depression (N=11) and Those without Depression (N=134)*

<table>
<thead>
<tr>
<th>Post-operative adherence component</th>
<th>Adherent subjects with a history of prior depression N (%)</th>
<th>Adherent subjects without depression N (%)</th>
<th>$\chi^2$</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-month follow-up</td>
<td>7/11 (63.6)</td>
<td>108/134 (80.6)</td>
<td>1.782</td>
<td>0.182</td>
</tr>
<tr>
<td>6-month diet</td>
<td>0/7 (0.0)</td>
<td>80/108 (74.1)</td>
<td>2.976</td>
<td>0.085</td>
</tr>
<tr>
<td>6-month physical activity</td>
<td>5/7 (71.4)</td>
<td>40/108 (37.0)</td>
<td>0.148</td>
<td>0.700</td>
</tr>
<tr>
<td>12-month follow-up</td>
<td>7/11 (63.6)</td>
<td>70/134 (52.2)</td>
<td>0.007</td>
<td>0.931</td>
</tr>
<tr>
<td>12-month diet</td>
<td>1/7 (14.3)</td>
<td>22/70 (31.4)</td>
<td>0.221</td>
<td>0.638</td>
</tr>
<tr>
<td>12-month physical activity</td>
<td>3/7 (42.9)</td>
<td>35/70 (50.0)</td>
<td>0.382</td>
<td>0.537</td>
</tr>
</tbody>
</table>

*Note.* $\chi^2$ = chi-squared

Table 25

*Comparison of the %EWL between Subjects with a History of Prior Depression (N=11) and Those with Current Depression (N=101)*

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Adherent subjects with a history of prior depression %EWL mean (SD)</th>
<th>Adherent subjects with current depression %EWL mean (SD)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months after LAGB</td>
<td>30.6 (17.1)</td>
<td>24.6 (13.5)</td>
<td>0.273</td>
</tr>
<tr>
<td>12 months after LAGB</td>
<td>33.7 (22.3)</td>
<td>35.7 (16.3)</td>
<td>0.755</td>
</tr>
</tbody>
</table>

*Note.* %EWL = percentage of excess weight loss; SD = standard deviation
Table 26

Comparison of the %EWL between Subjects with a History of Prior Depression (N=11) and Those without Depression (N=134)

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Adherent subjects with a history of prior depression %EWL mean (SD)</th>
<th>Adherent subjects without depression %EWL mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months after LAGB</td>
<td>30.6 (17.1)</td>
<td>26.1 (12.8)</td>
<td>0.221</td>
</tr>
<tr>
<td>12 months after LAGB</td>
<td>33.7 (22.3)</td>
<td>38.3 (16.8)</td>
<td>0.434</td>
</tr>
</tbody>
</table>

Note. %EWL = percentage of excess weight loss; SD = standard deviation

Summary of Findings

Adherence to the 6-month and 12-month post-operative regimens was independent of depression. There was no difference in the %EWL at 6 months or 12 months after LAGB between subjects with and without depression. Subjects who were adherent to the 6-month post-operative physical activity lost a greater %EWL 6 months after LAGB than those who were non-adherent. Subjects who were adherent to the 12-month post-operative diet lost a greater %EWL 12 months after LAGB than those who were non-adherent. There was no difference in the %EWL 6 months after LAGB based on adherence to 6-month post-operative diet. There was also no difference in the %EWL 12 months after LAGB based on adherence to the 12-month post-operative physical activity. There were no interactions between depression and adherence to the 6-month or 12-month post-operative regimens in their effects on the %EWL at 6 months or 12 months after LAGB.

Sex, use of antidepressant medication use, number of comorbidities, and social support did not affect the associations between depression and adherence to the 6-month and 12-month post-operative regimens. The association between depression and adherence to the 6-month and 12-month post-operative regimens on the %EWL at 6 months and 12 months after LAGB was
also not affected by the same aforementioned confounders. There were differences in sex, use of antidepressant medication use, number of comorbidities, and social support between subjects with depression and those without depression. There was no difference in the number of 6-month and 12-month post-operative regimen components to which subjects with and without depression adhered. There was also no difference in the %EWL at 6 months and 12 months after LAGB based on the number of post-operative diet and physical activity components to which subjects adhered. Adherence to the 6-month and 12-month post-operative regimens was independent of the symptoms of a major depressive episode and a history of prior depression. There was no difference in the %EWL at 6 months or 12 months after LAGB between subjects with a history of prior depression and those with current depression. There was also no difference in the %EWL at 6 months or 12 months after LAGB between subjects with a history of prior depression and those without depression.
Chapter 5: Discussion

In this final chapter, study results, potential confounding factors, conclusions in relation to previous research, limitations and strengths, the post hoc power analysis, implications for nursing practice, and recommendations for future research are discussed. The proposed theoretical model relating the association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased weight loss is considered. The use of the SRT to conceptualize the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB is also discussed.

The primary results of this study did not support the hypothesis that increased depression was associated with decreased adherence to the post-operative regimen, and subsequently decreased %EWL after LAGB. There were numerous confounders that were not considered in this study. A key contribution of this study was the elucidation of confounders so that future investigations can control for or account for these factors. Confounding factors, such as changes in the state of depression and the effect of depression on self-reporting of adherence to the post-operative diet and physical activity may have masked the hypothesized relationships.

Confounding Factors

Mediating effect of confounders.

It was possible that confounders mediated the effects between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased weight after LAGB. For instance, depressed subjects may have become less depressed after LAGB due to the mediating effect of social support which led to increased adherence to the post-operative regimen, and subsequently greater weight loss after LAGB. As another example, the onset of depression after the pre-operative mental health evaluation was possible if subjects’
comorbidities did not improve which led to decreased adherence to the post-operative regimen, and subsequently less weight loss.

Figure 3 depicts the possible mediating effects of confounders on the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB. Depending on the confounding variable, depression, adherence to the post-operative regimen, and weight loss would be increased or decreased.

Changes in the state of depression.

Changes in the state of depression after LAGB were not measured in this study or previous studies (Dixon, Dixon, & O’Brien, 2001; Busetto et al., 2002; Ma et al., 2006; Kinzl et al., 2007). Changes in the state of depression may have confounded the expected inverse associations between depression and adherence to the post-operative regimen in Hypothesis 1, depression and %EWL after LAGB in Hypothesis 3, and the interaction of depression and adherence to the post-operative regimen on %EWL after LAGB in Hypothesis 4. Subjects with depression at the pre-operative mental health evaluation may have become less depressed due to
antidepressant medication use, increased physical activity, decreased comorbidities, and social support which may have led to increased adherence to the post-operative regimen, and subsequently increased %EWL. For instance, in a previous study, bariatric surgery candidates reported decreased symptoms of depression after receiving surgical “clearance” via the pre-operative mental health evaluation. The recommendation to proceed with surgery was likely a relief for some candidates, especially if the selection process had begun several months earlier (Walfish, Wise, & Streiner, 2008). Other studies showed that decreased depression was associated with weight loss during and after both surgical and non-surgical weight loss treatments (Wadden et al., 1997; Gladis et al., 1998; Kodama et al., 1998; Rappaport, Clark, & Wardle, 2000; Cuntz, Leibbrand, Ehrig, Shaw, & Fichter, 2001; Bocchieri, Meana, & Fisher, 2002; Herpetz et al., 2003; Herpetz, Kiefmann, Wolfe, Hebebrand, & Senf, 2004; van Hout, van Oudheusden, & van Heck, 2004; Sarwer, Fabricatore, & Wadden, 2006; Ma et al., 2006) and specifically after LAGB (Dixon & O’Brien, 2002; Dixon et al., 2003; Ahroni, Montgomery, & Watkins, 2005). On the other hand, it was possible that subjects without depression at the preoperative mental health examination became depressed. A prior study showed that some subjects who were not depressed prior to bariatric surgery became depressed (Kodama et al., 1998). Perhaps the onset of depression among subjects without depression at the pre-operative mental health evaluation occurred if their levels of physical activity or comorbidities did not improve after LAGB.

**Antidepressant medication use.**

Among subjects with depression, use of antidepressant medications may have led to decreased depression and increased adherence to the post-operative regimen, and subsequently increased weight loss after LAGB. Antidepressant medications were prescribed for mental
illnesses such as major depressive episode, generalized anxiety disorder, panic disorder, adjustment disorder, depressive disorder not otherwise specified, stress disorders, depression secondary to a general medical condition, nicotine dependence, or premenstrual dysphoric disorder. Non-psychiatric indications for antidepressant medications included migraine, fibromyalgia, chronic fatigue syndrome, bereavement, and pain syndromes.

As expected, subjects with depression were prescribed more antidepressant medications than those without depression. Ninety (80.4%) of the 112 subjects with depression were prescribed antidepressant medications. Antidepressant medication dosages may have been adjusted by the psych-CNP during or after the pre-operative mental health evaluation. Subjects’ primary care providers or specialists may have also adjusted antidepressant medication dosages after the pre-operative mental health evaluation. It was unknown if there were changes in the state of depression among depressed subjects due to antidepressant medications because depression was only measured at the pre-operative mental health evaluation.

Changes in the state of depression were unknown because depression was measured at baseline only. However, logistic regression and linear regression findings suggested that antidepressant medication use did not attenuate the hypothesized associations between increased depression and decreased adherence, and subsequently decreased weight loss after LAGB. Caution was warranted when interpreting these findings because it was unknown if subjects took antidepressant medications as prescribed. Caution was also warranted when interpreting some models that included individual comorbidities due to small sample sizes.

Changes in physical activity.

Subjects with low levels of physical activity had a greater risk for depression when compared with those who reported high levels of physical activity (Camacho, Roberts, Lazarus,
Kaplan, & Cohen, 1991). Physical inactivity was commonplace among subjects with depression (Paluska & Schwenk, 2000). Also, low physical activity levels were common among subjects prior to bariatric surgery (Wadden & Sarwer, 2006). Among obese subjects with depression, increased physical activity was associated with decreased depression (Pafferberger, Lee, Leung, 1994; Dunn, Trivedi, & O’Neal, 2001; Friedman & Griffin, 2001; Lin et al., 2003; Galper et al., 2006; Zoeller, 2007). Regular physical activity, compared with a sedentary lifestyle, was associated with decreased depression (Goodwin, 2003). For instance, after 12 months of a physical activity training program, subjects’ symptoms of depression were reduced (King et al., 1993). Moreover, evidence supported a protective effect of physical activity against depression (Strawbridge et al., 2002; Paffenbarger et al., 1994; Camacho, Roberts, Lazarus, Kaplan, & Cohen, 1991; Farmer et al., 1988). Decreased depression was also shown to positively impact lifestyle changes. However, modifications in lifestyle habits for the treatment of obesity were more difficult among subjects with depression (Bonnett et al., 2005).

Based on the SRT, it was possible that increased physical activity among subjects with depression led to decreased depression and increased adherence to the post-operative regimen, and subsequently increased %EWL after LAGB. In contrast, subjects without depression at the pre-operative mental health evaluation may have become depressed if their level of physical activity did not improve after LAGB. This onset of depression may have led to decreased adherence to the post-operative regimen, and subsequently less weight loss. However, changes in the state of depression due to changes in physical activity were unknown because depression was measured at baseline only and levels of physical activity before LAGB were not assessed.
Effect of comorbidities on depression and adherence to the post-operative regimen.

Subjects with depression had more comorbidities than those without depression in this study. This was not surprising given the documented associations among depression, chronic medical illnesses, and obesity. Based on the SRT, it was possible that improvement and amelioration of comorbidities among subjects with depression led to decreased depression and increased adherence to the post-operative regimen, and subsequently increased %EWL after LAGB. However, it was also possible that subjects without depression at the pre-operative mental health evaluation became depressed after LAGB if their comorbidities did not improve. These subjects may have experienced decreased adherence to the post-operative regimen, and subsequently decreased weight loss. Both of these possibilities may have masked the hypothesized association between increased depression and decreased adherence to the post-operative regimen, and subsequently less %EWL after LAGB.

Comorbidities of obesity, such as type 2 diabetes, polycystic ovarian disease, and a history of gestational diabetes were associated with limited mobility and decreased weight loss (Fitzgibbon, Stolley, & Kirscehbaum, 1993). On the other hand, hypertension, osteoarthritis, back pain, asthma, gastroesophageal reflux disease, ischemic heart disease, obstructive sleep apnea, and sleep disorders were not predictive of weight loss after LAGB in another study (Dixon, Dixon, & O’Brien, 2001). A 10% reduction of initial body weight via surgical or non-surgical means produced a substantial improvement of comorbidities, such as obstructive sleep apnea syndrome, asthma, osteoarthritis, hypertension, heart disease, stress urinary incontinence, depression, and neuropathic pain from diabetes (Goldstein, 1991; Dixon et al, 1999; Horchner & Tuinebreijer, 1999; Dixon, Dixon, & O’Brien, 2001; Friedman & Griffin, 2001; Lin et al., 2003; Ahroni et al., 2005). In this study, improvement and amelioration of comorbidities may have led
to increased adherence to the post-operative regimen, specifically physical activity, which would lead to more %EWL after LAGB.

Changes in the state of depression due to improvement and amelioration of comorbidities and changes in adherence to the post-operative regimen due to changes in comorbidities were unknown because depression was measured at baseline only and changes in comorbidities were not measured. However, results of the logistic regression and linear regression suggested that comorbidities did not attenuate the hypothesized associations between increased depression and decreased adherence, and subsequently decreased weight loss after LAGB. However, caution was warranted when interpreting some models that included individual comorbidities (e.g., gout) due to small sample sizes.

**Social support.**

The importance of social support in subjects’ attempts to adhere to medical and surgical regimens has been documented (DiMatteo & DiNiccola, 1982; DiMatteo, 1994; Elkins et al., 2005). In previous studies, support group attendance was associated with enhanced functional performance and decreased psychological symptoms, such as depression, increased adherence and greater weight loss after bariatric surgery (Hildebrandt, 1998; Klemm & Hardie, 2002; Elakkary, Elhorr, Faisal, Gazayerli, & Silva, 2004; Elkins, et al., 2005; Stein, Epstein, Raynor, Kilanowski, & Paluch, 2005; Orth, Madan, Taddeucci, Coday, & Tichansky, 2008). Social support via groups or online may have decreased depression which led to increased adherence to the post-operative regimen, and subsequently increased %EWL after LAGB in this study.

Subjects with depression attended support groups more than those without depression. This was not expected because depression was associated with isolation and withdrawal from those who provided emotional support and assistance (Hoeg et al., 1984; Katz, Doctors, &
Siegal, 1986; Glasgow et al., 1989; Jamison, Lewis, & Burish, 1989; Di Matteo et al., 1993).
Also, severe obesity was associated with social isolation (Roberts, Kaplan, Shema, & Strawbridge, 1987; Papageorgiou et al., 2002). Perhaps, the availability of on-line social support attenuated the expected association between increased depression and decreased social support. For instance, chronically depressed and socially isolated subjects felt that interacting with support groups helped their symptoms, and over one third of subjects preferred interacting via on-line support to face-to-face support. Also, subjects with embarrassing or stigmatizing conditions (e.g., obesity and depression) may have found the relative anonymity from being on-line gave them freedom to discuss their concerns more openly (Houston, Cooper, & Ford, 2002). Moreover, involvement with peers who experienced similar dramatic lifestyle changes may have aided in sustaining self-management practices and identifying adverse outcomes after LAGB (Bradley, 2007).

Changes in depression due to social support were unknown because depression was only measured at the pre-operative mental health evaluation and frequency of social support was not assessed. However, logistic regression and linear regression findings suggested that social support did not effect the association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased weight loss after LAGB. However, some models required caution with interpretation due to small samples sizes.

**Study Design Limitations**

**Retrospective design.**

Retrospective design, investigator and recall bias, the definition of adherence to the post-operative diet and physical activity, instrumentation, and attrition were limitations that required consideration when interpreting the results of this study. The main limitation was that data were
originally collected for clinicians to assess progress toward band adjustments, weight loss, and improved health, not for research purposes. Therefore, control, rigor, and precision of data collection were limited.

Missing and conflicting data are common in retrospective study designs (Worster & Haines, 2004). This study was a retrospective review of medical records. This design was associated with decreased internal validity because data collection of adherence to the post-operative regimen and %EWL was limited to the information in the medical records. However, retrospective review of medical records was efficient, cost-effective, and posed minimal risk to the subjects. Also, this design was appropriate to initially explore the association between depression and adherence to the post-operative regimen, and subsequent %EWL after LAGB.

**Self-reporting of depression.**

Self-reporting of depression may have led to incorrect categorization of subjects as depressed or non-depressed at the pre-operative mental health evaluations. Erroneous categorization may have attenuated the hypothesized associations in Hypotheses 1, 3, and 4. For example, in a prior study, bariatric surgery candidates were concerned that being too honest at the pre-operative mental health evaluation would result in delays or denials of surgery. It was presumed that these candidates were motivated to minimize their psychiatric symptoms or “fake good” to receive surgical clearance (Walfish et al., 2008). Conversely, other candidates may have emphasized their weight-related distress to “make their case” for surgery as necessary to improve their emotional and physical health (Kinder, Walfish, Young, & Fairweather, 2008). Moreover, many candidates perceived bariatric surgery to be their “last resort.” Therefore, it was possible that candidates portrayed themselves in whatever light they believed was in their best interests (Fabricatore, Sarwer, Wadden, Combs, & Krasucki, 2007).
The definition of adherence to the post-operative regimen.

**Dichotomous definition of adherence to diet.** Adherence to the post-operative regimen was assessed at the 6-month and 12-month follow-up appointments. Perhaps subjects were non-adherent to these follow-up appointments, but were adherent at other times after LAGB. However, based on the definition of adherence, subjects who missed the 6-month and/or 12-month appointments were defined as non-adherent; therefore, adherence to diet and physical activity was not assessed. A more accurate measure of adherence to the post-operative regimen may have been obtained if assessment occurred at more frequent intervals.

Also, an inverse association between depression and adherence to the post-operative regimen had been documented (Poole et al., 2004; Poole et al., 2005). However, in this study, the binary definition of adherence to the post-operative diet may have contributed to the unexpected findings. For instance, adherence to the post-operative diet was defined as a dichotomous variable (i.e., adherent or non-adherent). To be defined as adherent, the subject was required to follow 17 dietary components. Non-adherence to one or more dietary components resulted in being classified as non-adherent. Although, total adherence is ideal; adherence to any regimen is rarely 100%.

To assess if a less strict definition of adherence to the post-operative diet would have resulted in supporting Hypothesis 1, a sensitivity analysis was conducted. Therefore, adherence to the post-operative diet was reanalyzed with number of components of the post-operative diet to which subjects adhered as a continuous variable. Results showed that the number of post-operative diet components to which subjects adhered was independent of depression. Also, there was no correlation between the number of post-operative diet components to which subjects adhered and %EWL after LAGB. Therefore, it was unlikely that the definition of adherence to
the post-operative diet led to the lack of associations and the lack of support for Hypotheses 1, 2, and 4.

Components of adherence. It was possible that one or more components of the post-operative regimen, such as avoiding high-fat foods and daily physical activity contributed more to weight loss after LAGB, than other components, such as taking a multivitamin daily or consuming adequate fiber. This approach was used to examine the association among adherence to scheduled follow-up appointments, diet, physical activity, other recommendations, and weight loss after LAGB in a previous study (Pontiroli et al., 2007). It could be that subjects in the current study were adherent to specific components and not the entire post-operative regimen, but lost weight.

Self-reporting of adherence to diet and physical activity. Nondisclosure, different interpretations of meaning, and social desirability were possible biases of self-reporting of adherence (Lichtman et al., 1992; Frank & Dingle, 1999; Schoeller, 2007). Adherence to the post-operative diet and physical activity was based on self-report. Erroneous self-reporting may have obscured what was hypothesized in Hypotheses 1, 2, and 4.

Self-reporting of weight-related behaviors, such as adherence to diet and physical activity were subject to issues of misreporting and social desirability (Lichtman et al., 1992; Schoeller, 2007). For instance, subjects in this study may have erroneously reported adherence to the post-operative diet and physical activity to avoid possible confrontation or disappointment from the RN or surgeon. Previous studies showed that self-reported adherence of weight-loss behaviors was generally higher than more objective measures, such as use of a pedometer to assess adherence to physical activity and unobtrusive observations (Lorenz, Christensen, & Pichert,
1985) or direct or indirect calorimetry to assess adherence to diet (Vitolins, Rand, Rapp, & Ribisl, 2000).

**Investigator bias.**

The pre-operative mental health evaluation was part of the routine medical care for LAGB candidates. However, investigator bias was possible because there was only one data abstractor, who was both the PI and the psych-CNP conducting the pre-operative mental health evaluations. The PI abstracted all data and may have been biased in collecting information from subjects’ medical records.

Recall bias was also possible because the PI conducted the pre-operative mental health evaluations and knew subjects from a clinical standpoint. Therefore, it was possible that the PI looked more diligently for symptoms of depression in the charts of subjects remembered to be depressed. On the other hand, she also may have reviewed charts less diligently among subjects remembered to be free of depression.

**Instrumentation.**

Instrumentation was a threat to this study’s internal validity because the bariatric practice did not have a protocol or formal training for measuring weight or assessing adherence to diet and physical activity. Subjects were weighed at baseline and at follow-up appointments on the same scale. However, inconsistencies among the methods used by the RNs and surgeons over time were possible. For instance, on one occasion subjects may have been weighed with shoes and/or heavy clothing (e.g., jackets and sweaters) and on other occasions subjects may have been weighed without these items. Also, the scale was not calibrated as recommended by the manufacturer. Therefore, erroneous and inconsistent weight measurements were possible.
Although adherence to diet and physical activity were defined, it was possible that subjects were misclassified as adherent or non-adherent to diet and physical activity by the RNs and surgeons. For instance, a surgeon or RN may have classified subjects as adherent to diet if they adhered to the majority of the 17 diet components. However, another surgeon or RN may have classified subjects as non-adherent if they were not adherent to all 17 dietary components.

Erroneous classification as adherent or non-adherent to diet and physical activity was possible, despite having a standardized checklist that defined diet and physical activity adherence. These discrepancies may have obscured the hypothesized association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased %EWL after LAGB; however, the inconsistency of these variables was expected to be minimal in magnitude.

**Attrition.**

It was possible for subjects to be non-adherent to the 6-month follow-up appointment and adherent to the 12-month follow-up appointment, and vice versa. In this study, 79.3% of the subjects were adherent to the 6-month follow-up appointment and 66.7% of the subjects were adherent to the 12-month follow-up appointment. A possible reason for these high rates of adherence was that follow-up appointments and band adjustments were included in the cost of the LAGB for one year. Despite these high adherence rates, a total of 61 subjects dropped out from baseline to the 12-month follow-up appointment.

Attrition or drop-out of subjects may have biased the results of all four hypotheses, with the exception of the association between depression and adherence to follow-up appointments in Hypothesis 1. Bias was likely when interpreting results based on data analyzed only for subjects who completed a study. Perhaps subjects in this study were non-adherent to follow-up
appointments because they were satisfied with their weight loss. Therefore, they did not feel that adherence to subsequent follow-up appointments was necessary (Tweddle, Woods, & Blamey, 2004). On the other hand, it was possible that non-adherence to follow-up appointments was due to poor weight loss and/or to avoid embarrassment, confrontation, and disappointment from staff regarding their non-adherence. For instance, in a previous study, attrition was associated with less weight loss when compared with subjects who completed the study (Pratt, McLaughlin, & Gaylord, 1992; Wadden, Foster, Letizia, & Stunkard, 1992; Karlsson et al., 1994). Both of these possibilities would have biased this study’s results.

The Effects of Confounders and Limitations on the Theoretical Model

The proposed model (see Figure1) was used as a framework to depict the hypothesis that increased depression led to decreased adherence to the post-operative regimen, and subsequently decreased weight loss after LAGB. The model was also used to guide data collection. Although the theoretical model was not tested in this study, confounders and study limitations may have affected this model.

The theoretical model did not account for changes in the state of depression or erroneous categorization of depression which may have affected adherence to the post-operative regimen and %EWL after LAGB. Also, the theoretical model did not account for subjects who were adherent to follow-up appointments at intervals besides 6 months and 12 months after LAGB. Adherence to follow-up appointments at other intervals may have resulted in increased adherence to diet and physical activity, and subsequently increased %EWL.

The model did not account for the individual components of the post-operative diet. However, the number of dietary components to which subjects adhered was independent of depression. Also, the number of post-operative diet components to which subjects adhered and
%EWL after LAGB were not correlated. Therefore, it was unlikely that the definition of adherence to the post-operative diet affected the association between increased depression and decreased adherence to the post-operative regimen and the positive association between adherence to the post-operative regimen and %EWL in the model.

Erroneous weight measurements due to instrumentation were not considered in the theoretical model. For instance, it was possible that depressed subjects seemed to lose weight when non-adherent to the post-operative regimen if weight measurements were inaccurate or inconsistent among staff. These inaccuracies and inconsistencies would counter what was expected in the theoretical model.

The retrospective design was not expected to affect the theoretical model because the relationships depicted in the model were not affected by when data were collected. However, attrition was expected to affect the model because adherence to diet and physical activity and subsequent %EWL could not be assessed.

**The Effects of Confounders and Limitations on the SRT**

The association between depression and adherence to the post-operative regimen, and subsequent %EWL after LAGB was conceptualized with the SRT. It was assumed that depression would negatively affect subjects’ ability to self-regulate adherence to the post-operative regimen which would lead to less %EWL. Although measures of the SRT were not tested in this study, it was possible that confounders and study limitations affected the SRT. For instance, decreased depression via antidepressant medication use, changes in physical activity, improvement and amelioration of comorbidities, and social support may have led to enhanced self-regulation. This enhanced self-regulation may have led to increased adherence to the post-operative regimen and increased %EWL.
Based on the SRT, if subjects lost weight, adherence to the post-operative regimen continued so weight loss persisted. This was anticipated because the feedback mechanism in the SRT was not limited by a scale of measurement or the method used to report adherence to the post-operative regimen. Therefore, self-reporting of adherence to the post-operative diet and physical activity, investigator and recall bias, the definition of adherence to the post-operative regimen, or instrumentation was not expected to affect the SRT.

The timeframe when data were collected was not anticipated to affect the feedback mechanism in the SRT. Therefore, a retrospective design and the 6-month and 12-month intervals when adherence to the post-operative regimen and %EWL were assessed probably did not affect subjects’ ability to self-regulate.

Finally, a trend toward decreased adherence to post-operative physical activity among subjects with depression was observed. This trend may have reflected that adherence to physical activity was more challenging among subjects with depression due to the possible effects of depression on self-regulation.

**Comparisons between the Present and Past Studies**

The male-to-female ratios, ages, pre-operative BMIs, and the number and types of comorbidities were similar to LAGB samples in previous studies (Karlsson, Sjostrom, & Sullivan, 1998; Busetto et al., 2000; Dixon, Dixon, & O’Brien, 2001; Pessina, Andreoli, & Vassallo, 2001; Dixon et al., 2003; Ren & Fielding, 2003; Dixon, Dixon, & O’Brien, 2004; Holloway, Forney, Gould, 2004; Chau et al., 2005; Fielding & Duncombe, 2005; Jan, Homg, Pereira, Patterson, 2005; Galvani et al., 2006; Kinzl et al., 2006; Meyers, Sarker, & Shayani, 2006; Ponce, Fromm, & Paynter, 2006; Phillips, 2008; Wheeler, Pretyman, Lenhard, & Tran, 2008). Forty-six percent of the subjects in this study had pre-operative depression. This rate was
similar to those in previous studies of bariatric surgery candidates (Averburkh et al., 2003; Clark et al., 2003; Cohn, 2003; Buddeburg-Fischer, Klaghofer, Sigrist, & Buddeburg, 2004; Sogg & Mori, 2004; Sarwer et al., 2008; Bond, Phelan, Leahy, Hill, & Wing, 2009).

The mean %EWL 6 months after LAGB in this study was 25.7% (SD = 13.1%). This weight loss was comparable to 26.4%EWL (SD not reported) which was previously reported (Weiner, Blanco-Engert, Weiner, Pomhoff, & Matkowitz, 2003; T. Curry, personal communication, May 5, 2010). However, the rate in this study was less than the 57.2%EWL reported in another study (O’Brien et al., 2006). The mean %EWL 12 months after LAGB in this study was 37.1% (SD = 6.8%), which was similar to the mean %EWL 12 months after LAGB in previous studies (Busetto et al., 2002; Tweddle et al., 2004 Rubinstein, Ferraro, & Raffel, 2002; Spivak, Hewitt, Onn, & Half, 2005), but less than the 41.7%EWL and 78.6%EWL reported in other LAGB studies (O’Brien & O’Brien., 2006; Weiner, Blanco-Engert, Weiner, Pomhoff, & Matkowitz, 2003; Dixon, Dixon, O’Brien, 2001). The differences in the %EWL at 6 months and 12 months after LAGB between this study and previous studies may have been due to different candidacy criteria for LAGB (i.e., not using the NIH criteria), dissimilar pre-operative routines, varying definitions of adherence to the post-operative regimen, instrumentation, and attrition.

**Hypothesis 1: The association between depression and adherence.**

An inverse association between depression and adherence has been documented (Bosley et al., 1995; Di Matteo et al., 2000; Benner et al., 2001, Molassiotis et al., 2002; Wing, Phelan, & Tate, 2002; Leserman, 2003; Kaplan, Bhadlokar, Brown, White, & Brown, 2004; Mackin & Arean, 2007). It was hypothesized that poorly sustained or suboptimal weight loss after LAGB was due to decreased adherence to the post-operative regimen. The post-operative regimen
included behaviors that helped to achieve the initial weight loss. It was also hypothesized that
non-adherence to the post-operative regimen was associated with depression. The SRT was used
to conceptualize the association between increased depression and decreased adherence to the
post-operative regimen. However, the hypothesized association between increased depression
and decreased adherence to the post-operative regimen was not supported by the study results.

Comparison of results between the present study and previous studies on depression
and adherence to the post-operative regimen.

The definition of depression. The contradictory findings between this study and previous
studies may have been due to different definitions of depression. Various methods have been
used to define depression among bariatric surgery candidates, such as scales of general
psychopathology, personality profiles, screening instruments, and review of medical records for
International Statistical Classification of Diseases and Related Problems Codes (ICD-9) for
depression, antidepressant medications, or depression on the problem list, review of systems, or
past medical history (Busetto et al., 2002; Ray et al., 2003; Devlin, Goldfein, Flancbaum,
Bessler, & Eisenstadt, 2004; Ahroni et al., 2005; Fabricatore, Crerand, Wadden, Sarwer, &
Sugerman, 2005; Gehi et al., 2005; Kalsekar et al., 2006; Gonzalez et al., 2007). Subjects in
previous studies may have been erroneously defined as depressed or non-depressed with these
methods.

Scales of general psychopathology showed only a modest relationship with specific DSM
criteria (Coyne, 1994). Therefore, their utility in diagnosing depression was limited. Personality
profiles such as the Millon Behavioral Medicine Diagnostic (Millon, Green, & Meagher, 1982)
were indicated for assessing personality profiles, not for diagnosing mental disorders. For
example, one study showed that the Millon Behavioral Medicine Diagnostic had inadequate
psychometric standards for internal consistency and low reliability and validity for use with bariatric surgical candidates (Walfish et al., 2008).

The BDI, a self-reporting screening instrument, was used in up to 55% of bariatric surgery practices for identifying depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961; Dixon & O’Brien, 2002; Averburkh et al., 2003; Dixon et al., 2003; Bauchowitz et al., 2005; Munoz et al., 2007). However, the biases of self-reported depression were numerous, such as different interpretations of meaning, skipping questions, and nondisclosure (Frank & Dingle, 1999). Also, screening instruments, such as the BDI may have erroneously classified subjects with depression since they do not incorporate all DSM-IV-TR criteria.

The DSM was the most accepted and frequently used reference for the diagnoses of mental disorders in the U.S. (Cohen, 2004). The gold standard of a structured clinical interview according to the standardized nomenclature of the DSM-IV-TR was recommended for the diagnoses of mental disorders (Scholtz et al., 2007).

In this study, the diagnoses of major depressive episodes were based on the DSM-IV-TR criteria. These criteria required the exclusion of symptoms that were direct physiological effects of a general medical condition. Ruling out medical causes and other mental illnesses often mistaken for major depressive episodes (e.g., depression secondary to a general medical condition, substance abuse, or psychological factors affecting a general medical condition) was not possible with scales of general psychopathology, personality profiles, screening instruments, self-reports, ICD-9 codes or antidepressant medications listed in medical records.

**Different post-operative regimens.** Results of this study were not consistent with prior studies. An inverse association between depression and adherence to treatment regimens, and specifically to obesity treatment regimens, had been documented (Kiley, Cow, Lam, & Pollack,
The association between depression and adherence to the post-operative regimen after LAGB was examined in two reports (Poole et al., 2004; Poole et al., 2005). Psycho-behavioral factors that predicted non-adherence to the post-operative diet via pouch dilation were examined in the first report. Results showed a positive association between non-adherence to the post-operative diet and affective disorders, specifically depression. All subjects with pouch dilation reported a history of major depression (Poole et al., 2004). However, psycho-behavioral factors were not defined and pouch dilation also may have been due to the creation of an oversized pouch or band slippage (Poole et al., 2004). Additionally, the report did not specifically focus on the association between depression and adherence to follow-up appointments, diet, and physical activity after LAGB. Therefore, the comparability of results between the current study and the prior report was limited. Moreover, the report included 18 subjects. Nine subjects were defined as adherent to the post-operative diet and the other nine subjects were non-adherent. This small sample size limited the generalizeability of the results.

In the second report, psychological characteristics were associated with poor adherence to follow-up appointments and diet. However, psychological characteristics, diet, follow-up appointments, and depression were not defined. Also, subjects with severe depression were excluded for unknown reasons (Poole et al., 2005). Moreover, this report was not focused specifically on the association between depression and adherence to follow-up appointments,
diet, and physical activity. Therefore, the comparability of results between the current study and this report was limited.

Based on the findings of this study and past studies, the association between depression and adherence to post-operative regimen remains unclear. Studies have shown an inverse association between depression and adherence to various treatment regimens. However, no previous studies directly examined the association between depression and adherence to follow-up appointments, diet, and physical activity after LAGB.

**Hypothesis 2: The association of adherence and weight loss.**

Based on the SRT, it was hypothesized that subjects who were adherent to the post-operative regimen would lose more weight after LAGB than those who were non-adherent. Subjects who were adherent to the 6-month physical activity lost more weight (27.3 %EWL) than those who were non-adherent (23.4 %EWL). Also, subjects who were adherent to the 12-month diet lost more weight (43.4 %EWL) than those who were non-adherent (34.8 %EWL). There was no difference in %EWL based on adherence to the 6-month diet or 12-month physical activity. These findings were not anticipated given the feedback mechanism of the SRT. The definition of adherence to the post-operative regimen, which was previously discussed, may have contributed to the inconsistent results. Also, although increased adherence to the post-operative regimen was hypothesized to lead to increased weight loss after LAGB, results were inconsistent. Perhaps subjects lost weight without adhering to the post-operative regimen due to the anatomical changes with the LAGB.
Comparison of results between the present study and previous studies on adherence to the post-operative regimen and weight loss.

Results of two previous studies showed a positive association between adherence and weight loss after LAGB (Shen et al., 2004; Pontiroli et al., 2005). The discrepancy between the results of this study and previous studies may have been due to different definitions of adherence to the post-operative regimen.

Follow-up appointments occurred at three weeks and every three months after LAGB in the first study. Subjects who were adherent to six or less follow-up appointments were compared with those who were adherent to more than six appointments. Weights were obtained from office scales or by telephone interview. Results showed that subjects who were more adherent to follow-up appointments experienced a greater %EWL than those who were less adherent. It was concluded that band adjustments at follow-up appointments were important to achieve clinically significant weight loss after LAGB (Shen et al., 2004). However, the association between adherence to follow-up appointments and weight loss after LAGB was difficult to critically appraise given the potential biases associated with self-reporting of weight. Also, the association between adherence to post-operative diet and physical activity and weight loss was not assessed.

In the second study, a set of predictors of clinical outcomes after LAGB that included adherence were examined. Follow-up appointments were scheduled every two weeks for two months, then monthly for a year. Poor adherence was defined via subjects’ self-report of continued inability to follow diet and physical activity regimens up to 12 months after LAGB. Results suggested a positive association among adherence to follow-up appointments, “rules”, and weight loss 12 months after LAGB (Pontiroli et al., 2005). However, the methods used to measure post-operative weights were not stated and adherence to diet, physical activity, and
“rules” was not defined. Also, adherence to follow-up appointments was defined differently in the present study and the two previous studies. Therefore, comparisons of the results of this study and the two prior studies were not possible.

**Hypothesis 3: The association between depression and weight loss.**

The hypothesized inverse association between depression and weight loss after LAGB was not supported. Different definitions of depression and different bariatric procedures, as well as changes in the states of depression and instrumentation, which were previously discussed, may have contributed to the unanticipated results of this study and previous studies.

**Comparison of results between the present study and previous studies on depression and weight loss.**

*Different definitions of depression.* Findings of previous studies on the association between depression and weight loss after bariatric surgery were mixed. Weight loss after LAGB was independent of depression in two previous studies. However, the BDI was used to define depression in these studies (Dixon, Dixon, & O’Brien, 2001; 2003). Another study used the presence of depression in the medical history to identify depression (Busetto et al., 2002). The limitations of using depression screening instruments, such as the BDI or the presence of depression in the medical history were explained previously in the discussion of Hypothesis 1. Although the BDI is the most commonly used measure of depression as a predictor of weight control, it did not adequately identify subjects with a low likelihood of successful weight management (Teixeira, Going, Sardinha, & Lohman, 2005). Depression should be identified via a structured clinical interview according to the standard nomenclature of the DSM-IV-TR. In the present study, major depressive episodes were defined in this manner.
Different bariatric procedures. Bariatric procedures, such as LAGB and gastric bypass involved different pre-operative routines, definitions of adherence to the post-operative regimen, and mechanisms of weight loss. Laparoscopic adjustable gastric banding was solely a restrictive procedure; whereas, gastric bypass involved caloric restriction, alterations in gastrointestinal hormones and nutrient absorption, and changes in energy metabolism which resulted in greater weight loss when compared to LAGB (Kenler, Brolin, & Cody, 1990; Brolin, Robertson, Kenler, & Cody, 1994; Flancebaum, Choban, Bradley, & Burge, 1997; Hell, Miller, Moorehead, Samuels, 2000; Dixon, Dixon, & O’Brien, 2001; Busetto et al., 2002; Dixon, Dixon, & O’Brien, 2003; Moize et al., 2003; Colquitt, Clegg, Sidhu, & Royle, 2004). Equal comparisons were not possible between this study and previous studies due to different bariatric techniques.

Hypothesis 4: The interaction of depression and adherence.

The hypothesis that there was an interaction between depression and adherence to the post-operative regimen in their effects on the %EWL after LAGB was not supported. Therefore, any effects of depression and adherence to the post-operative regimen on %EWL after LAGB were not interdependent. The lack of an interaction may have been due to confounding factors and study limitations that were previously discussed. Prior studies have not considered the interaction between depression and adherence to the post-operative regimen on weight loss after LAGB; therefore, comparisons were not possible.

Secondary analyses.

Potential confounding effects of age and sex.

Age and sex were potential confounders on the association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased %EWL after LAGB. Increasing age and female sex were associated with increased rates of depression in
previous studies (Nolen-Hoeksema, 1987; Mirowsy & Ross, 1992; Kessler et al., 1993; Bebbington, 1998; APA, 2010).

Age. Results of prior studies showed that younger subjects lost more weight than older subjects (Busetto et al., 2002; Averburkh et al., 2003; Capella & Capella, 2003). Increasing age negatively influenced the %EWL 12 months after LAGB in another study (Dixon, Dixon, & O’Brien, 2001). Perhaps younger subjects had less comorbidities and better mobility, making adherence to physical activity and subsequent weight loss more likely to occur. In this study, there were no differences in age between depressed and non-depressed subjects. This was expected given that the average age of subjects was 42.6 years, which was not considered advanced age; furthermore, advanced aged subjects (e.g., ≥65 years) rarely underwent LAGB. Also, age did not affect the hypothesized association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased %EWL after LAGB.

Sex. The association between sex and weight loss in previous studies was mixed. Being male was predictive of poorer weight loss after LAGB in one study (Busetto et al., 2002). However, results of another study suggested that sex was not predictive of greater weight loss after LAGB (Dixon, Dixon, & O’Brien, 2001). Females comprised the majority of subjects in this study and previous LAGB studies (Busetto et al., 2002; Dixon, Dixon, & O’Brien, 2003; Ren & Fielding, 2003; Dixon, Anderson, Cameron-Smith, & O’Brien, 2004; Holloway, Forney, & Gould, 2004; Mathus-Vliegen, de Weerd, & de Wit, 2004; Fielding & Duncombe, 2005; Jan, Hong, Pereira, & Patterson, 2005; Poole et al., 2005; Galvani et al., 2006; Myers, Sarker, & Shayani, 2006; Ponce, Fromm, & Paynter, 2006; Pontiroli et al., 2007; Colles, Dixon, & O’Brien, 2008; Wheeler, Prettyman, Lenhard, & Tran, 2008). There were more non-depressed females than
depressed females in this study. This was not surprising given that the majority of LAGB subjects are females without depression.

*Association among the number of individual components of the post-operative regimen to which subjects with and without depression adhered and the %EWL.* There was no difference in the number of post-operative regimen components to which subjects with and without depression adhered. Also, the number of post-operative components to which subjects adhered was not correlated with the %EWL after LAGB. Therefore, the use of a binary definition versus a continuous definition of adherence to the post-operative regimen was not a study limitation.

*Association between the symptoms of depression and individual components of the post-operative regimen.* The association between the symptoms of a major depressive episode and adherence to the individual post-operative regimen components had not been examined. It was possible that one of the nine symptoms of a major depressive episode was closely related to one of the individual components of adherence to the post-operative regimen. It was anticipated that certain symptoms of a major depressive episode, such as anergia and impaired appetite would impact subjects’ ability to adhere to specific post-operative regimen components, such as adequate physical activity and appropriate dietary choices. However, results suggested that symptoms of a major depressive episode were not related to adherence to individual components of the post-operative regimen.

*Adherence to the post-operative regimen and the %EWL among subjects with a history of prior depression.* Due to the chronicity of depression, it was anticipated that adherence to the post-operative regimen and %EWL after LAGB would be similar between subjects with a history of prior depression and those with current depression. Eleven subjects with a history of prior depression were included with the 112 subjects with current depression in the primary
analyses. In the secondary analyses, subjects with a history of prior depression were compared with those with current depression and those without depression. Results showed no difference in adherence to the post-operative regimen and %EWL after LAGB between subjects with a history of prior depression and those with current depression. There was also no difference in adherence to the post-operative regimen and %EWL between subjects with a history of prior depression and those without depression. Therefore, the inclusion of subjects with a history of prior depression with those with current depression did not bias the results for Hypotheses 1, 3, and 4.

**Post-hoc Power Analysis**

This study was designed to have sufficient power to detect the effects of depression and adherence to the post-operative regimen, and subsequent %EWL after LAGB. After the study was completed, the actual effect sizes that could have been detected based on the distribution of subjects with depression (N=112) and those without depression (N=134) was determined. There was 80% power to detect an odds ratio of 2.2 using a $\chi^2$ test to examine if adherence to the post-operative regimen was independent of depression. $T$-tests were used to examine the associations between adherence to the post-operative regimen and %EWL and between depression and %EWL. The $t$-tests were powered at 80% to detect an effect size of 0.38. Alpha level was set at 0.05 for statistical significance testing. Based on these calculations, the study had observed power similar to what was planned.

**Strengths of the Study**

Despite the study’s limitations, there were strong points. This was the first investigation known to the PI on the association between increased depression and decreased adherence to the post-operative regimen, and subsequently decreased weight loss at 6 months and 12 months after
LAGB. This study was important because the results added to the limited and equivocal research on factors that were associated with adherence and subsequent weight loss after LAGB.

The major strength of this study was the diagnoses of depression via structured diagnostic interviews based on DSM-IV-TR criteria for a major depressive episode by a certified and experienced mental health clinician. An additional strength was rigorous data collection via the DCF by a trained clinician.

**Implications for Nursing Practice**

The recommendation for the pre-operative mental health evaluation resulted from the NIH (1991) Conference Panel which convened nearly two decades ago, before LAGB was approved by the Food and Drug Administration. The panel did not comment on specific mental illnesses that may have affected adherence to the post-operative regimen and weight loss after LAGB. Results of this study showed that depression was not associated with adherence to the post-operative regimen and weight loss after LAGB. This was an important negative finding because up to 95.1% of bariatric surgery programs considered depression a contraindication for surgery (Bauchowitz et al., 2005). It was assumed that subjects with depression were at increased risk for non-adherence to the post-operative regimen, and subsequently decreased weight loss after bariatric surgery. However, results of this study and previous studies did not provide evidence for that assumption. This insufficient evidence raises questions about denials or delays of LAGB based on depression.

Additionally, the NIH panel for Gastrointestinal Surgery for Severe Obesity did not propose guidelines for the pre-operative mental health evaluation. These guidelines still do not exist, yet the pre-operative mental health evaluation continues to be a determinant for LAGB candidacy. Consequently, mental health specialists developed their own screening procedures...
and recommendations for LAGB candidacy without sufficient evidence (Bauchowitz et al., 2005). Based on this lack of evidence, healthcare professionals who care for LAGB patients and health insurers involved in determining coverage for LAGB should consider that the association between depression, adherence to the post-operative regimen, and weight loss after LAGB remains unclear.

Although depression did not impact adherence to the post-operative regimen and weight loss after LAGB, it was commonly found among bariatric surgery patients. Forty-six percent of the subjects in the current study had pre-operative depression, similar to rates found in previous studies of bariatric patients (Bond, Phelan, Leahy, Hill, & Wing, 2009; Sarwer et al., 2008; Buddeburg-Fischer, Klaghofer, Sigrist, Buddeburg, 2004; Sogg & Mori, 2004; Averburkh et al., 2003; Clark et al., 2003; Cohn, 2003). Also, results of one study showed a substantial excess of deaths among bariatric surgery patients due to suicide (Omalu et al., 2005). Therefore, it is essential that nurses and other healthcare professionals promptly identify depression before and after LAGB and make appropriate referrals for treatment. Perhaps, depression persists after bariatric surgery despite successful surgical control of obesity.

**Implications for Future Research**

Very few investigations on the association among depression, adherence to the post-operative regimen, and weight loss after LAGB have been conducted. Results of these studies were difficult to compare due to the effect of confounders, study limitations, different bariatric procedures, and varying definitions of depression and adherence to the post-operative regimen. Therefore, studies using the same criteria for depression, standardized definitions of adherence to the post-operative regimen, and similar bariatric procedures are indicated to adequately examine the association among depression, adherence, and weight loss after LAGB. Additionally,
assessment of depression at frequent intervals after surgery, based on DSM-IV-TR criteria is needed to account for changes in the state of depression.

Little data exist on how to best evaluate LAGB candidates (Bauchowitz et al., 2005). If the pre-operative mental health evaluation is used in determining LAGB candidacy, patients, healthcare professionals, and healthcare insurers are entitled to know that insufficient evidence exists to substantiate its use for this purpose (Ashton, Favretti, & Segato, 2008).

Studies on psychiatric variables as prognostic indicators of adherence to the post-operative regimen, and subsequent weight loss are needed. Results of these studies may inform the debate about whether or not pre-operative mental health evaluations are needed to assess LAGB candidacy.

Also, in future studies, the pre-operative mental health evaluation should be conducted by a trained mental health clinician who is not the PI to decrease the risk of investigator and recall bias. Moreover, pre-operative mental health evaluations independent of the LAGB approval process are needed to enhance LAGB candidates’ willingness to disclose personal information that they perceive as increasing the risk for delay or denial of surgery (Kalarchian et al., 2007).

Results of this study and previous studies suggested that the association among depression, adherence to the post-operative regimen, and weight loss after LAGB remain inconsistent. Predictors of adherence to the post-operative regimen and subsequent weight loss after LAGB have yet to be identified. The etiology of obesity is complex and involves many factors such as physiology, metabolism, and environment. These factors and others such as self-efficacy, genetics, socio-economic status, and ethnicity should be considered in further studies. Identification of both positive and negative influences on adherence to the post-operative regimen, and subsequent weight loss is essential because LAGB is often the last resort for
improved health (Benotti & Forse, 1995; Puzziferri, 2005; Kalarchian et al., 2007). Results of these studies may lead to theory building and the development of evidence-based nursing care of LAGB patients. Recognition of positive predictors of adherence to the post-operative regimen and weight loss may assist nurses and help LAGB patients to formulate tailored plans to achieve realistic goals, overcome barriers, reduce frustrations, increase self-confidence, and maintain adherence behaviors and weight loss in the long term.

Studies should be conducted on the relative importance or “weight” of adherence to individual components of the post-operative regimen that contribute most to weight loss and overall health after LAGB. It was possible that one or more components of the post-operative regimen, such as avoiding high-fat foods contributed more to weight loss after LAGB, than another component, such as taking a multivitamin daily. This approach was used to examine the association among adherence to scheduled follow-up appointments, diet, physical activity, and other recommendations and weight loss after LAGB in a previous study (Pontiroli et al., 2007). Results of these studies may lead to the development of an instrument that considers integrated adherence to follow-up appointments, diet, and physical activity via a summed score.

More reliable measures of adherence to the post-operative regimen require exploration in future studies. In the meantime, a food diary, the Block Food Frequency Questionnaire (Block et al., 1986), 24-hour food recall, or indirect calorimetry (Wadden & Sarwer, 2006) could be used to increase the accuracy of reporting adherence to the post-operative diet. To increase the accuracy of reporting adherence to the post-operative physical activity, a physical activity log, pedometer, or record of attendance at a gymnasium could be used. Also, measurement of adherence to the post-operative regimen at more frequent intervals (e.g., bi-monthly) after LAGB is also warranted.
Measures to decrease the threat of instrumentation should be employed in future studies. Formulating adherence and weight measurement protocols, adequate training on the use of weight scales, calibration of weight scales as recommended by the manufacturer and data collection checks are recommended for future studies to decrease the potential for instrumentation.

Dropout of 61 subjects from baseline to the 12-month follow-up appointment may have biased this study’s results. Prospective studies employing procedures to decrease dropout rates, as well as attempts to obtain data on subjects lost to follow-up are recommended (Schultz & Grimes, 2002). Data imputation methods such as last observation carried forward, multiple imputation methods, or mixed models that do not require imputation could be used in future studies (Liu & Gould, 2002; Gadbury, Coffey, & Allison, 2003).

Subjects in this study were assessed before and after LAGB by the same two surgeons, two RNs, and one psych-CNP in one bariatric practice in the Midwest. The same two surgeons performed all the subjects’ LAGB surgeries. It was possible that subjects in this study were not representative of the entire LAGB population. Studies on the association between depression and adherence to the post-operative regimen, and subsequent weight loss after LAGB should be conducted on subjects from various practices in other regions to increase generalizeability.

The theoretical framework was not tested (e.g., path analyses or structural equation modeling). However, the results of this study suggest that the proposed model describing the association between increased depression and decreased adherence to the post-operative regimen, and subsequent weight loss after LAGB was complex. Therefore, future studies should seek to formulate an accurate framework depicting the association between depression and
adherence to the post-operative regimen, and subsequent weight loss after LAGB while considering potential confounders.

The SRT was also not measured in this study. Therefore, studies should be conducted to evaluate the use of the SRT as an appropriate conceptualization of adherence to the post-operative regimen and weight loss after LAGB.

Finally, results of one long-term follow-up study showed “treatment failure” or a %EWL < 25% in 36.9% of LAGB subjects after seven years (Suter, Calmes, Paroz, & Giusti, 2006). Therefore, long-term studies on the association of adherence and weight loss over more than one year are needed.

**Conclusion**

In light of the confounders and study limitations, results suggested that 1) adherence to the post-operative regimen was independent of depression; 2) the association between adherence to the post-operative regimen and weight loss after LAGB was mixed; 3) weight loss after LAGB was independent of depression; and 4) there was no interaction of depression and adherence to the post-operative regimen in their effects on weight loss after LAGB. Findings of this study and previous studies underscore the need for continued research to determine if pre-operative mental health evaluations are needed to aid in determining LAGB candidacy. Future research is needed to identify the essential components of the post-operative regimen which would lead to the most successful outcomes after LAGB. Results of these studies may result in nursing theories, frameworks, and improved evidence-based care of LAGB patients focused on maintaining adherence to the post-operative regimen and weight loss.
References


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Appendix A

Instructions for Subjects Before and After LAGB

An extensive clinical multidisciplinary examination was performed on all subjects by a surgeon, RN, and psych-CNP to determined LAGB candidacy. The importance of adhering to follow-up appointments, diet, and physical activity was emphasized by all LAGB staff.

Subjects were informed that adherence to follow-up appointments was essential for appropriate band adjustments, further education, reinforcement of pre-operative and post-operative instructions, and support. During follow-up appointments, the RN or surgeon reviewed baseline information (i.e., surgery date, surgeon who performed the procedure, pre-operative weight in pounds, pre-operative BMI), date of most recent follow-up appointment, weight in pounds at last appointment, number of previous adjustments, and goal weight. Subjects were asked if they experienced hunger, ability to eat bread and eat large portions, nausea and vomiting, or reflux. If subjects experienced vomiting, nausea, or reflux, they were reminded to eat less food and more slowly, and to chew food more thoroughly to prevent the stomach from being obstructed by a large portion of unchewed or inappropriate food, such as bread.

A follow-up appointment was scheduled two weeks after LAGB. During this appointment, the surgeon ensured that incision sites were healing properly. The next follow-up appointment was scheduled in another four weeks for the initial band adjustment. However, the first adjustment may have been postponed to eight weeks to allow for further healing of the stomach or if complications occurred. After the second follow-up appointment, subjects were advised to self-monitor their eating behaviors, degree of satiety, and weight loss every two weeks to assess for further adjustments. Adjustments occurred until they reached their “sweet spot.” The “sweet spot” referred to the constriction of the stomal opening that slowed gastric emptying.
and led to early satiety. Early satiety led to decreased intake of food and subsequent weight loss. When subjects reached their “sweet spot” they were satiated with three to four ounces of meat and vegetables for four to five hours. On average, it took three to six adjustments to reach the “sweet spot.” However, the “sweet spot” sensation was different for each subject because of varying amounts of fat around the stomach. Also, the number of adjustments varied because saline volume in the band varied among subjects (Shen et al., 2004).

Subjects were instructed to follow-up with the RN or surgeon if reflux or vomiting occurred. Reflux and vomiting may have indicated too much constriction which may have required an “unfill” (i.e., removal of saline from the band). Subjects were also advised that as they lost weight, fat around the stomach was lost which required further adjustments. Further adjustments were made based on subjects’ ability to eat large portions of food, but not staying satiated until their next meal; the ability to eat bread; or losing less than four pounds in two weeks. Subjects were advised to return to the office if they experienced the inability to swallow liquids, significant heartburn, acid reflux, vomiting, or loss of less than one pound per week.

Adherence to the post-operative diet and physical activity was assessed at follow-up appointments. Meal frequency and snacking (what foods and how often); adequate fluids, protein, fruits, vegetables, fiber; avoidance of calorie-dense, high-fat, and soft foods; MVI daily; physical activity; and support group attendance were assessed. The RN or surgeon often documented in the progress notes if subjects made inappropriate food choices, such as “mashed potatoes, entire chicken sandwich, onion rings, ice cream, alcoholic beverages, and fried potatoes.” Appropriate diet choices were also noted. The RN or surgeon also noted subjects’ reliability when recalling diet and physical activity. For example, “ate two fish fillet sandwiches without bread and a large order of fries and probably more.” The type of physical activity was
often noted, such as Curves, gazelle, gym, walking, and swimming. Band volume and the amount of saline added or removed for adjustments were recorded in the progress notes. It was documented if subjects cancelled or missed follow-up appointments. Medical records were reviewed by the RNs periodically for adherence to follow-up appointments. If subjects were non-adherent to follow-up appointments, the RN typically sent an email or telephoned subjects to obtain an update on the subjects’ progress, and to encourage them to adhere to follow-up appointments.

Adherence to the post-operative diet included significant changes in eating behaviors. Subjects were instructed to eat three small meals and one small snack daily. This was recommended because the pouch at the top of the stomach held only approximately 50 ccs and filled quickly, and the passage of food from the top to the bottom of the stomach was slowed. Therefore, the upper part of the stomach had an early sensation of satiety. This sensation helped subjects to eat smaller portions of food. However, if subjects ate inappropriate foods or too much too quickly, vomiting, reflux, and pouch dilation often occurred.

Subjects were also instructed to eat slowly and chew 15 to 20 times per bite until the food was of liquid consistency. This eating behavior aided in the sensation of fullness and decreased the risk of obstruction. Subjects were instructed to stop eating at the first hint of fullness to avoid pain, nausea, vomiting, reflux, or pouch dilation.

To maintain adequate hydration, subjects were instructed to drink six to eight glasses of water and 16 ounces of non-fat or 1% milk daily. Subjects were instructed to drink only low-calorie or non-caloric fluids. They were also instructed to avoid carbonated liquids which could cause pouch dilation and discomfort.
Subjects were instructed to avoid drinking fluids 30 minutes prior to meals, with meals, or for one hour after meals. This avoidance was necessary because fluids moved through the band quickly and pushed the food. Thus, subjects would not experience the sensation of fullness which defeated the purpose of the band.

The quantity of food consumed was drastically reduced after LAGB. Therefore, subjects were instructed to eat a nutrient-dense diet which (1) met protein needs (computed by RN); (2) limited the intake of high-fat proteins; (3) included 20 to 25 grams of fiber per day (4) and avoided calorie-dense, high-fat, soft, and starchy foods. Avoidance of soft foods, such as cream-based soups, ice cream, and mashed potatoes was emphasized because these foods exited the stomach pouch quickly, allowing the subject to eat more and causing hunger between meals.

Subjects were instructed to avoid starchy foods, such as bread, pasta, rice, and potatoes, as well as fibrous, tough, and stringy foods that tended to cause discomfort, nausea, or vomiting.

Subjects were informed that some LAGB subjects may have been able to tolerate these foods, but making appropriate foods choices was of critical importance.

Subjects were instructed to engage in a minimum of 30 minutes of calorie-burning physical activity daily. Subjects were given examples of appropriate physical activities, such as walking and water aerobics.
Appendix B

Pre-operative Mental Health Evaluation

The pre-operative mental health evaluation was part of the pre-operative routine to assist in determining a candidate’s suitability for LAGB. It was assumed that mental illnesses among LAGB subjects led to increased risk of non-adherence to the post-operative regimen and less weight loss. Therefore, the main focus of the evaluation was to assess for mental illnesses and possible barriers to adherence to the post-operative regimen and weight loss. Subjects were informed that optimal weight loss and prevention of weight regain after LAGB required lifestyle changes, such as dietary restrictions and changes in eating behaviors. Subjects were also informed of possible altered body sensations and body image after LAGB, as well as the possibility of relationship changes. For instance, some patients “grieved” over the loss of their “friend” which was food after bariatric surgery (Vaidya, 2006). Subjects were informed that the onset of a mental illness, such as depression or anxiety was possible after LAGB. Subjects were advised to follow-up with the psych-CNP or their own mental health specialist, if they experienced depression or another mental illness after LAGB. Subjects were given a list of mental health providers in the community who could provide mental health treatment.

Subjects who were diagnosed with a mental illness, such as depression, or had under-treated mental illness at the pre-operative mental health evaluation were prescribed medications or advised to follow-up with their primary care physician or mental health specialist for treatment. Subjects were also advised to follow-up with counseling or psychotherapy. If medications were prescribed to subjects at the pre-operative mental health evaluation, they were advised to follow-up with the psych-CNP for continued treatment.

The psych-CNP reviewed subjects’ medication lists at the pre-operative mental health evaluation. If subjects were prescribed psychotropic medications known to have side effects
such as increased appetite and weight gain, the psych-CNP discontinued the medication and prescribed a similar medication that was weight “neutral” or advised subjects to follow-up with their primary care physician or mental health specialist for a medication evaluation.

During the pre-operative mental health evaluation, subjects were questioned about barriers to adherence to the post-operative regimen. If no barriers were identified, the psych-CNP discussed examples of typical barriers to adherence, such as depression, anxiety, family and work obligations, emotional eating, or job-related traveling. The psych-CNP and the subjects then discussed and planned for ways to deal with barriers. Subjects with poor coping skills, such as emotional eating were advised to follow-up with counseling or therapy to aid in the adoption of more appropriate coping skills. Subjects were informed that LAGB was not a cure for obesity, but a “tool” that could assist with weight loss if used in conjunction with adherence to the post-operative regimen. Subjects were encouraged to attend monthly support groups and access the on-line support group.
Appendix B: Pre-Operative Mental Health Evaluation (continued)

Pre-operative Bariatric Mental Health Evaluation Information Sheet

Name: ________________________________________________  DOB: ________________
Date: ________________

Developmental History: (details or complications of pregnancy; developmental delays; or childhood trauma)

Social History: (marital status, household members, occupation, etc.)

Past Psychiatric History: (previous psychiatric symptoms, hospitalizations, and treatments)

Abuse History: (to subject: sexual, physical, or emotional)

Family History: (psychiatric and obesity)

Current and Past Drug and ETOH Abuse History: (recreational, prescribed)
Appendix B: Pre-operative Mental Health Evaluation (continued)

**Weight History:** (onset of overweight/obesity)

Heaviest Lifetime Weight (lbs) _________

**Weight Loss History:** (most weight lost, longest maintained; weight loss methods)

Current Weight (lbs) _________

RN/ Surgeon calculated weight loss goal at initial appt (lbs) _________

Weight loss goal (lbs) _________ Is it realistic? (y/n) _________

Is the subject aware of the behaviors and lifestyle changes that will have to be made to meet and attain their weight loss goal and/or the weight loss goal calculated at the initial appointment? (y/n) _________

If so, what changes will be made?

Does the subject identify current or potential barriers to adhering to the post-operative regimen? (y/n) _________

If so, how will he or she overcome these?

Why does the subject believe LAGB will work when other past approaches have failed?

What does the subject think will be most difficult after surgery (i.e. diet, follow-up appointment attendance, exercise)?
Appendix B: Pre-operative Mental Health Evaluation (continued)

**Current/Recent Stressors:**
Have there been any major changes, adjustments, or stressful situations in the subject’s life or typical routine? If so, what are these?

**Means of Coping:**

**Eating Behaviors:** (emotional, binge)

Other inappropriate eating behaviors (snacking, grazing, skipping meals)

**Food Preferences:**

**Frequency of Eating Out** (where):

**Physical Activity:**
Current exercise:

Post-operative exercise plan:

Reported barriers to exercise plan:

**Support System:**

**Identifiable Saboteurs:**
Appendix B: Pre-operative Mental Health Evaluation (continued)

Mental Status Exam:

1. **Appearance:** Neatly dressed with clear attention to detail? Well groomed? Level of alertness; ability to remain focused on the questions and conversation; attention span? Have striking physical features or physical stigmata (i.e. tattoos)?

2. **Level of Alertness:** Is the subject conscious? Ability to remain focused on the questions and conversation; attention span?

3. **Speech:** Tone, rate, rhythm, pattern, volume, and quantity; perseveration, use of neologisms, puns, or rhymes?

4. **Behavior:** Pleasant? Cooperative? Agitated? Appropriate for the particular situation? Attitude towards the examiner? Demeanor, manner and mannerisms, rapport, and eye contact? Describe facial expressions, posture, motor activity (agitation/retardation), abnormal movements (tics, chorea, and tremor), stereotyped behaviors, or gait abnormalities. General health?

5. **Awareness of Environment** (also referred to as orientation): Person, place, time situation

6. **Mood:** Describe; Appropriate for the situation?

7. **Affect:** Appearance to the examiner; eye contact? Excitable? Appropriate inflection with tone?

8. **Thought Process:** Logical, organized fashion? If not, explain (i.e., thought blocking, slowed, disjointed, flight of ideas, tangential, circumstantial).

9. **Thought Content:** Paranoia, delusions, perceptual disturbances; obsessions/depersonalization; suicidal or homicidal ideation; plans/intent?

10. **Memory:** Recall (short-term, long term, and remote).
11. **Ability to Perform Calculations**: Simple addition, multiplication? Are the responses appropriate for their level of education? Have they noticed any problems balancing their checkbooks or calculating correct change when making purchases? This is also a test of the subject's attention span/ability to focus on a task.

12. **Judgment**: Provide a common scenario and ask what they would do (e.g. "If you found a letter on the ground in front of a mailbox, what would you do with it?").

13. **Insight**: Awareness of the problem and their level of understanding?

14. **Higher Cortical Functioning and Reasoning**: Interpretation of complex ideas. For example, you may ask them the meaning of the phrase, "People in glass houses should not throw stones." A few common interpretations include: concrete (e.g. "Don't throw stones because it will break the glass"); abstract (e.g. "Don't judge others"); or bizarre.

15. Is a Folstein Mini-Mental Status Exam indicated? If so, ______/30.

Axis I:

Axis II:

Plan:

Based on the psychiatric evaluation, is the subject appropriate for LAGB from a mental health standpoint?

(y/n) _______

OR

Is the subject a candidate with the following mental health recommendations?

(y/n) _______

If not, why?
## Appendix C

### Psychiatric Review of Systems

The psychiatric review of systems was a useful screening tool for identifying subjects who have a mental illness. It was part of the routine paper-work subjects were instructed to complete prior to meeting with the RN, surgeon, and the psych-CNP. The subjects were asked to circle the appropriate response about the following current psychological symptoms:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Feeling down</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Suicidal episodes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Mood swings for days at a time</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Hospitalized for psychiatric reasons</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Use of ETOH or drugs to cope</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Hospitalized for substance abuse</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Eating disorder</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Vomiting to lose weight</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Fasting to lose weight</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Laxatives to lose weight</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Life more stable than a year ago</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>If &lt; 18 y/o, history of frequent school absence</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>History of sexual abuse</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Psychiatric medication in the past or present</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Overeat in reaction to feelings</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Intend other weight loss surgery in the next year</td>
<td>yes</td>
<td>no</td>
</tr>
</tbody>
</table>

Age when you first became overweight: _____ years old
Appendix D
Data Collection Form

Study ID# ____________________________

Date of MH evaluation __________________ Treated by PI ________ (Y/N)

For 1° analysis: Depression (current or history of) ________ (Y/N)

For 2° analysis: Depression: Circle one

Current  OR  History of

Weight

Pre-operative weight: (lbs) __________ Pre-operative body mass index: __________

Ideal body weight: (lbs) __________ Excess weight: (lbs) __________

%Excess body weight: ____________

Taking antidepressants: _______ (Y/N)

Adherence up to 6 months

Post-Operative Regimen:

Followed-up at 5, 6, or 7 months after LAGB (Y/N) _______

%EWL ____________  # of adjustments to date _______

Last weight in lbs (m/d/yr) ____________ (  /  /  )

Current weight (lbs) ____________

Number of lbs: lost ____________ gained ____________

1st adjustment _______ (Y/N)  Previous # of adjustments _______

Support group attendance _______ (Y/N)

Online support _______ (Y/N)
Appendix D: Data Collection Form (continued)

Post-Operative Diet:

_____ Adequate fluids

_____ Adequate protein

_____ Adequate fruits and vegetables

_____ Adequate fiber

_____ Avoidance of sweets

_____ Avoidance of junk foods

_____ Avoidance of fried foods

_____ Avoidance of high-fat foods

_____ Avoidance of soft foods

_____ Avoidance of fast foods

_____ Avoidance of high-calorie beverages

_____ Daily MVI

_____ Eating slowly and chewing adequately (approximately 15 chews per bite)

_____ Avoidance of large volumes of food (greater than 50 cc)

_____ Not eating past the first hint of fullness

_____ Not drinking thirty minutes prior to meals, during meals, and/or one hour after meals

_____ Eating three meals and no more than one small low-fat snack that contains no more than 200 calories per day
Appendix D: Data Collection Form (continued)

Physical Activity:

_____ Participating in a minimum of 30 minutes daily of physical activity or the equivalent of 210 minutes over 158 hours

Follow-Up Appointments:

Appendix D: Data Collection Form (continued)

_____ No more than two missed appointments
_____ No more than two cancelled appointments
_____ Having three or fewer follow-up appointments six months after LAGB
_____ Having four or fewer follow-up appointments 12 months after LAGB

Adherence up to 12 months

Post-operative Regimen:

Followed-up at 11, 12, or 13 months after LAGB (Y/N) _______

%EWL ____________   # of adjustments to date _______

Last weight in lbs (m/d/yr) ____________ (   /  / )

Current weight (lbs) ____________

Number of lbs: lost ____________ gained ____________

1st adjustment _______ (Y/N)    Previous # of adjustments _______

Support groups _______ (Y/N)

Post-Operative Diet

_____ Adequate fluids
_____ Adequate protein
_____ Adequate fruits and vegetables
Appendix D: Data Collection Form (continued)

_____ Adequate fiber
_____ Avoidance of sweets
_____ Avoidance of junk foods
_____ Avoidance of fried foods
_____ Avoidance of high-fat foods
_____ Avoidance of soft foods
_____ Avoidance of fast foods
_____ Avoidance of high-calorie beverages
_____ Daily MVI
_____ Eating slowly and chewing adequately (approximately 15 chews per bite)
_____ Avoidance of large volumes of food (greater than 50 cc)
_____ Not eating past the first hint of fullness
_____ Not drinking thirty minutes prior to meals, during meals, and/or one hour after meals
_____ Eating three meals and no more than one small low-fat snack that contains no more than 200 calories per day

Physical Activity:

_____ Participating in a minimum of 30 minutes daily of physical activity or the equivalent of 210 minutes over 158 hours
Appendix D: Data Collection Form (continued)

**Follow-Up Appointments:**

- No more than two missed appointments
- No more than two cancelled appointments
- Having three or fewer follow-up appointments six months after LAGB
- Having four or fewer follow-up appointments 12 months after LAGB

**Secondary analyses:**

**Number and type of symptoms** among subjects with a history of depression and those with current depression: (check all that apply)

- Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).
- Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
- Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.
- Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
- Fatigue or loss of energy nearly every day
- Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
- Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
- Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

**Total number of symptoms:** ______________

Sex: _____  Age: _____

Types & total number of comorbidities: