

ACCEPTABILITY OF WEIGHT LOSS TREATMENTS AMONG OVERWEIGHT  
ADOLESCENTS AND THEIR CAREGIVERS

By

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ACCEPTABILITY OF WEIGHT LOSS TREATMENTS AMONG OVERWEIGHT ADOLESCENTS AND THEIR CAREGIVERS

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## Abstract

Obesity is a growing epidemic in the United States and has been linked to impairments in physical and psychosocial functioning. Consequently, treatments for obesity have flourished and health care professionals have increasingly turned to more invasive forms of treatment (e.g., bariatric surgery). In recent years, the availability of surgical obesity interventions has been extended from adults to adolescent populations. However, research examining the extent to which these procedures are acceptable to overweight adolescents and their parents is lacking. This study sought to examine the acceptability of adjustable gastric banding, a recently developed bariatric surgery procedure, in relation to four other common obesity treatments (i.e., dietary therapy, exercise program, family behavior therapy, and weight loss pills). Participants were recruited from a hospital-based weight management clinic. Inasmuch as acceptance is the basis for effective intervention programs, an understanding of adolescent and parental perspectives about obesity treatments is required to inform future weight loss program strategies. Results indicated that across informants (parents and children, boys and girls) gastric banding surgery and weight loss pills were perceived as less acceptable forms of treatment than diet, exercise, and family behavior therapy. There was also no significant correlation between treatment acceptability ratings and body mass index (BMI), health-related quality of life, or number of previously attempted weight loss strategies. Thus, although the number of bariatric surgeries occurring in the United States is on the rise and although gastric banding surgery in particular is being touted

as a safer form of bariatric surgery, parents and children perceive this form of treatment to be less acceptable than other weight loss treatments on the market. Further exploration of the factors that influence parents' and children's negative perceptions of gastric banding surgery is warranted because health professionals may have a difficult time encouraging even the most appropriate candidates to consider the surgery if acceptability for the procedure is low.

## Acceptability of Weight Loss Treatments Among Overweight Adolescents and Their Caregivers

The worldwide prevalence of obesity has grown at a staggering rate in recent years, leading the World Health Organization (WHO) to describe it as a “global epidemic” (WHO, 2000). Excess weight has particularly become a public health concern in the United States, where the prevalence of adult obesity doubled from 15% to approximately 30% between 1976 and 2002 (Fabricatore & Wadden, 2006). Perhaps even more alarming is the fact that pediatric obesity has more than doubled in the past 20 years (Ogden, Flegal, Carroll, & Johnson, 2002). Currently, it is estimated that obesity affects at least 15.3% of school-age children and 15.5% of adolescents (Pohl, Stephen, & Wilson, 2006). Pediatric obesity is associated with a number of immediate and long-term health risks. These may include, for example, hypertension, hyperlipidemia, iron deficiency anemia, sleep disturbances, kidney disease, increased cancer risk and increased risk for adult mortality (Pohl et al., 2006). In addition, studies have documented that overweight and severely obese children and adolescents have lower health-related quality of life than their non-overweight peers (Schwimmer, Burwinkle, & Varni, 2003; Williams, Wake, Hesketh, Maher, & Waters, 2005). Given the rapid growth of pediatric obesity in the United States and its associated harmful effects on health and health-related quality of life, obesity treatments have flourished.

### *Treatments for Obesity*

Treatment options for obesity generally fall into the three broad categories of lifestyle modification, pharmacotherapy, and bariatric surgery (Fabricatore & Wadden, 2006). Lifestyle modification programs consist of diet, exercise and behavior therapy. These programs are the first line of treatment for pediatric obesity (Xanthakos & Inge, 2007). Nevertheless, there are inherent disadvantages to these programs that might render them less appealing than other treatment modalities. For example, they tend to be very time intensive, typically result in only modest effects, and weight loss resulting from these programs is rarely maintained (Yanovski & Yanovski, 2003).

Pharmacological interventions work by decreasing hunger and, therefore, limiting food intake, or by blocking the amount of fat that is absorbed from food (Fabricatore & Wadden, 2006). The drawbacks to these interventions are similar to those of lifestyle modification programs. That is, pharmacological interventions have been shown to be only moderately effective and weight loss is rarely sustained once individuals stop taking weight loss medications (Berkowitz, Wadden, Tershakovec, & Cronquist, 2003).

Bariatric surgery is the most intensive form of obesity intervention, typically reserved for individuals who are severely obese, meaning that they have a Body Mass Index of 40 or higher. Bariatric surgery is intended to promote weight loss by limiting food intake, decreasing the amount of nutrients and calories absorbed from food, or both (Fabricatore & Wadden, 2006). Unlike lifestyle modification programs and

pharmacological interventions, bariatric surgery has resulted in significant and sustained weight loss, as well as significant improvements in obesity-related comorbidities (Brolin, 2002; Livingston, 2002). Thus, the popularity of bariatric surgery has grown tremendously. According to Steinbrook (2004), the number of bariatric surgeries performed in the United States has increased from 16,000 in 1992 to about 103,000 in 2003.

Of the bariatric surgery procedures currently available, the two most popular are the Roux-en-Y gastric bypass (RYGB) and the adjustable gastric band (Inge, Zeller, Garcia, & Daniels, 2004; Maggard et al., 2005). The RYGB involves creating a small stomach pouch and bypassing a portion of the small intestine. This procedure results in limited food intake and reduced nutrient and caloric absorption.

Adjustable gastric banding, also known as the lap-band procedure, is the most recently developed surgical procedure for weight management. It has been commonly performed in Europe for at least a decade and is growing in popularity in the United States (Buchwald & Williams, 2004). Adjustable gastric banding involves placing a synthetic gastric band around the upper stomach, which forms a smaller pouch and limits food intake. The band can be adjusted to allow for varying food intake capacity. Unlike the gastric bypass, this procedure can be reversed when medically indicated. It also requires less operative time and is associated with fewer complications than other bariatric procedures (Inge, Xanthakos, & Zeller, 2007; Pohl et al., 2006).

Studies examining the outcomes of these bariatric procedures in adolescents have been scarce in comparison to the dearth of adult outcome studies. However, preliminary evidence does suggest that adolescents who undergo bariatric procedures experience rapid weight loss and reductions in obesity-related comorbid conditions (Inge et al., 2004; Strauss, Bradley, & Brodin, 2001; Sugerman et al., 2003). Most adolescent outcome studies to date have focused on gastric bypass surgery. In a study conducted by Sugerman et al. (2003), the average Body Mass Index (BMI) of 33 adolescents who underwent gastric bypass surgery decreased from 52 pre-surgery to 29 at 5 years post-surgery. Similarly, in a study by Rand and MacGregor (1994), 30 adolescents who underwent RYGB had an average preoperative BMI of 47 and an average post-operative BMI of 32 six years after surgery.

Similar findings have been gleaned from studies examining the effects of adjustable gastric banding. In a study conducted by Dolan, Creighton, Hopkins, and Fielding (2003), the average BMI of 17 patients between the ages of 12 and 19 who underwent gastric banding surgery decreased from 44.7 pre-surgery to 30.2 at 2 years post-surgery. Similarly, Horgan et al. (2005) reported average weight losses of 57% at 30 months post-surgery in a sample of 4 adolescents who underwent gastric banding surgery.

The aforementioned findings suggest that bariatric surgery is a promising modality for treating obesity in adolescents. However, like all surgeries, bariatric surgery comes with associated risks. The risks associated with RYGB may include incisional hernias, nutrient deficiencies, marginal ulcers, pulmonary embolism, small

bowel obstruction, and wound infection, among others (Pohl et al., 2006). Although adjustable gastric banding is generally associated with fewer risks than other bariatric procedures, it may still lead to such complications as esophageal dysmotility, dysphagia, and band slippage (Pohl et al., 2006). Despite the risks and complications associated with bariatric surgery procedures, the number of weight loss operations for adolescents has increased threefold from 2000 to 2003 (Inge et al., 2007). Tsai, Inge, and Burd (2007) reviewed the National Inpatient Sample, a sizeable United States administrative database, and concluded that approximately 3000 bariatric procedures were conducted with adolescents between 1996 and 2003. The extent to which these procedures are acceptable to adolescents and their parents, however, remains unexplored.

#### *Treatment Acceptability*

Interest in “treatment acceptability” originated in the late 1970s and early 1980s. Throughout the 1970s behavioral researchers had been focusing their efforts on the effectiveness of behavioral interventions. Kazdin (1977) and Wolf (1978) argued, however, that it was not sufficient for treatments to be effective; the treatments also had to be accepted by the consumers with whom they were being applied. In 1981, Kazdin became the first to define treatment acceptability as “judgments by laypersons, clients, and others of whether treatment procedures are appropriate, fair, and reasonable for the problem or client” (p. 493). This paved the way for other researchers to develop tools to assess treatment acceptability throughout the 1980s (Miltenberger, 1990).

The assessment of treatment acceptability is important because professionals and consumers may view the acceptability of treatments differently. Although professionals may view a particular treatment as viable and acceptable, consumers may disagree and, therefore, refuse to utilize the treatment. Kazdin (1981) summarized this issue by asserting that “treatments that are viewed as more acceptable may be more readily sought, initiated, and adhered to than those viewed as less acceptable. Hence, acceptability may have direct implications for dissemination and utilization of treatments” (p. 494). Similarly, Nelson and Steele (2006) noted that “if a treatment is not well received by clients, it may be less likely to be widely used, regardless of the evidence for outcomes that may result from controlled and applied trials” (p. 392).

Previous treatment acceptability studies have employed several methodologies. Miltenberger (1990) described two methods commonly utilized in these studies: the analogue study and the clinical situation. In the traditional analogue study participants are provided with a case vignette describing an individual with a given clinical problem or condition, as well as a description of a potential treatment for that problem. Participants are then asked to rate the acceptability of the treatment for the identified problem using an acceptability scale. The clinical situation, on the other hand, involves actually implementing an intervention and asking participants to rate its acceptability at various points throughout the treatment process.

The analogue approach is advantageous for several reasons. First, it requires less time and effort than the clinical situation (Miltenberger, 1990). Second, it allows

investigators to rate the acceptability of multiple treatments, whereas the clinical situation typically involves rating only one treatment. Third, analogue studies may allow investigators to determine how a treatment that is still in the process of being devised, or a treatment that is not yet widely available, will be accepted by its target constituency. Fourth, by utilizing the analogue approach in this way, investigators can determine whether consumers are willing to utilize a treatment and, if not, what changes need to occur in order to increase the likelihood that the treatment will be utilized. For example, changes may need to be made to the components of the treatment itself (e.g., time required to implement it, effort required) or the way in which the treatment is advertised or explained to consumers.

As was mentioned previously, behavioral interventions have been the focus of numerous treatment acceptability studies, and many of them have exemplified the analogue approach. Kazdin, (1981), for example, used an analogue approach to assess the acceptability of various treatments for deviant child behavior. He asked undergraduate students to rate four different treatments (reinforcement of incompatible behavior, positive practice, time out from reinforcement, and medication) applied to clinical case descriptions of children exhibiting disruptive behaviors. After reading the case descriptions and descriptions of the four treatments, participants rated the acceptability of the treatments by completing a 15-item treatment acceptability rating scale, the Treatment Evaluation Inventory (Kazdin, 1980). Similarly, Miller, Manne, and Palevsky (1998) used the analogue approach to examine the acceptability of behavioral interventions targeting noncompliance in

children with cancer. Participants consisted of parents of children receiving treatment for cancer, pediatric oncology nurses, and parents of healthy children. Participants were presented with a clinical vignette and five treatment descriptions and were then asked to rate the treatments using the Treatment Evaluation Inventory-Short Form (Kelley, Heffer, Gresham, & Elliott, 1989), a 9-item acceptability rating scale.

Components of the analogue approach have also been utilized to examine the acceptability of hypothetical treatments. Liao and Zimet (2001), for example, assessed the acceptability of hypothetical HIV vaccines among undergraduates. Participants were provided with descriptions of 12 hypothetical vaccines, which were uniquely identified as a function of cost (free or \$300), efficacy (50% or 80%) and social saturation (10%, 50%, or 90%). The 12 vaccines were described as consisting of different combinations of these factors. Participants were then asked to rate the probability that they would get each vaccine using an 11-point scale ranging from zero (I will never get the vaccine) to one hundred (I will definitely get the vaccine).

A common goal of researchers in this area has been to identify factors that influence the acceptability of treatments. A number of studies have shown that acceptability ratings are higher when the problems they are intended for are viewed as more severe (Burgio, Hardin, Sinnott, Janosky, & Hohnman, 1995; Lindeman, Miltenberger, & Lennox, 1992; Reimers, Wacker, & Koepl, 1987; Zimet, Mays, et al., 2005) and when treatment efficacy is higher (Liao & Zimet, 2001; Zimet, Perkins, et al., 2005). In addition, treatments have been shown to receive higher acceptability ratings by people who believe the treatments are important to their physician and by

children who believe treatments are acceptable to their parents (Rosenthal, Kottenhahn, Biro, & Succop, 1995; Zimet et al., 2000). Still other studies have demonstrated that treatment acceptability is inversely related to cost of treatment (Reimers et al., 1987; Zimet et al., 2000), adverse side effects of treatment (Kazdin, 1981; Reimers et al., 1987), and time and effort involved in treatment implementation (Reimers et al., 1987; Witt & Martens, 1983). As Yates (2003) suggested, when evaluating treatments, cost-effectiveness should be considered not only in terms of the economic costs of a given treatment, but also the time and effort individuals must expend to utilize the treatment.

A variety of interventions have been the focus of treatment acceptability research. Behavioral interventions have comprised the majority of research in this area and have included interventions for child behavior problems (Jones, Eyberg, Adams, & Boggs, 1998; Kazdin, 1981, 2000; Kazdin, Marciano, & Whitley, 2005), attention-deficit hyperactivity disorder (Gage & Wilson, 2000; Krain, Kendall, & Power, 2005; Stinnett, Crawford, Gillespie, Cruce, & Langford, 2001; Vereb & DiPerna, 2004), classroom behavior (Amato-Zech et al., 2006; Reitman, Murphy, Hupp, & O'Callaghan, 2004; Witt & Martens, 1983), tic disorders (Woods & Twohig, 2002), trichotillomania (Elliott & Fuqua, 2002), and skin-picking (Teng, Woods, & Twohig, 2006), among others. Studies examining the acceptability of medical interventions have also been conducted and have focused, for example, on the acceptability of immunizations for HIV and other sexually transmitted infections

(Liau & Zimet, 2001; Mays, Sturm, & Zimet, 2004; Zimet, Fortenberry, & Blythe, 1999; Zimet et al., 2000; Zimet et al., 2005) and Hepatitis B (Rosenthal et al., 1995).

### *Acceptability of Obesity Interventions*

A small body of literature has been devoted to examining the acceptability of obesity interventions. Investigators have, for example, evaluated the acceptability of family-based behavioral treatments for obesity (Edwards et al., 2006), school-based obesity prevention programs (Mauriello et al., 2006), medications for obesity (Heraief, 1997), and internet-based weight loss maintenance programs (Harvey-Berino, Pintauro, & Gold, 2002). Despite the increasing number of bariatric surgery procedures being conducted in the United States in general, and with adolescents in particular, literature regarding the acceptability of these procedures is lacking.

Previous studies examining the acceptability of obesity interventions have been methodologically limited in that they have relied solely on treatment outcomes to infer acceptability, rather than asking participants to rate acceptability. As an example, Edwards et al. (2006) measured BMI, self-esteem, mood and eating attitudes in a sample of children aged 8 to 13 years who participated in a family-based behavioral intervention. The intervention resulted in weight loss and improvements in self-esteem and depression. Therefore, Edwards et al. (2006) judged the intervention to be an acceptable method for addressing adolescent obesity. However, this study is restricted in that investigators neglected to gather information regarding the participants' views of how acceptable the treatment was.

In addition to this methodological limitation, previous studies have tended to focus primarily on one or two obesity interventions, as opposed to assessing the acceptability of multiple treatment options in relation to one another. Whereas obese individuals are likely to be exposed to a variety of treatment options, it is important to know not only how acceptable they find each of these options to be, but also which treatments they deem to be most and least preferable.

#### *Purpose of Current Study and Hypotheses*

The purpose of this study was to examine the acceptability of five obesity treatments, with particular interest in adjustable gastric banding surgery. Given the growing obesity epidemic in the United States, obese adolescents are likely going to be encouraged to use this and other surgical forms of treatment. It is not yet known how well accepted these treatments will be or what goes into judgments of their acceptability. In order to address this gap in the literature, this study utilized an analogue approach to assess the acceptability of adjustable gastric banding relative to four other common forms of treatment for overweight and obesity (exercise program, dietary therapy, family behavioral therapy, and weight loss pills). It was hypothesized that there would be statistically significant differences among acceptability ratings for the five treatments. It was also hypothesized that these differences would be moderated by BMI, overall health-related quality of life, and number of previous weight loss methods attempted.

## Method

### *Participants*

Participants were recruited from an outpatient weight management clinic at a children's hospital in the northeastern United States. In order to be included in the study, adolescents had to be between the ages of 12 and 17. Caregivers were required to be the legal guardians of their children in order to participate in the study. No exclusions were made on the basis of sex, race, ethnicity, Body Mass Index (BMI), or length of time in weight management treatment. A total of 101 families agreed to participate, for a response rate of 94.4%. Participants consisted of 102 adolescents (41 males; 61 females) and 101 caregivers (one caregiver had two children who were patients in the weight management clinic and were eligible for the study).

The mean age of the adolescents in this study was 14.31 years. The majority were Caucasian or African American, comprising 48.1% ( $n = 51$ ) and 33.0% ( $n = 35$ ) of the sample, respectively. Of the remaining adolescents, 8.5% were reported to be multiracial ( $n = 9$ ), 0.9% were Asian ( $n = 1$ ), 0.9% were American Indian or Alaska Native ( $n = 1$ ), and no race was reported for the remaining 2.8% ( $n = 3$ ). Adolescents' BMIs ranged from 23.9 to 65.7 ( $M = 38.88$ ,  $SD = 8.55$ ), with their BMI percentiles ranging from 91.5 to 100. Adolescents' BMI percentiles were used to categorize them as either at risk of overweight or overweight using criteria set forth by the Centers for Disease Control and Prevention (Centers for Disease Control and Prevention, What is a BMI percentile, para. 1). Based on these criteria, the great majority of adolescents were overweight (94.2%,  $n = 98$ ), while only 3.8% ( $n = 4$ ) were at risk of overweight.

Based on self-report, the mean level of health-related quality of life of the adolescents in this sample was 75.09 ( $SD = 16.78$ ), while the mean level of health-related quality of life based on parent proxy-report was 68.06 ( $SD = 19.52$ ). These results are consistent with the health-related quality of life of overweight and obese children in previous studies (Schwimmer et al., 2003; Williams et al., 2005), and represent lower levels of quality of life than the healthy, non-overweight controls in those studies.

Demographic information regarding the caregivers in this study is presented in Table 1.

Table 1

*Demographic Characteristics of Caregivers*

	<i>N</i>	Percent of Sample
<b>Caregiver's Relationship to Child</b>		
Biological Parent	89	85.6
Adoptive Parent	3	2.9
Step-parent	2	1.9
Biological Maternal Grandparent	4	3.8
Full Sibling	1	1.0
Other Biological Relative	1	1.0
Other Nonbiological Relative	1	1.0
<b>Highest Educational Attainment</b>		
9 <sup>th</sup> to 11 <sup>th</sup> grade	4	3.8
High School diploma or GED	30	28.8
Vocational, trade school, associate's courses	13	12.5
Vocational, trade school, associate's degree	15	14.4
Courses at 4-year college	6	5.8
Bachelor's or 4-year college degree	18	17.3
Master's or professional degree	9	8.6

Total Household Income

Less than \$18, 745	11	10.6
\$18,745 - \$32,874	17	16.3
\$32,875 - \$48,999	10	9.6
\$49,000 - \$72,999	15	14.4
\$73,000 - \$126,500	24	23.1
More than \$126,500	12	11.5

Marital Status

Never married	14	13.5
Married	65	62.5
Separated	1	1.0
Divorced	15	14.4
Widowed	4	3.8

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*Measures*

*Sociodemographic Variables.* A brief Background Questionnaire was developed by the investigator for use in this study. Demographic variables assessed by this questionnaire included child age, child gender, child race/ethnicity, parent-reported child academic achievement, parent weight in pounds, parent marital status, parent education, parent occupation, spouse's education and occupation, and family and child history of previously attempted weight loss strategies. See Appendix A for a copy of the Background Questionnaire. Information regarding

children's Body Mass Index (BMI) was gathered from EPIC, the hospital's electronic medical record system.

*Treatment Acceptability.* The Obesity Treatment Acceptability Questionnaire (OTAQ) was created by the investigator for use in this study. In adhering to the analogue approach set forth by previous treatment acceptability researchers (Kazdin, 1981; Liao & Zimet, 2001; Miller, Manne, & Palevsky, 1998), this measure consisted of a case vignette describing an obese adolescent, as well as brief descriptions of five obesity treatments (gastric banding surgery, weight loss pills, dietary therapy, exercise program, family behavior therapy) and 9 items assessing the acceptability of each of the five treatments.

Similar to previous studies in treatment acceptability, the case vignette and treatment descriptions were derived based on the literature about common obesity treatments. Male and female versions of the case vignette were created in order to control for possible effects of gender on treatment acceptability ratings. These two versions differed only in terms of the name of the person who was described in each vignette (i.e., male version = David; female version = Sara). Male participants and their parents/caregivers completed the OTAQ with the male vignette, while female participants and their parents/caregivers completed the OTAQ with the female vignette. The five treatment approaches included on the OTAQ were (a) gastric banding surgery, (b) weight loss pills, (c) family behavior therapy, (d) exercise program, and (e) dietary therapy. Professionals knowledgeable about obesity treatments and the characteristics of patients who would typically be suitable for

gastric banding surgery (i.e., staff from the weight management clinic in which data were collected) were consulted to ensure appropriateness of the case vignette and accuracy of the treatment descriptions. The treatment descriptions were randomly ordered to control for sequencing effects.

Treatment acceptability was assessed by the following 9 items: (a) This treatment would be effective; (b) This treatment would be easy; (c) David's/Sara's weight and health status are severe enough for this treatment; (d) This treatment would not have bad side effects; (e) I think my parent(s)/child would approve of this treatment; (f) This is an acceptable treatment for David's/Sarah's weight; (g) My/my child's weight and health status are severe enough for this treatment; (h) I would be willing to use this treatment/I would be willing to let my child use this treatment; (i) Other adolescents would be willing to use this treatment. These 9 items were based on aforementioned research findings indicating a positive relationship between treatment acceptability and problem severity, perceived treatment efficacy, and perceived approval by others of the treatment, and an inverse relationship between treatment acceptability, negative side effects, and effort involved in treatment. These items were rated on a 5-point scale (1 = strongly disagree; 5 = strongly agree). Ratings for the 9 items were summed to provide a total treatment acceptability score for each of the five treatments, such that acceptability scores for each treatment could range from 9 (low acceptability) to 45 (high acceptability). Participants were also asked to rank order the five weight loss treatments in order of acceptability (1 = most acceptable, 5 = least acceptable). It was thought that rank orderings would provide

useful information above and beyond that gleaned from acceptability ratings because participants could plausibly rate several treatments similarly but would be forced to categorize treatments differently by rank ordering them.

Internal consistency reliability coefficients (Cronbach’s alpha) were calculated for the five scales (Gastric Banding Surgery, Weight Loss Pills, Dietary Therapy, Exercise Therapy, Family Behavior Therapy) of the OTAQ. Overall, coefficient alphas demonstrated good to adequate internal consistency reliability across the parent and child versions of this measure. Alphas ranged from .79 to .87 on the parent-report version and from .82 to .89 on the child-report version. Coefficient alphas for each of the parent and child OTAQ scales are presented in Table 2.

Table 2

*Internal Consistency Reliability of the OTAQ*

Scale	Cronbach’s Alpha	
	Parent	Child
Gastric Banding	.92	.89
Weight Loss Pills	.87	.85
Family Behavior Therapy	.85	.86
Dietary Therapy	.79	.82
Exercise Program	.83	.84

Please see Appendix B for a copy of the male child version of this questionnaire (COTAQ-Male), Appendix C for a copy of the female child version of this questionnaire (COTAQ-Female), Appendix D for a copy of the male parent version (POTAQ-Male), and Appendix E for a copy of the female parent version (POTAQ-Female).

*Health-Related Quality of Life.* The PedsQL 4.0 (Varni, Seid, & Kurtin, 2001) is a 23-item measure, which was developed to measure health-related quality of life in children and adolescents who are between the ages of 2 and 18. The PedsQL 4.0 is available in both a child self-report and a parent proxy-report version. Items on this inventory comprise four core scales (Physical, Emotional, Social, School). This measure requires that children and parents rate whether an item/behavior is never a problem (0), almost never a problem (1), sometimes a problem (2), often a problem (3), or almost always a problem (4). Total scores can range from 0 to 100, with higher scores indicating better quality of life. This inventory has been found to demonstrate adequate validity and internal consistency reliability in previous samples, with coefficient alphas ranging from .86 to .90 for the parent proxy-report version and from .80 to .88 for the child self-report version (Varni et al., 2001). Coefficient alphas were calculated to determine the internal consistency reliability of this measure for the current study sample. Alphas for the individual subscales ranged from .84 to .90 on the parent proxy-report version and from .82 to .86 on the child self-report version, demonstrating adequate internal consistency. Coefficient alphas for each of the PedsQL subscales are presented in Table 3. See Appendix F for a copy of the PedsQL

4.0 parent proxy-report and see Appendix G for a copy of the PedsQL 4.0 child self-report.

Table 3

*Internal Consistency Reliability of the PedsQL 4.0*

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Scale	<u>Cronbach's Alpha</u>	
	Parent Proxy-Report	Child Self-Report
Physical	.85	.85
Emotional	.84	.83
Social	.90	.86
School	.84	.82

---

*Procedure*

Approval to conduct this study was obtained from the appropriate hospital research review board. Eligible children and their parents were approached by a member of their medical team during their routinely scheduled clinic visit. The medical team member asked families whether they were willing to be interviewed by a researcher about participating in a study about perceptions of different weight loss treatments. Those adolescents and parents who agreed were then approached by the study investigator, who explained the project in more detail and followed the hospital's required procedures for obtaining informed consent and assent (see Appendix F for a copy of the Parent Permission/Consent Form and Appendix G for a

copy of the Adolescent Assent Form). Participants who consented/assented were asked to complete all questionnaires (Background Questionnaire, PedsQL 4.0, OTAQ) before the end of their clinic visit. Participation in the study was voluntary and participants were not offered any compensation for completing the study questionnaires.

## Results

### *Preliminary Analyses*

*Descriptive Statistics:* Means and standard deviations were calculated for continuous sociodemographic variables (i.e., age, BMI, health-related quality of life). Frequency statistics were calculated for categorical sociodemographic variables (i.e., caregiver relationship to child, child ethnicity, caregiver level of education, caregiver marital status, total annual household income). Results pertaining to these sociodemographic variables were presented in the Participants section and in Table 1 above.

In addition, means were calculated for caregivers' and adolescents' rankings of the five weight loss treatments. These means are reported in Table 4. Overall, parents and children ranked gastric banding surgery and weight loss pills as least acceptable of the five weight loss treatments. This pattern remained true regardless of whether participants were ranking the treatments for themselves or their own child or for the hypothetical adolescent in the OTAQ vignette.

Table 4

*Caregivers' and Adolescents' Rankings of Weight Loss Treatments*

Treatment Type	Mean Rankings			
	<u>Adolescent Report</u>		<u>Caregiver Report</u>	
	Self	Vignette	Own Child	Vignette
Gastric Banding Surgery	4.47	4.32	4.61	4.63
Weight Loss Pills	3.59	3.65	4.00	4.03
Family Behavior Therapy	2.99	2.95	2.78	2.74
Dietary Therapy	2.06	2.13	1.79	1.81
Exercise Program	1.89	1.93	1.83	1.80

Note: Self refers to adolescents' rankings of treatments for themselves; Vignette refers to adolescents' and caregivers' rankings of treatments for the adolescent described in the OTAQ vignette; Own child refers to caregivers' rankings of treatments for their own child; Rank orderings range from 1 (most acceptable) to 5 (least acceptable)

*Correlations:* In order to determine whether BMI, health-related quality of life, and number of previously attempted weight loss methods should be included as covariates in the primary analyses, correlations were calculated to assess the relationship of these variables with mean parent and child acceptability ratings across the five weight loss treatments. The resulting Pearson product-moment correlation coefficients are presented in Table 5. Cohen's (1988) guidelines for interpreting correlation coefficients were used to determine which, if any, of these variables

should be retained as covariates. As such, significant or large correlations were defined as those with coefficients equal to or greater than .50. Applying these guidelines, results indicated that none of the variables of interest (BMI, health-related quality of life, and number of previously attempted weight loss methods) were significantly correlated with treatment acceptability ratings. Therefore, these variables were excluded from the primary statistical analyses.

Table 5

*Correlations of Treatment Acceptability with BMI, Quality of Life (QOL), and Number of Previous Weight Loss Strategies Attempted*

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	BMI	Parent- Reported QOL	Child- Reported QOL	Previous Strategies
Child surgery rating	.039	-.068	.055	.070
Child pills rating	.184	-.272	-.125	.002
Child therapy rating	-.058	-.112	-.006	.096
Child diet rating	-.033	.111	.127	.168
Child exercise rating	.093	.155	.163	.171
Parent surgery rating	.218	-.256	-.173	.014
Parent pills rating	.200	-.205	-.077	-.044
Parent therapy rating	-.065	-.122	.009	.147
Parent diet rating	-.031	.233	.251	.011
Parent exercise rating	-.021	.276	.232	-.093

---

*Primary Analyses*

An alpha level of .05 was used for all statistical tests.

*Hypothesis 1:* It was hypothesized that there would be statistically significant differences among acceptability ratings for the five weight loss treatments. In order to test this hypothesis, while also examining the degree to which ratings differed significantly between boys and girls or between parents and children, a two-way mixed factor analysis of variance was conducted. The dependent variable was treatment acceptability scores, with possible values ranging from 9 to 45. The within subjects factors were *Treatment type* with five levels (gastric banding surgery, weight loss pills, family behavior therapy, dietary therapy, exercise program) and *Rater* with two levels (parent and child). The between subjects factor was *Gender*. The *Treatment type* main effect was significant,  $F(4,388) = 218.676, p < .001, \eta^2 = .693$  (observed power = 1.000). The *Rater X Treatment type* interaction was also significant,  $F(4,388) = 10.503, p < .001, \eta^2 = .098$  (observed power = 1.000). The *Gender X Treatment type* main effect was nonsignificant,  $F(1,97) = 1.075, p = .302, \eta^2 = .011$ .

Four within-subjects contrasts were conducted to follow up the significant *Rater X Treatment type* interaction. Differences in mean ratings of acceptability among the five weight loss treatments were significantly different between gastric banding surgery and weight loss pills,  $F(1,97) = 4.066, p = .047, \eta^2 = .040$  (observed power = .515), gastric banding surgery and family behavior therapy,  $F(1,97) = 11.377, p = .001, \eta^2 = .105$  (observed power = .916), and gastric banding surgery and dietary therapy,  $F(1, 97) = 6.614, p = .012, \eta^2 = .064$  (observed power = .721).

Marginal means for parent and child treatment acceptability ratings are presented in Table 6.

Table 6

*Marginal Means for Parent and Adolescent Treatment Acceptability Ratings*

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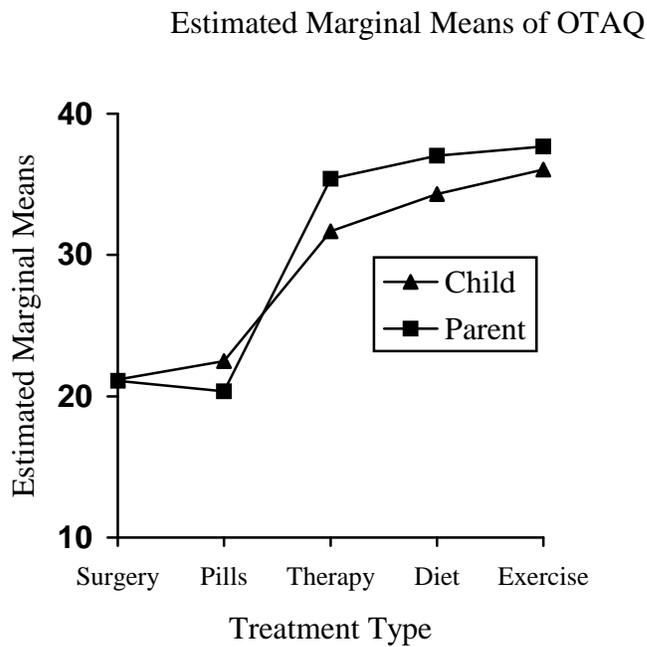
Treatment Type	Acceptability Ratings	
	Child Report	Parent Report
Gastric Banding Surgery	21.19	21.05
Weight Loss Pills	22.53	20.36
Family Behavior Therapy	31.68	35.46
Dietary Therapy	34.44	37.20
Exercise Program	36.22	37.91

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Although the aforementioned differences between parent and child treatment acceptability ratings are statistically significant, an examination of their small effect sizes and the marginal means suggests that they possess little clinical meaningfulness. Of importance is the fact that, overall, parents and adolescents rated gastric banding surgery and weight loss pills as less acceptable than the other three treatments. The significant *Rater X Treatment* interaction is best explained by the fact that parents rated gastric banding surgery and weight loss pills as less acceptable than their

children did while, for the other treatments, parents provided higher acceptability ratings than their children. This trend is depicted in Figure 1.

Figure 1. Estimated marginal means of OTAQ



*Hypothesis 2:* It was hypothesized that BMI, health-related quality of life, and number of previous weight loss methods attempted would moderate the differences in treatment acceptability ratings among the five weight loss treatments. However, as mentioned previously, correlational analyses revealed that there were no significant associations between treatment acceptability ratings and BMI, health-related quality of life, or number of previously attempted weight loss strategies. Thus, these variables were excluded as covariates from the primary two-way repeated measures ANOVA.

## Discussion

### *Overview*

With the rising prevalence of pediatric obesity in the United States, interest in the development and implementation of effective weight loss interventions for children and adolescents has burgeoned. Bariatric surgery, once offered only to morbidly obese adults, is now among the treatments being offered to obese adolescents by health care professionals. In particular, gastric banding surgery has recently received widespread attention as a promising new surgical modality for both adults and adolescents, given the reversibility of this procedure and its increased safety compared to surgeries of the past. Despite the apparent benefits of gastric banding surgery relative to other surgical alternatives, the acceptability of this procedure among prospective consumers has been unreported in the literature. Thus, this study assessed the acceptability of gastric banding surgery relative to four other common weight loss treatments (i.e., weight loss pills, family behavior therapy, dietary therapy, exercise program) in a sample of adolescents and caregivers recruited from a hospital-based weight management program.

### *Primary Findings*

As predicted, there were significant differences among acceptability ratings for the five weight loss treatments. Specifically, gastric banding surgery and weight loss pills were rated as less acceptable than diet, exercise, and family behavior therapy. These differences remained constant across participants (i.e., males and females; caregivers and adolescents). These differences also emerged when

participants were asked to rank order the treatments and did not change regardless of whether participants were ranking the treatments for themselves or their own child or for the hypothetical adolescents described in the case vignettes. Furthermore, acceptability ratings were found to have no correlation with BMI, health-related quality of life, or previous number of weight loss methods attempted. Thus, it appears that perceptions about weight loss treatments are influenced by factors other than the individual characteristics of prospective consumers (e.g., aspects of the treatments themselves, underlying fear associated with the term “surgery”) and that individuals perceive treatments in generally the same way regardless of whether they are thinking about using the treatments themselves or whether the treatments are intended for someone else.

Health care professionals might, on one hand, be relieved to learn that adolescents prefer diet and exercise to weight loss pills and surgery. After all, diet and exercise are generally the first line choice of treatment among professionals working with overweight patient populations. Moreover, it would be cause for concern if overweight adolescents would rather have surgery than try other less invasive approaches to weight loss (i.e., if adolescents preferred the “quick fix” rather than the safest, most appropriate one). On the other hand, findings from this study suggest that health care professionals might face challenges when confronted with patients for whom surgery is deemed the most appropriate and, possibly life-saving, course of treatment if that patient and his caregivers do not consider the procedure to be acceptable. When health care professionals would like to encourage particular

patients to consider gastric banding surgery, discussions or written measures to assess treatment acceptability should be utilized because acceptability may influence patients' desire to have the surgery and to adhere to important post-operative care regimens.

### *Exploratory Findings*

The current study built upon previous treatment acceptability studies by developing the OTAQ as a new model for measuring acceptability. The OTAQ was developed so that items reflected factors (i.e., perceived negative side effects; whether the treatment would be easy; whether the problem for which the treatment is intended is severe enough for the treatment; whether parents/adolescents would approve of the treatment) shown in previous studies to be correlated with treatment acceptability. Results indicated that this measure had adequate internal consistency reliability, providing preliminary evidence that it could serve as a useful new modality for measuring treatment acceptability. Use of the OTAQ with other populations is needed to confirm its reliability. In addition, validation of this measure and exploration of its factor structure are recommended directions for future research.

### *Study Limitations and Future Directions*

In reviewing this study retrospectively, several methodological limitations were noted which have bearing on how the results should be interpreted. Participants' acceptability ratings may have been skewed by the treatment descriptions provided to them on the OTAQ. Specifically, the descriptions of gastric banding surgery and weight loss pills included potential side effects (e.g., band slippage with the surgery;

heart problems and dizziness with the pills), while side effects were not mentioned in the descriptions of the three remaining treatments. When developing this study, the treatment descriptions were created this way because diet, exercise, and family behavior therapy do not have “side effects” in the same sense that surgery or weight loss pills might. However, these treatments do have inherent drawbacks that were not mentioned. For example, consumers would have to use diet, exercise or family behavior therapy for much lengthier periods of time to see positive effects. Even then, the effects could be minimal and would likely be very difficult to maintain. Had the treatment descriptions in the present study included these variables, participants might not have rated surgery and weight loss pills so negatively compared to the other treatments. In future research endeavors, it is recommended that acceptability be reassessed after the treatment descriptions are manipulated. For example, the treatment descriptions could be revised to include an equal number of advantages and disadvantages and/or information regarding the general success rate of each treatment.

The possibility still remains that, despite making such changes in the treatment descriptions, participants would rate gastric banding surgery as significantly less acceptable than diet, exercise, and family behavior therapy. In the event that these findings prevail, it would be beneficial to conduct more narrowly focused studies in which the goal is to better understand what factors persuade or dissuade consumers from considering gastric banding surgery as an acceptable weight loss treatment. Focus groups with overweight adolescents and their caregivers could serve

as one possible avenue for pursuing this goal. In addition, researchers could examine whether participants' ratings of the surgery change as they are provided with different pieces of information about the procedure (e.g., mortality rates associated with the surgery; the fact that surgery requires less time than diet, exercise, or family behavior therapy and results in greater weight gain; more details regarding how the procedure is performed and how it can be reversed).

As mentioned previously, health care providers may find themselves in a situation in which gastric banding surgery is the most appropriate course of action for a patient who finds the surgery to be completely unacceptable. The present study helps to identify barriers that health care providers may encounter in their discussions with obese patients and highlights a need for providers to learn how to overcome these barriers with appropriate patients (e.g., those patients who are morbidly obese, have health-related comorbidities, and have exhausted all other weight loss treatment options). Strategies that are less commonly utilized in health care venues, such as motivational interviewing, may be required to persuade appropriate surgery candidates to consider the procedure. Motivational interviewing is a directive, client-centered counseling style for eliciting behavior change (Rollnick & Miller, 1995). It was first applied by Miller (1983) in the treatment of problem drinking and has since gained widespread popularity as a counseling method for promoting various types of behavior change. In recent years, there has been a growing interest in applying motivational interviewing to health care settings (Emmons & Rollnick, 2001). Present findings suggest that this interest is well founded and that motivational interviewing

might be particularly useful in health care settings where gastric banding surgery is among the available treatment options.

In addition to the aforementioned limitations, results from the present study may have limited generalizability because data were collected from a single hospital-based weight management clinic. Participants' ratings of weight loss treatments may have been inadvertently influenced by, for example, the attitudes of their treating medical team or by what they have heard about surgery and weight loss pills from their medical team in the past.

It should also be noted that, although it has been suggested that treatment acceptability influences utilization of treatments, this connection is not absolute. Although participants rated diet, exercise, and family behavior therapy as more acceptable than surgery and weight loss pills, they may not necessarily be utilizing these approaches or using them in a manner consistent with what their doctors have recommended. Additional research should seek to narrow the gap between perceptions and practice/utilization of treatment. For example, it could be beneficial to administer the OTAQ to patients when they enter treatment and to follow-up with them throughout the course of treatment to determine whether their acceptability ratings correspond with their subsequent utilization of or adherence to treatments.

### *Conclusion*

In conclusion, results from this study suggest that overweight adolescents and their caregivers prefer diet, exercise and family behavior therapy to gastric banding surgery. However, treatment acceptability ratings may have been unintentionally

influenced by a number of extraneous variables, particularly the treatment descriptions provided the participants. The present study serves as a useful starting point for evaluating perceptions of gastric banding surgery among prospective consumers and provides a new model for evaluating treatment acceptability. However, subsequent studies in which gastric banding surgery and other treatments are cast in a more equal light are needed before definitive conclusions regarding overall perceptions of gastric banding surgery to other weight loss interventions can be drawn.

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## Appendix A: Background Questionnaire

## BACKGROUND QUESTIONNAIRE

1) What is your child's age? \_\_\_\_\_

2) What is your child's gender (circle one)?      Male      Female

3) Please indicate your relationship to the child who is participating in this study:

- a. Biological parent
- b. Adoptive parent
- c. Step-parent
- d. Foster parent
- e. Biological maternal grandparent
- f. Biological paternal grandparent
- g. Full sibling
- h. Other biological relative, specify \_\_\_\_\_
- i. Other non-biological relation, specify \_\_\_\_\_

4) What is your child's ethnicity? (Check all that apply)

\_\_\_\_\_ Hispanic or Latino (Specify in question 5)

\_\_\_\_\_ Not Hispanic or Latino

\_\_\_\_\_ Unknown or Not Reported

5) Specify your child's Hispanic or Latino ethnicity: Select only one category

\_\_\_\_\_ Cuban

\_\_\_\_\_ Mexican

\_\_\_\_\_ Puerto Rican

\_\_\_\_\_ South or Central American

\_\_\_\_\_ Other Spanish culture or origin, specify \_\_\_\_\_

\_\_\_\_\_ More than one Hispanic ethnicity, specify \_\_\_\_\_

\_\_\_\_\_ Unknown or Not Reported

\_\_\_\_\_ Not applicable: not Hispanic or Latino

6) What is your child's race:

\_\_\_\_\_ American Indian or Alaska Native

\_\_\_\_\_ Asian

\_\_\_\_\_ Black or African American

\_\_\_\_\_ Native Hawaiian or Other Pacific Islander

\_\_\_\_\_ White or Caucasian

\_\_\_\_\_ More than one race (Specify in question 7)

\_\_\_\_\_ Unknown or not reported

**7) Specify child's multiple races: Select all that apply**

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White or Caucasian
- Unknown or not reported
- N/A: not multi-racial

**8) What is your marital status (please circle one)?**

Never Married      Married      Separated      Divorced      Widow

**9) What is your current weight? \_\_\_\_\_**

**10) What is the highest level of education you completed (please circle one)?**

- a) 6<sup>th</sup> grade or less than 6<sup>th</sup> grade
- b) 7<sup>th</sup> to 8<sup>th</sup> grade
- c) 9<sup>th</sup> to 11<sup>th</sup> grade
- d) High school diploma or GED
- e) Vocational, trade school, or Associate's courses after high school
- f) Vocational, trade school, or Associate's degree
- g) Courses toward four-year college degree
- h) Bachelor's degree or four-year college degree
- i) Master's degree
- j) Professional degree (M.D., Ph.D., J.D.)

**11) If married, what is the highest level of education your spouse completed (please circle one)?**

- a) 6<sup>th</sup> grade or less than 6<sup>th</sup> grade
- b) 7<sup>th</sup> to 8<sup>th</sup> grade
- c) 9<sup>th</sup> to 11<sup>th</sup> grade
- d) High school diploma or GED
- e) Vocational, trade school, or Associate's courses after high school
- f) Vocational, trade school, or Associate's degree
- g) Courses toward four-year college degree
- h) Bachelor's degree or four-year college degree
- i) Master's degree
- j) Professional degree (M.D., Ph.D., J.D.)

**12) What is your current occupation? \_\_\_\_\_**

**13) If married, what is your spouse's occupation? \_\_\_\_\_**

**14) What is your total annual household income before taxes (please circle one)?**

- a) Less than \$18,745
- b) \$18,745 to \$32,874
- c) \$32,875 to \$48,999
- d) \$49,000 to \$72,999
- e) \$73,000 to \$126,500
- f) More than \$126,500

**15) Please circle which of the following methods, if any, your child has used to try to lose weight (please circle all that apply):**

- Exercising
- Changing his or her diet
- Surgery
- Over-the-counter weight loss pills/medications
- Prescription weight loss pills/medications
- Weight loss powder
- Therapy/Counseling

**16) What sorts of grades is your child earning in school (please circle one):**

- a) Mostly A's
- b) Mostly B's
- c) Mostly C's
- d) Mostly D's
- e) Mostly F's

**17) What, if any, special educational services does your child receive?**

---

**18) Please circle which of the following methods those family members have used to try to lose weight (circle all that apply):**

- Exercising
- Changing his or her diet
- Surgery
- Over-the-counter weight loss pills/medications
- Prescription weight loss pills/medications
- Weight loss powder
- Therapy or counseling

**19) Please list all of the people who live in your household, other than you and your child:**

Name	Age	Relationship to Child (e.g., grandmother, brother, sister)

**20) Please list any other people who spend a significant amount of time with your child:** \_\_\_\_\_

\_\_\_\_\_

Appendix B: COTAQ – Male Form

## COTAQ – MALE FORM

David is 16 years old. He is in the 10<sup>th</sup> grade and has just gotten his drivers license. He weighs 110 pounds more than most kids his age. David has lots of friends at school, is liked by his teachers, and plays the drums in his best friend's rock band. However, because David is very overweight, he has some medical problems. He has Type 2 diabetes and has to prick his finger twice a day and take medication. He also has high blood pressure, back pain, and trouble breathing. Below are descriptions of some treatments David could try to help him lose weight.

**Weight loss pills:** These are pills your doctor can give you. They work by lowering a person's appetite, making them feel full, or blocking how much fat their body absorbs from the foods they eat. Sometimes these pills can lead to side effects including serious heart problems, trouble sleeping, dizziness, diarrhea, and high blood pressure. These are used for 3 months or less.

**Dietary Therapy:** This involves helping a person learn how to change their diet so that they make healthier food choices. They might learn about how many calories are in certain foods, how to read nutrition labels, what types of foods to buy, and how to prepare foods in a healthy way.

**Exercise Program:** This focuses on choosing enjoyable physical activities that can be scheduled into a person's regular routine. The idea is to begin slowly and gradually increase the amount of exercise they do, until they are able to do 30 minutes of exercise or more almost every day.

**Gastric Banding Surgery:** This surgery works by limiting the amount of food a person's stomach can hold, which allows the person to feel full after eating only a small amount of food. A band is placed around the upper part of the stomach, making a small pouch. When food goes into the small pouch, the band controls the amount of food that goes to the rest of the digestive tract. A complication of this surgery is that sometimes the band can slip or wear into the stomach, in which case it can be surgically adjusted.

**Family Behavior Therapy:** A therapist or counselor works with a person and his or her family to change their diet and physical activity habits to new behaviors that help with weight loss. The therapist may have the person record their diet and exercise in a diary, help them learn to avoid situations that make them want to eat, and help them come up with positive and realistic goals about weight loss.

Now that you have read a little about each of these treatments, please rate how you view them:

<i>Weight Loss Pills</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Dietary Therapy</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Exercise Program</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Gastric Banding Surgery</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for	1	2	3	4	5

this treatment					
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<b>Family Behavior Therapy</b>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5

**Please rank order these treatments according to which ones you think are most acceptable for helping David lose weight (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
 Dietary Therapy \_\_\_\_\_  
 Exercise Program \_\_\_\_\_  
 Gastric Banding Surgery \_\_\_\_\_  
 Family Behavior Therapy \_\_\_\_\_

**Please rank order the treatments according to which ones you think would be most acceptable for you (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
 Dietary Therapy \_\_\_\_\_  
 Exercise Program \_\_\_\_\_  
 Gastric Banding Surgery \_\_\_\_\_  
 Family Behavior Therapy \_\_\_\_\_

**Please rate how much control you believe you have over changing your weight (circle a number):**

1                      2                      3                      4                      5  
 No Control      A Little Control      Some Control      A Lot of Control      Complete Control

Appendix C: COTAQ – Female Form

## COTAQ – FEMALE FORM

Sara is 16 years old. She is in the 10<sup>th</sup> grade and has just gotten her drivers license. She weighs 110 pounds more than most kids her age. Sara has lots of friends at school, is liked by her teachers, and plays the drums in her best friend's rock band. However, because Sara is very overweight, she has some medical problems. She has Type 2 diabetes and has to prick her finger twice a day and take medication. She also has high blood pressure, back pain, and trouble breathing. Below are descriptions of some treatments Sara could try to help her lose weight.

**Weight loss pills:** These are pills someone can get from their doctor. They work by lowering a person's appetite, making them feel full, or blocking how much fat their body absorbs from the foods they eat. Sometimes these pills can lead to side effects including serious heart problems, trouble sleeping, dizziness, diarrhea, and high blood pressure. These are used for 3 months or less.

**Dietary Therapy:** This involves helping a person learn how to change their diet so that they make healthier food choices. They might learn about how many calories are in certain foods, how to read nutrition labels, what types of foods to buy, and how to prepare foods in a healthy way.

**Exercise Program:** This focuses on choosing enjoyable physical activities that can be scheduled into a person's regular routine. The idea is to begin slowly and gradually increase the amount of exercise they do, until they are able to do 30 minutes of exercise or more almost every day.

**Gastric Banding Surgery:** This surgery works by limiting the amount of food a person's stomach can hold, which allows the person to feel full after eating only a small amount of food. A band is placed around the upper part of the stomach, making a small pouch. When food goes into the small pouch, the band controls the amount of food that goes to the rest of the digestive tract. A complication of this surgery is that sometimes the band can slip or wear into the stomach, in which case it can be surgically adjusted.

**Family Behavior Therapy:** A therapist or counselor works with a person and his or her family to change their diet and physical activity habits to new behaviors that help with weight loss. The therapist may have the person record their diet and exercise in a diary, help them learn to avoid situations that make them want to eat, and help them come up with positive and realistic goals about weight loss.

Now that you have read a little about each of these treatments, please rate how you view them:

<i>Weight Loss Pills</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Dietary Therapy</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Exercise Program</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Gastric Banding Surgery</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for	1	2	3	4	5

this treatment					
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<b>Family Behavior Therapy</b>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my parent(s) would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5

**Please rank order these treatments according to which ones you think are most acceptable for helping Sara lose weight (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
 Dietary Therapy \_\_\_\_\_  
 Exercise Program \_\_\_\_\_  
 Gastric Banding Surgery \_\_\_\_\_  
 Family Behavior Therapy \_\_\_\_\_

**Please rank order the treatments according to which ones you think would be most acceptable for you (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
 Dietary Therapy \_\_\_\_\_  
 Exercise Program \_\_\_\_\_  
 Gastric Banding Surgery \_\_\_\_\_  
 Family Behavior Therapy \_\_\_\_\_

**Please rate how much control you believe you have over changing your weight (circle a number):**

1                      2                      3                      4                      5  
 No Control      A Little Control      Some Control      A Lot of Control      Complete Control

Appendix D: POTAQ-Male Form

## POTAQ-MALE FORM

David is 16 years old. He is in the 10<sup>th</sup> grade and has just gotten his drivers license. He weighs 110 pounds more than most kids his age. David has lots of friends at school, is liked by his teachers, and plays the drums in his best friend's rock band. However, because David is very overweight, he has some medical problems. He has Type 2 diabetes and has to prick his finger twice a day and take medication. He also has high blood pressure, back pain, and trouble breathing. Below are descriptions of some treatments David could try to help him lose weight.

**Weight loss pills:** These are pills your doctor can give you. They work by lowering a person's appetite, making them feel full, or blocking how much fat their body absorbs from the foods they eat. Sometimes these pills can lead to side effects including serious heart problems, trouble sleeping, dizziness, diarrhea, and high blood pressure. These are used for 3 months or less.

**Dietary Therapy:** This involves helping a person learn how to change their diet so that they make healthier food choices. They might learn about how many calories are in certain foods, how to read nutrition labels, what types of foods to buy, and how to prepare foods in a healthy way.

**Exercise Program:** This focuses on choosing enjoyable physical activities that can be scheduled into a person's regular routine. The idea is to begin slowly and gradually increase the amount of exercise they do, until they are able to do 30 minutes of exercise or more almost every day.

**Gastric Banding Surgery:** This surgery works by limiting the amount of food a person's stomach can hold, which allows the person to feel full after eating only a small amount of food. A band is placed around the upper part of the stomach, making a small pouch. When food goes into the small pouch, the band controls the amount of food that goes to the rest of the digestive tract. A complication of this surgery is that sometimes the band can slip or wear into the stomach, in which case it can be surgically adjusted.

**Family Behavior Therapy:** A therapist or counselor works with a person and his or her family to change their diet and physical activity habits to new behaviors that help with weight loss. The therapist may have the person record their diet and exercise in a diary, help them learn to avoid situations that make them want to eat, and help them come up with positive and realistic goals about weight loss.

Now that you have read a little about each of these treatments, please rate how you view them:

<i>Weight Loss Pills</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Dietary Therapy</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Exercise Program</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Gastric Banding Surgery</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this	1	2	3	4	5

treatment					
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<b><i>Family Behavior Therapy</i></b>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
David's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for David's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5

**Please rank order these treatments according to which ones you think are most acceptable for helping David lose weight (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
 Dietary Therapy \_\_\_\_\_  
 Exercise Program \_\_\_\_\_  
 Gastric Banding Surgery \_\_\_\_\_  
 Family Behavior Therapy \_\_\_\_\_

**Please rank order the treatments according to which ones you think are most acceptable for your child (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
 Dietary Therapy \_\_\_\_\_  
 Exercise Program \_\_\_\_\_  
 Gastric Banding Surgery \_\_\_\_\_  
 Family Behavior Therapy \_\_\_\_\_

**Please rate how much control you believe your child has over changing his/her weight (circle a number):**

1                      2                      3                      4                      5  
 No Control      A Little Control      Some Control      A Lot of Control      Complete Control

Appendix E: POTAQ Female Form

## POTAQ-FEMALE FORM

Sara is 16 years old. She is in the 10<sup>th</sup> grade and has just gotten her drivers license. She weighs 110 pounds more than most kids her age. Sara has lots of friends at school, is liked by her teachers, and plays the drums in her best friend's rock band. However, because Sara is very overweight, she has some medical problems. She has Type 2 diabetes and has to prick her finger twice a day and take medication. She also has high blood pressure, back pain, and trouble breathing. Below are descriptions of some treatments Sara could try to help her lose weight.

**Weight loss pills:** These are pills your doctor can give you. They work by lowering a person's appetite, making them feel full, or blocking how much fat their body absorbs from the foods they eat. Sometimes these pills can lead to side effects including serious heart problems, trouble sleeping, dizziness, diarrhea, and high blood pressure. These are used for 3 months or less.

**Dietary Therapy:** This involves helping a person learn how to change their diet so that they make healthier food choices. They might learn about how many calories are in certain foods, how to read nutrition labels, what types of foods to buy, and how to prepare foods in a healthy way.

**Exercise Program:** This focuses on choosing enjoyable physical activities that can be scheduled into a person's regular routine. The idea is to begin slowly and gradually increase the amount of exercise they do, until they are able to do 30 minutes of exercise or more almost every day.

**Gastric Banding Surgery:** This surgery works by limiting the amount of food a person's stomach can hold, which allows the person to feel full after eating only a small amount of food. A band is placed around the upper part of the stomach, making a small pouch. When food goes into the small pouch, the band controls the amount of food that goes to the rest of the digestive tract. A complication of this surgery is that sometimes the band can slip or wear into the stomach, in which case it can be surgically adjusted.

**Family Behavior Therapy:** A therapist or counselor works with a person and his or her family to change their diet and physical activity habits to new behaviors that help with weight loss. The therapist may have the person record their diet and exercise in a diary, help them learn to avoid situations that make them want to eat, and help them come up with positive and realistic goals about weight loss.

Now that you have read a little about each of these treatments, please rate how you view them:

<i>Weight Loss Pills</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Dietary Therapy</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Exercise Program</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<i>Gastric Banding Surgery</i>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this	1	2	3	4	5

treatment					
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5
<b><i>Family Behavior Therapy</i></b>	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
This treatment would be effective	1	2	3	4	5
This treatment would be easy	1	2	3	4	5
Sara's weight and health status are severe enough for this treatment	1	2	3	4	5
This treatment would not have bad side effects	1	2	3	4	5
I think my child would approve of this treatment	1	2	3	4	5
This is an acceptable treatment for Sara's weight	1	2	3	4	5
My child's weight and health status are severe enough for this treatment	1	2	3	4	5
I would be willing to let my child use this treatment	1	2	3	4	5
Other adolescents would want to use this treatment	1	2	3	4	5

**Please rank order these treatments according to which ones you think are most acceptable for helping Sara lose weight (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
Dietary Therapy \_\_\_\_\_  
Exercise Program \_\_\_\_\_  
Gastric Banding Surgery \_\_\_\_\_  
Family Behavior Therapy \_\_\_\_\_

**Please rank order the treatments according to which ones you think are most acceptable for your child (1 = most acceptable; 5 = least acceptable).**

**Rank**

Weight loss pills \_\_\_\_\_  
Dietary Therapy \_\_\_\_\_  
Exercise Program \_\_\_\_\_  
Gastric Banding Surgery \_\_\_\_\_  
Family Behavior Therapy \_\_\_\_\_

**Please rate how much control you believe your child has over changing his/her weight (circle a number):**

1                      2                      3                      4                      5  
No Control      A Little Control      Some Control      A Lot of Control      Complete Control

Appendix F: Parent Permission/Consent Form

**NEMOURS**  
**Wilmington, Delaware**  
**PARENTAL PERMISSION AND INFORMED CONSENT FOR**  
**PARTICIPATION IN A RESEARCH STUDY**

You have been asked to be in a research study with your child. This form explains the research, your rights and your child's rights as research participants, and any responsibilities that you may have as a result of you and your child's participation. You should understand the research study before you agree to be in it and to permit your child to be in it. *Read this form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.*

**1. WHAT IS THE TITLE OF THE STUDY?** Acceptability of Obesity Interventions Among Overweight Adolescents and Their Parents

**2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?**

This study is being conducted by Jennifer Shroff Pendley, Ph.D. (Division of Behavioral Health) and Danielle Rosnov, MA (Division of Behavioral Health). Other members of their research team include Sandra Hassink, MD (Weight Management Program), George Datto, MD (Weight Management Program), Michelle Eakin, Ph.D. (Division of Behavioral Health) and Stephen Gonce (Division of Behavioral Health). If you have any questions about this study, you can contact Dr. Pendley at 302-651-4508, Danielle Rosnov at 302-651-4555, or Dr. Hassink and Dr. Datto at 302-651-6040.

**3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?**

Carlos Rose, M.D., Chairperson, Nemours-Delaware Institutional Review Board at (302) 651-5970.

Paul Garfinkel, MSH, Director, Nemours Office for Human Subjects Protection, (904) 390-3687.

(800) SOS-KIDS (800-767-5437) (Nemours Long Distance Operator)

**4. WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to find out how overweight adolescents and their parents/guardians view different weight loss treatments. This information will hopefully help health care professionals to have a better understanding of which treatments are most and least preferred among adolescent patients and their families. It is also hoped that the results of this study will guide professionals in their future efforts to develop weight loss programs.

**5. WHO CAN BE IN THE STUDY?**

Male and female adolescents, who are between the ages of 12 and 17 and are being followed for treatment in the Weight Management Program at A.I. duPont Hospital for Children can be in this study. Their parents/legal guardians can also be in the study.

**6. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?**

About 100 adolescents and parents will be enrolled for this study at Nemours/A.I. duPont Hospital for Children.

**7. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?**

You and your child will only be asked to participate in this study today, during your current visit to the Weight Management Clinic. It is estimated that your participation and your child's participation will last about 20 to 30 minutes.

**8. WHAT ARE THE RESEARCH PROCEDURES?**

If you agree to participate in this project:

- a. You will be asked to complete three questionnaires: A Background Questionnaire, a questionnaire about how you view different weight loss treatments, and a questionnaire about how well you think your child is functioning emotionally, socially, academically, and physically.
- b. You will be asked to complete these questionnaires only once, during your visit to the Weight Management Clinic
- c. If you are married and your spouse is not here at the Clinic with you, you will be asked to take the same questionnaires home for your spouse to complete. You will be provided with a stamped, addressed envelope for this.

If you agree to allow your child to participate in this project:

- a. Your child will be asked to complete two questionnaires: one about how they view different weight loss treatments, and one about how they think they are functioning emotionally, socially, academically, and physically.

Your participation and your child's participation in this study will in no way affect your child's medical care.

**9. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?**

Any research has some risks (things that could make you or your child sick, feel uncomfortable, or hurt). The risks with the most chance of happening to someone in

this study are listed below. Also, there is a chance of other risks that almost never happen, or unknown risks that have never happened before.

The main risks that you or your child might face by taking part in this study are:

- Some of the questions you are asked to answer might make you feel uncomfortable. You will be allowed to skip these questions.
- You will have to spend time completing the questionnaires.
- There may be a risk of loss of the confidentiality of your responses. However, the study investigators will try to protect confidentiality by not putting your name on any of the study questionnaires and by, instead, replacing your name with an identification number.

#### **10. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

You and your child may not directly benefit from participating in this study. However, the study may assist your child's doctors and other health care providers by allowing them to learn how overweight adolescents and their caregivers view the treatments they are offered. Health care providers will hopefully be able to use this knowledge in the future when they are developing new weight loss programs and working with other children who are trying to lose weight.

#### **11. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?**

If you think that you or your child has a problem related to the study, you should tell one of the study investigators. The study investigators or research staff will tell you what you should do. The investigators' names and phone numbers are on the first page of this form.

#### **12. IS BEING IN THE STUDY VOLUNTARY?**

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your child's usual medical care if you and/or your child decide not to be in the study or decide to stop being in the study. No one will be angry with you or your child, or treat your child any differently than before your child was asked to be in the study.

If you stop your/your child's participation in this study, your child may continue treatment with his/her doctor, or you may seek treatment for your child from another doctor of your choice. In the event that you withdraw your child from the study all clinical data related to the study may continue to be collected from your child's medical records. You may however, ask the researcher to destroy your/your child's information. Your request must be in writing. The researcher will tell you if this is possible. There may be legal reasons for keeping your child's information or samples.

**13. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?**

You can refuse participation in this study. There may be other research choices that could be considered. If you and your child decide not to participate in this study, your decision will in no way affect your child's current or future medical care.

**14. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?**

The researchers can remove you or your child from the study after you have already agreed to participate in the study. This can happen if you or your child do not understand the study questionnaires and, therefore, cannot complete them.

**15. WHAT ARE THE COSTS OF BEING IN THIS STUDY?** There are no financial costs involved in this study. The time and effort required to complete the study questionnaires are the only costs to you.

**14. WILL PEOPLE BE PAID FOR BEING IN THIS STUDY?**

You will not receive any financial benefits resulting from this study. This includes present and future payment or profit.

**15. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO PARTICPATE AND TO PERMIT MY CHILD TO STAY IN THE STUDY?**

Any new information that may change your mind about participation in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while you and your child are taking part in this study, it will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

**16. WHAT INFORMATION ABOUT MY CHILD WILL BE USED OR DISCLOSED?**

Health information will be used by Nemours researchers and/or disclosed to people outside of Nemours for this research study. This health information will be connected to one or more items that can identify you and your child to those who will use the study data. Your and your child's health information will be used and/or disclosed to conduct the research study, for follow up of possible adverse events and for monitoring and audit purposes.

By signing this informed consent/parental permission form, you consent to the use and/or disclosure of your health information and give permission for the use and/or disclosure of your child's health information for the research study described in this form.

The health information that will be used within Nemours includes: your child's weight, Body Mass Index, and type of health insurance.

The individual identifiers that may be disclosed include: your child's age, gender, race, and ethnicity, and your yearly household income, marital status, level of education and occupation.

The individuals and groups within Nemours that will use your and your child's health information may include:

- The investigators listed on the first page of this permission form and their staff
- A research safety committee
- The Nemours Institutional Review Board (IRB) (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;
- Nemours internal audit staff.

Only health care organizations have to follow laws and rules about protecting the privacy of health information. Other kinds of organizations such as drug companies, private foundations or data management firms can disclose your and your child's health information without your permission once they have received it.

This authorization to use or disclose your and your child's protected health information will end when the research study is complete and analysis and publication have ended. At that point, all personal identifiers will be removed from the data file and it will no longer be possible to determine which data are yours and your child's.

Your and your child's identity will be protected as much as the law permits.

Nemours will protect your and your child's health information by not including your child's name on any of the study questionnaires. This will prevent your child's name from being linked to his/her responses. In addition, all of the questionnaires completed by you and your child will be stored in a locked office in a locked filing cabinet to ensure that they can only be accessed by individuals who are directly involved with this study.

The research results may be presented at meetings or in print. Participants' identities will not be disclosed in those presentations.

## **17. SIGNATURES:**

I am making a decision whether or not to consent to participate and to permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before he/she will be allowed to be in this study. I have read, or had read to me in a language that I understand, all of the above. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly consent to participate and give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw this permission by writing to the person in charge of the study listed on the first page of this form. The use and/or disclosure of my/my child's protected health information will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- My/my child's protected health information may be disclosed again by the person or entity (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this consent/permission form.
- If I refuse to sign this form, my child will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my/my child's protected health information.
- I have the right to revoke my authorization for the use and disclosure of my/my child's health information at any time, which would end our participation in this study.
- I will receive a signed and dated copy of this permission form.

My signature indicates that:

- I give the researchers and Nemours permission to use and/or disclose my/my child's individually identifiable health information, for this research study, as described in Section 16.

As his or her parent or legal representative, I give my permission for the minor child named below to participate and give consent for my participation in the research study described in this form.

\_\_\_\_\_  
Name of Minor  
Participant (Print)

Minor Participant Date of Birth:

\_\_\_\_\_  
Signature of  
Parent/Legal Representative

\_\_\_\_\_  
Printed Name of Parent/Legal  
Representative

\_\_\_\_\_  
Date

Relation to Minor Participant:     Parent     Legal Guardian

I the undersigned, certify that to the best of my knowledge the parent/legal representative signing this consent/permission form had the study fully and carefully explained and that he/she understands the nature, risks and benefits of participation in this research study.

\_\_\_\_\_  
Name of Person Obtaining  
permission (Investigator or Designee)

\_\_\_\_\_  
Signature of Person Obtaining  
permission

\_\_\_\_\_  
Date

[   ] Copy provided to participant on \_\_\_\_\_Date

Appendix G: Adolescent Assent Form

## **ADOLESCENT ASSENT FORM FOR YOUTH AGES 12-17**

You are being asked to be in a research study. A research study is how doctors or scientists try to answer important questions about health care. Before you decide about being in this research study, we want to tell you about it so you can ask questions. You can then choose to be in the study, not be in the study or take more time to decide.

The study is called Acceptability of Obesity Interventions Among Overweight Adolescents and Their Parents. The doctor in charge of the study is Jennifer Shroff Pendley, Ph.D. This doctor would like to find out what you and your parents/caregivers think about different weight loss treatments. You are being asked to be in the study because you are receiving treatment in the Weight Management Clinic at A.I. duPont Hospital for Children. The doctor in charge of this study thinks it is important because it will help your doctors and other doctors learn what types of treatments you and other adolescents like most or least. This information will help doctors and other professionals in the future when they are developing or changing weight loss programs.

If you decide to be in the study, here is what will happen: You will be asked to fill out two questionnaires. One asks questions about what you think of different weight loss treatments. The other one asks questions about how you think you're doing emotionally, socially, physically, and academically. You will only be asked to fill out these questionnaires one time, during your visit to the Weight Management Clinic.

There are often some risks to people who take part in research studies. The main risks that you would face by taking part in this study are:

- Some of the questions you are asked might make you feel uncomfortable. You will be allowed to skip these questions.
- You'll have to spend time completing the questionnaires.
- There may be a risk of loss of the confidentiality of your responses. However, the study investigators will try to protect confidentiality by not putting your name on any of the study questionnaires and by, instead, replacing your name with an identification number.

Taking part in this research may also cause some good things to happen to you. You may feel good about contributing to research that might influence doctors' understanding of how adolescents view different weight loss treatments.

You will not be paid for being in this study. You don't have to do the study if you don't want to. If you are in the study, you can stop being in it at any time. Nobody will be upset with you if you don't want to be in the study or if you want to stop being in the study. The doctors and nurses will take care of you as they have in the past. If

you have any questions or don't like what is happening, please tell the doctor or nurse.

Your parent or guardian knows about this study and has given permission for you to be in it if you wish. You have had the study explained to you and you have been given a chance to ask questions about it. By writing your name below, you are saying that you know what will happen to you in the study and that you want to be in it.

\_\_\_\_\_  
Adolescent's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Obtaining Assent

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

Appendix H: Letter of Permission to Reproduce PedsQL 4.0

**TO:** Jennifer Shroff Pendley, PH.D.  
Danielle Rosnov, M.A.

**FROM:** Gabriela Ramirez, PhD, MPH  
Associate Director, NCMP

**SUBJECT:** PedsQL™ User Agreement

**DATE:** 04/16/2007

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Thank you for your Consultation Request for use of the PedsQL™. I am attaching electronic copies of the PedsQL Generic Core Scales you requested (Adolescent and Child Self report and Parent Proxy report) along with the Administration Guidelines and Scoring Manual.

In addition, attached is also a copy of the User Agreement that Nemours signed outlining our terms of use. Several areas in the User Agreement may relate to your specific use of the PedsQL™. Specifically, please note:

- a) Section 1: The PedsQL™ is copyrighted with all rights reserved for Dr. Varni.
- b) Section 3: The user may not change the instrument without the written consent of Dr. Varni.
- c) Section 4: The user may not reproduce the questionnaires for a third party (i.e. anyone outside of Nemours).
- d) Section 5 and 6: In the event there are publications, credits need to be incorporated as per the list on the User Agreement and the author requests acknowledgement.
- e) We will note on our data base that you will be using these instruments from 4/16/2007 through 12/31/2007. We do ask that you notify us should the end date change.

Please read through the User Agreement and call me at (407) 650-7062 if any part of this User Agreement is unclear. We will be happy to help answer your questions.