Longitudinal Assessment of Bariatric Surgery (LABS-3): Psychosocial Issues and Bariatric Surgery

Design Synopsis

Hypotheses

1. Patients undergoing bariatric surgery will experience significant decreases in the rates of psychopathology, in particular depressive illness, and significant improvements in quality of life, post-operatively.
2. Untreated psychopathology that persists well beyond the surgery (e.g. to one-year follow-up) or that develops post-operatively will be associated with less weight loss and decreased quality of life.
3. Untreated psychopathology at the time of bariatric surgery, including affective disorders and substance abuse/alcohol abuse will be associated with increased short-term (e.g. 90 day) complications (e.g. problems with plugging, vomiting, and dehydration)
4. Syndromal/subsyndromal eating disorders prior to surgery including binge eating disorder and night eating syndrome will be associated with eating disorder symptoms and less weight loss at long-term follow-up.
5. Greater levels of affect dysregulation, greater deficits in cognitive control and greater deficits in reward processing will be associated with less favorable outcomes (higher affective disorder rates, less favorable net weight change, and increased eating disorder pathology/alcohol use pathology) following surgery.

Type of Study

- Prospective cohort study done at three (3) LABS centers.

Inclusion Criteria

- Male and female patients who are at least 18 years of age and undergo bariatric surgery by a LABS certified surgeon.
- Previous enrollment in LABS-1 and LABS-2.
- BMI at baseline of greater than or equal to 35.

Exclusion Criteria

- Informed consent not obtained
- Type 1 Diabetes Mellitus
- Unlikely to comply with follow-up protocol (ie: geographically inaccessible for study visits)
- Unable to communicate with local study staff

Sample Size

- In order to sample a sufficient number of subjects with significant psychopathology at baseline, the sample size for the assessment of psychopathology is 250. The assessment of eating behavior will be done on a subset of 100 subjects.

Duration of Follow-up

- Up to 7 years following bariatric surgery

Outcomes

- Changes in medical and psychosocial measures

Data Collection Schedule

- The LABS-3 Psychosocial baseline data will be collected within 30 days prior to bariatric surgery.
- Follow-up assessments will occur approximately 12 months and annually thereafter up to 7 years following date of bariatric surgery with an additional assessments at 6 and 18 months following the date of bariatric surgery.
- Participants at NRI who have completed the 7 year assessment will be recontacted to complete the additional 1 time measures and task. This will take place as close to the 7 year appointment as possible.

1 Introduction

1.1 Background. Obesity has become an alarmingly common problem for Americans, with more than 30.4% of adult Americans now being considered obese with a BMI greater than 30 (Hedley, et al., 2004). There is also growing awareness that most obesity treatments that attempt to change food intake and increase physical activity result in modest weight loss at best (Wadden, et al., 1999). Bariatric surgical procedures, on the other hand, particularly the last generation of procedures including RYGBP and Band procedures, have resulted in pronounced and clinically significant reductions in body weight which are well maintained at long-term follow-up. However, there are many aspects of bariatric surgery procedures that remain largely understudied, including predictors of response, feeding problems post-operatively, psychosocial adjustment, and long-term quality of life. The purpose of this study is to bring together expertise in these areas of interest to better understand the outcome of patients who undergo bariatric surgical procedures.

A. Psychopathology and Outcome of Bariatric Surgery

The literature addressing the relationship between comorbid psychopathology and bariatric surgical outcome, as well as long-term psychosocial adjustment and quality of life, is limited. In addition to the fact that only a finite amount of research has addressed these relationships; most of the literature has addressed these problems in ways which markedly limit the interpretability of what has been published:

1. In the vast majority of the published work, routine clinical interviews have been used rather than structured diagnostic psychiatric interviews. The validity and reliability of psychiatric diagnoses made on the basis of such interviews are quite limited, and such a methodology would be unacceptable in contemporary studies of comorbid psychopathology.
2. In most of the published literature, subjects were aware that the information obtained would be shared with the surgical team, and that the results of the interviews might impact on whether or not they would continue to be considered candidates for surgery. There would be a powerful incentive for these individuals to deny any current or previous forms of psychopathology which might decrease their chance of receiving the procedure. Indeed, as will be discussed, in our 13-15 year follow-up data set which used structured diagnostic interviewing, two subjects admitted to

having had problems with alcohol abuse and 8 to having had problems with alcohol dependence (representing 12.9% of the sample) prior to surgery, although none had admitted to such problems when evaluated prior to undergoing the procedure.

Because of these two problems, we believe that a careful assessment of psychopathology pre-surgically and longitudinally, particularly examining possible forms of psychopathology as predictor variables will require two things: 1) The use of validated, reliable structured psychiatric interviews, such as the SCID I and the EDE. 2) Subjects be made aware that part of the assessment will not be shared with the surgical team and will be used for research purposes only unless they admit to something that will significantly increase the risk of the procedure (e.g., risk of developing delirium tremens during hospitalization) or requires a prompt intervention (e.g., suicidal ideas).

Many symptoms of depression seen in the obese may result from the societal views and discrimination that they suffer as well as the physical and medical complications of being overweight (Wadden, et al., 2001). It also appears clear that the presence of binge eating, female gender, greater BMI, and greater impairments in quality of life increase the likelihood of both depression and anxiety (Wadden, et al., 2001; Fabricatore & Wadden, 2004). Women with a BMI greater than 30 have been shown to have a 37% higher likelihood of major depressive disorder within a year of assessment than normal or overweight females. Additionally, increased BMI in a general population study has been associated with major depression and suicide ideation among women, but not among obese men in the same population (Carpenter, et al., 2000). Glinski, et al. (2001) reported rates of comorbid psychopathology in subjects pre-bariatric surgery, finding 70% met lifetime criteria for at least one Axis I disorder (56% meeting lifetime criteria for major depressive disorder) and 50% having a current Axis I disorder. It appears also that the rate of personality disorders is also increased in this population compared to controls (Powers, et al., 1999).

In studies that have examined rates of comorbid psychopathology, most have found improvement post-operatively on psychological symptoms (Dixon, et al., 2001; Dymek, et al., 2001; Kalarchian, et al., 1999), although one study found depression as a complication (Kodama, et al., 1998). Herpertz, et al. (2004) recently reviewed this literature, including data from 40 studies which had a minimum follow-up period of at least one year. The overall finding was that weight loss surgery led to a decline in the presence of Axis I disorders but did not alter the course of Axis II disorders. Other research has found improvement in depressive symptomatology, and it is of note that the decrease correlated with the amount of weight loss at follow-up (Larsen & Torgersen, 1989; Larsen, et al., 2003). Also improvement in anxiety and phobias has been reported (Larsen, 1990; Hafner, et al., 1990). However, increased rates of psychopathology have been associated with less weight loss (Guisado, et al., 2002).

Rowston, et al. (1992) studied 16 bariatric surgery patients, 8 of who were characterized as having a history of "self-damaging and addictive behaviors". The presence of such behaviors was not a predictor of poor outcome. Guisado, et al. (2001) compared 40 "psychiatric obese" to 60 "non-psychiatric obese" subjects, finding that comorbid psychopathology established in clinical interviews correlated with binge eating behavior but wasn't shown to have predictive potential. Powers, et al. (1988) reported that patients who had an Axis I comorbid disorder diagnosed through clinical interview had more postoperative complications following bariatric surgery, an important finding we will attempt to replicate in the current study. Busetto, et al. (2002) did not find that the presence of psychopathology predicted outcome of bariatric surgery, but again the investigators did not use structured interviews. In one study, surprisingly, the

degree of depression presurgery positively correlated with amount of weight loss 1 year later (Averbukh, et al., 2003).

Of concern, and of particular relevance to this study, is the finding from several studies that mood and anxiety problems post bariatric surgery return 2 years after the surgery at the time when patients experience weight regain (Hsu, et al., 1997; Hsu, et al., 1998). However, no study to date has longitudinally assessed individuals for comorbid psychopathology in a systematic, structured way, reevaluating them for the emergence of psychopathology and examining the impact of psychopathology on outcome periodically over time. Such a study would be of great importance to the field, and should be done before firm guidelines can be offered regarding exclusion criteria and risks for psychopathology post-operatively. Given the growing number of bariatric procedures being undertaken, the important of such a study cannot be overemphasized.

C. Aberrant Eating Behavior and Bariatric Surgery Outcome

It is now widely recognized that binge eating and full syndromal BED are common among the obese seeking treatment including bariatric surgery (Vamacho, et al., 1997). A recent survey demonstrated a lack of consensus among bariatric surgeons concerning what to do with these patients. Twenty percent proceeded with surgery, 2.7% recommended against it, 27.3% postponed surgery, while 50% indicated their management varied (Devlin, et al., 2004).

A number of research groups have studied whether binge eating and full syndromal BED might represent a relative contraindication or predict a poorer outcome in subjects undergoing various kinds of bariatric surgery procedures. The studies that have addressed the rates of binge eating or BED either at baseline or follow-up are summarized in Table 1.

Table 1. BE/BED Before and After Bariatric Surgery

Year	Authors	Site	Procedures	N	Baseline		FU		Duration
					BE	BED	BE	BED	
1995	Adami et al.	Genoa	"Bariatric Surgery"	92	69%	47%	---	---	---
1996	Busetto et al.	Padova	Band	80	---	13%	---	---	---
1996	Adami et al.	Genoa	BPD	65	64%	---	9%	---	2 years
1996	Hsu et al.	Pitt	VBG	24	---	38%	---	21%	3.5 years
1997	Hsu et al.	Tufts	VBG	27	---	48%	---	7%	21 months
1998	Kalarchian et al.	Rutgers	RYGBP	64	39%	---	---	---	---
1998	Saunders et al.	VA	RYGBP	125	61%	---	---	---	---
1999	Powers et al.	USF	"Gastric Restriction"	116	52%	16%	0%	---	5.5 years
1999	Kalarchian et al.	UMDNJ	RYGBP	50	44%	---	0%	---	4 months
2002	Lang et al.	Zürich	Band	66	64%	11%	71%	---	12 months
2001	Herpertz et al.	Essen	Band	150	20%	1%	---	---	---
2001	Wadden et al.	Penn	RYGBP	115	10%	27%	---	---	---
2001	Dymek et al.	U of C	RYGBP	32	---	32%	---	0%	6 months
2001	Mitchell et al.	NRI	RYGBP	78	---	49%	---	7%	14 years
2002	Busetto et al.	Padova	Band	260	---	29%	---	---	3 years
2002	Kalarchian et al.	UMDNJ	RYGBP	99	---	---	46%	---	2-7 years
2002	Hsu et al.	Tufts	VBG	37	25%		---	---	---
2002	Delgado et al.	Pontevedra	RYGBP	80	---	17%	---	---	
2003	Sanchez-Johnsen et al.	U of Chic.		210	---	26%	---	---	---

2004	Boan et al.	Duke	RYGBP	40	30%	---	0%	---	6 months
2004	Green et al.	U of Chic.	RYGBP	65	50%	26%	---	---	---
2004	Malone et al.	Albany	RYGBP	109	52%		55%		12 months
2004	Larsen et al.	Utrecht	Band	93/160	56%	---	37%	---	---
2005	Burgmer et al.	Bochum	Band	149	20%	2%	---	---	---

It is important to bear in mind that some investigators have used a modified version of the criteria for binge eating/BED in post-surgery patients, not requiring that subjects eat a "large amount of food" but instead meet other diagnostic criteria (e.g., feeling out of control). As can be seen, there is a large amount of variability in the findings among these studies but they clearly substantiate that a reasonably large percentage of patients meet criteria for BED and a larger percentage admit to binge eating at baseline.

In examining this literature, a number of issues surface. First, techniques for establishing criteria for binge eating or BED have varied widely, ranging from an operationalization of the DSM diagnostic criteria to the use of self-report measures, to the use of state-of-the-art structured interviews such as the Eating Disorder Examination (de Zwaan, et al., 2002). Systematic studies examining binge eating/BED pre-surgically and then periodically during a period of follow-up are needed. All the follow-up studies to date have been single cross-sectional assessments and in some cases, the baseline presence of binge eating/BED was assessed retrospectively, which significantly reduces the reliability of psychiatric assessment.

One possibility that has surfaced repeatedly in this literature is that the presence of binge eating or BED might predict lack of weight loss, or greater weight regain. The studies that have evaluated this possibility are shown in Table 2.

Table 2. Weight Regain after Surgery and BE/BED

Year	Authors	Site	Procedure	N	F/U (x)	Pre BE/BED Predicts Weight Regain	Post BE/BED Correlates with Weight Regain
1992	Rowston et al.	London	BPD	16	2 yrs.	---	Yes
1994	Pekkarinen et al.	Helsinki	VBG	27	5.4 yrs.	---	Yes
1996	Busetto et al.	Padova	RYGBP	80	12 mos.	No	---
1996	Hsu et al.	UMDNJ	VBG	24	3.5 yrs.	No	Yes
1997	Hsu et al.	Tufts	RYGBP	27	21 mos.	Yes	---
1999	Powers et al.	USF	"Gastric Restriction"	72	5.5 yrs.	No	---
2001	Dymek et al.	U of Chic.	RYGBP	32	6 mos.	Yes	---
2001	Mitchell et al.	NRI/UND	RYGBP	78	14 yrs.	---	Yes
2002	Busetto et al.	Padova	Band	260	3 yrs.	No	---
2002	Kalarchian et al.	Pitt	RYGBP	99	2-7 yrs.	---	Yes
2002	Sabbioni et al.	Bern	VBG	82	2 yrs.	No	---
2003	Guisado & Vaz	Extram.	VBG	140	18 mo.	---	Yes
2004	Boan et al.	Duke	RYGBP	40	6 mo.	No	---
2004	Larsen	Utrecht	Band	160	>2 yrs.	---	Yes
2005	Burgmer et al.	Bochum	Band	149	14 mos.	No	---

As can be seen, only 2 out of 9 studies found that pre-operative binge eating or BED predicted weight regain. However, of the 8 studies that examined this found that BE/BED at follow-up was associated with more weight regain, and that the patients who developed this problem were almost exclusively binge-eaters prior to surgery. Again, the methodologies varied across these studies. Establishing a possible relationship between BE/BED and lack of weight

loss or weight regain in this population could be of great importance, and definitive data are not now available. Of note as well are data suggesting that patients who binge-eat after surgery have more psychopathology, depression, and alcohol dependence as well as less weight loss (Guisaldo & Vaz, 2003).

Another disorder of relevance to this application is night eating syndrome. The concept of the night eating syndrome (NES) is in a state of transition (Allen, 2000; Arnoff, et al., 2001; Birketvedt, et al., 1999; Bjork, et al., 2001; Greeno, et al., 1995; Stunkard, 2000; Geliebter, 2000; Gluck, et al., 2001). We recently reviewed this literature (de Zwaan, et al., 2002). The original criteria by Stunkard, et al. (1955) included evening hyperphagia, insomnia, morning anorexia, and feeling tense, upset, or anxious as bedtime nears. Research has shown that NES is associated with psychological problems, and other research has suggested that there is overlap with BED (de Zwaan, et al., 2002). There is also overlap with two other syndromes. One is Nocturnal Eating/Drinking Syndrome (NEDS), a dysomnia in the International Classification of Sleep Disorders Diagnostic and Coding Manual (1990). This is characterized by frequent and recurrent awakenings during the night to eat or drink. The patient is fully aware, is not amnestic for the event, and doesn't have any other primary eating or sleep disorder. Research on this entity shows great variability in food intake, and in sleep studies, low levels of sleep efficiency as well as awakenings during non-REM sleep are seen, with other dysomnias commonly co-occurring. The other entity is Nocturnal Sleep-Related Eating Disorder (NSRED) (Shenck, et al., 1993). This is characterized by partial arousal from sleep associated with eating; a reduced level of awareness, reduced level of recall, and at times ingestion of inedible substances. A variety of other sleep disorders have been described in association with this, including restless leg syndrome and somnambulism.

NES in bariatric surgery patients has been studied by several investigators. Powers, et al. (1999), Kuldau and Rand (1986), and Adami, et al. (1999) reported presurgical NES prevalence rates of 10%, 15%, and 8% respectively. Studies using retrospective recall have reported higher prevalence figures for preoperative NES of 33% (Hsu, et al., 1998), 42% (Hsu, et al., 1996), and 31% (Rand, et al., 1997). Only three studies have examined post-surgical rates of NES in bariatric surgery patients. Hsu, et al. (1997) reported NES in 3 of 27 patients (11%) two or more years following gastric bypass. Another study reported full NES in only 1 of 160 patients who had received RYGB one year earlier, but subthreshold symptoms occurred in a much larger proportion (Rand, et al., 1997). Hsu, et al. (1996) reported that two of ten patients (out of a total of 24 patients studied) who reported pre-surgical night eating returned to night eating, at 12 and 18 months post-surgery. Hsu, et al. (1996) also examined excessive fluid intake and found that one-third (n = 8) of his patients also reported drinking excessive quantities of high-calorie fluids before surgery, while 4 patients resumed drinking excessive amounts of high-calorie fluids post-surgery. In this study, the presence of any eating disturbance, including BED, NES or excessive fluid drinking was associated with weight regain.

One apparently uncommon, but unfortunate outcome of patients undergoing bariatric surgery procedures is the development of clinically significant eating disorders such as anorexia nervosa (AN) and bulimia nervosa (BN). Reports in the literature (including one published by the P.I. in 1985) are summarized in Table 3. The exact incidence of such an outcome is unknown. Segal, et al. (2004) have proposed a new syndrome: "Post-Surgical Eating Avoidance Disorder", which has many features of AN and BN. One of the benefits of a prospective, longitudinal assessment of patients' status post-bariatric surgery would be that one could

examine these types of eating disorders, both full syndromal and subsyndromal, and establish risk factors for their development, based on pre-surgical characteristics.

Table 3. Bariatric Surgery and ED

	Authors	Site	Procedure	N	Report
1985	Thompson et al.	U of SF	Gastroplasty	1	BN
1985	Mitchell	U of MN	Gastric Stapling	1	BN
1987	Shamblin et al.	U of Georgia	VBG	1	BN
1992	Viens et al.	U of Ottowa	Gastrectomy (?)	1	BN
1996	Bonne et al.	Jerusalem	Gastroplasty	2	AN
1998	Atchison et al.	U of Adelaide	GBP	2	AN
1999	Scioscia et al.	Virginia	VBG	1	AN
2001	Counts	U of Maryland	GBP	1	AN (Prader-Willi)
2002	Deitel	Boston	GBP	1	AN
2002	Guisado et al.	Badajoz	VBG	1	"Anorectic-like"
2004	Segal et al.	Sao Paulo	?	5	"Post-Surgical Eating Avoidance Disorder"

D. Effects of Bariatric Surgery on Eating and Related Behaviors

A few studies have examined the effects of various bariatric surgery procedures on eating behavior. Most of these have relied on available questionnaires or developed something new specifically for this purpose (Bull, et al., 1983). Kenler, et al. (1990) provided data on self-reported eating behavior in patients' status post horizontal gastroplasty or RYGBP and found that those in the latter group reported lower intake of sweet tasting substances, milk and ice cream, and high calorie liquids after the surgery. Cook and Edwards in 1999 reported that patients who were successful following gastric bypass could be characterized as having an eating pattern including eating three balanced meals a day with two snacks. Delin, et al. in 1997 studied three groups of individuals using a questionnaire they developed for the purposes of their study: 1) a group status post-RYGBP, 2) a group who were morbidly obese but had not undergone surgery, 3) a normal weight control group. Patients status post-RYGBP reported a number of changes in their eating behavior and in particular indicated that they could eat markedly less food "before feeling full", and that there were certain foods that they no longer consumed. They also indicated that they had less hunger on several variables and were less likely to engage in emotional eating. Hörchner, et al. in 2002 reported a study of subjects status post adjustable silastic gastric band and also found decreased emotional eating in subjects post surgery as well as decreased "external" eating, indicating less precipitation of eating episodes by cues in the environment. Lang, et al. in 2002 also reported that patients' status post-lap band surgery reported decreased hunger and decreased disinhibition in their eating on self-report measures. All of these studies are limited, however, by retrospective methods to assess eating behavior, which may be inaccurate.

Two other studies are of interest concerning vomiting behavior. Busetto, et al. (1996) studied patients status post adjustable gastric banding and found that those who met criteria for BED prior to surgery were more likely to have problems with vomiting and to develop neostoma stenosis post operatively. Pessina, et al. (2001) studied patients' status post-vertical banding gastroplasty and classified patients into three groups: 1) those that had a low frequency of

vomiting and good weight loss; 2) those who had a medium frequency of vomiting and somewhat less weight loss; and 3) those that had frequent vomiting and poor weight loss. This last group was broken down into those who overate too quickly and those who tended to consume high calorie fluids. The authors discussed the "avoidance of vomiting" as an important feature, suggesting that most of these subjects wished to avoid vomiting. Another study suggested that some binge-eaters switched to "grazing" or snacking continuously over a long period, as a problematic eating behavior post-operatively (Saunders, 2004).

E. Bariatric Surgery, Psychosocial Outcome and Quality of Life

Recently published papers review the literature on psychosocial outcomes in clinically severe obesity (Bocchieri, et al., 2002a; Herpertz, et al., 2003; Van Hout, 2005; Sarwer, et al., 2005) and the relation between obesity and quality of life (Kolotkin, et al., 2001; Fontaine & Barofsky, 2001; Kushner & Foster, 2000). Because of the occurrence of rapid, dramatic weight reduction following bariatric surgery, there have been numerous investigations of the associated psychosocial changes and improvements in quality of life that occur following surgery. In most cases the changes experienced by patients after undergoing bariatric surgery are overwhelmingly positive; however, for some individuals, some changes are experienced as "tension-generating" (Bocchieri, et al., 2002b).

The earliest investigations into quality of life issues in obesity were based on unvalidated measures of quality of life as well as clinical observations. These early studies consistently indicated improvement in self-esteem and self-confidence post-bariatric surgery (Harris & Green, 1982; Hall, et al., 1983; Rand, et al., 1986; Delin, et al., 1995; Larsen & Torgensen, 1989; Gentry, et al., 1984). In general, research in the area of marital/sexual functioning has found improvement (e.g. Harris & Green, 1982; Hafner, et al., 1991; Hawke, et al., 1990; Dubovski, et al., 1985; Rand, et al., 1984). Despite increasing marital harmony three years post-operatively, the decrease remains higher among bariatric surgery patients than a comparison group in marriages that were troubled pre-operatively (Rand, et al., 1982). Additionally, in a study by Crisp, et al. (1977) only a minority of patients indicated that their marriage improved post-operatively, and the study by Neill, et al. (1978) found evidence of marital disruption following the surgery.

In the last decade, studies examining quality of life and psychosocial variables in bariatric surgery have become more sophisticated, utilizing validated measures of health-related quality of life (HRQOL), control groups, and longer follow-up periods (e.g. Sullivan, et al., 1993; Karlsson, et al., 1998; Van Gemert, et al., 1998; Choban, et al., 1999; Temple, et al., 1993; Isacsson, et al., 1997; de Zwaan, et al., 2002; Dymek, et al., 2001; Dixon, et al., 2001), as well as obesity-specific measures (Boan, et al., 2004; de Zwaan, et al., 2002). Prior to bariatric surgery, obese individuals experience poorer quality of life than matched reference groups in the general population (Kolotkin, et al., 2002). Additionally bariatric surgery patients experience poorer quality of life presurgically than obese persons seeking treatment in an intensive day-treatment program, obese persons seeking outpatient weight management, and obese participants in pharmacological clinical trials (Kolotkin, et al., 2002). Furthermore, white women seeking bariatric surgery experience poorer weight-related quality of life pre-surgically than other race and gender groups despite having a lower BMI (White, et al., 2004).

Studies assessing quality of life in bariatric surgery patients have utilized either generic measures of HRQOL (such as the SF-36 and the Nottingham Health Profile) (e.g. Choban, et al,

1999; Temple & Victorzon, 1995), obesity-specific measures (such as the IWQOL-Lite, BAROS, Moorehead-Ardel-Gettinger Quality of Life) (e.g. Tolonen, 2003; Boan, et al, 2004) or a combination of the two (e.g. de Zwaan, et al., 2002; Dymek, et al., 2001; Sullivan, et al., 1993). Regardless of the type of instrument used to assess quality of life, most studies find that quality of life improves after bariatric surgery (de Zwaan, et al., 2002; Boan, et al., 2004; Dixon, et al., 2001; Dymek, et al., 2001). However, obesity-specific measures may be more sensitive to longer term changes than generic measures. Dymek et al. (2001) found significant post-surgical improvements in quality of life between the six and 12-month follow-up visits on the IWQOL-Lite, whereas there were no significant changes during that same time period reported on the SF-36.

Improvements in quality of life are generally commensurate with amount of weight lost. In the Swedish Obese Subjects studies of patients undergoing bariatric surgery, a battery of measures indicated peak improvements in health-related quality of life at 6 and 12 months post-operatively, with slight deterioration at 2 years post-operatively. Changes in quality of life at 2 years were positively correlated with the amount of weight loss at that time (Karlsson, et al., 1998). Despite considerable weight loss after bariatric surgery, many patients remained obese, yet they reported quality of life scores more similar to community values than to a control group of unrelated obese persons (Dixon, et al., 2004). These authors suggested that the post-weight loss state conveys benefits that are greater than predicted by the attained BMI.

Hörchner and Tuinebreijer (1999) reported significant improvement on the SF-36 one year post-operative Lap-Band placement. Hörchner, et al. (2001) found evidence of significant improvement on three sub-scales on the SF-36 in a two-year follow-up of patients who had undergone the Lap-band procedure. Using a much larger sample, Dixon, et al. (2001) found significant improvements on the SF-36 subscales in a cohort status post Lap-Band placement. They also found that improvement was greater among those with more disability preoperatively, and that the amount of weight loss was not a good predictor of changes in quality of life. Dymek, et al. (2001) administered the SF-36 pre-surgery, 1 to 3 weeks post-surgery, and at 6 month follow-up to 32 morbidly obese subjects and found marked improvement in health-related quality of life, depression, and self-esteem. Our group reported improvement in health-related quality of life at long-term follow-up using the SF-36 (de Zwaan et al., 2002). While most studies indicate that quality of life improves after bariatric surgery, at least one study reported no change. Schok and colleagues in the Netherlands followed 74 patients for one to three years after Lap-Banding and found no significant differences between preoperative and postoperative SF-36 scores at any of the follow-up periods (Schok, et al., 2000).

Studies that assess quality of life outcomes have also been used to compare different types of surgical procedures. For example, Hell, et al. (2000) compared post-surgical changes in quality of life for patients who had undergone either vertical banded gastroplasty, laparoscopic adjustable gastric banding, or RYGBP, finding that although RYGBP patients experienced more weight loss, patients receiving vertical banded gastroplasty and laparoscopic adjustable gastric banding experienced greater quality of life improvements on the BAROS. In another study, laparoscopic RYGBP patients had comparable weight loss at 1 year to patients who received an open RYGBP, but they experienced a more rapid improvement in the QOL than those receiving open RYGBP (Nguyen, et al., 2001). We believe it is essential to study changes in QOL and to relate such changes to the amount of weight loss and weight regain, changes in psychopathology and changes and problems with eating behavior.

Questionnaires that assess HRQOL, whether general or obesity-specific, only give patients' subjective appraisals of the way in which health conditions interfere with daily functioning. Larsson and Mattsson (2001) found that correlations between perceived and observed limitations while completing a variety of tasks ranged from .14 to .61 with a mean correlation of .56. That is, these subjective and objective measures of HRQOL, on average, had only 31% of their variance in common. Despite this finding that questionnaire and performance-based methods for assessing functioning are largely orthogonal, surprisingly few studies have included objective assessments of obesity-related limitations on physical functioning. Existing studies that have examined the longitudinal relationship between weight change and functional abilities in obese patients have included only moderately obese women with a mean BMI ~ 37 kg/m^2 (Larsson, 2004; Larsson & Mattson, 2003). Results from those studies indicate that functional abilities improved with weight loss and were maintained despite subsequent weight regain. No study has yet attempted to replicate those findings in a diverse sample of extremely obese individuals seeking bariatric surgery.

LABS has designed a prospective, longitudinal cohort study with three components. LABS-1 includes all patients who are at least 18 years of age and who undergo bariatric surgery by LABS certified surgeons during a 4 year period, with the primary goal of evaluating the short-term **safety** of bariatric surgery. Important adverse outcomes (i.e., death, rehospitalization, reintervention) occurring within 30 days of surgery are recorded to assess the relationship between short-term morbidity and mortality rates and various patient, operative, and post-surgical care characteristics. LABS-2 will include a randomly-selected subset of patients from the LABS-1 cohort, with the primary goal of evaluating the longer-term **efficacy** of bariatric surgery. More extensive data collection (i.e. demographic, anthropometric, surgical, clinical, and behavioral) and longer follow-up will allow LABS-2 to identify longer-term safety and efficacy (up to 3 years) outcomes, both risks and benefits, and to determine their associations with patient, surgical, and post-surgical care characteristics. Finally, LABS-3, as described in this protocol, will include selected subsets of patients from the LABS-2 cohort to conduct detailed studies of **mechanisms** involved in weight loss and weight gain, energy expenditure, glucose control, and other aspects of the pathophysiology of obesity and obesity-related complications.

This protocol refers specifically to the LABS-3 component (**mechanisms**) of LABS. Specifically, the psychosocial and eating behavior issues that may be related to bariatric surgery.

2 Objectives and hypotheses

2.1 Primary Objective. Despite the obvious impact of bariatric surgery procedures on intake, no study to date has included a careful assessment of psychological factors, feeding patterns, energy intake and eating problems in this group of patients longitudinally. We believe that a careful examination of the structure of eating behavior and eating problems (e.g. vomiting) would be very helpful in guiding bariatric surgeons and dieticians who work with this group of patients in terms of dietary advice and recommendations, and with the prediction of eating problems and poor nutrient intake in the subgroup that develops such problems. This study involves prospective assessment of psychosocial outcomes of surgery by adding a supplemental battery to the LABS-2 assessment schedule. Conducting assessments at three of the LABS clinical sites assures the geographic, ethnic, and racial diversity of the sample, and hence

enhances the potential to identify a subgroup or subgroups of patients susceptible to poor outcomes after surgery and the generalizability of study results.

This study would also include an evaluation of psychopathological and behavioral variables that might impact on weight loss and weight regain, and psychosocial complications post-operatively, as well as quality of life.

The overall goal of this study is to obtain detailed information that will allow a careful assessment of psychopathology, quality of life and eating behavior pre-surgically and at regular intervals for up to 7 years after the surgical intervention.

Clearly subjects will have additional burden placed on them in terms of measurement; however, strategies will be used to minimize the fatigue to participants by spreading testing over several days. The staff will be cognizant of this risk. The protocol will take 3 hours in the clinic (or by phone) at certain times (baseline, 12 months and annually), and 30 minutes at 6 and 18 months, an additional hour of time will be required at the 7 year time point for the additional measures and tasks. Because of these time demands, the subjects being interviewed will be given frequent breaks.

We believe that the time points selected will allow us to examine changes midway through and at the end of the first year when many of the positive effects of the surgery will become obvious and then at 18 to 24 months when weight regain will begin to reoccur and certain psychopathological changes may reemerge in a subset of patients.

We believe that the instruments and procedures we have selected will allow us to examine psychopathology, eating pathology and quality of life in detail, while we will not be able to cover a variety of other areas which would also be of interest but which are beyond the scope of this project (e.g. self-esteem, work functioning, relationships, parenting, friendships, sexual functioning).

We believe that the measures and tasks added at year 7 will allow us to examine theories of affect regulation, cognitive control, and reward processing in understanding postsurgical outcomes regarding pathological eating behavior and alcohol/substance use and their shared similarities as well as underlying neurobiological systems.

3 Study Design

3.1 Study Summary. Bariatric surgery is associated with long-term weight loss, as well as short-term improvements in obesity-related medical comorbidities (Buchwald, et al., 2004). However, a significant proportion of patients fail to lose sufficient weight, or experience significant weight regain. Although no robust predictors of response have been identified, pilot data that will be presented and reviewed suggest that surgery has profound effects on eating behaviors and psychosocial functioning, and that these factors may affect postoperative weight control.

The present investigation capitalizes on the Longitudinal Assessment of Bariatric Surgery (LABS) consortium to conduct an in-depth examination of the psychosocial aspects of surgery among a geographically, ethnically, and racially diverse sample of men and women undergoing bariatric surgery. This project unites experts in the areas of psychopathology, eating behaviors and quality of life to conduct a naturalistic study using state-of-the-art assessment tools; to document the relationships among psychosocial factors over a three-year period; and to examine psychosocial predictors of surgical outcomes.

3.2 Study Population

3.2.1 Sources of Patients. Patients will be approached for inclusion into LABS-1 and LABS-2 at the MeritCare Bariatric Surgery Department, Fargo ND, at the University of Pittsburgh Medical Center and at Cornell/Columbia Medical Center in New York. LABS-3 Psychosocial participants will be selected from those individuals participating in LABS-1 and LABS-2.

3.2.2 Inclusion Criteria

- Male and female patients at least 18 years of age who undergo bariatric surgery by a LABS-certified surgeon.
- Previous enrollment in LABS-1 and LABS-2.
- BMI of greater than or equal to 35.

3.2.3 Exclusion Criteria

- Informed consent not obtained
- Type 1 Diabetes Mellitus
- Unlikely to comply with follow-up protocol (ie: geographically inaccessible for study visits)
- Unable to communicate with local study staff

3.2.4 Criteria for Study Withdrawal

- Patient withdraws consent
- The Principal Investigator or NIDDK ends the study

3.3 Enrollment Procedures. Once a candidate for LABS-3 Psychosocial has been identified, study details will be carefully discussed with the patient by a member of the LABS staff. All study related procedures will be explained and questions about the research protocol will be answered. If the patient agrees to participate, the study coordinator or Principal Investigator will go through the informed consent process with the patient. The patient will be asked questions to assure a thorough understanding of the consent document. Once a patient has consented to LABS-3 Psychosocial, they will be enrolled into the protocol.

3.4 Study Visits and Database Contents. Patients will be scheduled 1-30 days prior to surgery for their LABS-3 Psychosocial baseline evaluation at the Neuropsychiatric Research Institute, at the University of Pittsburgh Medical Center and at Cornell/Columbia in New York. Complete follow-up data collection will occur at approximately 12 months, and annually following surgery, along with a brief follow up assessments at 6 months and 18

months following surgery. There will also be data collected about weight loss, and psychological and quality of life measures that will be obtained from the LABS-2 database. All data are collected during an in-person visit, by phone assessment, or by accessing the LABS-2 data set. The tables below indicate the schedule of measures by study visit. A copy of all measures is included in the Appendix. New measures/ tasks are being incorporated for one time administration at the 7 year follow up time point. The new measures/ task will be accessible online for participant convenience which allows for the ability to complete these at home.

3.4.1 Clinical Forms and Interview Schedule

Measure/Test	Form Details	Baseline/ Presurgery	6 month follow up	12 month follow up	18 month follow up	annual follow up
PSYCHOPATHOLOGY N= 250						
INTERVIEW						
SCID/IP	Structured Clinical Interview for DSM-IV	X				X
EDE- BSV	Eating Disorders Examination-Bariatric Surgery Version	X		X		X
M-FED-BSV	MFED- Bariatric Surgery Version	X	X	X	X	
SELF-REPORT						
BDI*	Beck Depression Inventory	X	X	X		X
SF-36*	Short Form-36	X	X	X		X
IWQOL- Lite	Impact of Weight on Quality of Life- Lite	X*	X	X*		X*
PETS	Psychiatric and Emotional Test Survey	* X	X	* X	X	* X
MED	Medication Form	* X	* X	* X	X	* X
CTQ	Childhood Trauma Questionnaire					X (one time)
EATING BEHAVIOR N= 100						
NDS	48 Hour Dietary Recall-Nutritional Data System	X	X	X		X

*** Gathered as a part of LABS-2**

INTERVIEW SCHEDULE WITH NEW MEASURES AND TASKS AT YEAR 7:

LABS Baseline and F/U Funding for Part of Cohort						RO1 Funding				
	Pre-surg	6 mo	1 yr	18 mo	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs
INTERVIEW										
SCID/IP	X				X	X	X	X	X	X
EDE-BSV	X		X		X	X	X	X	X	X
M-FED-BSV		X	X	X	X	X	X	X	X	X
72-hour dietary recall (NDS-R)	X	X	X		X	X	X	X	X	X
SELF-REPORT										
Administered as a part of LABS 2*	X	X	X	X	X	X	X	X	X	X
The following have been added as a new, separate final visit.										
DERS										X
AIM										X
UPPS-P										X
ATQ-ECS										X
SPSRQ										X
Go/No-Go Task										X
Delay Discounting Task										X

3.4.2 Interview Description

- Structured Clinical Interview for DSM-IV, Patients Edition (SCID-IP; First, et al., 2001). The SCID-P is a widely used semi-structured interview that will be administered to assess comorbid Axis I disorders. Further, an impulse control module will be administered to assess impulsive/compulsive disorders for participants at their 72 month visit and beyond. A review of reliability studies for the SCID found kappa coefficients (measures of inter-rater reliability) ranging from .03 to 1.00, although the majority of the studies found kappas in the range of .7 to .8; test-retest coefficients ranged from .37 to .89.
- M-FED Bariatric Surgery Version (M-FED-BSV). Data will be obtained on other treatment received using the M-FED, an instrument designed for this purpose that has been used in several multi-center BN treatment and longitudinal studies (See for example, Mitchell, et al., 2002; Crow, et al., 2002). A modified version is available for bariatric surgery patients (M-FED-BSV).
- Eating Disorder Examination (EDE-BSV; Fairburn & Cooper, 2006). The diagnostic version of the EDE will be used as the primary measure of eating behavior and pathology. The EDE is an investigator-administered interview used to assess current eating disorder symptoms. The EDE contains four subscales (Restraint, Eating Concern, Shape Concern, and Weight Concern) associated with core psychopathology of eating disorders, as well as frequency measure of binge eating and compensatory behavior. The

validity and reliability of the EDE have been well documented (Fairburn & Cooper, 1993). We have modified a version of the EDE for use with bariatric surgery patient and this form will be used (EDE-Bariatric Surgery Version, EDE-BSV). The modified version of the EDE quantifies eating behavior, experiences of plugging and dumping syndrome, binge eating, grazing, compensatory behaviors, such as vomiting, and chewing and spitting food. This version includes assessment of night eating and excessive fluid intake. The modified version of the EDE has been used in gathering data on eating behaviors in RYGBP patients in prior studies.

3.4.3 Self-Report Description

- Beck Depression Inventory. (BDI; Beck et al, 1961). The BDI is a 21-item instrument that is widely used to assess depressive symptoms. A meta-analysis of reliability studies found mean coefficient alphas of .86 (psychiatric patients) and .81 (non-psychiatric patients). In addition, the BDI has been found to correlate highly with other measures of depression, and discriminate between groups of individuals with and without depression.
- ShortForm-36 (SF-36, Stewart & Ware, 1992). The SF-36 is a 36-item questionnaire that assesses functioning and quality of life as it relates to health status. The SF-36 assesses health status in 8 areas: physical functioning, physical role limitations, emotional role limitations, bodily pain, general mental health, vitality and general health perceptions. Composite scores for physical and mental functioning are also available. Test-retest reliabilities on the SF-36 scales range from .68 (social functioning) to .93 (physical functioning). The test-retest reliabilities for physical and emotional composite scores are .92 and .88 respectively. A variety of studies have established the validity of the SF-36 across different patients and cultural populations.
- Impact of Weight on Quality of Life Questionnaire (IWQOL-Lite; Kolotkin, et al 2001; Kolotkin et al, 2002). This is a 31-item, self-report, obesity-specific quality of life measure. The IWQOL-Lite provides five subscales (Physical Function, Self-Esteem, Sexual Life, Public Distress, Work) and a total score. Scores on the IWQOL-Lite range from 0 to 100, with 100 representing the best and 0 the most impaired quality of life. In previous studies the IWQOL-Lite has demonstrated excellent psychometric properties: internal consistency ranged from 0.90 to 0.94 for scales and was 0.96 for total score; test-retest reliability ranged from 0.81 to 0.94 for total score; the scale structure was confirmed by factor analysis; there was good support for construct validity in that scales correlated well with BMI, weight loss, treatment-seeking status, and appropriate collateral measures. The 31-item IWQOL will be administered intact, along with additional quality of life questions specific to bariatric surgery patients. Additional items will include eating-related problems such as involuntary and voluntary vomiting, plugging, and dumping, physical symptoms such as diarrhea, heartburn, bloating, and abdominal pain, and psychosocial variables such as issues related to appearance, changes in marital relationships and friendships, increased feelings of vulnerability, establishing new eating behavior, and coping with stress without food. Psychometric analyses will be performed to derive one or more bariatric surgery-specific quality of life scales.
- Psychiatric and Emotional Test Survey: (PETS) This questionnaire was developed by the LABS consortium to collect psychiatric and emotional health information on patients enrolled in LABS.

- Medication Form: (MED) This questionnaire was developed by the LABS consortium to collect medication and supplement use on patients enrolled in LABS.
- Childhood Trauma Questionnaire (CTQ) This 28-item self-report is useful with individuals referred for a broad range of psychiatric symptoms and problems, including: Post-traumatic stress disorder,Depression,Eating disorders, Addictions, Suicide attempts, Personality disorders and Sexual problems. As a part of the LABS 3 protocol, this questionnaire will only be administered one time at the participants next scheduled annual follow up.

3.4.4 Eating Behavior Assessment Description

- The NDS-R is a windows-based nutrient calculation system which allows for the detailed assessment specific of food intake over a 24-hour time intervals. The NDS-R was released by the Nutrition Coordinating Center in the Division of Epidemiology and School of Public Health at the University of Minnesota. Over 800 dietary interviewers have been trained in this system. The NDS-R is administered as a telephone interview or face-to-face, is typically administered in the evening, and data from it are entered directly into a computer. The NDS-R system contains over 18,000 foods and 8,000 brand name products, including many ethnic foods. The system has been used widely in nutrient research (e.g. Shakel, Sievert & Buzzard, 1988; Feskanich et al., 1999). It is considered the gold standard method of assessment of food intake. The NDS-R has been used successfully with overweight and obese samples (Yaroch, Resnicow, Petty, & Khan, 2000; Djuric, DiLaura, Jenkins, Darga, Jen, Mood, et al. 2002; Ebbeling, Sinclair, Pereira, Garcia-Lago, Feldman, Ludwig,2004; Quatromoni, Copenhafer, D'Agostino, & Millen, 2002).

3.4.5 New Self-Report Measures/Computer Tasks for Psychopathology Dimensions

- The measures outlined below have been added to be assessed at the final assessment time point (year 7). The self-report measures and computer tasks will administered via the web using software from Millisecond Software using the Inquisit 4 program.

- Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004). The DERS is a 36-item self-report questionnaire that assesses six domains of emotion dysregulation (i.e., non-acceptance of negative emotions, inability to engage in goal-directed behavior when distressed, difficulties controlling impulsive behavior when distressed, limited access to effective emotion regulation strategies, lack of emotional awareness, lack of emotional clarity) and has been found to have acceptable internal consistency as well as adequate test-retest reliability and construct validity (Gratz & Roemer, 2004).
- Affect Intensity Measure (AIM; Larsen & Diener, 1987). The AIM is a 40-item self-report measure of positive and negative emotional intensity and reactivity. Evidence supports the reliability and validity of the measure (Larsen & Diener, 1987; Bryant et al., 1996).
- UPPS-P Impulsive Behavior Scale (UPPS-P; Cyders & Smith, 2007). This is a 59-item self-report measure assessing five dimensions of impulsivity. Only the negative urgency and positive urgency subscales will be administered. The measure has demonstrated good internal consistency and validity (Cyders & Smith, 2007).

- Effortful Control Scale of the Adult Temperament Questionnaire (ATQ-ECS; Evans & Rothbart, 2007). This 19-item self-report measure assesses several components of dispositional effortful control, including attentional control (i.e., ability to voluntarily focus or shift attention), inhibitory control (i.e., ability to inhibit behavior), and activation control (i.e., ability to activate behavior as needed). The measure has evidenced good reliability and validity (Evans & Rothbart, 2007).
- Sensitivity to Punishment and Sensitivity to Reward Questionnaire (SPSRQ; Torrubia et al., 2001). This is a 44-item self-report measure that is based on Gray's behavioral inhibition and activation motivational systems conceptualization, and assesses sensitivity to punishment and reward. The measure has demonstrated adequate internal consistency, test-retest reliability, and construct validity (Torrubia et al., 2001). Only the Sensitivity to Reward subscale of the measure will be administered.
- Go/No-Go Task (Osman et al., 1992). This computerized task assesses the capacity for suppressing previously reinforced responses. Participants are asked to quickly respond to a target stimulus (e.g., letter A) and to inhibit responding to other stimuli (e.g., letters B, D, E, etc.). The target stimulus is presented more frequently to establish a learned (prepotent) response, thus requiring an inhibition process to not respond to an incorrect stimulus. The index of inhibitory control will be the number of mistaken responses (commission errors) made on No-Go trials.
- Delay Discounting Task (Kirby et al., 2000; Kishhinevsky et al., 2012). Delay discounting tasks require participants to choose between receiving a larger amount of money after a delay versus receiving a smaller amount immediately. The size of the smaller immediate reward is adjusted based on previous responses, narrowing the range of choices until an indifference point (i.e., amount at which the smaller more immediate reinforcer and larger delayed reinforcer are judged as being of equal value) is determined for each delay interval.

3.4.6 Other Forms

- The **Off-Protocol Form** will be completed by the study coordinator to report deviation(s) from study protocol (e.g., missed visit, incomplete data collection).
- An **Inactivation Form** will be utilized to report patient drop-outs or inactivations and reason(s) for dropping out or inactivation.
- An **Enrollment Form** will be completed to report those participants who are enrolled into LABS-3 Psychosocial. This form reports whether patients provided consent to LABS-3 Psychosocial, along with dates of consent. If the patient does not consent, the reason why is reported.

4 Data Analysis and Statistical Power

Statistical Analyses

1. Preliminary Analysis

a. Descriptive Statistics. Descriptive statistics (e.g., means, standard deviations, ranges, frequency distributions) at each assessment point will be performed on all demographic,

psychopathology (SCID-I, BDI), eating behavior (EDE-BSV, NDS) and quality of life (SF-36, IWQOL-Lite) measures.

b. Site Comparisons. Baseline comparisons between sites will be made on demographic, psychopathology, eating behavior and quality of life measures using ANOVA for continuously distributed measures, Kruskal-Wallis for ordinal or continuous non-normal measures, and chi-square tests for nominal measures.

c. Missing Data Analysis. A pattern mixture model (Little, 1993; 1994; 1995; Hedeker & Gibbons, 1997) based on a random regression model (RRM) (Gibbons, et al., 1993) will be used to examine the impact of missing data pattern on longitudinal eating-related variables, weight loss, quality of life, and depressive symptomatology. Subjects will be divided logically into groups based on their missing data pattern following the guidelines provided by Hedeker & Gibbons (1997). These groups will then be included as a between-subjects factor and the impact of this factor on the trajectory of outcome measures will be evaluated. This will provide a determination of the extent to which trajectories depend on the pattern of missing data.

2. Hypothesis Testing

a. Hypothesis #1. Hypothesis #1 posits that patients undergoing bariatric surgery will experience significant decreases in rates of psychopathology and quality of life. This hypothesis will be evaluated using a linear RRM (Gibbons, et al., 1988; Gibbons, et al., 1993; Bock, 1983) for depression (BDI total score) and quality of life (IWQOL-Lite total, SF-36 mental and physical component). A logistic RRM (Stiratelli, et al., 1984) will be used for psychopathology (current mood disorder, current anxiety disorder, current substance use disorder). All of the basic models will include a random effect for subject, and fixed effects for site, assessment time, and time-by-site interaction. Additional variables may include relevant covariates and missing data patterns. Bonferroni contrasts will be used to compare mean scores (for depression and quality of life) or rates of psychopathology between pre-surgical and subsequent assessment points. Analyses will include data from all participants completing at least one post-surgery assessment.

b. Hypothesis #2. Hypothesis #2 states that untreated psychopathology that persists beyond surgery will be associated with less weight loss and poorer quality of life. The effects of post-surgical psychopathology upon weight loss and quality of life will be evaluated using linear RRM's. The basic models will include a random effect for subject, fixed effects for baseline assessment, assessment time, and time-varying covariates for psychopathology (current mood disorder, current anxiety disorder, current substance use disorder, any Axis I disorder). The main effect for assessment time will be used to evaluate within-person change. The use of time-varying covariates for psychopathology allows for the possibility that a given diagnosis may be present for a given subject at one time point but absent at another. Outcome measures for these analyses for weight loss will be BMI, and for quality of life will include the IWQOL-Lite total and SF-36 mental and physical components.

c. Hypothesis #3. Hypothesis #3 states that untreated psychopathology at the time of bariatric surgery will be associated with increased short-term complications. A logistic regression analysis will be used to evaluate the influence of psychopathology at the time of surgery on short-term surgical complications. Analyses will evaluate the impact upon both DSM-IV diagnostic psychopathology (e.g., current mood disorder, current anxiety disorder, current substance use disorder, any Axis I disorder, any Axis II disorder) and a continuous measure of depressive symptoms, the BDI, upon short-term post-surgical complications.

d. Hypothesis #4. Hypothesis #4 posits that syndromal or subsyndromal eating disorders prior to surgery will be associated a greater frequency of eating disorder symptoms and less weight loss at long-term follow-up. Data from the EDE-BSV and the NDS dietary recall will be aggregated to determine the frequency of various eating disorder symptoms (binge eating, grazing, vomiting, chewing and spitting) at each assessment point. RRM's will then be used to evaluate the effect of pre-surgical eating disorder syndromes (including binge eating disorder and night eating) on eating disorder frequency (Poisson-based RRM) and BMI (linear RRM). The basic models will include a random effect for subject, and fixed effects for site, assessment time, time-by-site interaction, and pre-surgical eating disorder diagnoses (both syndromal and subsyndromal diagnoses).

Power Analysis and Sample Size

Hypothesis #1. Power analyses below assume an attrition rate of 15% at 12 months, and a 10% attrition rate at 24 month assessments. An enrolled sample size of 250 would provide an estimated sample size of 213 at 12 months and 191 at 24 months.

Power analyses regarding the reduction of psychopathology following surgery is based on the finding of Glinski et al. (2001) that 50% of pre-bariatric surgery candidates meet criteria for at least one current Axis I disorder. Assuming a conservative two-tailed alpha of .01, the proposed sample size would provide a power of .90 to detect a reduction in psychopathology of just over 10% from pre-surgery at 12 months and 12% at 24 months (Hintze, 2001). These reductions for Axis I disorders are consistent with those reported in the literature following bariatric surgery (Herpetz et al. 2004).

Effect size estimates for changes in quality of life and depression scores after post-surgery are taken from the Utah Obesity Surgery Study (Adams et al., 2005). A total of 224 bariatric surgery patients were evaluated using the IWQOL-Lite and SF-36 prior to surgery and at 1-year follow-up. The IWQOL-Lite total score improved from 32.4$\pm$16.1 pre-surgery to 86.6$\pm$16.1 at 1-year follow-up (effect size = 3.37); the SF-36 mental component, which is highly correlated with measures of depression, improved from 41.1$\pm$6.4 pre-surgery to 44.8$\pm$6.4 at 1-year follow-up (effect size = .58); the SF-36 physical component improved from 35.4$\pm$6.5 pre-surgery to 45.2$\pm$5.8 at 1-year follow-up (effect size = 1.51). Power estimates assume a conservative two-tailed alpha of .01, a correlation between pre-surgical and follow-up assessments of .50, and differences between pre-surgical and post-surgical assessments in quality of life and depression comparable to those from the Utah study. The proposed sample size would provide a power of greater than .98 to detect these differences between pre-surgical and subsequent post-surgical assessments quality of life and depression scores at each follow-up assessment (Hintze, 2001).

Hypothesis #2. Power analyses for Hypothesis #2 are based upon a study by Averbukh et al. (2003) reporting a correlation between pre-surgical BDI score and subsequent weight loss of .397, corresponding to an effect size (d) of .64 (Cohen, 1988; p. 82). Power analysis for this hypothesis is based upon the procedures described by Hedeker and colleagues (Hedeker, et al., 1999) for longitudinal random effects models with attrition. Power analyses assume a conservative two-tailed alpha of .01, a 50% rate of pre-surgical Axis I disorder, and 4 observation points (6, 12, 18 and 24 months), and a correlation of .30 between observations.

Power analyses focus on the differences weight loss between those individuals with and without pre-surgical psychopathology. The proposed sample size will provide a power of approximately .95 to detect an attrition-adjusted effect size of .64 (Hedeker et al., 1999).

Hypothesis #3. Power analysis estimates for Hypothesis #3 are based upon a study by Powers et al. (1988) reporting an association between the presence of pre-surgery Axis I diagnosis and post-surgical complications. All 9 (100%) patients with a pre-surgical Axis I diagnosis experienced post-surgical complications, compared to 7 of 15 (47%) of those without a pre-surgical Axis I diagnosis (contingency coefficient = .42). It would be unrealistic to expect that every patient with an Axis I disorder would develop post-surgical complications. However, if we assume that 80% of those with an Axis I disorder would develop complications post-surgery, and further assume a conservative two-tailed alpha of .01, the proposed sample size of 250 enrolled patients would provide a power of .98 to detect this association and would provide a power of .80 to detect a contingency coefficient of .165 (Hintze, 2001).

Hypothesis #4. Power analysis for Hypothesis #4 is based upon a study of Hsu et al. (1996) reporting an association between pre-surgical eating disturbance and weight regain post-surgery. They report that 8 of 19 (42%) patients with pre-existing eating disturbance regained weight after surgery, compared to 0 of 5 (0%) without a pre-existing eating disturbance (contingency coefficient = .341), corresponding to an effect size (d) of .57. Power analyses assume a conservative two-tailed alpha of .01, a 50% rate of pre-surgical eating disturbance, and 5 observation points (6, 12, 18 and 24 months), and a correlation of .30 between observations. Power analyses focus on the differences weight loss between those individuals with and without pre-surgical psychopathology. The proposed sample size of 100 subjects for the assessment of eating behavior will provide a power of approximately .88 to detect an attrition-adjusted effect size of .57 (Hedeker et al., 1999).

5 Study Organization

5.1 LABS-3 Psychosocial Sites

Participating LABS Clinical Centers

- Neuropsychiatric Research Institute, Fargo ND
- New York Cornell/Columbia-Presbyterian Medical Center
- University of Pittsburgh Medical Center

Data Coordinating Center

- University of Pittsburgh, Graduate School of Public Health

5.2 Advisory Groups to the NIDDK. Data and Safety Monitoring Board: The Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) to monitor patient safety and evaluate the progress of the study.

DSMB Responsibilities. The initial responsibility of the DSMB will be to approve the initiation of LABS-2. This will include review of the research protocol, informed consent documents, and plans for safety and data monitoring. After this approval and at periodic intervals (to be determined) during the course of the study, the DSMB responsibilities are to:

- review the research protocol, informed consent documents and plans for data safety and monitoring if they changed from the original proposal or need to be reviewed due to issues arising during the course of the study;

- evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment and retention, participant risk versus benefit, performance of the individual study sites, and other factors that can affect study outcome;

- consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study;

- protect the safety of the study participants;

- report on the safety and progress of the study;

- make recommendations to the NIDDK, the LABS Steering Committee, the LABS-3 Investigators and, if required, to the Institutional Review Boards (IRBs) concerning continuation, termination or other modifications of the study

- ensure the confidentiality of the study data and the results of monitoring; and,

- assist NIDDK by commenting on any problems with study conduct, enrollment, and sample size and/or data collection.

Membership. The DSMB will consist of at least five members. Three members will constitute a quorum. The members have been recommended by the LABS Steering Committee*;* the NIDDK has approved the composition of the DSMB, and appointed the members. Membership consists of persons completely independent of the investigators who have no financial, scientific, or other conflict of interest with LABS. Collaborators or associates of any of the investigators or the study sites are not eligible to serve on the DSMB. Written documentation attesting to absence of conflict of interest is required. The DSMB includes experts in or representatives of the fields of:

- bariatric surgery
- biostatistics
- Others to be determined

A chairperson will be selected by NIDDK in consultation with the Executive Committee to oversee the meetings, develop the agenda in consultation with the NIDDK Project Scientist, the LABS Executive Committee, and the DSMB Executive Secretary. The chair is the contact person for the DSMB. Rebecca Torrance will serve as the Executive Secretary (ES) for the DSMB. The DCC shall provide the logistical management and support of the DSMB.

A Safety Committee will be identified at the first meeting. The chair of this committee will be the contact person for severe adverse event reporting. Procedures for notifying the Chair of the DSMB and the NIDDK Project Scientist will be discussed at the first meeting.

Board Process. The first meeting will take place face-to-face to discuss the protocol, any modifications of the trial, and to establish guidelines to monitor the study. The, DSMB Chairperson, the LABS Executive Committee, and the Executive Secretary will prepare the agenda to address the review of manual of operating procedures, modification of the study design, initiation of recruitment, identification of the safety committee, reporting of adverse events, and reports of study progress.

Meetings of the DSMB will be held two times a year at the call of the Chairperson, with advance approval of the NIDDK Project Scientist. At least one NIDDK Official will be present at every meeting.

Meetings shall be closed to the public because discussions may address confidential participant data. Meetings may be convened as conference calls as well as in person, although the initial meeting will be face-to-face. An emergency meeting of the DSMB may be called at any time by the Chairperson or by NIDDK should questions of patient safety arise.

Meeting Format. An appropriate format for DSMB meetings consists of an open and a closed session. The open sessions may be attended by the Executive Committee, DCC staff and NIDDK staff. Issues discussed at open sessions will include conduct and progress of the study, including patient accrual, compliance with protocol, and problems encountered. Patient-specific data may not be presented in the open session.

The closed session will be attended only by voting DSMB members and the NIDDK ES. The DSMB may request others to attend by part or all of the closed session (e.g., study statistician, NIDDK staff). All safety and efficacy data are and must be presented at this session. The discussion at the closed session is completely confidential.

Should the DSMB decide to issue a termination recommendation, full vote of the DSMB will be required. In the event of a split vote, majority vote will rule and a minority report should be appended.

Reports

Interim Reports. Interim reports are generally prepared by the study statistician and distributed to the DSMB at least 10 days prior to a scheduled meeting. These interim reports are numbered and provided in sealed envelopes within an express mailing package or by secure email as the DSMB prefers. The contents of the report are determined by the DSMB. Additions and other modifications to these reports may be directed by the DSMB on a one-time or continuing basis. Interim data reports generally consist of two parts:

Part 1 (Open Session Report) provides information on study aspects such as accrual, baseline characteristics, and other general information on study status.

Part 2 (Closed Session Report) may contain data on study outcomes, including safety data, and perhaps efficacy data. The Closed Session Report is considered confidential and should be destroyed at the conclusion of the meeting. Data files to be used for

interim analyses should have undergone established editing procedures to the extent possible.

Reports from the DSMB. A formal report containing the recommendations for continuation or modifications of the study prepared by the ES with concurrence from the DSMB Chairperson will be sent to the full DSMB within 4 weeks of the meeting. Once approved by the DSMB, the NIDDK will forward the formal DSMB recommendation report to the DCC which will distribute the formal DSMB recommendation report to all investigators who are responsible for submitting it to their IRB.

As previously stated, the formal DSMB report should conclude with a recommendation to continue or to terminate the study. This recommendation should be made by formal majority vote. A termination recommendation may be made by the DSMB at any time by majority vote. The NIDDK is responsible for notifying the Executive Committee of a decision to terminate the study. In the event of a split vote in favor of continuation, a minority report should be contained within the regular DSMB report.

Mailings to the DSMB. On a scheduled basis (as agreed upon by the DSMB) safety data should be communicated to all DSMB members or to the safety committee. Any concerns noted should be brought to the attention of the DSMB Chairperson or chair of the safety committee and the NIDDK Project Scientist.

Confidentiality. All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

6 Human Subjects Issues

6.1 Overview. The LABS-3 Psychosocial study protocol, consent forms, and data collection forms will be submitted to each participating clinical center's Institutional Review Board (IRB). Additionally, each clinical center will submit any recruitment materials to be used at their site to their IRB. A site may not initiate any patient contact for LABS-3 until the site has IRB approval. All study personnel will have completed training in the Protection of Human Subjects per NIH guidelines.

6.2 Institutional Review Board Approval. It is the investigator's responsibility to ensure that the LABS-3 Psychosocial protocol and informed consent documents are reviewed and approved by the appropriate IRB. Each participating clinical site must obtain a letter of approval from the IRB prior to enrolling patients into this study. Sites must provide the DCC with copies of the initial IRB approval notice prior to enrolling the first patient, and subsequent renewals, as well as copies of the IRB approved consent. Additionally, the NIDDK must review the IRB approved informed consent prior to enrollment.

The IRB must also review and approve any other written information provided to the patient prior to any registration of patients.

If, during the study, it is necessary to amend either the protocol or informed consent document, the investigator will be responsible for ensuring the IRB reviews and approves the amended documents. IRB approval of the amended informed consent document must be obtained before new patients consent to participate in the study using the new version of the consent form.

The informed consent document will inform patients of their right to refuse any release of their protected health information.

6.3 Informed Consent

6.3.1 Informed Consent Document. A sample informed consent document has been provided at the end of this protocol (see Appendix). Each clinical site, according to local IRB requirements, is allowed to modify this informed consent document and make any necessary editorial changes as long as the meaning or intent of any section is not changed. To accommodate the additional measures incorporated at year 7, an Addendum Consent form will be presented to all participants for a re-consent process. Participants will have the opportunity to decide whether or not to take part in the new measures/tasks. (Please see Addendum Consent Form in the Appendix)

6.3.2 Informed Consent Process. The investigator or his/her designee (i.e., research coordinator or study nurse) will inform the patient or the patient's legally authorized representative of all aspects of the study pertaining to the patient's participation in the study. The process for obtaining informed consent will be in accordance with all applicable regulatory requirements. Once a candidate for LABS-3 Psychosocial has been identified, details will be carefully discussed with the subject. The subject will be asked to read and sign the IRB-approved LABS-3 Psychosocial informed consent document. The patient will receive a copy of the consent document and the originals will be retained in the patient's study file. For candidates that are not able to go through the informed consent process in person, the consent forms will be mailed to them to read, a call to review the consent form and answer concerns or questions will be scheduled with research staff, and the signed consent form will be mailed back in postage paid envelopes to the investigator or his/her designee.

6.3.3 Research Study Costs: Remuneration: Subjects will be remunerated for their participation in this protocol. Remuneration will be according to the following schedule: The 250 subjects who participate in only the assessments of psychopathology remuneration will be: $30 at Baseline, 12 month and 24 month appointment, $10 at the 6 and 18 month time points and $45 for annual appointments thereafter. The 100 subjects who also participate in the eating behavior assessment will receive an additional $20 at Baseline, 6 months, 12 months and annually. The renumeration structure will change as a part of the RO1 extension to the following: Participants who take part in the psychopathology assessment will be remunerated $150 for these assessments. Participants who take part in the addititional eating behavior assessment will receive an additional $100. Participants who complete the final measures/tasks incorporated at year 7, will be remunerated an additional $100 for the added time and burden.

6.4 Confidentiality of Patient Data. Each participating clinical site is responsible for the confidentiality of the data associated with participants enrolled in this study in the same manner that it is responsible for the confidentiality of any participant information within its sphere of

responsibility. All forms used for the study data will be identified by coded identification number, which will be generated at the clinical center, to maintain subject confidentiality. All records will be kept in locked file cabinets at the clinical centers with access limited to LABS-3 Psychosocial study staff, and all study staff will identify participants via their unique identifier. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by the IRB, those that audit IRB procedures or Data & Safety Monitoring Board (DSMB). All consent forms and identifying information will be stored in separate locked files from the research records. All research records and consent forms will be kept for an indefinite period of time (minimum of three years). All research records and consent forms will be shredded if ever destroyed.

Consent procedures and forms, and the communication, transmission and stoppage of participant data will comply with individual site IRB and NIH requirements for compliance with The Health Insurance Portability and Accountability Act (HIPAA). The Privacy Rule of HIPAA governs the protection of an individual's identifiable health information. The DCC will ensure that the participating clinical centers associated with the LABS-3 Psychosocial project are complying with HIPAA regulations by requiring documentation from the IRBs with the appropriate authorization or consent form. The DCC will maintain copies of all relevant documents from each clinical center. If IRB approvals are not current, data will not be accepted by the DCC.

6.5 Risk/Benefit Ratio. Of minimal risk to patients is the possible inconvenience of reporting psychological status to the research staff. Some of the questions may be upsetting. For example, questions will be asked regarding alcohol and drug abuse, eating behavior and emotional problems such as depression. You will be informed that you can decline to answer any questions you wish not to answer. Another possible risk is a breach of confidentiality, although steps have been taken to minimize such an occurrence. All information collected for this research study will be kept confidential. Participants' names will be used only for the informed consent form and contact information. Participants will be given unique study identifiers, which will be written on all data collection forms. In addition, data collection forms will be kept in a locked file cabinet or locked room and a secure database that can only be accessed by the investigators (and their research staff) listed on the consent form. There will be close communication between the PI, the data entry personnel and the clinic and research staff to ensure the quality and accuracy of the data collected. Each member of the study team will meet with the PI and review confidentiality issues, prior to having contact with research subjects.

There will be no direct benefits to participants who participate in LABS-3 Psychosocial, only nominal remuneration (see § 6.3.3). Participation may benefit other patients who undergo weight-control surgery.

6.5.1 Data and Safety Monitoring Plan. A data and safety monitoring committee will oversee the study. Their main tasks are to ensure that there are no changes in the risk/benefit ratio during the course of the study, that the study is implemented appropriately, and that the confidentiality of research data is maintained. Investigators and study personnel will meet routinely to discuss the study (e.g., study goals and modifications of those goals; subject recruitment and retention; progress in data entry; documentation, identification of adverse events or research subject complaints; violations of confidentiality) and address any issues or concerns at that time.

Minutes will be kept for these meetings. The yearly IRB renewal for this study will include a summary report of the Data and Safety Monitoring Board recommendations from the prior year.

Given the nature of this protocol, problems with subject recruitment, drop-outs or data management would be most likely to trigger the stopping of the protocol rather than adverse events, although both sources of problems will be monitored. It is unlikely that any new information will become available that would necessitate stopping the trial. It is possible that excessive study drop-outs and missing data would limit the data analysis. We have powered all parts of the study to include drop-outs.

6.5.2 Data Sharing Plan. It is the intention of the investigators on this protocol to make data that evolves from this study available to the general scientific community. All data will be de-identified using HIPAA guidelines, given that the entities involved must be HIPAA compliant. Our intent is to have the baseline data available for other researchers within three months of the conclusion of the study and follow-up data as it develops and is analyzed. Our current plan would be to have the data set available via the Web through postings of the availability of the information on the Academy for Eating Disorders Website, the Eating Disorders Research Society Website, and the American Society for Bariatric Surgery Website. Data will be provided in several "user friendly" statistical formats including SAS and SPSS. We will also provide detailed protocols describing study methodology and a codebook describing all data elements in detail. The availability of the de-identified data also will be announced in various journals and publications of interest to clinicians and researchers in the areas of eating disorders, obesity, psychopathology and bariatric surgery. If additional archive platforms are available at the time through NIH it is our intent to use those archives as well. We also intend to eventually transfer all materials to the NIDDK Central Biosample and Data Repositories or another archival storage facility designed by NIDDK.

7 Adverse Event Reporting

Any instances of adverse events occurring as a result of procedures performed solely for research purposes, as opposed to standard clinical care, will be reported immediately to the local site IRB using the standard forms and procedures that have been established by the IRB.

7.1 Definitions

Serious Adverse Event
An adverse reaction is considered serious if it is fatal or life-threatening; requires or prolongs hospitalization; produces a disability; or results in a congenital anomaly/birth defect.

Severity of Adverse Event

An adverse reaction is considered to be of moderate or greater severity if it requires medical evaluation (such as additional laboratory testing) or medical treatment; or if it is a serious adverse reaction.

Unexpected Adverse Event
An adverse reaction is considered to be unexpected if it is not identified in nature, severity or frequency in the current IRB-approved research protocol or informed consent process

Adverse Event Associated with Research Intervention
An adverse reaction is considered to be associated with the research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (i.e., a causal relationship between the reaction and the research intervention cannot be ruled out by the investigator(s)).

Relatedness
With respect to the research intervention, an adverse event can be considered to be definitely, probably, possibly, or unrelated, or relatedness may be indeterminate.

7.2 Guidelines for Adverse Event Reporting. Investigators involved in LABS-3 Psychosocial will report to their local IRB, the DCC, the NIDDK and the DSMB, adverse events which are moderate or of greater severity and are a result of a research-specific procedure or intervention. Moreover, investigators involved in LABS-3 Psychosocial will report to their respective IRB, external adverse events which are unexpected, serious and associated with a research-specific procedure or intervention. Any instances of adverse events that necessitate reporting as defined above will be reported immediately to the local IRB using the standard forms and/or procedures that have been established by that IRB.

Adverse reactions of minor severity, or adverse reactions which are determined by the investigator to be unrelated to research-specific procedures or interventions need not be reported to the local IRB.

8 Other Considerations

8.1 Clinical site eligibility. The clinical site must be formally part of or affiliated with one of the six institutions (East Carolina University, Neuropsychiatric Research Institute [Fargo ND], New York Columbia-Presbyterian / Cornell, Oregon Health & Sciences University, University of Pittsburgh Medical Center, University of Washington) participating in the LABS consortium. The clinical sites for the LABS-3 Psychosocial study are: the Neuropsychiatric Research Institute, Pittsburgh Medical Center and New York Columbia-Presbyterian/Cornell.

8.2 Performance Monitoring. The DCC will perform statistical analyses and prepare materials for monitoring study progress (e.g., recruitment, retention, data processing timeliness and accuracy) and protocol adherence (e.g., proportion of follow-up visits completed on time). Problems with adhering to study protocols, data collection, entry, and management will be identified and addressed.

Another critical dimension will be the quality of data entry. During data audits at the clinical centers, the DCC will visually check randomly selected source documents, as well as source documents selected because of suspected problems, against the computerized version. The number and nature of errors will be tabulated. These audits will also provide information about the accuracy of data collection.

Inadequate performance in any aspect of the study (e.g., protocol adherence, data collection, data entry, data completeness, data accuracy) will be reported to the site principal investigator and NIDDK project scientist. A subsequent evaluation will be performed to determine whether corrections have been made. Should problems persist, the Steering Committee will be notified and recommendations will be made for resolving persisting inadequacies.

9 References

IX. Literature Cited

Adami GF, Gandolfo P, Bauer B, Scopinaro N. Binge eating in massively obese patients undergoing bariatric surgery. Int J Eat Disord 1995; 17:45-50.

Adami GF, Gandolfo P, Scopinaro N. Binge eating in obesity. Int J Obes 1996; 20:793-794.

Adams TD, Avelar E, Cloward T. Crosby RD, Gress R, Halverson RC, Hopkins P, Kolotkin RL, LaMonte MJ, Litwin S, Nuttall, RT, Pendelton R, Rosamond W, Simpler SC, Smith SC, Strong M, Walker J, Wiebke G, Yanowitz FG, Hunt SC. Design and rationale of the Utah obesity study. A study to assess morbidity following gastric bypass surgery. Contemporary Clinical Trials, in press.

Allen RP. Article reviewed: Behavioral and neuroendocrine characteristics of the night-eating syndrome. Sleep Medicine 1, 2000; 1:167-168.

Aronoff NJ, Geliebter A, Zammit G. Gender and body mass index as related to the night-eating syndrome in obese outpatients. J Am Diet Assoc 2001; 10:102-104.

Atchison M, Wade T, Higgins B, Slavotinek T. Anorexia nervosa following gastric reduction surgery for morbid obesity. Int J Eat Disord 1998; 23:111-116.

Averbukh Y, Heshka S, El-Shoreya H, Flancbaum L, Geliebter A, Kamel S, Pi-Sunyer FX & Laferrere B. Depression score predicts weight loss following Roux-en-Y gastric bypass. Obes Surg. 2003, 13:833-836.

Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch Gen Psychiatry 1961; 4:561-571.

Birketvedt GS, Florholmen J, Sundsfjord J, Osterud B, Dinges D, Bilker W, Stunkard A. Behavioral and Neuroendocrine Characteristics of the Night-Eating Syndrome. JAMA 1999; 282:657-663.

Björk CC, Andersson I, Rössner S. Night eating and nocturnal eating-two different or similar syndromes among obese patients? Int J Obes 2001; 25:365-372.

Boan H, Kolotkin RJ, Westman EC, McMahonRl, Grant JP. Binge eating, quality of life and physical activity improve after Roux-en-Y gastric bypass for morbid obesity. Obes Surg, 2004; 14:341-348.

Bocchieri LE, Meana M, Fisher BL. A review of psychosocial outcomes of surgery for morbid obesity. J Psychosom Res 2002a; 52:155-165.

Bocchieri LE, Meana M, Fisher BL. Perceived psychosocial outcomes of gastric bypass surgery: A qualitative study. Obes Surg 2002b; 12:781-788.

Bock RD. (1983). Within-subject experimentation in psychiatric research. In: R. D. Gibbons & M. W. Dysken (Eds.). Statistical and Methodological Advances in Psychiatric Research. New York: Spectrum.

Bonne OB, Bashi R, Berry EM. Anorexia nervosa following gastroplasty in the male: two cases. Int J Eat Disord 1996; 19:105-108.

Buchwald H, Avidor Y, Braunwald E, Jensen MD, Pories W, Fahrbach K, Schoelles K. Bariatric Surgery, A Systematic Review and Meta-analysis. JAMA; 2004, 292:1724-1737.

Bull RH, Engels WD, Engelman F, Bloom L. Behavioral changes following gastric bypass surgery for morbid obesity: a prospective, controlled study. J Psychosom Res 1983; 27:457-467.

Burgmer R, Grigutsch K, Zipfel S, Wolf AM, de Zwaan M, Husemann B, Albus C, Senf W, Herpertz S. The influence of eating behavior and eating pathology on weight loss after gastric restriction operations. Obes Surg. 2005 May;15(5):684-91.

Busetto L, Segato G, De Marchi F, Foletto M, De Luca M, Caniato D, Favretti F, Lise M, Enzi G. Outcome Predictors in Morbidly Obese Recipients of an Adjustable Gastric Band. Obes Surg 2002; 12:83-92.

Busetto L, Valente P, Pisent C, Segato G, de Marshi F, Favretti F, Lise M, Enzi G. Eating pattern in the first year following adjustable silicone gastric banding (ASGB) for morbid obesity. Int J Obes 1996; 20:539-546.

Carpenter KM, Hasin DS, Allison DB, Faith MS. Relationships between obesity and DSM-IV major depressive disorder, suicide ideation, and suicide attempts; results from a general population study. Am J Public Health, 2000; 90:251-257.

Choban PS, Onyejekwes J, Burge JC, Flanebaun L. A health status assessment of the impact of weight loss following Roux-en-Y gastric bypass for clinically severe obesity. J Amer Coll Surg, 1999; 188:491-497.

Cohen J. Statistical Power Analysis for the Behavioral Sciences, Second Edition. Hillsdale, NJ: Lawrence Erlbaum, 1988.

Cook CM, Edwards C. Success habits of long-term gastric bypass patients. Obes Surg 1999; 9:80-82.

Cooke EA, Guss JL, Kissileff HR, Devlin MJ & Walsh BT. Patterns of food selection during binges in women with binge eating disorder. Int J Eat Dis, 1997; 22:187-193.

Counts D. An adult with prader-willi syndrome and anorexia nervosa: a case report. Int J Eat Disord 2001; 30:231-233.

Crisp AJ, Kalucy RS, Pilkington TR. Some psychological consequences of ileojejunal bypass surgery. Am J Clin Nutr 1977;30:109-120.

Crow SJ, Agras WS, Halmi KA, Mitchell JE, Kraemer HC. Full syndromal versus subthreshold anorexia nervosa, bulimia nervosa, and binge-eating disorder. Int J Eat Disord 2002; 32:309-318.

Deitel M, Anorexia nervosa following bariatric surgery. Obes Surg. 2002, 12:729-730.

Delgado C, Morales Gorria MJ, Maruri Chimeno I, Rodrigues del Toro C, Benavente Martin JL, Nunez Bahamonte S. Eating behavior, body attitudes and psychopathology in morbid obesity. Actas Esp Psiquiatr, 2002; 30:376-381.

Delin CR, Watts JM, Bassett DL. An exploration of the outcomes of gastric bypass surgery for morbid obesity: patient characteristics and indeces of success. Obes Surg, 1995; 5:159-170.

Delin CR, Watts JM, Saebel JL, Anderson PG. Eating behavior and the experience of hunger following gastric bypass surgery for morbid obesity. Obes Surg 1997; 7:405-413.

Devlin MJ, Goldfein JA, Flancbaum L, Bessler M, Eisenstadt R. Surgical management of obese patients with eaeting disorders: a survey of current practices. Obes Surg. 2004, 14:1252-1257.

de Zwaan M, Burgard M, Schenck C, Mitchell JE. Nighttime eating: a review of the literature. Eat Disord Rev 2002; 10:1-18.

de Zwaan M, Lancaster KL, Mitchell JE, Howell LM, Monson N, Roerig JL, Crosby R. Health-related quality of life in morbidly obese patients: effect of gastric bypass surgery. Obes Surg 2002; 12:773-780.

de Zwaan M, Mitchell JE, Howell LM, Monson N, Swan-Kremeier L, Kolotkin RL, Crosby RD. Two measures of health related quality of life in morbid obesity: the role of binge eating, eating specific and general psychopathology. Obes Res 2002;10:1143-1151.

Dixon JB, Dixon ME, O'Brien PE. Quality of life after lap-band placement: influence of time, weight loss, and comorbidities. Obes Res 2001; 9:713-721.

Dixon JB, Anderson M, Cameron-Smith D, O'Brien PE. Sustained weight loss in obese subjects has benefits that are independent of attained weight. Obes Res 2004; 12:1895-1902.

Djuric Z, DiLaura NM, Jenkins I, Darga L, Jen CK, Mood D, Bradley E, Hryniuk WM. Combining weight-loss counseling with the weight watchers plan for obese breast cancer survivors. Obes Res. 2002 Jul;10(7):657-65.

Dubovski SL, Haddenjorst A, Murphy J. A preliminary study of the relationship between preoperative depression and weight loss following surgery for morbid obesity. Int J Psychiatry Med 1985; 15:185-196.

Dymek MP, le Grange D, Neven K, Alverdy J. Quality of life and psychosocial adjustment in patients after roux-en-Y gastric bypass: a brief report. Obes Surg 2001; 11:32-39.

Ebbeling CB, Sinclair KB, Pereira MA, Garcia-Lago E, Feldman HA, Ludwig DS. Compensation for energy intake from fast food among overweight and lean adolescents. JAMA. 2004 Jun 16;291(23):2828-33.

Fabricatore AN, Wadden TA. Psychological aspects of obesity. Clin Dermatol, 2004; 22:332-337.

Fairburn CG, Cooper Z. The Eating Disorders Examination (12th Edition). In CG. Fairburn and GT. Wilson (Eds.). Binge Eating: Nature, Assessment, and Treatment. New York: Guilford Press 1993:317-360.

First MB, Spitzer R, Gibbon M, Williams JBW. Structured Clinical Interview for DSM-IV Axis I Disorders. Patient Edition (SCID-I/P. Version 2.0). New York, NY: Biometrics Research Department, New York State Psychiatric Institute, 1995.

Fontaine KR, Barofsky I. Obesity and health-related quality of life. Obes Rev. 2001; 2:173-182.

Geliebter A. New developments in binge eating disorder and the night eating syndrome. 2000 Appetite, 2002; 39:175-177.

Gentry K, Halverson JD, Heisler S. Psychological assessment of morbidly obese patients undergoing gastric bypass: a comparison of preoperative and postoperative adjustments. Surg 1984; 95:218-220.

Gibbons RD, Hedeker D, Elkin I, Waternaux C, Kraemer HC, Greenhouse JB, Shea MT, Imber SD, Sotsky SM, Watkins JT. Some conceptual and statistical issues in analysis of longitudinal psychiatric data. Archives of General Psychiatry, 1993; 50:739-750.

Gibbons R, Hedeker D, Waternaux C, Davis J. Random regression models: A comprehensive approach to the analysis of longitudinal psychiatric data. Psychopharmacology Bulletin, 1988; 24:438-443.

Glinski J, Wetzler S, Goodman E. The Psychology of Gastric Bypass Surgery. Obes Surg 2001; 11:581-588.

Gluck ME, Geliebter A, Satov T. Night eating syndrome is associated with depression, low self-esteem, reduced daytime hunger, and less weight loss in obese outpatients. Obes Res. 2001; 9:264-267.

Green AE, Dymek-Valentine M, Pytluk S, Le Grange D, Alverdy J. Psychosocial outcome of gastric bypass surgery for patients with and without binge eating. Obes Surg, 2004; 14:975-985.

Greeno CG, Wing RR, Marcus MD. Nocturnal eating in binge eating disorder and matched-weight controls. Int J Eat Disord 1995;18:343-349.

Guisado JA, Vaz FJ, López-Ibor JJ, López-Ibor MI, del Río J, Rubio MA. Gastric surgery and restraint from food as triggering factors of eating disorders in morbid obesity. Int J Eat Disord 2002; 31:97-100.

Guisado JA, Vaz FJ, López-Ibor JJ, Rubio MA. Eating behavior in morbidly obese patients undergoing gastric surgery: differences between obese people with and without psychiatric disorders. Obes Surg 2001;11:576-580.

Guisado JA, Vaz FJ, Alarcon J, Lopez-Ibor JJ Jr, Rubio MA, Gaite L. Psychopathological status and interpersonal functioning following weight loss in morbidly obese patients undergoing bariatric surgery. Obes Surg, 2002; 12:835-840.

Guisado JA, Vaz FJ. Personality profiles of the morbidly obese after vertical banded gastroplasty. Obes Surg, 2003a; 13:394-398.

Guisado JA, Vaz FJ. Psychopathological differences between morbidly obese binge eaters and non-binge eaters after bariatric surgery. Eat Weight Disord. 2003b, 8:315-318.

Hafner RJ, Rogers J, Watts JM. Psychological status before and after gastric restriction as predictor of weight loss in the morbidly obese. J Psychosom Res, 1990; 34:295-302.

Hafner RJ, Watts JM, Rogers J. Quality of life after gastric bypass for morbid obesity. Int J Obes, 1991; 15:555-560.

Hall JC, Horne K, O'Brien PE, Watts JM. Patient well-being after gastric bypass surgery for morbid obesity. Aust NZ J Surg 1983; 53:321-324.

Harris MB, Green D. Psychosocial effects of gastric reduction surgery for obesity. Int J Obes 1982;6:527-539.

Hawke A, O'Brien P, Watts JM, Hall J, Dunstan RE, Walsh JF, Slavotin AH, Elmslie RG. Psychosocial and physical activity changes after gastric restrictive procedures for morbid obesity. Aust N Z Surg, 1990; 60:755-758.

Hedeker D, Gibbons RD, Waternaux C. Sample size estimation for longitudinal designs with attrition: comparing time-related contrasts between two groups. J Ed Beh St 1999; 24:70-93.

Hedeker D, Gibbons RD. Application of random-effects pattern-mixture models for missing data in longitudinal studies. Psychological Methods, 1997; 2:64-78.

Hedley AA, Ogden CL, JohnsonCL, Carroll MD, Curtin LR, Flegal KM. Prevalence of overweight and obesity among US children, adolescents, and adults, JAMA, 2004, 1999-2002; 291:2847-2050.

Hell E, Miller KA, Moorehead MK, Norman S. Evaluation of health status and quality of life after bariatric surgery comparison of standard Roux-en-Y gastric bypass, vertical banding, gastroplasty and laparoscopic adjustable silicone gastric banding. Obes Surg, 2000; 10:214-219.

Herpetz S, Kielmann R, Wolf AM, Langkafel M, Senf W, Hebebrand J. Does obesity surgery improve psychosocial functioning? A systematic review. Int J Obes Relat Metab Disord, 2004; 27:1300-1314.

Herpertz S, Saller B. Psychosomatic aspects of obesity. Psychother Psychosom Med Psychol 2001;51:336-349.

Hintze J. NCSS and PASS. Kaysville, Utah: Number Cruncher Statistical Systems, 2001.

Hörchner R, Tuinebreijer W, Kelder H. Eating patterns in morbidly obese patients before and after a gastric restrictive operation. Obes Surg 2002; 12:108-112.
Hörchner R, Tuinebreijer W. Improvement of physical functioning of morbidly obese patients who have undergone a Lap-Band operation: one-year study. Obes Surg, 1999; 9:399-402.
Hörchner R, Tuinebreijer W, Kelder H. Quality-of-life assessment of morbidly obese patients who have undergone a lap-band® operation: 2-year follow-up study is the MOS SF-36 a useful instrument to measure quality of life in morbidly obese patients? Obes Surg 2001; 11:212-218.
Hsu LK, Mulliken B, McDonagh B, Krupa Das S, Rand W, Fairburn C, Rolls B, McCrory MA, Saltzman E, Shikora S, Dwyer J, Roberts S. Binge eating disorder in extreme obesity. Int J Obes Relat Metab Disord 2002; 26:1398-1403.
Hsu LKG, Betancourt S, Sullivan SP. Eating disturbances before and after vertical banded gastroplasty: a pilot study. Int J Eat Disord 1996; 19:23-24.
Hsu LKG, Sullivan SP, Benotti PN. Eating disturbances and outcome of gastric bypass surgery: a pilot study. Int J Eat Disord 1997; 21:385-390.
Hsu LK, Benotti PN, Dwyer J, Roberts SB, Saltzman E, Shikors S, Rolls BJ, Rand W. Nonsurgical factors that influence the outcome of bariatric surgery: a review. Psychosom Med, 1998; 60:338-346.
Isacsson A, Frederiksen SG, Nilsson P, Hedenbro JL. Quality of life after gastroplasty is normal: a controlled study. Eur J Surg 1997;163:181-186.
Kalarchian MA, Marcus MD, Wilson GT, Labouvie EW, Brolin RE, LaMarca LB. Binge eating among gastric bypass patients at long-term follow-up. Obes Surg 2002;12:270-275.
Kalarchian MA, Wilson GT, Brolin RE, Bradley L. Binge eating in bariatric surgery patients. Int J Eat Disord 1998;23:89-92.
Kalarchian MA, Wilson GT, Brolin RE, Bradley L. Effects of bariatric surgery on binge eating and related psycholopathology. Eating Weight Disord 1999; 4:1-5.
Karlsson J, Sjostrom L, Sullivan M. Swedish obese subjects (SOS)—an intervention study of obesity. Two-year follow-up of health-related quality of life (HRQL) and eating behavior after gastric surgery for severe obesity. Int J Obes Relat Metab Disord 1998; 22:113-126.
Kenler HA, Brolin RE, Cody RP. Changes in eating behavior after horizontal gastroplasty and Roux-en-Y gastric bypass. Am J Clin Nutr 1990; 52;87-92.
Kodama K, Noda S, Murakami A, Azuma Y, Takeda N, Yamanouchi N, Okada S, Komatsu N, Sato T, Miyazawa Y, Kawamura I. Depressive disorders as psychiatric complications after obesity surgery. Psychiatry Clin Neurosci 1998; 52: 471-476.
Kolotkin RL, Crosby RD, Kosloski KD, Williams GR. Development of a brief measure to assess quality of life in obesity. Obes Res 2001; 9:102-111.
Kolotkin RL, Crosby RD, Pendelton R, Strong M, Gress RE & Adams T. Health-related quality of life in patients seeking gastric bypass surgery vs non-treatment-seeking controls. Obes Surg, 2002; 13:371-377.
Kolotkin RL, Crosby RD, Williams GR, Hartley GG, Nicol S. The relationship between health-related quality of life and weight loss. Obes Res 2001; 9:564-571.
Kolotkin RL, Crosby RD, Williams GR. Health-related quality of life varies among obese subgroups. Obes Res 2002;10:748-756.
Kuldau JM, Rand CS. Jejunoileal bypass for obesity: general and psychiatric outcome after one year. Psychosomatics 1986;21:534-539.
Kushner RF,Foster GD. Obesity and quality of life. Nutrition, 2000; 16:947-952.

Laird NM, Ware JH. Random effects models for longitudinal data. Biometrics, 1982; 38:963-974.
Lang T, Hauser R, Buddeberg C, Klaghofer R. Impact of gastric banding on eating behavior and weight. Obes Surg 2002; 12:100-107.
Larsen F. Psychosocial function before and after gastric banding surgery for morbid obesity: a prospective psychiatric study. Acta Psychiatr Scand 1990; 82:1-57.
Larsen JK, Geenen R, van Ramshorst B, Brand N, de Wit P, Stroebe W,, Doorne LJ. Psychosocial functioning before and after laparascopic adjustable gastric banding: a cross-sectional study. Obes Surg, 2003; 13:629-636.
Larsen F, Torgersen S. Personality changes after gastric banding surgery for morbid obesity. A prospective study. J Psychosom Res, 1989; 33:323-334.
Larsen JK, van Ramshorst B, Geenen r, Brand N, Stroebe W, van Doornen LJ. Binge eating and its relationship to outcome after laparoscropic adjustable gastric banding. Obes Surg 2004; 14:1111-1117.
Larsson UE. Influence of weight loss on pain, perceived disability and observed functional limitations in obese women. Int J Obesity 2004; 28:269-277.
Larsson UE, Mattsson E. Perceived disability and observed functional limitations in obese women. Int J Obesity 2001; 25:1705-1712.
Larsson UE, Mattsson E. Influence of weight loss programs on walking speed and relative oxygen cost (%VO_2max) in obese women during walking. J Rehabil Med 2003;35:91-97.
Little RJA. Pattern-mixture models for multivariate incomplete data. Journal of the American Statistical Association, 1993; 88:125-133.
Little RJA. A class of pattern-mixture models for normal incomplete data. Biometrika, 1994; 81:471-483.
Little RJA. Modeling the drop-out mechanism in repeated-measures studies. Journal of the American Statistical Association, 1995; 90:1112-1121.
Malone M, Alger-Mayer S. Binge status and quality of life after gastric bypass surgery: a one-year study. Obes Res, 2004; 12:473-481.
Mitchell JE, Halmi K, Wilson GT, Agras WS, Kraemer H, Crow S. A randomized secondary treatment study of women with bulimia nervosa who fail to respond to CBT. Int J Eat Disord, 2002; 32:271-281.
Mitchell JE, Lancaster KL, Burgard MA, Howell LM, Krahn DD, Crosby RD, Wonderlich SA, Gosnell BA. Long-term follow-up of patients' status after gastric bypass. Obes Surg 2001; 11:464-468.
Mitchell JE. Bulimia With Self-Induced Vomiting After Gastric Stapling. Am J Psychiatry 1985;142:656.
Neill JR, Marshall JR, Yale CE. Martial changes after intestinal bypass surgery JAMA, J Am Med Assoc 1978; 240:447-450.
Nguyen NT, Goldman C, Rosenquist CJ, Arango A, Cole CJ, Lee SJ, Wee BM. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. Ann Surg, 2001; 234:279-289.
Pekkarinen T, Koskela K, Huikuri K, Mustajoki P. Long-Term Results of Gastroplasty for Morbid Obesity: Binge-Eating as a Predictor of Poor Outcome. Obes Surg 1994; 4:248-255.
Pessina A, Andreoli M, Vassallo C. Adaptability and Compliance of the Obese Patient to Restrictive Gastric Surgery in the Short Term. Obes Surg; 11:459-463.

Powers PS, Perez A, Boyd F, Rosemurgy A. Eating pathology before and after bBariatric surgery: a prospective study. Int J Eat Disord 1999; 25:293-300.
Powers PS, Rosemurgy AS, Coovert DL, Boyd FR. Psychosocial sequelae of bariatric surgery: a pilot study. Psychosomatics 1988; 29:283-288.
Quatromoni PA, Copenhafer DL, D'Agostino RB, Millen BE. Dietary patterns predict the development of overweight in women: The Framingham Nutrition Studies. J Am Diet Assoc. 2002 Sep;102(9):1239-46.
Rand CS, Kowalske K, Kuldau JM. Characteristics of marital improvement following obesity surgery. Psychosomatics, 1984; 25:221-223, 226.
Rand CS, Kuldau JM, Robgbins L. Surgery for obesity and marriage quality. Jama 1982; 247:1419-1422.
Rand CS, MacGregor AM, Hankins G. Gastric bypass surgery for obesity: weight loss, psychosocial outcome and morbidity one and three years later. South Med J 1986; 79:1511-1514.
Rand CSW, MacGregor AM, Stunkard AJ. The night eating syndrome in the general population and among postoperative obesity surgery patients. Int J Eat Dis, 1997; 22:65-69.
Rowston WM, McCluskey SE, Gazet JC, Lacey JH, Franks G, Lynch D. Eating behavior, physical symptoms and psychological factors associated with weight reduction following the scopinaro operation as modified by Gazet. Obes Surg 1992; 2:355-360.
Sabbioni MEE, Dickson MH, Eychmüller, Franke D, Goetz S, Hürny C, Naef M, Balsiger B, de Marco D, Bürgi U, Büchler MW. Intermediate results of health related quality of life after vertical banded gastroplasty. Int J Obes 2002; 26:277-280.
Sanchez-Johnsen LA, Dymek M, Alverdy J, le Grange D. Binge eating and eating-related cognitions and behavior in ethnic diverse obese women. Obes Res, 2003; 11:1002-1009.
Sarwer DB, Wadden TA, Fabricatore AN. Psychosocial and behavioral aspects of bariatric surgery. Obes Res 2005; 13:639-648.
Saunders R, Johnson L, Teschner J. Prevalence of eating disorders among bariatric surgery patients. Eat Disord 1998; 6:309-317.
Saunders R. Post-surgery group therapy for gastric bypass patients. Obes Surg, 2004; 14:1128-1131.
Schakel SF, Sievert YA, Buzzard IM. Sources of data for developing and maintaining a nutrient database. J Am Diet Assoc. 1988 Oct;88(10):1268-71.
Schenck CH, Hurwitz TD, Bundie SR, Mahowald MW. Sleep-related eating disorders. Polysomnographic correlates of a heterogeneous syndrome distinct from daytime eating disorders. Sleep;14:419-431.
Schenck CH, Hurwitz TD, O'Connor KA, Mahowald MW. Additional categories of sleep-related eating disorders and the current status of treatment. Sleep. 1993 Aug;16(5):457-66.
Schok M, Geenen R, van Antwerpen T, de Wit P, Brand N, van Ramsho. Quality of life after laparoscopic adjustable banding for severe obesity: postoperative and retrospective preoperative evaluations. Obes Surg, 2000; 10:502-508.
Scioscia TN, Bulik CM, Levenson J, Kirby DF. Anorexia nervosa in a 38-year-old woman 2 years after gastric bypass surgery. Psychosomatics, 1999;40:86-88.
Segal A, Kinoshita Kussunoki D & Larino MA. Post-surgical refusal to eat: anorexia nervosa, bulimia nervosa a new eating disorder? A case series. Obes Surg, 2004; 14:353-360.
Shamblin JR, Shamblin WR. Gastroplasty for morbid obesity in older patients. J La State Med Soc 1987; 139:45-8.
Statistical Analysis Software (SAS) Version 8. Cary, North Carolina: SAS Institute Inc., 2001.

Statistical Package for the Social Sciences (SPSS), Version 13.0. Chicago, Illinois: SPSS Inc., 2004.
Stephan Herpertz, Winfried Siffert, Johannes Hebebrand. Binge Eating as a Major Phenotype of Melanocortin 4 Receptor Gene Mutations. New England Journal of Medicine; Aug 2003; 349(6); p. 606-607
Stewart AL, Ware JE. Measuring functioning and Well-Being: The medical outcomes study approach. Durham, NC: Duke University Press, 1992.
Stiratelli R, Laird NM, Ware JH. Random-effects models for serial observations with binary response. Biometrics 1984; 40:961-971.
Stunkard A. Two eating disorders: binge eating disorder and the night eating syndrome. Appetite 2000; 34:333-334.
Stunkard AJ, Grace WJ, Wolff HG. The Night-eating syndrome: A pattern of food intake among certain obese patients. Am J Med 1955; 78-86.
Sullivan M, Karlsson J, Sjostrom L, Backman L, Bengtsson C, Bouchard, DahlgrennS, Jonsson E, Larsson B, Lindstedt S. Swedish obese subjects (SOS)—an interventionstudy of obesity. Baseline evaluation of health and psychosocial functioning in the first 1743 subjects examined. Int J Obes Relat Metab Disord, 1993; 17:503-512.
Temple PC, Travis B, Sachs L, Strasser S, Choba P, Flancbaum L. Functioning and well-being of patients before and after elective surgical procedures. J Am Coll Surg, 1995; 181:17-25.
Thompson JK, Weinsier RL, Jacobs B. Self-Induced vomiting and subclinical bulimia following gastroplasty surgery for morbid obesity: a case description and report of a multi-component cognitive-behavioral treatment strategy. Int J of Eat Disord 1985; 4:609-615.
Tolonen P, Victorzon M. Quality of life following laparoscopic adjustable gastric banding, Swedish band and the Moorehead-Ardelt questionnaire. Obes Surg, 2003; 13:424-426.
Vamacho PJ, Williamson DA, Bartz BG, Ryan DH, Rhodes SK, O'Neil P, Sebastian SB, Barker SE. Prevalence of binge eating disorder in obese adults seeking weight loss treatment. Eat Weight Disord; 1997 2:117-124.
van Gemert WG, Adang EM, Greve JWM, Soeters PB. Quality of life assessment of morbidly obese patients: effect of weight-reducing surgery. Am J Clin Nutr 1998;67:197-201.
Van Hout G. Psychosocial effects of bariatric surgery. Acta Chir Belg 2005, 105:40-43.
Viens MJ, Hranchuk K. The treatment of bulimia nervosa following surgery using a stimulus control procedure: a case study. J Behav Ther & Exp Psychiat 1992; 23:313-317.
Wadden TA, Sarwer DB, Berkowitz RI. Behavioral treatment of the overweight patient. Baillieres Best Pract Res Clin Endocrinol Metab 1999; 13:93-107.
Wadden TA, Sarwer DB, Womble LG, Foster GD, McGuckin BG, Schimmel A. Psychosocial aspects of obesity and obesity surgery. Surg Clin North Am 2001; 81:1001-1024.
White MA, O'Neil PM, Kolotkin RL, Byrne TK. Gender, race, and obesity-related quality of life at extreme levels of obesity. Obes Res. 2004; 12:949-955.
Yaroch AL, Resnicow K, Petty AD, Khan LK. Validity and reliability of a modified qualitative dietary fat index in low-income, overweight, African American adolescent girls. J Am Diet Assoc. 2000 Dec;100(12):1525-9.