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# TREATMENT ACCEPTABILITY FOR THE PREVENTION OF OBESITY AND TYPE 2 DIABETES MELLITUS: THE EFFECTS OF ETHNICITY, WEIGHT, AND GENETIC PREDISPOSITION

#### A Dissertation

Submitted to the Graduate Faculty of the Louisiana State University and Agricultural and Mechanical College in partial fulfillment of the requirements for the degree of Doctor of Philosophy

in

The Department of Psychology

by Jean Marie Thaw B.A., Furman University, 1992 M.A., Louisiana State University, 1998 December, 2002

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#### Abstract

Childhood obesity and its associated health consequences, such as type 2 diabetes mellitus, have dramatically increased over the past 30 years, with the greatest rise in African-American female children and adolescents. Although current prevention efforts show promising results, recent genetic findings may soon expand treatment strategies to include new medications and gene therapies specifically designed to prevent the development of obesity and type 2 diabetes in children. However, little is known about the acceptability of these interventions. The primary aim of this study was to examine the hypothetical impact of genetic knowledge on treatment acceptability in the prevention of childhood obesity and type 2 diabetes. This study compared the effects of ethnicity (African-American, Caucasian), maternal weight status (Normal, Overweight/Obese), and genetic predisposition to obesity or diabetes on mothers' perceptions of six interventions for their children: no treatment, dietary change, physical activity, medication, family lifestyle change, and gene therapy. Ethnicity and parent weight have both been found to influence outcomes in weight-loss programs. Thus, the design of the study was a 2 (ethnicity) x 2 (weight status) x 2 (type of problem) x 6 (treatment) multi-factorial design. Participants were 146 females whose children were between the ages of 2 and 17 years. Using the Treatment Evaluation Inventory-short form (Kelley, Heffer, Gresham, & Elliott, 1989), mothers rated the acceptability of the six strategies for their children. General findings suggest that mothers viewed the behavioral and lifestyle strategies as acceptable prevention interventions, whereas they considered the medical strategies (and no treatment at all) as unacceptable alternatives. Heightened disease risk of type 2 diabetes increased acceptability for all forms of treatment, specifically medication. However, gene therapy was generally ranked as more acceptable than medication, suggesting that mothers might consider this treatment option instead of medication when more intrusive strategies

are preferred. Overall, these findings provide a basis for future investigations of the impact of genetic knowledge on treatment and prevention choices. These findings are further discussed within the framework of future marketing strategies directed at potential consumers.

#### Introduction

People will soon have the possibility to learn about their genetic susceptibility to specific diseases and chronic medical conditions. Genetic testing is being increasingly sought by individuals who wish to learn their predisposition to later-onset illness (Patterson, Eaton, & Potter, 1999) due to the recent advances in genetics research, specifically, the findings of the Human Genome Project (HGP). Begun in 1990, this international research program recently completed its primary goal of sequencing the entire human genome. Since completing the 'map', investigators have been searching for the functions of the genes, attempting to relate specific phenotypes to regions of the genome.

However, the recent genetic findings have outpaced our ability to respond to the implications of the resulting data. Individuals will have to cope with information about risk factors in their genes, factors that predispose them to developing conditions in association with specific environmental variables. Armed with this genetic information, they will have to choose among various treatments or preventive interventions for themselves and for their children. This information may affect their treatment and prevention choices. Bio-ethicists are questioning the impact of genetic knowledge: Will parents treat a child at increased risk for disease differently than an unaffected child? How does genetic information affect planning for the future? (Ridley, 1999). Medical researchers are predicting the development of new medications and procedures tailored to specific genotypes. Already, media broadcasts and publications are informing the public that human cloning and genetic engineering will soon be possible in order to create 'designer' children (e.g., Rowland, 2000). Experimental gene therapy has been initiated, with both favorable and tragic results. Debates are raging both for and against the possibilities, for and against the acceptability of these procedures.

Despite these worries, the HGP provides a new direction for prevention efforts in chronic conditions, such as obesity and type 2 diabetes. Childhood obesity, dramatically increasing in prevalence, is strongly associated with adult obesity as well as a multitude of serious health consequences, including type 2 diabetes (T2DM). The recent surge in research on the prevention of obesity and the creation of 'obesitology' clinics is due in part to the potential for identification of genes for obesity (Epstein, 1999; Sorensen & Stunkard, 1993). Because obesity in adulthood can be prevented by treatment in childhood/early adolescence, early identification of 'genetically-predisposed' individuals is critical for early intervention efforts. Genetic susceptibility has traditionally been defined by having at least one obese parent (Lake, Power, & Cole, 1997); however, a more specific test may soon be available. Although the test will yield only probabilities, some parents may not want to know this information or may feel uncomfortable about making a 'prevention decision.' This poses an ethical problem that needs to be addressed—the role of the psychologist is to minimize harm to others while respecting their rights and dignity (American Psychological Association, 1992).

Knowledge of a genetic predisposition to obesity and T2DM may affect the acceptability of the treatment choices. There are certain strategies likely to be tested as prevention approaches: (a) dietary change; (b) physical activity; (c) medication; (d) gene therapy; and (e) family lifestyle change. However, we do not know whether parents will prefer (i.e., find acceptable) one approach to another, regardless of the efficacy of the approaches. Different parental characteristics (e.g., ethnicity, weight concerns) may influence choices of acceptable and unacceptable interventions. A child's probability of becoming obese or developing T2DM could sway prevention decisions. For example, a parent with a child who has a high probability of becoming obese might opt for an intrusive intervention (e.g., gene therapy) over traditional

treatments that alter environmental and behavioral variables (e.g., dietary intake or physical activity). As an illustration, Milner and colleagues (1998) found that the hypothetical availability of "curative gene therapy" significantly increased the desire for prenatal testing of obesity.

The present study will be the first to address the hypothetical impact of genetic knowledge on treatment acceptability in the prevention of obesity and T2DM. To date, little is known about the acceptability of prevention efforts in response to genetic testing. Therefore, the following sections will provide a rationale for prevention as well as identify factors that affect the success of prevention efforts. A brief discussion of treatment acceptability is necessary to identify other factors that could influence the perceived acceptability of interventions.

#### Review of the Literature

## Rationale for the Prevention of Obesity

Prevalence. The increasing prevalence, numerous health and psychosocial risks, and exorbitant economic costs of obesity – approximately \$100 billion per year in the US (Quesenberry, Caan, & Jacobson, 1998; Wolf & Colditz, 1998) – clearly justify the need for prevention efforts. Data from successive national surveys conducted from 1960 through 1999 indicate a dramatic increase in the prevalence of obesity in children and adolescents, with the largest increase occurring during the most recent surveys (Flegal, Carroll, Kuczmarski, & Johnson, 1998; Flegal, Ogden, Wei, Kuczmarski, & Johnson, 2001; National Center for Health Statistics, 2001; Popkin & Udry, 1998; Troiano & Flegal, 1998). From 1963 to 1965, approximately 4% of children and adolescents were considered obese<sup>1</sup>, compared to 11% in 1988 to 1994 and 13% in 1999. An additional 14% were considered 'at-risk' for becoming overweight (Troiano & Flegal, 1998). The prevalence of obesity in African-American (AA) female children (16.4%) and Mexican American female children (14.3%) was higher than that of Caucasian female children (9.1%; Troiano & Flegal, 1998). This pattern continues into adolescence and adulthood; the prevalence of obesity was higher for AA (37.4%) and Mexican American women (34.2%) than Caucasian women (22.4%), indicating that obesity is disproportionately higher among minority women (Gannon, DiPietro, & Poehlman, 2000).

Associated Health Risks. The increasing prevalence of obesity in children and adolescents is alarming due to the associated health risks. Obesity that begins early in life tends to persist into adulthood, with an increased risk of obesity-related morbidity later in life regardless of adult weight (Calle, Thun, Petreli, Rodriguez, & Heath, 1999; Dietz, 1998; Goran, Reynolds, & Lindquist, 1999; Guo, Roche, Chumblea, Gardner, & Siervogel, 1994). Obesity is closely related

to an increased risk of T2DM, cardiovascular disease (CVD), osteoarthritis, respiratory dysfunction, and some forms of cancer (Calle et al., 1999; Flegal et al., 1998; Goran et al., 1999; Kuczmarski et al., 1993). Data indicate that the health risks of T2DM and CVD are increasing in children and adolescents.

Until recently, T2DM was considered rare in the pediatric population, historically accounting for approximately 2% of all newly diagnosed cases (Pinhas-Hamiel & Zietler, 1998). However, the incidence of T2DM has increased 10-fold in children in recent years, a finding most apparent among obese children (Pinhas-Hamiel et al., 1996). T2DM is now accounting for almost 40% of new-onset cases of DM among adolescents (Pinhas-Hamiel & Zeitler, 1998), with a decreasing age of onset (Young, Dean, Flett, & Wood-Steiman, 2000). T2DM occurs at a higher rate among female than male children/adolescents (ratio = 1.7:1) and concentrates in some groups (i.e., Hispanics, AA) more than others (Pinhas-Hamiel & Zeitler, 1998). The finding that T2DM is disproportionately higher among black and Hispanic adult females than non-Hispanic whites parallels that of obesity prevalence. The pathogenesis and associated risks of T2DM are described more fully in the following section.

National and community studies of children and adolescents also indicate a marked increase in CVD risk factors, such as high blood pressure and elevated cholesterol levels, most notably in black female children and adolescents (Hubert, Feinleib, McNamara, & Castelli, 1983; NGHS Research Group, 1992; Morrison, James, Sprecher, Khoury, & Daniels, 1999; Rabkin, Matthewson, & Hsu, 1977; Williams et al., 1992). These increased CVD risk and ethnic differences continue into adulthood, especially in AA women, corresponding with obesity trends (Wattigney, Webber, Srinivasan, & Berenson, 1995; Kumanyika, 1994; Morrison et al., 1994; NGHS, 1992). Unfortunately, the cumulative effects of obesity, high blood pressure, and high

cholesterol levels may produce physiologic changes that are not fully repairable at a later date by changes in diet and weight (Jeffery, 1988; Power, Lake, & Cole, 1997). New data in adults suggest that a balanced weight loss diet can improve CVD risk factors in adults who already demonstrate cardiovascular disease (McCarron & Reusser, 2001). Weight loss in childhood may reduce the risk of adult obesity and has been related to improvement in CVD risk factors (Epstein, Kuller, Wing, Valsoki, & McCurley, 1989), suggesting the importance of early intervention.

Quality of Life. The consequences of childhood and adolescent obesity extend beyond health risks. Studies comparing obese and nonobese individuals have generally failed to find consistent differences in global aspects of psychological functioning, such as depression and anxiety. Overall, it appears that among non-clinical samples of obese individuals, rates of diagnosable psychopathology are no greater than among non-obese groups (Stunkard & Wadden, 1992; Wadden & Stunkard, 1985; Wadden, Womble, Stunkard, & Anderson, 2002; Williamson & O'Neil, in press). However, some domains of function are negatively affected by overweight status and particular subsamples of overweight individuals (e.g., obese adolescents) are at increased risk for psychosocial distress, including body image disturbance, peer relationship difficulties, negative self-perceptions, and lower self-esteem (Friedman & Brownell, 1995; Kimm, Sweeney, Janovsky, & MacMillan, 1991; Strauss, 2000; Striegel-Moore et al., 2000). Obesity in adolescence has been found to predict (in adulthood) lower rates of marriage, and for females, lower educational achievement and income and higher rates of poverty in adulthood (Gortmaker, Must, Perrin, Sobol, & Dietz, 1993; Sargent & Blanchflower, 1994; Stunkard & Sorensen, 1993). These results were independent of baseline education, self-esteem, and household income, suggesting that early obesity in females may actually be an important determinant of later socioeconomic status (Gortmaker et al., 1993).

Long-Term Weight Loss. Researchers of obesity have debated the efficacy of weight loss programs for adults. Although weight control research has dramatically improved short-term treatment efficacy in adults, it has been less successful in improving long-term success. Several critics question the usefulness of dieting, citing evidence that most individuals regain their lost weight within five years (Garner & Wooley, 1991; Goodrick & Foreyt, 1991). Other researchers cite long-term efficacy and continue to support the treatment of overweight adults (Brownell & Rodin, 1994). Most reports of successful long-term weight loss, however, are associated with longer duration of treatment (Diabetes Prevention Program [DPP] Research Group, 2002; Goldfield, Raynor, & Epstein, 2002; Jeffery et al., 2000) and/or in a pediatric population (Jeffery et al., 2000). In light of evidence that obesity tends to track into adulthood, the inability to achieve and maintain weight losses in adulthood is alarming and provides further rationale for prevention efforts.

# Type 2 Diabetes as a Consequence of Obesity

In most cases, T2DM should itself be considered a complication of obesity (Pinhas-Heimel & Zeitler, 2000). As such, the dramatically increasing prevalence of T2DM in children and adolescents calls for further obesity prevention efforts (e.g., Pinhas-Heimel & Zeitler, 2000). Diabetes mellitus (DM) is a name given to a group of metabolic disorders arising from defects in insulin secretion, insulin action, or both. Type 1 DM is characterized by absolute insulin deficiency as a result of autoimmune destruction of the pancreatic  $\beta$ -cell. Type 2 DM describes peripheral insulin resistance and relative (rather than absolute) insulin deficiency.

Those considered as at-risk for developing T2DM tend to exhibit a constellation of risk factors: abdominal obesity, hypertension, dyslipidemia, and insulin resistance (Reaven, 1988). This metabolic syndrome, also known as Syndrome X or Insulin Resistance Syndrome (IRS), appears

to be genetically based, as shown in twin studies (Newman et al., 1987; Medici, Hawa, Ianari, Pyke, & Leslie, 1999; Poulsen, Ohm Kyvik, Vaag, & Beck-Nielsen, 1999; Poulsen, Vaag, & Beck-Nielsen, 1999; Poulsen, Vaag, Kyvik, & Beck-Nielsen, 2001) and gene searches (e.g., Elbein, 1997; Klannemark et al., 1998; Plum et al., 2000). However, researchers admit that the influence of genetic factors in the expression of T2DM is unclear. They conclude that although a genetic predisposition for T2DM exists, modifiable risk factors such as obesity, sedentary lifestyle, and increased saturated fat intake are important determinants in the expression of T2DM (Glaser, 1997; Helmrich, Ragland, Leung, & Paffenbarger, 1995; Kitagawa, Owada, Urakami, & Yamauchi, 1998; Pinhas-Heimel et al., 1999; Knowler, Pettitt, Saad, & Bennett, 1990).

Obesity especially seems to precipitate overt diabetes in 'genetically' prone individuals. The primary defect in T2DM is a peripheral insulin resistance. Obesity and sedentary lifestyle are associated with reduced insulin sensitivity and the risk factors identified in the IRS, which are occurring in children as young as five years old (Burke, Hale, Hazuda, & Stern, 1999; Danadian et al., 1999; Ferrannini & Camastra, 1998; Gower, Nagy, & Goran, 1999; Srinivasan, Myers, & Berenson, 1999; Young-Hyman, De Luca, Schlundt, Counts, & Herman, 2001). Initially, there is a compensatory increase in insulin secretion, as indicated by elevated fasting insulin levels. However, pancreatic  $\beta$ -cell function eventually declines and insulin secretion decreases. The consequent hyperglycemia ("high blood sugar") further worsens peripheral insulin resistance and  $\beta$ -cell function.

In children, the average age of onset of T2DM is 12 to 14 years (Glaser, 1997; Pinhas-Heimel & Zeitler, 1996), an age which coincides with the increase in insulin resistance known to occur during normal pubertal development (Amiel, Sherwin, & Simonson, 1986). This resistance likely compounds the problem of impaired glucose tolerance in populations at risk for T2DM

(Callahan & Mansfield, 2000). Ethnicities with higher rates of T2DM among adults also exhibit higher rates of glucose intolerance/insulin resistance and T2DM among children and adolescents. For example, AA children with normal glucose levels have been shown to exhibit increased fasting insulin levels and decreased insulin sensitivity when compared to age- and weight-matched white children, indicating an uneven baseline that starts in childhood (Arslanian, 1998; Arslanian & Suprasongsin, 1996; Glaser, 1997; Goran, 2001; Libman & Arslanian, 1999). These findings, in conjunction with the finding that childhood obesity predicts the development of IRS in adulthood (Srinivasan, Myers, & Berenson, 2002), underscore the importance of weight control early in life.

Associated Health Risks. The long-term consequences of T2DM in children and adolescents are not well studied. In adults, sustained hyperglycemia (resulting from poor glucose control) accelerates the micro- and macrovascular disease leading to neuropathy, retinopathy, nephropathy, and CVD (Expert Committee, 1999). Disease duration and the level of hyperglycemia are associated with the development of these complications (Klein, 1995; Uusitupa, Niskanen, Siitonen, Voutilainen, & Pyörälä, 1993). Correspondingly, an earlier age of onset will lead to an earlier onset of diabetic complications (Fagot-Campagna et al., 2000). For example, adherence to the complicated management of T2DM in childhood is extremely low, resulting in lengthy periods of hyperglycemia. Poor glucose control during the teenage years and the long duration of T2DM may predispose to an early onset of complications (Fagot-Campagna et al., 2000). These findings highlight the critical importance of early identification and intervention of childhood obesity in populations at high risk for T2DM to avert long-term health consequences (Pinhas-Heimel & Zeitler, 2000; Young et al., 2000).

# **Brief Review of Obesity Prevention Studies**

The development of obesity is not completely understood (Ravussin & Swinburn, 1992; Rosenbaum, Leibel, & Hirsch, 1997). In most cases, obesity probably results from an interaction between genetic factors and environmental conditions – inherited metabolic characteristics combined with unfavorable environmental conditions (e.g., minimal physical demands) can lead to the development of obesity. To date, genome-wide scans have identified over 250 genes, markers, and chromosomal regions that are associated or linked with human obesity phenotypes (Pérusse et al., 2001), several of which overlap with those linked to T2DM (Elbein, 1997). Studies of adoptees and twins reared apart indicate that approximately 66% of the variability in body size and body composition can be attributed to genetic factors (Allison et al., 1996; Allison, Matz, Pietrobelli, Zannolli, & Faith, 2001; Price & Gottesman, 1991; Stunkard, Harris, Pedersen, & McClearn, 1990). Genetic predisposition to obesity has been further demarcated. Evidence from prospective studies attributes 12% of the variability in body size to metabolism, 10% to spontaneous physical activity, 5% to fat oxidation, and 40% to the regulation of food intake and/or intentional activity (Ravussin & Bogardus, 2000). The remaining 33% of the variability in body size is attributed to environmental factors.

Prevention research targets the modifiable environmental factors that may increase the risk of obesity (e.g., diet, physical activity, parental/family support) in 'genetically-predisposed' individuals. Most studies have focused on treatment of childhood obesity, based on the rationale that treating obesity in children may prevent or delay adult obesity (Schmitz & Jeffery, 2002). Although adult treatment focuses on weight loss, childhood treatment usually targets the prevention of weight gain. Because lean body mass increases as children age, keeping fat mass constant will result in a normalization of body weight (Rees, 1990). Therefore, the major goal of

prevention efforts in children is to establish lifelong behavior patterns that reduce the likelihood of weight gain and the development of obesity.

General Short-term and Long-term Findings. Short-term efficacy up to 12 months has been established for behavioral interventions with childhood obesity (ages 6 to 12 years), with an average stable reduction in percent overweight of 25% across studies (Epstein, Wing, Steranchak, Dickson, & Michelson, 1980; Israel, Stolmaker, & Adrian, 1985; Goldfield et al., 2002). Percent overweight in untreated comparison groups tended to remain the same or increase in the shortterm. Maintenance of treatment efficacy has been documented in a series of studies conducted by Epstein and colleagues. Children treated in four studies of family-based behavioral interventions were assessed at 5- and 10-year periods. At 10-year follow-up, a significant proportion (approximately 30%) of children across the four treatment interventions had achieved nonobese status (Epstein, Valoski, Wing, & McCurley, 1994). Weight loss studies in adolescents (ages 12 to 18 years), however, report more modest effects, with a rate of weight regain similar to that reported by adult studies (Jelalian & Saelens, 1999). Treatment effects appear to be more stable in children than in adolescents; however, the literature targeting adolescents is not as well developed as that for children, making it difficult to draw conclusions about treatment efficacy (Jelalian & Saelens, 1999).

Lifestyle Change. A second generation of studies has attempted to identify the specific treatment modalities that lead to short-term and long-term weight loss (Jelalian & Saelens, 1999). Most studies asserting successful treatment outcome describe behavior modification interventions (e.g., Epstein et al., 1980). Treatment is typically conducted in weekly groups that receive nutrition and exercise education. Training in behavioral techniques usually includes contingency management, self-monitoring of diet and physical activity, stimulus control, and reinforcement of

behavior change. Behaviors targeted during treatment may be changes in eating behavior, selection of low calorie meals, and parent use of praise. Generally, behavioral treatments targeting dietary intake and physical activity are superior to wait-list control (Aragona, Cassady, & Drabman, 1975; Epstein, Wing, Koeske, & Valoski, 1984) and to nutrition education alone (Epstein et al., 1980) in achieving short-term weight loss in children. Treatment conditions with superior long-term outcomes target a combination of dietary change with lifestyle or aerobic activity or targeted weight-loss in both children and parents (Epstein, McCurley, Wing, & Valoski, 1990; Epstein et al., 1994). However, there does not appear to be enough data to determine which specific strategy or combination of strategies is more successful than others for weight loss (Jelalian & Saelens, 1999).

Family-based interventions require parental involvement in the treatment of obese children. Cooperation is considered critical – parents are able to arrange an environment that may prompt, model, and reinforce eating and activity patterns which can lead to weight loss or gain. Several studies have explicitly examined variations of parental involvement and concluded that actively involving parents in treatment is beneficial (e.g., Brownell, Kelman, & Stunkard, 1983; Coates, Killen, & Slinkard, 1982; Flodmark, Ohlsson, Ryden, & Sveger, 1993; Israel, Solotar, & Zimand, 1990). In the short-term, studies do not indicate an advantage of parent participation over no involvement (Kingsley & Shapiro, 1977; Kirschenbaum, Harris, & Tomarken, 1984). However, studies that document long-term decreases in percent overweight in children include parental participation as essential treatment components (e.g., Epstein and colleagues). Findings also suggest that parent involvement in all aspects of treatment for preadolescents is beneficial whereas a distant support role for adolescents may be more appropriate (Jelalian & Saelens, 1999).

Physical Activity. Variations of physical activity have been examined in the treatment of obesity in children. Exercise interventions can be programmed aerobic (i.e., specific type, intensity, and duration) or lifestyle change (i.e., menu of activities from which to choose; flexible times and duration). Currently, few data suggest that exercise, independent of dietary change, results in decreases in percent overweight in children (Jelalian & Saelens, 1999). Generally, researchers have not found significant differences between interventions of dietary change combined with exercise and interventions of either diet or exercise alone in the short-term (Epstein, Wing, Koeske, Ossip, & Beck, 1982; Rocchini et al., 1988). However, the combination of dietary change and lifestyle or programmed aerobic exercise was superior to a diet and weak exercise program (i.e., calisthenics) at 10-year follow-up (Epstein et al., 1994). Additional data indicate that targeting decreases in sedentary behaviors (rather than increases in physical activity) is associated with decreases in percent overweight (Epstein, Paluch, Gordy, & Dorn, 2000). These findings suggest that dietary change and some form of regular physical activity are needed to produce weight loss (or prevent relative weight gain) in children.

Medication. Medication has become popular in the treatment of adult obesity. Medication is typically reserved for individuals who fail to lose weight or maintain their weight loss after conventional therapy. The usual practice is to prescribe medication as an adjunct to a program of dietary restriction and exercise. At present, there are currently no published studies involving pharmacologic treatment of obesity in children and only three in adolescents. There are two reports in adolescents of the use of metformin, a medication typically prescribed to improve glucose tolerance in diabetic patients (Freemark & Bursey, 2001; Kay et al, 2001). Kay and colleagues (2001) conducted a small randomized, double-blind, placebo controlled trial in 24 non-diabetic obese adolescents who exhibited elevated insulin levels. The research participants were

placed on a low calorie diet; half were given placebo, half were administered metformin. Although all adolescents lost weight, those in the metformin treatment group lost significantly more weight and body fat than those in the placebo group (Kay et al., 2001). Freemark and Bursey (2001) also conducted a randomized, double-blind, placebo controlled trial of metformin in adolescents. However, dietary changes were not prescribed as part of the study. At the end of the study, the placebo and medication group did not differ significantly in weight loss.

The third report tested orlistat, a gastrointestinal lipase inhibitor (McDuffie et al., 2002), as a treatment for adolescent obesity. The open-label pilot trial investigated the safety and efficacy in an adolescent population. As such, all subjects were enrolled in a 12-week lifestyle change program and were prescribed the medication. Although results indicate a significant weight loss by the end of the 12 weeks, there was no placebo-controlled comparison group – definitive conclusions cannot be made on the effect of orlistat on body weight in adolescents. In summary, there are new developments in the medical management of childhood and adolescent obesity; however, findings are preliminary or in-progress.

Additional Factors Related to the "Success" of Obesity Treatments. Parent weight has been shown to influence response to obesity treatments. After five years, obese children with obese parents are less successful at weight control than obese children with normal-weight parents (Epstein, Wing, Valoski, & Gooding, 1987). Obese children with normal-weight parents adhere more to changes in diet and physical activity than obese children with obese parents (Epstein, Wing, Koeske, & Valoski, 1986); normal-weight parents also rate their children as more successful in implementing and maintaining eating and exercise changes (Epstein et al., 1987). These findings may be partially explained by the relationship of parent weight and children's hedonic ratings of food and physical activity before any weight-loss intervention – palatability and

enjoyment ratings of food and physical activities have been shown to be consistently lower for children of obese parents than the offspring of normal-weight parents (Epstein et al., 1989). Shared family environment increases exposure to specific foods and patterns of exercise, which can influence preference (Birch & Marlin, 1982). Epstein and his colleagues (1989) conclude that parent weight may be central in the implementation of and response to obesity intervention — parent weight may affect preference and acceptability of particular treatment strategies.

Culture is another factor that might moderate acceptability and the success of obesity interventions. Obesity is less central to self-evaluation and is not equally stigmatized in all cultures (Abrams, Allen, & Gray, 1993; Burke et al., 1992; Greenberg & LaPorte, 1996; Kumaniyika, Wilson, & Guilford-Davenport, 1993; Smith, Thompson, Raczynski, & Hilner, 1999). Researchers suggest that black females experience less social pressure about their weight and have more positive attitudes about overweight than white females (Kumaniyika et al., 1993). Although more weight-tolerant attitudes in the AA community may provide a protective factor against the development of eating disorders (Rodin, Striegel-Moore, & Silberstein, 1990), these attitudes could actually increase the risk for obesity and obesity-related health problems (Jeffery, 1991; Kumanyika et al., 1994; Rucker & Cash, 1992). The greater acceptance of higher body weights (Kemper et al., 1994; Rand & Kuldau, 1990), the higher levels of body satisfaction at heavier weights (Story, French, Resnick, & Blum, 1995), and the frequent efforts to gain weight (Schreiber et al., 1996) may all result in the higher rates of obesity observed in black females (Smith et al., 1999). Research also indicates a shorter duration of dieting and lower levels of physical activity and fitness among black females than among white females (Kumanyika et al., 1993; Schreiber et al., 1996). Overall, the attitudinal and behavioral factors might limit the ability

of some black females to lose weight or maintain weight loss (Kumanyika et al., 1993) and reduce the acceptability of any anti-obesity treatments.

Some studies have attempted to explain the success (or lack of success) in achieving long-term weight loss by a variety of personality tendencies, such as locus of control (LOC; Nir & Neumann, 1995). The phrase "locus of control" refers to one's belief about the extent to which the individual has control over his/her life. A belief in external control leads to the perception that reinforcement (e.g., improved health, weight loss) is the result of luck, chance, or fate or that it is under the control of powerful others. The perception that reward is the result of one's own self-control indicates an internal locus of control. In particular, LOC has been examined for its relevance in predicting fluctuations in health status and health behaviors (Wallston, Wallston, & DeVellis, 1978) as well as in weight loss and dieting behaviors (Saltzer, 1978; Stotland & Zuroff, 1990; Westenhoefer, 2001). The theory posits that those who value health highly and report a high internal LOC will be more likely to adopt or have a positive attitude toward preventive behaviors (Norman, Bennett, Smith, & Murphy, 1998), such as the prevention of T2DM or obesity. Those with a high external LOC will be less likely to endorse (i.e., find acceptable) or engage in preventive behaviors.

A series of studies applied this theory to obesity and weight loss, with initial studies providing inconsistent results (Balch & Ross, 1975; Gormally, Rardin, & Black, 1980; Ross, Kalucy, & Morton, 1983; Tobias & MacDonald, 1977). However, LOC seems to be a better predictor of weight loss when the value of health and appearance is considered. Individuals with a higher internal LOC and value for health or appearance have been found to be more likely to consume healthy foods than individuals with an external LOC (Bennett, Moore, Smith, Murphy, & Smith, 1994; Saltzer, 1978). In addition, individuals with an internal LOC are more likely than

those with an external LOC to maintain their weight loss up to two years, despite no weight-loss differences between groups at the end of treatment (Nir & Neumann, 1995). However, this effect diminishes after a two-year period. Thus, the belief in one's ability to control weight (an internal LOC) and a corresponding value of health/appearance may affect acceptability and maintenance of weight-loss interventions and obesity prevention efforts.

#### Brief Review of T2DM Prevention Studies

The recent surge in T2DM prevalence has stimulated research pertaining to the prevention of the disease during the past 10 years. However, there is a paucity of studies concerning the prevention of childhood T2DM. The close link to obesity has prompted researchers to suggest that T2DM is a complication of obesity and that the prevention of obesity will, in effect, delay or prevent the onset of T2DM (Anderson, 2000; Pinhas-Heimel & Zeitler, 2000; Young et al., 2000). Preliminary findings point to this possibility.

Dietary Change/Weight Loss. Acute energy restriction and weight loss have been shown to improve insulin sensitivity and improve glycemic control in obese patients with T2DM (Henry, Scheaffer, & Olefsky, 1985; Kelly et al., 1993). In addition, long-term weight loss has been shown to delay the onset of T2DM in obese adults without T2DM (DPP Research Group, 2002; Klein, 2001; Pan et al., 1997; Swinburn, Metcalf, & Ley, 2001). Data from a 16-year observation period of the Framingham Study indicate that the risk of T2DM was reduced by one-third in those who lost 3.0-7.5 kg. and by one-half in those who lost greater than 7.5 kg. (Moore et al., 2000). Weight loss achieved by gastric surgery is associated with a five-fold decrease in the risk of T2DM during an 8-year observation period after surgery (Sjöström, Peltonen, Wedel, & Sjöström, 2000). Although little is known at this time about T2DM prevention with weight loss/dietary changes in children, these findings suggest the possibility that preventing weight gain

in children/adolescents may delay or prevent the onset of T2DM. Ongoing research is examining this possibility (Sudi et al., 2001).

Physical Activity. Clinical, epidemiological, and basic research in adults suggests physical activity as a tool for prevention of chronic disease and enhancement of overall health (Haskell et al., 1992; Pate et al., 1995). In children, the replacement of sedentary behaviors (e.g., television viewing, computer games) by activities of moderate intensity may enhance overall health and assist in preventing chronic disease in at-risk youth (Epstein, Coleman, & Myers, 1996; Sheldahl, 1986). The effect of regular exercise training on individuals with T2DM is widely accepted (Bonen, 1995). A single bout of exercise increases blood flow and glucose delivery, adding to the effect of maximal insulin concentrations (Flemming, Mikines, Sonne, & Galbo, 1994). Preliminary data indicate that the effect increases with regular exercise training (Flemming et al., 1994). These findings led Sothern and colleagues (1999) to suggest that the health benefits of exercise/resistance training in children may be similar to that of adults – regular physical activity might improve insulin sensitivity and possibly delay or prevent the onset on T2DM in children. However, the potential health benefits of increased physical activity for high-risk youth are still under investigation.

Medication. Children and adolescents are exhibiting impaired glucose tolerance (IGT; "pre-T2DM") at younger and younger ages (Young-Hyman et al., 2001). Medications that increase glucose tolerance in diabetic patients (e.g., metformin) might prove useful in preventing the progression of IGT to glucose intolerance in these high-risk youth. In obese non-diabetic adults, metformin has been shown to delay the onset of T2DM by approximately 31% for at least three years (DPP Research Group, 2002). Although there are far fewer pediatric studies examining the effects of medication on the development of T2DM, preliminary findings provide

limited support for the use of medication as a prevention strategy (Freemark & Bursey, 2001; Kay et al., 2001). Freemark and Bursey (2001) conducted a small double-blind, placebo-controlled study of the effects of metformin on BMI, and insulin and glucose blood levels in obese adolescents with fasting hyperinsulinemia. They found that metformin treatment was associated with slight reductions in BMI and fasting blood glucose and insulin concentrations. However, the changes were small in magnitude, prompting the researchers to conclude that metformin might complement the effects of lifestyle interventions in high-risk youth, a conclusion supported by studies combining diet with metformin (Kay et al., 2001).

Lifestyle Change. Early lifestyle intervention studies on individuals with IGT and with newly diagnosed T2DM have provided encouraging results (Eriksson & Lindgärde, 1991; Laitinen et al., 1993; Pan et al., 1997; Tuomilehto et al., 2001; Uusitupa, 1996; Wing, Polley, Venditti, Lang, & Jakicic, 1998) – moderate changes in weight, diet, and physical activity can result in significant improvements in glucose tolerance, potentially reversing the development of T2DM. As a result, two large multi-site, randomized control trials have been conducted to determine whether it is possible to prevent T2DM by lifestyle change or medication in individuals with a high risk of diabetes.

The Finnish Diabetes Prevention Study (DPS) examined the effects of a lifestyle change intervention (i.e., intensive diet and exercise program) in 523 overweight adult subjects with IGT. Preliminary data at one-year follow-up indicated a significant reduction in body weight and improvement in glucose tolerance in the intervention group (Eriksson et al., 1999); at two years, subjects had maintained their weight loss and demonstrated an improvement in physical fitness (Uusitupa et al., 2000). The DPS researchers recently announced the four-year results – a lifestyle change program effectively delayed the onset of T2DM (cited in DPP Research Group, 2000).

In the U.S., the Diabetes Prevention Program (DPP) compared the effects of a lifestyle intervention with metformin or placebo on the development of diabetes in 3234 overweight adults with IGT (DPP Research Group, 2002). The lifestyle intervention involved training in diet, exercise, and behavior modification in 16 sessions during the first 24 weeks, then monthly. At three years, almost 40% of participants in the lifestyle condition had a weight loss of at least 7% and 58% had met the goal of 150 minutes of weekly physical activity. Participants in the medication intervention took metformin twice daily, with 72% of participants in this condition taking at least 80% of their prescribed doses. At three years, there was minimal weight loss (2.1 kg.) and no significant change in level of physical activity in the medication condition. The lifestyle intervention reduced the risk of developing T2DM by 58% and metformin by 31% when compared to placebo. The interventions were effective in men and women and in all ethnic groups (DPP Research Group, 2002). The findings that lifestyle change can delay the onset on T2DM for at least three years prompted the DPP research group and funding institution to end the study early.

Among children and adolescents, T2DM is probably as closely linked to the modifiable risk factors (i.e., obesity, poor nutrition, and physical inactivity) as it is among adults (Expert Committee, 1999). Because childhood and adolescence are periods when behaviors are established, increasing physical activity and decreasing obesity might reduce the incidence of T2DM and prevent other chronic diseases (Fagot-Campagna et al., 2000). Preliminary results indicate that a short-term diet and exercise/sports intervention program can reduce adiposity and improve insulin sensitivity (Sudi et al., 2001). In recent years, community and school interventions targeting high-risk youth have begun to promote physical activity and improved diet (Cook &

Hurley, 1998; Dean, 1998; Teufel & Ritenbaugh, 1998). However, the long-term effectiveness of these programs is not yet established.

Potential Factors Related to the "Success" of T2DM Prevention and Treatment. As discussed, strategies to prevent obesity are being increasingly studied for their effects on the development of T2DM in children. Therefore, the factors that affect the success of obesity treatments will most likely have the same effects in T2DM prevention strategies. It is not known at this time if the perceived severity of the disease potential will affect treatment adherence. Evidence suggests that a significant proportion of parents with T2DM do not believe that prevention of T2DM is possible (external locus of control) or that their children are likely to develop the disease (Pierce, Hayworth, Warburton, Keen, & Bradley, 1999). The belief that any preventive strategy is futile or unnecessary will likely impede treatment acceptability and adherence.

In addition, children and adolescents with T2DM are usually asymptomatic and do not feel ill. Treatment of T2DM can require extensive lifestyle changes, including dietary changes, frequent blood glucose monitoring, daily oral medication and/or insulin injections, and recommended increases in physical activity and/or weight loss. Adherence to this strict medical regimen is typically low. Treatment itself can require painful injections or produce side effects more distressing than the symptoms of the disease (Callahan & Mansfield, 2000). In addition, nonadherence to treatment has few acute physical consequences. As a preventive strategy, it is likely that medication therapy will show a similar level of nonadherence (Callahan & Mansfield, 2000) with lower ratings of acceptability.

# Summary of Obesity and T2DM Interventions

In general, several factors appear to influence the "success" of obesity (and T2DM) interventions in children. Behavioral methods have met with more success than purely nutrition education formats. Parental participation in some form seems to be associated with long-term maintenance of relative weight loss for children, through reinforcement and/or modeling of dietary changes and physical activity, although parental obesity may negate these effects. Increasing physical activity and/or decreasing sedentary behaviors appear to be related to long-term efficacy of obesity treatments, although the effects on T2DM development in children are unknown at this time. Social acceptance of higher weights in some cultures and an external locus of control may curtail the success of obesity and T2DM interventions. Overall, Jelalian and Saelens (1999) conclude that the most successful interventions minimize the "cost" associated with adherence; that is, interventions that minimize the effort and inconvenience of strategies tend to produce more favorable outcomes. This conclusion coincides with general findings in treatment acceptability research – an intervention requiring less time and effort is more likely to be rated acceptable.

#### Treatment Acceptability Research

Treatment acceptability research flourished about 20 years ago, when behavior therapy was first becoming 'mainstream.' Investigators found that equally efficacious treatments were not necessarily equally acceptable to consumers (Kazdin, 1981). A basic hypothesis of this line of research is that acceptable treatments are more likely to be sought out, implemented, adhered to, and maintained (Frentz & Kelley, 1986; Kazdin, 1980a, 1981; Wolf, 1978). In general, treatment acceptability refers to the "judgments about the treatment procedures by nonprofessionals, laypersons, clients, and other potential consumers of treatment" (Kazdin, 1980a, p. 259). For a

treatment to be considered acceptable, it must be appropriate to the problem, reasonable, nonintrusive, and "meet with conventional notions about what treatment should be" (Kazdin, 1980a, p. 259).

This method could be applied to a new problem –prevention and treatment of obesity and T2DM. As described, most childhood anti-obesity/T2DM interventions employ behavioral strategies. Although several aspects of the prevention/treatment strategies have been shown to be efficacious, the procedures must also be accepted by the individuals who use them. If participants do not like specific interventions offered, they are less likely to implement the treatment with integrity, and maintenance of behavior change is unlikely (Kazdin, 1977; Miller & Kelley, 1992; Wolf, 1978).

The majority of published research on treatment acceptability has focused on interventions aimed at changing child conduct problems, e.g., self-injury, aggression. Typical interventions examined include a variety of behavioral procedures, medication, spanking, and contingent electric shock. The methodology is primarily analogue – raters are presented with a written case description of the child exhibiting a problem behavior along with a written description of treatment procedures that can be applied to the problem; the rater then completes an acceptability rating scale for each treatment as applied to that problem. Researchers generally use potential or actual consumers to rate the interventions (e.g., parents, institutional staff), increasing the ecological/social validity of the analogue studies. Few studies have measured acceptability after treatment implementation (consumer satisfaction studies; e.g., Reimers & Wacker, 1988).

Because of similar treatment characteristics, general treatment acceptability findings could be extended to obesity interventions. Overall, acceptable interventions tend to be the least restrictive, require little time to implement, have the fewest side effects, and are the least

disruptive to others (Elliott, 1988; Kazdin, 1980a). Nutrition education could be considered as the least restrictive and least time-consuming, with no obvious side effects, and as non-disruptive to others. However, nutrition education alone has not been shown to have any effect on weight reduction. The more "successful" behavioral interventions for obesity tend to be reinforcementbased and vary in the amount of time and effort required of parents and children/adolescents, possibly influencing treatment preference and acceptability. Findings from earlier treatment acceptability studies on problems other than obesity suggest that the typical reinforcement-based obesity intervention would be rated as more acceptable than medication (a potential future intervention). However, as more parental involvement is required, treatment acceptability ratings may decrease (e.g., reinforcement of physical activity alone vs. family-based intervention). In addition, positive reinforcement-based procedures are consistently rated more acceptable than (1) restrictive or punishment-based treatments or (2) medication (Jones, Eyberg, Adams, & Boggs, 1998; Reimers, Wacker, & Koeppl, 1987; Tarnowski, Simonian, Park, & Bekeny, 1992; Witt & Elliott, 1985). Treatments viewed as strong, controlling, and intrusive to the client and problem tend to be rated as the least acceptable (Kazdin, 1980b). Treatments with adverse side effects are also associated with lower acceptability ratings (Kazdin, 1981). Gene therapy and medication are anti-obesity strategies that could be considered as strong and intrusive with (possible) adverse side effects. These interventions would probably be rated as the least acceptable for the prevention of obesity.

Rater characteristics that have been studied include ethnicity and income. Ethnic background of the rater and socioeconomic status (SES) have not consistently influenced ratings of treatment acceptability (Heffer & Kelley, 1987; Tarnowski et al., 1992). However, slight differences in treatment acceptability ratings according to ethnicity and income suggest that

further research is warranted. For example, Heffer and Kelley (1987) found that low-income black mothers generally favored less labor-intensive treatments, though this finding was not statistically significant. It is conceivable that this relationship may have relevance for some obesity/T2DM interventions that are labor-intensive.

Severity of targeted behaviors is another factor thought to influence treatment acceptability ratings. These findings are particularly salient for obesity/T2DM interventions and culture. Caregivers must consider obesity and T2DM to be potential health risks before deciding treatment is appropriate. Generally, most studies indicate that treatments are more acceptable for more severe problems (Reimers et al., 1987). Specifically, restrictive procedures are considered more acceptable for the more severe problems whereas reinforcement-based procedures are rated more acceptable for mild behavior problems (e.g., Tarnowski, Rasnake, Mulick, & Kelly, 1989; Miltenberger, Parrish, Rickert, & Kohr, 1989). However, evidence suggests that a significant proportion of black parents whose children are obese or "super-obese" do not consider their children's weight as a health risk (Young-Hyman, Herman, Scott, & Schlundt, 2000). Additional findings indicate that parents with T2DM do not consider their children as at-risk for developing diabetes (Pierce et al., 1999). These findings may translate into lower acceptability ratings for anti-obesity/T2DM interventions for black parents when compared to white parents.

Treatment Acceptability and Adherence. Simply knowing that one treatment is more or less acceptable than another does not clarify whether the most acceptable treatment is also the most likely to be implemented with integrity. Early investigators suggested a positive (and causal) relationship between acceptability and treatment adherence (Kazdin, 1980a; Wolf, 1978) and existing models continue to associate acceptability with treatment use and integrity (Eckert & Hintze, 2000). Although there has been limited research testing these models, clinical findings

suggest a moderate relationship between treatment use/adherence and its level of acceptability to parents (Reimers, Wacker, Cooper, & De Raad, 1992a, 1992b; Walle, Hobbs, & Caldwell, 1984). Reimers and colleagues (1992b) compared parental acceptability ratings of various analogue treatments to ratings of treatments actually recommended to the parents for the behavioral problems of their children. The researchers found that treatments were distinguished by their acceptability ratings by actual consumers, i.e., parents seeking treatment for their children. This finding suggests some correspondence between analogue and naturalistic assessments.

Reimers and colleagues then examined parental levels of acceptability and treatment adherence at various times before and after treatment initiation (Reimers & Wacker, 1988; Reimers et al, 1992a, 1992b). Parents who rated the recommended treatments as the most acceptable reported higher levels of adherence and treatment effectiveness at 1-, 3-, and 6-month follow-up than parents who rated their recommended treatments as less acceptable. In addition, parents' level of adherence to treatment at one month was significantly related to their ratings of acceptability at three months. The investigators suggested that initial acceptance refers to a willingness to implement a specific treatment and that this willingness is a prerequisite for initial treatment adherence. However, other variables associated with treatment acceptability (i.e., effectiveness and reasonableness) are important for the long-term maintenance of adherence (at 3-and 6-months). These clinical findings provide preliminary support for the relationship between treatment acceptability and use/adherence, however, additional research is necessary to further clarify the relationship (Finn & Sladeczek, 2001).

## Summary, Rationale, and Design

Pediatric obesity and associated health-risks, such as T2DM and CVD, have increased dramatically over the past 30 years, with the greatest rise in black female children and adolescents.

Obesity and T2DM prevention efforts are increasing and show promising long-term results. However, several variables affect the success of prevention efforts, variables that require parental acceptance and participation. If parents do not like or accept the procedures, long-term behavior change in children to treat and/or prevent weight gain and T2DM will probably not occur. In addition, the imminent identification of "obesity genes" may dramatically affect what parents are willing to consider as viable treatment alternatives.

The present study is the first to examine the differential effects of ethnicity, parent weight, and genetic predisposition to obesity or T2DM on parents' perceptions of six prevention treatments. Independent variables included parent/child ethnicity (AA, Caucasian), genetic probability of becoming obese or developing T2DM (Obesity, T2DM), and maternal weight status (Normal, Overweight/Obese). Thus, the design of the present study is a 2 (ethnicity) x 2 (type of problem) x 2 (weight status) x 6 (treatment) multi-factorial design. The treatment procedures rated included the following: (a) no treatment, (b) physical activity alone, (c) medication, (d) dietary change alone, (e) gene therapy, and (f) family lifestyle change (i.e., behavioral modification of dietary change and physical activity). These interventions, with the exception of gene therapy, represent the range of treatments commonly studied in obesity prevention and treatment research.

Gene therapy was included because the possibility of genetic modification increases with the identification of obesity genes and subsequent susceptibility testing. Studies using animal models have reported short-term success in the treatment of obesity and diabetes with gene therapy (Muzzin, Eisensmith, Copeland, & Woo, 1996) and ongoing animal studies are exploring the long-term effects of gene therapy in obesity treatment and T2DM prevention (Dhillon et al., 2001; Murphy et al., 1997). Two additional treatments have been typically studied – nutrition education and child lifestyle change. However, pilot study results and expert opinion indicated

that the treatments were perceived as the same as two other treatments (nutrition education v. dietary change; child lifestyle change v. family lifestyle change). Thus, nutrition education and child lifestyle change were eliminated as treatment options due to slight perceived differences in method and ratings. The "no treatment" option was included due to an unexpected level of acceptance and the variability in ratings, derived from the pilot study.

## **Hypotheses**

Based on the previous discussion, the specific hypotheses of the present study are as follows:

Hypothesis 1. Ethnic background of parents was expected to influence acceptability for obesity prevention strategies. The greater acceptance of and body satisfaction at higher weights in the AA community was hypothesized to translate into lower acceptability ratings of anti-obesity treatments for AA parents than for Caucasian parents.

Hypothesis 2. Parent weight has been shown to influence adherence to and response to anti-obesity/T2DM interventions, possibly due to lifestyle behaviors already present in the family environment. It was hypothesized that Normal weight parents would rate the behaviorally-oriented treatments as more acceptable than Overweight/Obese parents.

Hypothesis 3. It was hypothesized that perceived severity of the condition would affect treatment acceptability. Parents, regardless of ethnic background or weight status, would rate all treatments for T2DM as more acceptable than the same preventive treatments for obesity. It was also expected that that the more intrusive treatments would be rated as more acceptable for T2DM than for obesity prevention.

Hypothesis 4. It was hypothesized that weight status would interact with ethnic background to affect acceptability of anti-obesity treatments. Overweight/Obese AA parents would rate treatments for obesity as less acceptable than Caucasian parents of all weights. Normal

weight AA parents would rate the preventive treatments for obesity as less acceptable than Caucasian parents, although not to the degree of their Overweight/Obese counterparts. Parent weight and ethnic background were not expected to influence acceptability ratings for the T2DM interventions (see Hypothesis 3).

Hypothesis 5. It was hypothesized that locus of control would be correlated with ratings of treatment acceptability. Overall, parents with an external LOC would rate more intrusive treatments as more acceptable than parents who endorse an internal LOC and this effect would be mediated by personal weight/appearance concerns and previous dieting attempts. Specifically, parents with an external weight-related LOC would rate the more intrusive treatments for obesity more acceptable than parents with an internal weight-related LOC. Parents who endorsed an external health-related LOC would rate the more intrusive treatments for T2DM as more acceptable than parents with an internal health-related LOC.

#### Method

### Pilot Study

A sample size of 112 parents was chosen based upon a power analysis using data collected in a pilot study that used an identical procedure and a similar sample of parents. Measures of central tendency and variance from this study were used to assess statistical power to detect differences in treatment acceptability ratings. With a sample size of 112 parents (14 subjects in each of the eight groups), a large effect size of 1.00 <u>SD</u> should be detected with 80% power. Inclusion/Exclusion Criteria

Subjects were included according to female gender, ethnic background (AA, Caucasian), age (25-50 years), and weight status (Normal, Overweight/Obese). Normal weight was defined by a BMI of 19-24.9 kg/m² and Overweight/Obese by a BMI of 25-45 kg/m². Exclusion criteria included male gender, a history of diabetes, or previous participation in research sponsored by the Pennington Biomedical Research Center (a non-profit institution that specializes in nutrition and preventive medicine research). Parents with a history of diabetes were excluded due to the probable effects on treatment ratings (e.g., personal experience with treatment difficulties may bias ratings). Parents whose children had been diagnosed with diabetes were also excluded for the same reason.

The Obesity Expert Committee recommends that research and treatment of childhood obesity begin as early as two years old (Barlow & Dietz, 1998), although most obesity prevention research focuses on the 5-17 age range. The 2000 U.S. Census reported that parents of children in the selected age range (2-17 years) are primarily 25 to 50 years old (U.S. Census Bureau, 2001), thus, the selection of the maternal age range.

#### Recruitment

Participants were recruited from the database at Pennington Biomedical Research Center (PBRC). Relevant variables in the database included gender, age, ethnicity, presence of T2DM, previous participation in PBRC-sponsored research, and weight at time of initial contact. Over 7,000 potential subjects met the gender, age, ethnic background, weight, and absence of diabetes or previous research experience criteria and comprised this sample of convenience.

Initially, fifty participants were mailed the study materials and a small gift (i.e., 45-minute phone card). However, after two weeks, the response rate to this strategy was less than 5% (n = 2). In reaction to this low response rate, the study materials were mailed to another 50 individuals with a promise of a gift that they may choose (i.e., \$10 gift card at a local store). Once the study materials were returned, the \$10 gift card was mailed to their address. Because the response rate to this second strategy was 28% (n = 14), this strategy was used for the remainder of the study. Participants

The sample of 7000 potential participants who met inclusion criteria at the time of initial contact was stratified by ethnicity and weight status. A total of 650 packets were mailed to potential participants randomly selected from the stratified sample. Of these, 72 packets were returned by the postal service due to incorrect or vacant addresses. Of the remaining 578 packets mailed, 11 packets were returned by recipients who did not complete the packets due to exclusion criteria (i.e., child out of age range, mother out of age range, or unknown reasons). Also, there were a total of 183 completed packets returned. Therefore, the total return rate for this study was 33.6% (n = 194). However, an additional 37 participants were excluded due to maternal age (n = 15), child age (n = 4), and incorrect responses to the procedural question (n = 18). The procedural question was included at the end of the packet and asked participants to indicate how

they completed the treatment acceptability questionnaires (Appendix A). A total of 146 females met the inclusion criteria and were included in the final data analyses.

Participants were 146 females whose children were between the ages of 2 and 17 years. Participants in this study ranged from 25 to 50 years old, with a mean age of 39.5 years. The ethnic composition of the sample was split: 47.9% were African-American (n = 70), and 52.1% were Caucasian (n = 76). In addition, 39.7% of the sample were normal weight (n = 58), with an average BMI of 22.70 (SD=1.81). The remaining 60.3% were overweight (n = 88), with an average BMI of 32.22 (SD=5.55). The participants were assigned to groups according to ethnicity, weight status, and type of problem case description (Obesity, T2DM) presented in the packet. The number of participants in each group is summarized in Table 1.

Table 1: Number of participants according to group.

	African-	African-American		ıcasian		
Type of Problem Description	Normal weight	Overweight	Normal weight	Overweight	Total	
Obesity	9	31	17	23	80	
T2DM	14	16	18	18	66	

### Materials

<u>Demographic questionnaire (Appendix B).</u> Participants completed a demographic questionnaire that included participant's age, ethnicity, and marital status; years of formal education; and household annual income. The questionnaire also included the participant's height, weight, personal and family medical history, and questions about previous weight loss attempts.

Questions about their child's age, gender, height, weight, presence of diabetes, and experience with health care services were included.

Body Shape Questionnaire – short form (BSQ-sf; Evans & Dolan, 1993; Appendix C).

Parent preoccupation about body weight might affect treatment acceptability ratings. The BSQ-sf, an eight-item measure of concern about body weight and shape, was used to assess parental body dissatisfaction and its relation to treatment acceptability ratings.

Weight Locus of Control Scale (WLOC; Saltzer, 1982; Appendix D). The WLOC scale is a four-item measure that assesses the beliefs that individuals have in the amount of perceived control they have over their weight. The WLOC was designed to measure expectancies for locus of control with respect to personal weight and has been found to primarily measure the rejection of uncontrollable factors within the individual as causes of being overweight (e.g., luck, genes, fate; Stotland & Zuroff, 1990). The WLOC demonstrates moderate test-retest reliability and convergent validity (Saltzer, 1982) and is the most commonly used measure of weight LOC.

Multidimensional Health Locus of Control Scale (MHLC; Wallston et al., 1978; Appendix E). The MHLC is an 18-item measure that consists of three subscales designed to assess beliefs an individual has about the level of control over his/her health. The Internal scale assesses the degree to which an individual believes that his/her own behavior is responsible for health or illness. The Chance scale (external) measures beliefs that an individual's level of health or illness is a function of luck, chance, fate, or uncontrollable factors. The Powerful Others (external) scale assesses an individual's beliefs that the degree of health or illness is determines by important figures such as physicians or friends. All items are rated on a 6-point Likert-type format with a reading level of 5<sup>th</sup>-6<sup>th</sup> grade. Internal consistency is high for the three subscales (coefficient alpha ranges from 0.67 to 0.77). The MHLC has been shown to predict behavioral involvement in personal health

care (Rock, Meyerowitz, Maisto, & Wallston, 1987). The Chance and Powerful Others scales were used to define external health-related LOC; the Internal scale defined the level of internal health-related LOC.

Case Descriptions (Appendix F). Mothers were presented with a description of the HGP and the anticipated identification of obesity and diabetes genes. They were asked to imagine their child in one of two case descriptions. One case description provided information on the health and psychosocial risks of childhood obesity along with the probability that her child would become obese. A second case description described the health and psychosocial risks of T2DM in childhood as well as the probability of her child developing the disease. Both case descriptions were subjected to expert review during the planning phase of the study and were deemed appropriate.

Treatment Options (Appendix G). Parents were presented with six methods which might be used to prevent the development of obesity and T2DM: no treatment; dietary change; physical activity; medication; family lifestyle change; and gene therapy. Only the medication treatments were described differently for the obesity and T2DM case descriptions; benefits and side effects were modeled on the current drugs of choice for the two conditions (i.e., sibutramine for obesity, metformin for T2DM). Treatment descriptions were written at the 5<sup>th</sup> to 6<sup>th</sup> grade level; all contained between 126 to 197 words. All six treatments were presented randomly after each case description to control for sequencing effects. Treatment descriptions were also reviewed and edited by experts in obesity/T2DM research during the planning stage of the study.

Treatment Evaluation Inventory – short form (TEI-sf; Kelley, Heffer, Gresham, & Elliott, 1989; Appendix H). The TEI-sf, a 9-item questionnaire designed to measure an adult's acceptance of treatments used with children, will be used to evaluate the acceptability of each

treatment. Each TEI-sf item is rated on a five-point Likert-type scale. The TEI-sf has an overall reading level of 4.2 and demonstrates high internal consistency (coefficient alpha = .85; Kelley et al., 1989). The TEI-sf has also been shown to discriminate among alternative treatment methods (Adams & Kelley, 1992; Kelley et al., 1989). The measure was slightly altered to focus on obesity/T2DM treatments rather than child conduct problems.

# Procedure

Participants were mailed a packet containing the demographic questionnaire, case description, treatment descriptions (each followed by a TEI-sf), BSQ-sf, WLOC, and the MHLC. They were informed that the researchers are interested in obtaining parents' opinions about several methods used to prevent weight gain and disease development in children. Participants were instructed to complete the packet in the order it was given to them without looking forward or backward in the packet. Fifty percent of the mailed packets asked mothers to answer the questions in reference to their youngest child between the ages of 2 and 17 years; 50% included instructions to answer question regarding their oldest child within the age range. They were then asked to return the study materials in the enclosed addressed stamped envelope.

#### Results

## Missing Data

The imputation method used to estimate missing item values was mean substitution according to group membership. There were 7 cases with one item response missing, 21 cases with two item responses missing, 4 cases with three item responses missing, and 2 cases with five item responses missing. There was no discernible pattern in the missing values.

# **Demographic Characteristics**

Analyses of demographic variables were conducted in order to determine whether different groups were comparable with respect to a variety of descriptive characteristics. Chisquare analyses of dichotomous variables (i.e., employment status, marital status, sex of target child) were performed. Results indicated that the groups differed in employment status, according to weight status,  $\underline{X}^2 = 6.20$ ,  $\underline{p} < .05$ . Overweight participants (n = 75; 85.2%) were more likely than Normal weight participants (n = 40; 69.0%) to be employed. In addition, a significant difference in marital status was found between AA and Caucasian mothers,  $\underline{X}^2 = 37.22$ ,  $\underline{p} < .0001$ . Specifically, more Caucasian mothers (n = 69, 47.3%) were married than were AA mothers (n = 32, 21.9%). However, there were no differences in marital status according to weight status or type of problem. In addition, employment status and the sex of the target child did not differ across subgroups of parents.

Analyses of variance were used for the comparison of groups on continuous dependent variables (see Table 2). The ANOVAs were conducted with three between-group variables – ethnicity, maternal weight status, and type of problem. Results indicated that the Overweight/Obese group weighed significantly more than the Normal weight group,  $\underline{F}(1, 146) = 143.72$ ,  $\underline{p} < .0001$ . The Overweight group reported significantly more prescribed medications than

the Normal weight group,  $\underline{F}(1, 146) = 10.25$ ,  $\underline{p} < .01$ . In addition, the Overweight group reported a significantly lower total annual income than the Normal weight group,  $\underline{F}(1, 146) = 10.01$ ,  $\underline{p} < .01$ . Total annual income also differed according to Ethnicity; AA mothers ( $\underline{M} = \$41,562.15$ ,  $\underline{SD} = 32307.72$ ) reported a significantly lower total annual income than the Caucasian mothers ( $\underline{M} = \$71,854.33$ ,  $\underline{SD} = 28704.57$ ),  $\underline{F}(1, 146) = 29.06$ ,  $\underline{p} < .0001$ . Maternal age and years of education did not differ according to ethnicity, weight status, or type of problem. Table 2 summarizes the findings for demographic variables according to weight status.<sup>2</sup>

Comparisons of child variables indicated that the target children of the Overweight group weighed significantly more than the children of the Normal weight group,  $\underline{F}(1, 124) = 4.50$ ,  $\underline{p} < .05$ . Target child BMI also differed according to Ethnicity; AA children ( $\underline{M} = 22.06$ ,  $\underline{SD} = 6.78$ ) weighed significantly more than Caucasian children ( $\underline{M} = 19.86$ ,  $\underline{SD} = 5.65$ ),  $\underline{F}(1, 124) = 4.83$ ,  $\underline{p} < .05$ . Target child age, number of prescribed medications, and level of health care did not differ according to ethnicity, weight status, or type of problem (see Table 2).

# Questionnaire Data

An analysis of covariance (ANCOVA) was conducted to identify group differences in subjects' scores on the BSQ. Between-group variables were ethnicity, maternal weight status, and type of problem. Total annual income, a measure of SES, was included as a covariate due to its relationship with both the ethnicity and weight status variables. A main effect of ethnicity,  $\underline{F}(1, 146) = 4.07$ ,  $\underline{p} < .05$ , was revealed, suggesting that Caucasian mothers were less satisfied with their bodies ( $\underline{M} = 28.43$ ) than were AA mothers ( $\underline{M} = 25.67$ ). A main effect of weight status,  $\underline{F}(1, 146) = 33.06$ ,  $\underline{p} < .001$ , was also revealed. Overweight mothers were significantly less satisfied with their bodies ( $\underline{M} = 30.23$ ) than were Normal-weight mothers ( $\underline{M} = 22.37$ ). This analysis did not reveal a significant ethnicity by weight interaction,  $\underline{F}(1, 146) = 2.69$ ,  $\underline{p} = .10$ , failing to

support previous research findings of higher levels of body satisfaction at heavier weights in the AA culture (Kumaniyika et al., 1993).

Table 2: Summary of means and standard deviations of demographic characteristics by weight status.

Demographic	Normal weight	Overweight
Characteristic	(n=58)	(n=88)
Age	38.45	40.28
	(6.04)	(6.55)
BMI	22.70*	32.22*
	(1.81)	(5.55)
Years of education	15.18	14.57
	(2.73)	(2.60)
Total annual income	\$68,562.43*	\$49,927.94*
Total almaal meome	(38,296.79)	(28,671.00)
Number of prescribed	0.72*	1.47*
medications	(0.93)	(1.58)
Target child age	9.22	11.10
Turgot omia ago	(4.88)	(4.68)
Target child BMI	19.10*	22.06*
rargot omia Bivii	(4.57)	(6.85)
Level of health care	3.27	3.30
Do , or or mount out	(0.95)	(1.06)
Number of prescribed	0.47	0.44
medications for target child	(1.03)	(0.84)

Note: BMI = Body mass index. Level of health care items were rated on a 5-point Likert scale (1=significantly below average; 5=significantly above average). Standard deviations are in parentheses. \* indicates that group means differ at p < .01.

A multivariate analysis of covariance (MANCOVA) was conducted to identify group differences in subjects' scores on the MHLC subscales and the WLOC. The groups did not differ

significantly on the LOC measures. Means and standard deviations of subjects' scores on the assessment measures according to weight status are presented in Table 3.

Table 3: Summary of means and standard deviations of assessment measures by weight status.

Assessment Measure	Normal weight (n=58)	Overweight (n=88)
1/1045410	(11 20)	(H 00)
BSQ-sf	22.67*	30.23*
	(8.30)	(9.38)
WLOC	9.41	9.97
WLOC	(2.93)	(3.18)
MHLC-I	26.70	27.26
WHILE I	(4.10)	(3.78)
NAME OF CO.	16.62	16.70
MHLC-C	16.63	16.70
	(4.07)	(4.15)
MHLC-PO	18.37	19.00
	(4.43)	(4.67)

Note: BSQ-sf = Body Shape Questionnaire – short form; WLOC = Weight Locus of Control Scale; MHLC-I = Multidimensional Health Locus of Control Scale – Internal subscale; MHLC-C = Multidimensional Health Locus of Control Scale – Chance subscale; MHLC-PO = Multidimensional Health Locus of Control Scale – Powerful Others subscale. Standard deviations are in parentheses. \* denotes significance at p < .01.

# Scale Reliability

The TEI-sf was originally developed to determine the acceptability of interventions targeting child behavior problems – none of the previous research using the TEI-sf specifically focused on the acceptability of obesity or T2DM prevention strategies. Therefore, reliability (internal consistency) analyses were conducted on the TEI-sf measures for each treatment type. Separate analyses were conducted for each type of problem, obesity and T2DM. Inter-item correlations were calculated for each treatment measure using Cronbach's alpha.

Acceptable levels of reliability were found for each treatment type. Table 4 presents reliability estimates for the TEI-sf at each treatment level for obesity. Cronbach's alpha for the TEI-sf at each treatment level ranged from .87 (physical activity) to .91 (no treatment). Table 5 presents reliability estimates for the TEI-sf at each treatment level for T2DM. Cronbach's alpha for the TEI-sf at each treatment level ranged from .77 (physical activity) to .92 (gene therapy).

Table 4: Reliability of TEI-sf (at each treatment type) for Obesity problem.

Treatment	Coefficient α
No treatment	0.91
Medication	0.88
Gene therapy	0.89
Diet only	0.89
Physical activity	0.87
Family lifestyle change	0.87

Table 5: Reliability of TEI-sf (at each treatment type) for Type 2 Diabetes problem.

Treatment	Coefficient α
No treatment	0.89
Medication	0.91
Gene therapy	0.92
Diet only	0.86
Physical activity	0.77
Family lifestyle change	0.88

# **Group Analyses**

To evaluate the effects of ethnicity, maternal weight, and type of problem on TEI scores, a 2 x 2 x 2 x 6 mixed ANCOVA was performed with three between subject variables (ethnicity, maternal weight status, type of problem) and one within subject variable (treatment). Because low SES has been found to be associated with higher body weights and health risk behaviors (Winkleby et al., 1998; Lowry, Kann, Collins, & Kolbe, 1996), the possible influence of SES on treatment acceptability ratings was controlled for by including SES as a covariate. Therefore, total annual income, a measure of SES, was entered as a covariate due to its relationship to both the ethnicity and weight status variables.

A significant main effect for treatment,  $\underline{F}(5, 137) = 176.51$ ,  $\underline{p} < .0001$ , was obtained. Post hoc comparisons using the Tukey method indicated significant differences among most of the treatments. Mothers rated family lifestyle change ( $\underline{M} = 38.02$ ,  $\underline{SD} = 5.32$ ) as significantly higher than all other treatments, suggesting that this intervention was more acceptable than the remaining treatments. Diet ( $\underline{M} = 34.69$ ,  $\underline{SD} = 5.67$ ) and physical activity ( $\underline{M} = 35.75$ ,  $\underline{SD} = 4.93$ ) were rated as similarly acceptable; both were rated significantly higher than the remaining treatments. Gene therapy ( $\underline{M} = 23.40$ ,  $\underline{SD} = 7.37$ ) was rated significantly higher than both no treatment and medication. The post-hoc comparisons yielded no difference between no treatment ( $\underline{M} = 20.67$ ,  $\underline{SD} = 6.96$ ) and medication ( $\underline{M} = 18.99$ ,  $\underline{SD} = 7.15$ ).

It was hypothesized that ethnic background of the raters would influence treatment acceptability ratings (see Hypothesis 1). Although a main effect for ethnicity was not found, the analysis yielded a significant interaction of ethnicity by treatment type,  $\underline{F}(1, 137) = 2.43$ ,  $\underline{p} < .05$ . Table 6 presents the mean TEI-sf scores and standard deviations of the treatments according to ethnicity. As revealed by Tukey/Kramer post-hoc comparisons, Caucasian mothers rated the diet

only treatment significantly lower than AA mothers. The two groups did not differ significantly in their ratings of no treatment, medication, gene therapy, physical activity, or family lifestyle change. In addition, the two groups did not differ in their rankings of the treatments. However, the Caucasian mothers' rating of gene therapy as being more acceptable than no treatment approached significance (p = .07).

Maternal weight was also hypothesized to affect treatment ratings (see Hypothesis 2). However, there were no differences in TEI-sf ratings according to weight status,  $\underline{F}(1, 137) = 1.92$ , p = .10. Neither a main effect of weight nor an interaction of weight by treatment type was found.

Perceived severity of the problem was predicted to influence acceptability ratings (see Hypothesis 3). A significant main effect for type of problem,  $\underline{F}(1, 137) = 6.11$ ,  $\underline{p} < .05$ , was found. Overall, mothers rated all treatments for T2DM ( $\underline{M} = 29.19$ ,  $\underline{SD} = 9.97$ ) significantly higher than the same treatments for obesity ( $\underline{M} = 28.09$ ,  $\underline{SD} = 10.26$ ). However, this effect is qualified by the significant interaction between treatment and type of problem,  $\underline{F}(5, 137) = 5.42$ ,  $\underline{p} < .0001$ . Table 7 presents the mean TEI-sf scores and standard deviations of the treatments according to the type of problem. Tukey/Kramer post-hoc comparisons yielded significant differences among the means. Specifically, mothers in both the Obesity and T2DM groups rated family lifestyle change similarly to physical activity but significantly more acceptable than the other treatments. In addition, there was no difference in mothers' ratings of physical activity and diet in either group. However, mothers in the Obesity group rated gene therapy and no treatment similarly, but rated both treatments significantly higher than medication, which was rated the least acceptable as a treatment for obesity. Mothers in the T2DM group rated gene therapy and medication significantly higher than no treatment (for T2DM). Figure 1 depicts group mean differences.

Table 6: Summary of means and standard deviations of TEI-sf, Treatment Type by Ethnicity.

	No		Gene		Physical	Family
	treatment	Medication	therapy	Diet only	activity	lifestyle
African-	21.07 <sup>a,b</sup>	18.16 <sup>b</sup>	23.47 <sup>a</sup>	35.89°*	36.18°	37.96°
American (n=70)	(7.45)	(7.20)	(7.49)	(6.01)	(4.78)	(5.78)
Caucasian	20.30 <sup>a,b</sup>	19.75 <sup>b</sup>	23.34 <sup>a</sup>	33.58°*	35.36°	38.07 <sup>d</sup>
(n=76)	(6.50)	(7.08)	(7.30)	(5.13)	(5.07)	(4.90)

Note: Different superscripts indicate significant differences between Treatments at  $\underline{p} < .01$ . \* indicates significant differences between Ethnicity groups at  $\underline{p} < .05$ .

Table 7: Summary of means and standard deviations of TEI-sf, Treatment Type by Type of Problem.

	No		Gene		Physical	Family
	treatment	Medication	therapy	Diet only	activity	lifestyle
Obesity	21.25 <sup>a</sup>	16.53 <sup>b</sup> *	22.50 <sup>a</sup> *	34.96 <sup>c</sup>	35.52 <sup>c,d</sup>	37.75 <sup>d</sup>
(n=80)	(6.89)	(6.22)	(7.02)	(5.98)	(5.10)	(5.32)
Type 2 Diabetes	19.97ª	21.97 <sup>a,b</sup> *	24.49 <sup>b</sup> *	34.35°	36.04 <sup>c,d</sup>	38.33 <sup>d</sup>
(n=66)	(7.03)	(7.12)	(7.67)	(5.30)	(4.74)	(5.35)

Note: Different superscripts indicate significant differences between Treatments at p < .01. \* indicates significant differences between Type of Problem groups at p < .05.

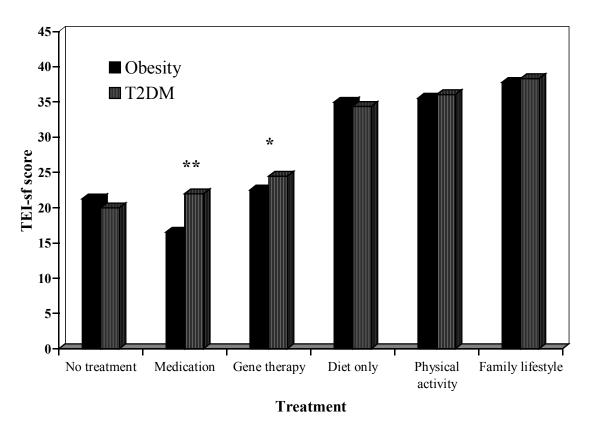


Figure 1: Means of TEI-sf scores, Treatment by Type of Problem. \* indicates significant difference at p < .05. \*\* indicates significant difference at p < .01.

Weight status, ethnicity, and type of problem were hypothesized to interact to influence acceptability of the anti-obesity treatments (see Hypothesis 4). However, a significant interaction of ethnicity, weight status, and problem condition was not obtained,  $\underline{F}(1, 137) = 0.25$ ,  $\underline{p} = .94$ .

Translation of TEI-sf Scores into Categorical Groupings

The results of the group analyses can be considered in a more descriptive manner. The TEI-sf has a total score range of 9 to 45, with each item scored on a 5-point Likert-type scale (Strongly Disagree/Unacceptable = 1; Neutral = 3; Strongly Agree/Acceptable = 5). If the average rating of a group is divided by the lowest possible treatment rating (i.e., 9), the rating can then be translated into a descriptive category. For example, the overall mean of family lifestyle change was 38.02, significantly higher than all other treatments. When divided by 9, the average family lifestyle rating becomes 4.22, a score which corresponds with Acceptable for this treatment option. The descriptive categories are presented in Table 8 and Table 9, showing the treatment type by ethnicity and treatment type by type of problem interactions, respectively. This descriptive strategy is further employed in the Discussion section.

#### Locus of Control

Locus of control was hypothesized to be associated with ratings of treatment acceptability (see Hypothesis 5). It was expected that higher endorsement of external LOC would be associated with higher ratings of no treatment, medication, and gene therapy. Hierarchical regression was used to determine how much of the variance in treatment acceptability ratings could be explained by LOC after adjustment for background variables, child age, child weight, and level of body satisfaction. Six regression analyses were conducted to identify predictors of acceptability ratings at each treatment level. Predictor variables were entered into the analysis in the following order: (1) background and confounding variables (i.e., ethnicity, maternal BMI, type of problem, total

Table 8: Summary of translated TEI-sf scores, Treatment Type by Ethnicity.

	No treatment	Medication	Gene therapy	Diet only	Physical activity	Family lifestyle
African- American (n=70)	2.34 (U-N)	2.02 (U)	2.61 (N)	3.99 (A)	4.02 (A)	4.22 (A)
Caucasian (n=76)	2.26 (U-N)	2.19 (U)	2.59 (N)	3.73 (N-A)	3.93 (A)	4.23 (A)

Note: Each original mean was divided by 9, the lowest possible acceptability rating on the TEI-sf. SA = Strongly Acceptable; A = Acceptable; N = Neutral; U = Unacceptable; SU = Strongly Unacceptable.

Table 9: Summary of translated TEI-sf scores, Treatment Type by Type of Problem.

No		Gene			Family
treatment	Medication	therapy	Diet only	activity	lifestyle
2.36	1.84	2.50	3.88	3.95	4.19
(U-N)	(SU-U)	(U-N)	(N-A)	(A)	(A)
2.22	2.44	2.72	3.82	4.00	4.26
(U)	(U-N)	(U-N)	(N-A)	(A)	(A)
	2.36 (U-N) 2.22	treatment         Medication           2.36 (U-N)         1.84 (SU-U)           2.22         2.44	treatment         Medication         therapy           2.36 (U-N)         1.84 (SU-U)         2.50 (U-N)           2.22         2.44         2.72	treatment         Medication         therapy         Diet only           2.36 (U-N)         1.84 (SU-U)         2.50 (U-N)         3.88 (N-A)           2.22         2.44         2.72         3.82	treatment         Medication         therapy         Diet only         activity           2.36 (U-N)         1.84 (SU-U)         2.50 (U-N)         3.88 (N-A)         3.95 (N-A)           (U-N)         (SU-U)         (U-N)         (N-A)         (A)           2.22         2.44         2.72         3.82         4.00

Note: Each original mean was divided by 9, the lowest possible acceptability rating on the TEI-sf. SA = Strongly Acceptable; A = Acceptable; N = Neutral; U = Unacceptable; SU = Strongly Unacceptable.

annual income, child age); (2) total score on the BSQ; and (3) LOC scores (i.e., WLOC total; MHLC-Internal subscale; MHLC-Chance subscale; MHLC-Powerful Others subscale).

At each step, all indicators for each predictor variable were entered simultaneously into the model. The total TEI-sf score for each type of treatment was entered as the criterion variable. Background variables and BSQ scores were entered first into the model to remove potential confounding effects of such variables on acceptability ratings. Square root transformations were used on total annual income and maternal BMI due to their moderate levels of negative skewness (Tabachnick & Fidell, 2001). With the use of a p < .001 criterion for Mahalanobis distance, no outliers among the cases were identified. No cases had missing data and no suppressor variables were identified,  $\underline{N} = 146$ . At each step, the contribution to the model of (a) each individual indicator (shown by the individual  $\underline{p}$ -value), and (b) the class of predictor as a whole (shown by the change in  $\underline{R}^2$ ) was examined.

No individual or class variables were found to significantly correlate with acceptability ratings of gene therapy, diet alone, physical activity, and family lifestyle change. However, acceptability ratings of medication and no treatment were found to have significant correlates. Results from the hierarchical regression assessing correlates of medication acceptability ratings are outlined in Table 10. At step 1, the background variables were entered into the equation,  $\underline{R}^2 = .19$ , adjusted  $\underline{R}^2 = .16$ ,  $\underline{F}(5, 134) = 6.34$ ,  $\underline{p} < .0001$ , explaining 16% of the variance in acceptability ratings for medication. Of the variables entered, the type of problem (i.e., Obesity, T2DM) and the square root of maternal BMI were significantly associated with treatment acceptability ratings for medication. At step 2, the total score on the BSQ was entered into the regression model,  $\underline{R}^2 = .19$ , adjusted  $\underline{R}^2 = .15$ ,  $\underline{F}(1, 134) = 0.31$ . Addition of BSQ total score to the equation with background variables did not result in a significant increment in  $\underline{R}^2$  (i.e.,

explained variance remained at 19%). Locus of control measures were added at step 3,  $\underline{R}^2$  = .20,  $\underline{F}(4, 134) = 0.62$ . Addition of LOC to the equation did not reliably improve  $\underline{R}^2$  and none of the variables were individually associated with medication acceptability ratings. After step 3, with all IVs in the equation,  $\underline{R}$  = .45,  $\underline{R}^2$  = .20, adjusted  $\underline{R}^2$  = .14,  $\underline{F}(10, 134)$  = 3.40,  $\underline{p}$  < .001, explaining 14% of the variance in medication acceptability ratings.

Only the type of problem remained individually associated with acceptability ratings of medication at all steps. In this model, the Obesity condition was assigned a value of 1 and the T2DM problem was assigned a value of 2. Therefore, the positive relationship between type of problem and acceptability ratings, as indicated by  $\beta = 0.39$ , suggested that increased disease risk (i.e., T2DM) was associated with higher acceptability ratings for medication.

Results from the hierarchical regression assessing predictors of acceptability ratings for the no treatment option are outlined in Table 11. The regression analysis did not reach significance at p < .05 – however, the predictor class at step 1 reached p = .53 and two individual indicators reached significance within predictor classes. Therefore, the results of this regression analysis are described to explore possible correlates of the acceptability of the no treatment option. At step 1, the background variables were entered into the equation,  $peaksize{R}^2 = .08$ , adjusted  $peaksize{R}^2 = .04$ ,  $peaksize{F}(5, 134) = 2.25$ ,  $peaksize{P}(5, 134) = 2.25$ , explaining only 4% of the variance in acceptability ratings for the no treatment option. Of the variables entered, target child age was significantly associated with treatment acceptability ratings for no treatment – older child age predicted lower acceptability ratings for no treatment. At step 2, the total score on the BSQ was entered into the prediction equation,  $peaksize{R}^2 = .05$ ,  $peaksize{R}^2 = .04$ ,  $peaksize{R}^2 = .04$ ,  $peaksize{R}^2 = .04$ ,  $peaksize{R}^2 = .05$ , peaks

Table 10: Hierarchical regression predicting acceptability ratings of medication.

Variables entered	<u>p</u> -value at entry	$R^2$	$\Delta R^2$	<u>F</u> -test for $\Delta R^2$	d.f.	$\underline{p}$ -value for $\Delta R^2$
Step 1: background variables		0.19	0.19	6.34	5	0.0001
Ethnicity Type of problem	0.42 0.0001					
Maternal BMI (square root transformation)	0.02					
Total annual income (square root transformation)	0.28					
Target child age	0.57					
Step 2: body dissatisfaction		0.19	0.002	0.31	1	0.58
BSQ-sf total score	0.58					
Step 3: locus of control		0.20	0.02	0.62	4	0.65
WLOC	0.56					
MHLC-I	0.87					
MHLC-C	0.21					
MHLC-PO	0.66					

Note: BMI = body mass index; BSQ-sf = Body Shape Questionnaire – short form; WLOC = Weight Locus of Control Scale; MHLC-I = Multidimensional Health Locus of Control Scale – Internal subscale; MHLC-C = Multidimensional Health Locus of Control Scale – Chance subscale; MHLC-PO = Multidimensional Health Locus of Control Scale – Powerful Others subscale.

Table 11: Hierarchical regression predicting acceptability ratings of no treatment.

Variables entered	<u>p</u> -value at entry	$R^2$	$\Delta R^2$	<u>F</u> -test for $\Delta R^2$	d.f.	p-value for $\Delta R^2$
Step 1: background variables		0.08	0.08	2.25	5	0.053
Ethnicity	0.57					
Type of problem	0.15					
Maternal BMI (square root transformation)	0.35					
Total annual income (square root transformation)	0.57					
Target child age	0.01					
Step 2: body dissatisfaction		0.08	0.00	0.03	1	0.87
BSQ-sf total score	0.87					
Step 3: locus of control		0.11	0.04	1.42	4	0.23
WLOC	0.46					
MHLC-I	0.05					
MHLC-C	0.99					
MHLC-PO	0.44					

Note: BMI = body mass index; BSQ-sf = Body Shape Questionnaire – short form; WLOC = Weight Locus of Control Scale; MHLC-I = Multidimensional Health Locus of Control Scale – Internal subscale; MHLC-C = Multidimensional Health Locus of Control Scale – Chance subscale; MHLC-PO = Multidimensional Health Locus of Control Scale – Powerful Others subscale.

1.42. Addition of LOC to the equation did not reliably improve  $\underline{R}^2$ . Of the variables entered, the MHLC-Internal subscale was significantly associated with acceptability ratings for no treatment – higher levels of internal LOC predicted lower acceptability ratings of no treatment. After step 3, with all IVs in the equation,  $\underline{R} = .34$ ,  $\underline{R}^2 = .11$ , adjusted  $\underline{R}^2 = .05$ ,  $\underline{F}(10, 134) = 1.70$ ,  $\underline{p} = .09$ , explaining only 5% of the variance in acceptability ratings.

#### Discussion

The primary aim of the current study was to evaluate the impact of hypothetical genetic knowledge on treatment acceptability in the prevention of obesity and T2DM, attempting to partially answer Ridley's (1999) question of how genetic information affects planning for the future. Because ethnicity and parental weight have been shown to influence the "success" of pediatric anti-obesity/T2DM treatments, these factors were hypothesized to differentially affect the acceptability of the preventive treatments, potentially influencing the outcomes of prevention efforts. The following discussion of the results is organized according to the five hypotheses of the study. In addition, a discussion of the rankings of the preventive treatments is provided. Finally, limitations of the current study are discussed and suggestions for future research are provided.

# **Hypotheses and Treatment Rankings**

Hypothesis 1. Ethnic background of the raters was hypothesized to influence treatment acceptability ratings. Although AA mothers endorsed higher levels of body satisfaction than Caucasian mothers, they did <u>not</u> rate anti-obesity treatments for their children lower than Caucasian mothers. The most probable explanation for this finding is that endorsement of higher levels of body satisfaction does not negate the knowledge of and concern for the health and psychosocial consequences of obesity. The higher levels of body satisfaction may simply weaken the urgency with which to engage in prevention strategies over the long-term, undermining the overall success of obesity prevention programs but not necessarily the acceptability of those same programs.

The findings suggest that AA mothers were more willing than Caucasian mothers to consider diet modification as a prevention strategy. It is possible that recent efforts to promote

lifestyle changes within the AA community have increased exposure to and, thus, acceptance of dietary changes (Kumanyika, 2002). Although statistically significant, the difference between the ethnicity groups might not be practically meaningful. The AA mothers rated diet in the Acceptable range, whereas Caucasian mothers rated diet only slightly lower in the Neutral-Acceptable range. In addition, diet was as acceptable as physical activity and lifestyle change for the AA mothers and only slightly less acceptable than those treatments for the Caucasian mothers. That is, the diet option for both groups was still ranked well above the remaining treatment options of gene therapy, medication, and no treatment. Therefore, the difference might not be practically significant.

Hypothesis 2. Maternal weight was hypothesized to influence treatment acceptability ratings – when compared with Overweight mothers, the Normal-weight mothers were predicted to rate the behaviorally oriented treatments as more acceptable. However, results indicated that body weight status of the parent was not a significant factor associated with treatment acceptability. Examination of the means revealed that the ratings of the behavioral treatments (i.e., family lifestyle, physical activity, diet) were almost exactly the same between the two weight groups. The finding that both weight groups found the behaviorally-oriented treatments similarly acceptable is understandable – lifestyle changes in diet and/or physical activity seem to be generally viewed as 'healthy,' as evidenced by the high ratings of the behavioral treatments overall.

Hypothesis 3. Acceptability ratings were strongly influenced by the type of problem presented in the case description. As predicted, mothers rated treatments for T2DM as more acceptable than treatments for obesity. In addition, the more intrusive gene therapy and medication treatments were considered more acceptable for T2DM than for obesity. However, the

behavioral methods were still ranked well above the more intrusive treatments, suggesting that although mothers do not consider the intrusive treatments as acceptable, they are more willing to consider them as treatment alternatives in light of increased disease risk for their children. This trend is supported by previous findings that preference for all treatments and the acceptability of more intrusive treatments seem to vary as a function of problem severity (Calvert & Johnson, 1990; Tarnowski et al., 1989).

These findings have direct implications for recommendations related to treatment delivery by health-care providers. Because T2DM is considered a consequence of obesity (Pinhas-Heimel & Zeitler, 2000), recommendations might need to emphasize the health consequences of obesity. The lower preventive acceptability ratings shown in the current study suggest that obesity alone does not have the disease and perceived risk status of diabetes. The case description in the current study provided both the health and social consequences of obesity, but did not focus on one over the other. Further investigation is needed to determine if emphasis of the physical complications of pediatric obesity increases acceptability ratings and, potentially, implementation of prevention strategies.

Hypothesis 4. Ethnicity, maternal weight, and type of problem were all expected to interact to influence acceptability ratings – Caucasian mothers were predicted to rate anti-obesity treatments as more acceptable than AA mothers, presumably due to lower levels of body satisfaction. In addition, Overweight AA mothers were expected to provide the lowest ratings of anti-obesity treatments (again, due to higher levels of body satisfaction at higher weights). Ratings of T2DM treatments were not expected to differ. Results indicated no significant differences in acceptability ratings among the groups.

The previous findings might augment the failure to find significant differences among the ethnicity and weight groups. As discussed, there were no differences in anti-obesity treatment ratings between the ethnic groups. Higher levels of body satisfaction did not translate into lower treatment acceptability ratings for obesity. In addition, the weight status groups did not differ in their ratings of the preventive treatments – Overweight and Normal-weight mothers rated the various treatments similarly. A possible explanation echoes the previous rationale: mothers tend to find behavioral lifestyle methods that include changes in diet and/or physical activity as 'healthy' and, therefore, as highly acceptable. This possibility is further discussed in the next section of general treatment rankings.

Hypothesis 5. It has been suggested that the increased 'geneticization' of society might lead to an increased fatalism (i.e., external LOC) about health, which could undermine prevention efforts (Hunt, Davison, Emslie, & Ford, 2000). Therefore, LOC was hypothesized to be associated with acceptability of prevention strategies, with high endorsement of external LOC expected to predict higher acceptability ratings of no treatment, medication, and gene therapy. Findings did not support this hypothesis – in general, LOC was not significantly correlated with preventive treatment acceptability ratings. In addition, the analysis did not identify any variables that were significantly associated with the behavioral interventions or gene therapy.

The lack of an association between external LOC and preventive treatment acceptability is interesting. Locus of control has been posited as a factor in the search for and use of health-related behaviors (Norman et al., 1998). Fatalism, defined by the belief in an external LOC, has been linked with decreased preventive behaviors, such as cancer screening, condom use, cessation of cigarette use, and HIV-antibody testing and treatment (Carey, Gordon, Morrison-Beedy, & McLean, 1997; Facione, Miaskowski, Dood, & Paul, 2002; Foss, 1973; Hardeman, Pierro, &

Mannetti, 1997; Mayo, Ureda, & Parker, 2001). It is possible that the specific measurement of health-related LOC in the current study was too restrictive; a more general measure of LOC (e.g., Rotter's Generalized Internal-External LOC Scale, Powe Fatalism Inventory) might reveal associations between LOC and acceptability ratings.

It is also possible that treatment acceptability and LOC are not directly related. For example, individuals, regardless of LOC, might find preventive strategies as highly acceptable. However, LOC might moderate the adoption of those preventive strategies. The finding that higher levels of internal LOC (as an individual indicator) predicted lower acceptability ratings of no treatment seems to support this possibility. Endorsement of a higher level of internal LOC might have decreased the acceptability of no preventive action at all, implying that some form of preventive action would be considered acceptable. However, LOC was not found to be associated with acceptability ratings for any form of preventive strategy in this study. Further research is needed to explore the relationship among LOC, the acceptability of prevention interventions, and the use of the interventions.

The hierarchical regression revealed two additional predictors of treatment acceptability. First, the type of problem was associated with medication acceptability ratings. Increased risk of disease (as defined by the type of problem) was correlated with higher levels of medication acceptance. This finding is supported by previous findings of increased acceptance of intrusive treatments for more severe conditions (Calvert & Johnson, 1990). Second, child age predicted acceptability ratings of the no treatment option: older child age predicted lower acceptability ratings for no treatment and, conversely, younger child age predicted higher 'no treatment' acceptability ratings. These results suggest that as their children age, mothers increasingly rate some form of preventive action as acceptable. It is possible that when children are younger,

mothers remain optimistic about their children's health potential; as the children grow, this optimism might weaken, with a consequent acceptance of some form of preventive action. However, child age was not associated with any form of preventive strategy presented in the current study. In addition, no published reports of child age as a factor in prevention strategies were found to support this possibility, indicating that further exploration is necessary. Specifically, the finding that younger child age predicts higher acceptability of no treatment is extremely important in the prevention of obesity and T2DM. Research has shown that the prevention of obesity and T2DM should begin in children as young as two years old (Barlow & Dietz, 1998). If parents with younger children are more willing to consider not treating their children (until the children age), prevention efforts will be ineffective.

General Treatment Rankings. Comparisons of within-group ratings revealed some interesting findings – the rankings of the treatments varied slightly according to the different groupings. Overall, mothers found the behavioral treatments the most acceptable, with family lifestyle change the most preferred treatment option (categorically rated as Acceptable-Strongly Acceptable). The preference for some form of lifestyle change remained consistent in all the groups. These findings are understandable –behavioral treatments that include some form of dietary change and/or physical activity define many commercial weight-loss programs (Womble, Wang, & Wadden, 2002). The changes involved are also typically considered part of a 'healthy' lifestyle. Within the framework of general treatment acceptability research, the behavioral prevention strategies seem to be consistent with consumer expectations of what anti-obesity/T2DM treatments should entail (Kazdin, 1980a).

This pattern of acceptability is encouraging in that the more lifestyle-oriented treatments are generally well researched and are promoted as first-line preventive strategies. Treatment

acceptability has been shown to be related to intervention usage, adherence, and outcome (Reimers et al., 1992b). Specifically, TA appears to be involved in the mediation of negative clinical outcomes, including treatment termination, nonadherence, and lack of improvement (Calvert & Johnson, 1990; Elliott, 1988; Reimers et al., 1992b; Tarnowski et al., 1992). Relatively strong acceptance of the behavioral interventions that include diet and/or physical activity would suggest longer implementation of and adherence to these strategies. However, treatment effects tend to be more stable in children than in adolescents. Early termination of and nonadherence to interventions are evidenced by the modest findings of weight loss studies in adolescents, suggesting that child age might be an additional factor influencing treatment acceptability.

The no treatment option and the more intrusive treatments did not seem to fit with the conventional notions of prevention for any of the groups. All three strategies were ranked well below the behavioral methods in all groups, categorically ranging from Strongly Unacceptable to Neutral. It is important to note that the current study is the first to include a no treatment option in an investigation of treatment acceptability. The low ratings (and rankings) of this option indicate that mothers did not consider this a viable alternative; mothers seem to prefer some form of lifestyle action if told that their children are at risk for obesity or T2DM. However, the relative group rankings were surprising. Mothers rated gene therapy just as acceptable as not treating their children and as more acceptable than medication. They preferred medication to not treating their children only when a more serious health problem (i.e., T2DM) was considered.

These findings lend support to the trend seen in previous TA research – mothers might be more willing to consider more intrusive and radical treatments if the risk to their children is increased. Previous research has found that treatments are generally more acceptable when

applied to more severe behavior and health problems (Calvert & Johnson, 1990; Elliott, 1988; Frentz & Kelley, 1986; Kazdin, 1980a; Reimers & Lee, 1991). In addition, the acceptability of more intrusive treatments has been shown to vary as a function of problem severity (Tarnowski et al., 1989). For example, Reimers and Lee (1991) found that medication was rated by parents as relatively more acceptable when applied to a more severe health problem as opposed to a mild problem.

The suggestion that a more intrusive and radical treatment such as gene therapy would be considered acceptable over the more traditional medication treatment is an unexpected finding. Genetic research has been gaining momentum, funding, and media exposure over the past several years. Although actual research findings are still preliminary, the media has suggested the numerous possibilities that will be available when gene therapy has more fully progressed (e.g., Rowland, 2000). Perhaps these reports (and their increasing frequency) have influenced maternal ratings of this treatment alternative. Gene therapy might also be considered a 'permanent' and effective solution, requiring little time and effort in the long-term (as depicted in the treatment description). These considerations might have increased acceptability over medication, an alternative that requires daily effort to maintain its effect. Further investigation is needed to determine if new research findings and decreased perceived risks in treatment might increase preference for gene therapy as a prevention alternative.

Preliminary investigation of direct-to-consumer (DTC) advertising of prescription medications suggests that it is possible to alter consumer perception of the more intrusive treatments. In 1997, the Federal Drug Administration issued guidelines for the broadcast advertising of prescription drugs directly to consumers. Subsequently, annual spending on DTC advertising tripled between 1996 and 2000, when it reached nearly \$2.5 billion (Rosenthal,

Berndt, Donohue, Frank, & Epstein, 2002). Recent national and clinic-based surveys suggest that DTC advertising has increased consumer awareness of disease symptoms and specific medications and that this awareness is associated with specific medication requests made to physicians (Meade-D'Alisera, Merriweather, & Wentland, 2001; U.S. Food and Drug Administration, 2002). The increase in DTC advertising is also associated with a rise in sales figures. Total US drug expenditures increased by almost 19% from 1998 to 1999. Prescriptions for the top 25 medications directly marketed to consumers rose by 34% during this time, compared with 5.1% for all other prescription drugs (Charatan, 2000).

Content analyses indicate that the DTC advertisements appeal to emotions and address the variables that constitute the treatment acceptability construct: effectiveness, ease of use, safety/side effects, and benefits/psychosocial enhancement (Bell, Kravitz, & Wilkes, 2000; Woloshin, Schartz, Tremmel, & Welch, 2001). In other words, pharmaceutical companies have increased consumer demand for and purchase of prescription medications by focusing on the factors associated with treatment acceptability. These data suggest that this marketing strategy could influence the demand for (i.e., acceptance of) new medications and gene therapy for the prevention of obesity and T2DM. This possibility bears further investigation.

### Limitations of the Current Study

It should be noted that the present study is subject to the limitations inherent in analogue investigations. First, the generalizability of these findings to clinic populations remains unknown, that is, generalizing from potential clients to actual clients (Pickering, Morgan, Houts, & Rodriguez, 1988). Second, the ecological validity of the independent variables used in TA research has been questioned (Elliott, 1988). The case and treatment descriptions used in previous TA research and in the current study contained minimal information. In actual situations where

consumers (e.g., parents) are faced with a choice among treatments, much more information is typically available concerning both the case and treatment plans. Although analogue investigations permit the study of multiple independent variables in a highly controlled manner, there is need to obtain data in the context of applied service delivery. However, this direct test of acceptability is difficult to accomplish for a variety of practical and ethical reasons. For example, one cannot reasonably ask parents to provide acceptability ratings before their child is treated, and then provide a treatment that the parents judged to be unacceptable. Retrospective ratings are also problematic in that treatment ratings might be confounded by case-specific outcomes, therapist variables, and patient selection factors. Thus, analogue methods provide a cost-effective and viable method for the preliminary identification of variables that influence treatment acceptability.

The generalizability of the findings may also have been limited due to the difficulty in recruitment of normal-weight females. Although there were over 7000 potential participants in the PBRC database who met inclusion criteria, only 3% were AA females and 14% were Caucasian females who were within the normal BMI range at the time of initial contact. PBRC is a non-profit research institution devoted to nutrition and preventive medicine research – its primary research tracks focus on obesity, nutrition and chronic disease, and health and performance enhancement. As such, the majority of the database participants have BMIs of 25 kg/m² and above. To remedy this problem, a recruitment effort focused on normal-weight females by mailing a higher percentage of packets to those subjects; however, many of those who returned completed packets from this mail-out had gained weight in the interim (from time of initial contact to the current contact) to BMIs above the normal range. This weight gain, combined with incorrect addresses, indications of no children, and children outside the specified age range of 2-17 years, resulted in too few normal-weight AA females (see Table 1). Post-hoc power analysis also

revealed that a small effect size of 0.30 <u>SD</u> could be detected with 67% power; that is, the low number of normal-weight AA females might have resulted in a decreased ability to detect the interaction among ethnicity, weight status, and type of problem. However, in the current study, such a small effect size might be practically meaningless. The power analysis also indicated that there were a sufficient number of participants to detect a large effect size of 1.00 <u>SD</u> with 92% power. The lack of a significant interaction, with sufficient power to detect a large difference, might actually indicate the 'true' and meaningful finding.

### **Future Directions**

Despite these limitations, the current study provides the groundwork for a new line of research in the prevention of obesity and T2DM. Overall findings suggested that mothers generally considered lifestyle changes that involve diet and/or physical activity as acceptable treatments for their children. However, the limited success of the behavioral strategies with adolescents and the identification of child age as a predictor of 'no treatment' acceptability demand further examination.

Although maternal weight did not have the expected effects on acceptability ratings, slight trends in the data suggested that a history of higher weight might increase acceptability of the more intrusive preventive treatments. That is, prior experience with the problem condition might influence treatment acceptability. Future studies should examine the effect of different problem histories (e.g., presence or absence of T2DM) on treatment acceptability. Prior history might alter acceptance of preventive treatments.

Gene therapy and no treatment were consistently rated as more acceptable than medication, unless disease risk was increased. However, all three alternatives were consistently ranked as unacceptable treatments. Future research should investigate the effect of an increased

genetic probability of developing a problem (e.g., 20% v. 80%). Increased genetic risk might influence the acceptance of the more intrusive preventive strategies, potentially increasing them to acceptable levels. Direct-to-consumer marketing strategies might also influence preference for these alternatives. An examination of the social and ethical ramifications of these possibilities are necessary with the increasing societal focus on genetic predisposition.

Another area of future research involves parent gender. Most treatment acceptability studies have included only mothers as potential consumers. However, in many cases, both parents would be involved in preventive treatment decisions for their child. In addition, early treatment acceptability research indicates that males tend to favor more intrusive/medical treatments over less intrusive treatments (Miller & Kelley, 1992). This finding suggests that inclusion of fathers in future studies is warranted.

### General Conclusions

In summary, the current study used a novel approach to identify the acceptability of treatments designed to prevent the occurrence of obesity and T2DM. Identification of variables that are related to obesity/T2DM prevention acceptability is necessary if future prevention efforts are to succeed. The possibility that gene therapy will someday be developed to counter the development of obesity and/or T2DM demands investigation of the acceptability of prevention efforts in response to genetic testing. In the present study, acceptability ratings varied according to treatment type and type of problem (i.e., genetic predisposition to obesity or T2DM). General findings suggest that mothers found the lifestyle strategies as acceptable preventive interventions, whereas they considered the medical/intrusive strategies (and no treatment at all) as unacceptable alternatives. Heightened disease risk increased acceptability for all forms of treatment, specifically medication. However, gene therapy was generally ranked as more acceptable than medication,

suggesting that mothers might consider this treatment option in lieu of medication when more intrusive strategies are preferred and/or recommended. Advertising efforts on the part of pharmaceutical companies may further increase the acceptance and preference for these alternatives. These findings provide the groundwork for future investigations on the variables that influence treatment acceptability in response to genetic information.

#### Endnotes

<sup>&</sup>lt;sup>1</sup> Body mass index (BMI) is considered a measure of adiposity based on height and weight (kg/m²). Among the height-weight indices available for study, BMI has been shown to be a satisfactory index of overweight associated with adiposity. Overweight and obesity in adults are defined as follows: Overweight (BMI ≥ 25); pre-obesity (BMI 25.0 − 29.9); class I obesity (BMI 30.0 − 34.9); class II obesity (BMI 34.9 − 39.9); class III obesity (BMI ≥ 40.0). For children and adolescents, BMI values above the 95<sup>th</sup> percentile are considered obese/overweight whereas values between the 85<sup>th</sup> and 95<sup>th</sup> percentiles are considered 'at-risk' for becoming overweight (Troiano & Flegal, 1998). However, some researchers consider BMI values at or above the 85<sup>th</sup> percentile as indicative of obesity.

<sup>&</sup>lt;sup>2</sup> The Overweight/Obese group (M = 4.02,  $\underline{SD}$  = 7.50) also reported a significantly higher number of previous diets than the Normal weight group ( $\underline{M}$  = 1.69,  $\underline{SD}$  = 2.44),  $\underline{F}(1, 95)$  = 4.33, p < 0.05. However, 50 participants did not report the number of previous diets, indicating that there were "too many" diets to remember/count.

<sup>&</sup>lt;sup>3</sup> Child BMI and number of previous diets were not included as predictor variables due to extensive missing data ( $\underline{n} = 27$  and  $\underline{n} = 50$ , respectively).

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### Appendix A

#### **Procedural Question**

## One last question!!

Which one of the following fits what you were supposed to do for this study?

The researchers would like to know your perception of the study.

I answered the questions as if my child were answering the questions.
I answered the questions according to what my child would be willing to do and would
want to do, <i>not</i> what I would do.
I imagined my child in the Story and rated the approaches/treatments for what I would be
willing to do for that child.
I answered the questions how I thought the researchers would want me to.
I rated the treatments for how I thought other parents would rate the treatments, not what
I would do.
I answered the questions according to what my child's father and I would be willing to do
for our child.
Other
Please explain:

#### You're done!!

Please be aware that Gene Therapy is not available for obesity or diabetes at this time. It is a possible future treatment. Pennington does not offer or conduct this type of treatment.

# Thank you!!!

We would like to thank you for participating in this study. All you need to do now is return everything in the pre-paid envelope. We appreciate you for taking the time to fill out the questionnaires!

# Appendix B

# Demographic Questionnaire

Your Date of Birth:				Age:									
Occup	ation:					_							
Sex:		Male											
		Femal	e										
Heigh	t:	feet		_inche	S		Wei	ght:		_lbs.			
Marit	al Statu	ıs: _	_ Sing	gle		Married	l						
			_ Div	orced		Separat	ed						
			Wid	lowed									
Race:		Black						Asian					
	White Hispanic origin					American Indian, Aleutian, Alaska native, or Eskimo							
	American Indian, Aleutian, Alaska native, or Eskimo												
		Other	(please	specif	y:				)				
						ith the							
		Type 2	2 diabet	tes									
		Heart	disease										
		Other	(please	specif	y:				)				
	Does a	nyone	in you	r famil	y suffe	r from	the foll	owing?					
		Type 2	2 diabet	tes (if s	so, who	in your	family	?			)		
		Heart	disease	(if so,	who?				)				
			•			ucation ocationa	•		compl	eted. (p	lease ir	iclude all	
0	1	2	3	4	5	6	7	8	9	10	11	12	
	13	14	15	16	17	18	20	21+					

What is the tot	al annual	income of y	our household?		dollars per year.
Have you ever	been on a	diet previo	usly? Yes	No	
If yes,	how man	y times?			
Have you ever	participat	ed in a stud	ly conducted by	PBRC? Yes	s No
Please answer the ages of 2 ar	-		s according to yo	our <u>Oldest (or You</u>	ngest) child between
Sex of c	hild:	Male		Age of child:	
	_	_ Female		Date of birth:	
Child h	eight:	feet	inches	Child weight:	lbs.
Has you	ır child ev	er been dia	gnosed with dial	oetes?	
		Yes	No		
If yes, w	hat type o	of diabetes l	has your child be	een diagnosed wit	th?
	Type 1	diabetes			
	Type 2	diabetes			
	Not su	re			
If yes, a	t what age	e was your o	child diagnosed	with diabetes? _	years
How mu	ıch experi	ence do you	ı have with healt	th care services fo	or your child?
1		2	3	4	5
-		Below average	Average	Above average	Significantly above average

# Appendix C

## Body Shape Questionnaire - Short Form

We would like to know how you have been feeling about your appearance over the *PAST FOUR WEEKS*. Please read each question and circle the appropriate number. Please answer all the questions.

I = Neve	r									
2 = Rarel	V									
	= Sometimes									
	= Often									
5 = Very										
6 = Alwa	ys									
1.	Have you worried about your flesh not being firm enough?									
2.	Have you noticed the shape of other men/women and felt that your own shape compared unfavorably?									
3.	Have you avoided wearing clothes which make you particularly aware of the shape of your body?									
4.	Have you felt ashamed of your body?									
5.	Has worry about your shape made you diet?									
6.	Have you felt happiest about your shape when your stomach has been empty									
	(e.g., in the morning)?									
7.	Have you felt that it is not fair that other men/women are thinner than you?									
8.	Have you worried about your flesh being dimply?									

Appendix D

# Weight Locus of Control

Please complete the items listed below by circling the number that best indicates how you feel.

		Strongly <u>Disagree</u>	<u>Disagree</u>	Slightly <u>Disagree</u>	Slightly Agree	<u>Agree</u>	Strongly Agree
1.	Whether I gain, lose, or maintain my weight is entirely up to me.	1	2	3	4	5	6
2.	Being the right weight is largely a matter of good fortune.	1	2	3	4	5	6
3.	No matter what I intend to do, if I gain or lose weight, or stay the same in the near future, it is just going to happen.	1	2	3	4	5	6
4.	If I eat properly, and get enough exercise and rest, I can control my weight in the way I desire.	1	2	3	4	5	6

Appendix E

# MHLC Scale

Please complete the items listed below by circling the number that best indicates how you feel.

	Y0Y1	Strongly <u>Disagree</u>	<u>Disagree</u>	Slightly <u>Disagree</u>	Slightly <u>Agree</u>	<u>Agree</u>	Strongly Agree
1.	If I become sick, I have the power to make myself well again.	1	2	3	4	5	6
2.	Often I feel that no matter what I do, if I am going to get sick, I will get sick.	1	2	3	4	5	6
3.	If I see an excellent doctor regularly, I am less likely to have health problems.	1	2	3	4	5	6
4.	It seems that my health is greatly influenced by accidental happenings.	1	2	3	4	5	6
5.	I can only maintain my health by consulting health professionals.	1	2	3	4	5	6
6.	I am directly responsible for my health.	1	2	3	4	5	6
7.	Other people play a big part in whether I stay healthy or become sick.	er 1	2	3	4	5	6
8.	Whatever goes wrong with my health is my own fault.	1	2	3	4	5	6
9.	When I am sick, I just have to let nature run its course.	1	2	3	4	5	6
10	. Health professionals keep me healthy.	1	2	3	4	5	6
11	. When I stay healthy, I'm just plain lucky.	1	2	3	4	5	6
12	. My physical well-being depends on how well I take care of myself.	1	2	3	4	5	6

	Strongly <u>Disagree</u>	Disagree	Slightly <u>Disagree</u>	Slightly Agree	Agree	Strongly Agree
13. When I feel ill, I know it is because I have not been taking care of myself properly.	1	2	3	4	5	6
14. The type of care I receive from other people is what is responsible for how well I recover from						
an illness.	1	2	3	4	5	6
15. Even when I take care of myself, it's easy to get sick.	1	2	3	4	5	6
16. When I become ill, it's a matter of fate	1	2	3	4	5	6
17. I can pretty much stay healthy by taking care of myself.	1	2	3	4	5	6
18. Following doctor's orders to the letter is the best way for me to stay healthy.	1	2	3	4	5	6

### Appendix F

#### Participant Instructions

On the next page, you will read about some recent scientific discoveries and how these discoveries could affect parents like you. When reading the story, <u>imagine that it is about you and your Oldest/Youngest child between the ages 2 to 17 years old</u>. After you read each story, you will be asked several questions. <u>Please do not look ahead or look back in the packet</u>. Please answer the questions in the order in which they are given. Also, please call Jean Thaw at 763-3111 for help if you do not understand what you should do or if you have trouble with any of the questions. Thank you.

#### Appendix G

#### Introduction

After ten years of study, scientists have identified all of the genes that make up the human body. Genes are in every cell of our bodies. They cause height, hair color, and eye color. They also can cause us to be more likely to get certain illnesses, like diabetes or cancer. In the next few years, scientists will know what each gene does. They will know which genes cause eye color, which genes cause height, and which genes cause cancer. Knowing what the genes do will change the medical field forever. Scientists will be able to make medicines that will attack only the illness, leaving the rest of the body alone. And, doctors will be able to tell if someone is more likely to get sick, such as with diabetes, before the person actually gets sick. However, it is up to people to decide what to do with the information. Sometimes, parents will be asked to decide if anything should be done to stop the illness from happening to their children. These questions may be hard for parents to answer.

#### Case Description

We would like you to imagine yourself in the following story and answer questions about each of the different approaches that follow the story. You should imagine that the child is **your**Oldest/Youngest child between the ages of 2 to 17 years old. Please answer the questions in the order in which they are given.

#### Case Description (diabetes):

Your child's genes have been tested. The doctor told you that your child is likely to get Type 2 diabetes during the next 10 to 40 years, unless you do something to prevent it. Type 2 diabetes is a disease in which the body "forgets" how to break down food. When this happens, there is too much sugar in the blood for too long. Over time, this causes many serious health problems, even if the disease is treated. If Type 2 diabetes develops, your child will feel tired and weak and will become sick more often. Cuts, burns, and scrapes will take longer to heal. Your child's eyesight may get worse until, after many years, he/she could go blind. Your child may have some heart problems. The blood vessels may become more and more blocked, until he/she has a heart attack as a young adult. Your child's kidneys may stop working properly, and your child might need a kidney machine or a kidney transplant. Over time, your child might lose feeling in his/her feet, which could result in foot sores or a foot amputation. As an adult, pregnancy and having a child will be more difficult. However, you can choose among several treatments that will be paid by a third-party to prevent diabetes and these other problems.

#### Case Description (obesity):

Your child's genes have been tested. The doctor told you that your child is likely to become obese during the next 10 to 40 years, unless you do something to stop it. Obese means that someone is very heavy or weighs too much. If your child gains too much weight during the next few years, he/she will likely be obese as an adult. Being obese has many serious risks. Your child may have high blood pressure and heart disease, leading to a heart attack as a young adult. Your child will be more likely to get cancer and develop diabetes. Other people may tease your child because of his/her weight. Your child may have a low self-esteem and problems making friends. Even if your child is able to lose the weight when he/she is an adult, many of the health problems may still happen if your child becomes obese before he/she grows up. Also, your child will be less likely to go to college and marry someone if he/she is obese as a child or teenager. As an adult, an obese person is less likely to get raises at his/her job and is less likely to marry. However, you can choose among several treatments that will be paid by a third-party to stop your child from gaining too much weight and having these problems.

#### Appendix H

#### Treatment Descriptions

#### **Note:** Treatment titles were not included in the study materials.

#### No Change

Because the doctor told you that your child only has a chance of getting diabetes, you choose to do nothing different. You pay no attention to the information. You raise your child as you have been doing. Your child plays inside and outside as much as he/she has always done. There is no change in the amount of time spent watching TV or playing sports. You do not change the foods that you feed your child. Your child eats what he/she has been always been eating at school. Your child does not take any new medicine, except for what he/she usually takes. You allow your child to do what he/she enjoys as much as you have always done. You bring your child to the doctor as much as you have always done. You raise your child as you have always done. The possibility that your child could get diabetes is not changed.

#### Physical Activity Alone

To stop your child from getting diabetes, you decide to improve your child's health and fitness. At the beginning of treatment, you and your child attend a 1-hour class every week for 10 weeks. Your child is able to do things he/she enjoys if he/she is active or works out at least 3-4 times a week. Being active can be swimming, walking quickly around the block, riding a bicycle, and playing in sports (such as basketball or tennis). You praise your child when he/she is physically active instead of watching TV or playing video games. You encourage your child to play sports. When your child chooses to play sports or do something active at least 3-4 times in a week, your child gets to go to the movies or go to a party or do something he/she enjoys (but is something that you both agree on). It could be hard to get your child to be active if he/she does not want to be active. It takes time to encourage and teach your child to be active. Your child might get hurt if the physical activity is not safe or if he/she does too much at once.

#### Medication (Sibutramine/Meridia)

The doctor gives your child medicine to keep him/her from becoming obese. The medicine will help your child eat less every day. You give your child a pill every morning at breakfast. You will also bring your child back to the doctor for a check-up about every three months. The medicine can cause your child to have a dry mouth or have a hard time falling asleep. Your child may have headaches. Your child may become constipated or have oily stools and toileting accidents. The medicine also affects the heart. It could speed up the heart rate and cause your child to become jittery. Also, your child may not be able to drink anything with a large amount of caffeine, such as cola or tea. Some children get rashes from the medicine.

#### Medication (Metformin/Glucophage)

The doctor gives your child medicine to keep him/her from getting diabetes. The medicine will help to keep your child's blood sugar at a healthy level. By doing this, your child's body can use the food better and is less likely to get diabetes. You give your child a pill every evening at supper. You also bring your child back to the doctor for a check-up about every three months.

The medicine can cause your child to have mild stomachaches and feel like throwing up. Your child may not feel like eating and could lose weight. Your child may have diarrhea. Your child also may complain about a metallic taste in the mouth. Some children have trouble breathing, are extra tired, get dizzy, or throw up.

#### Dietary Change Alone

You change your child's regular eating habits to keep him/her from getting diabetes. At the beginning of treatment, you and your child attend a 1-hour class every week for 10 weeks. The class teaches how to eat properly at home and when eating out. You feed your child healthy foods and snacks, such as fruits and vegetables. You learn to not reward your child with food. You encourage your child to choose fruits, vegetables, and lean meats (like chicken) at school. You praise your child when he/she chooses the healthy foods. You reward your child with something he/she enjoys when he/she eats less junk food and more fruits and vegetables at home or at school. You also reward your child when he/she eats smaller amounts of food during meals and at snack-time. It might be hard to change the foods that your child eats. Your child might not like some of the foods. It might be difficult to make your child eat different foods than the rest of the family. It might be hard to keep track of what your child eats when he/she is not at home.

#### Family Lifestyle Change

You change your family's lifestyle by improving the eating habits and fitness of the whole family to keep your child from getting diabetes. At the beginning of treatment, your family attends a 1-hour class every week for 10 weeks. You learn about healthy eating and exercise. The family learns about what foods to eat and what foods not to eat. You learn to cook healthy meals with vegetables, fruits, and chicken or fish (not fried foods). You learn to be active 3-4 times a week, such as riding a bicycle, walking quickly, or playing sports, instead of watching TV or just sitting around. You learn to reward your family by letting them do things they enjoy, only when they eat healthy and exercise. The goal is to make these things a part of everyday life, such as taking the stairs instead of the elevator. This treatment takes a long time to learn and a lot of effort to make a part of everyday life. Your whole family must take part, and it may be hard to keep track of your family during the day.

#### Gene Therapy

You choose gene therapy for your child to keep him/her from getting diabetes. Genes are in every cell of our bodies. They cause height, hair color, and eye color. They also can cause us to be more likely to get certain illnesses, like diabetes. Gene therapy is something that doctors can do to change the genes in our cells. The goal of gene therapy is to give your child healthy genes that will make your child less likely to get diabetes. To do this, the doctor injects healthy genes into your child's body by giving him/her a shot. The body makes copies of the new healthy genes. This means that the genes that would have caused diabetes are now gone and replaced with healthy genes. Getting a shot is painful to some children. There is a small chance that your child could reject the new healthy genes, which could cause severe health risks. Your child also could have children who carry these new genes that may or may not work for them.

### Appendix I

### Treatment Evaluation Inventory – Short Form

Please complete the items listed below by placing a checkmark on the line next to each question that best indicates how you feel about the treatment. Please read the items very carefully because a checkmark accidentally placed on one space rather than another may not represent the meaning you intended.

		Strongly <u>Disagree</u>	Disagree	Neutral	Agree	Strongly Agree
1.	I find this approach to be an acceptable way of dealing with the child's weight. (diabetes/problem)					_
2.	I would be willing to use this procedure if I had to change the child's weight. (diabetes/problem)					
3.	I believe that it would be acceptable to use this approach without children's consent.					
4.	I like the procedure used in this approach.					
5.	I believe this approach is likely to be effective.					
6.	I believe the child will experience discomfort during the approach.					
7.	I believe this approach is likely to result in permanent improvement.					
8.	I believe it would be acceptable to use this approach with individuals who cannot choose treatments for themselves.	· ——				
9.	Overall, I have a positive reaction to this approach.					

#### Vita

Jean Marie Thaw was born in Jacksonville, Florida. She received her bachelor of arts degree in psychology from Furman University in 1992, magna cum laude. During college, she was awarded a research internship at Duke University, working with John E. R. Staddon, Ph.D. After graduation, Ms. Thaw was employed as a research associate at the Medical University of South Carolina in Charleston, South Carolina, until she entered Louisiana State University to pursue her graduate studies in clinical psychology. Ms. Thaw completed her master of arts degree at Louisiana State University in 1998 and is currently completing the degree of Doctor of Philosophy in psychology. She recently completed her residency at the University of Mississippi Medical Center in Jackson, Mississippi, as Chief Resident. With a research focus on obesity and eating disorders, she has published journal articles on the diagnosis, treatment, and prevention of obesity and eating disorders in both the pediatric and adult populations. Recently, Ms. Thaw has also co-authored a funded state grant on improving treatment adherence in adolescent diabetics. Ms. Thaw is currently employed at the Pennington Biomedical Research Center in Baton Rouge, Louisiana.