EFFECTS OF A LOW-DOSE BEHAVIORAL TREATMENT FOR OBESITY

By

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A THESIS PRESENTED TO THE GRADUATE SCHOOL
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To my Dad for instilling love in our hearts, teaching us to be proud of our difference, and allowing us to be creative, learn by travel, and serve the community

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Behavioral treatment of obesity, delivered via 16–24 weekly group sessions, commonly produces clinically meaningful weight changes. However, the cost of "high" dose interventions represents a barrier to dissemination, and there is a need to examine the potential benefits of less costly, "low" dose interventions. The current study examined the effects of a low-dose (8 session) behavioral treatment on weight change and reported health-related quality of life, compared with an 8-session education program highlighting national recommendations for appropriate diet and exercise practices for weight management. Participants included 317 obese adults (mean ± SD, BMI = 36.2 ± 3.9 kg/m^2) recruited from rural counties in northern Florida. Outcomes included change in body weight and percentage of participants achieving a clinically meaningful weight loss (defined as body weight reduction $\geq$ 5%) as well as changes in health-related quality of life. Outcomes measures were taken prior to treatment and at a 6-month follow-up assessment. The results showed that, compared with the education control group, the low-dose behavioral intervention produced a greater mean change in body weight (mean ± SD, 7.60kg ± 6.40 vs. 4.46kg ± 4.9, $p < .001$) and a higher percentage of participants achieving body weight reductions of 5% or more (55.4% vs.

36.1%, $p < .001$). The analysis of the quality of life data revealed that, compared with the health education control group, the low-dose behavioral intervention group reported significantly greater improvements in, physical functioning (F (1) = 3462.067, $p < .001$), general health (F (1) = 12.826, $p < .001$), and vitality (F (1) = 19.376, $p < .001$). Moreover, a mediational analysis revealed that weight loss partially mediated the effect of the behavioral intervention on health-related quality of life. These findings demonstrate the potential benefits of low-dose behavioral interventions for weight management.

CHAPTER 1
INTRODUCTION

Obesity and Health Disparities in Rural Areas

The United States today faces multiple public health issues, including increased prevalence in chronic conditions such as diabetes mellitus, cardiovascular disease, and certain cancers. Furthermore, obesity is implicated in many of these chronic diseases, contributing to both their etiology and poor treatment outcomes (Allison, Fontaine, Manson, Stevens, & VanItallie, 1999; Lew & Garfinkel, 1979; Manson et al., 1990). Recent studies further confirm the scope of the problem of obesity in the United States; an estimated two thirds of the nation is either obese (with a body mass index $\geq$ 30 kg/m^2) or overweight (with body mass index $\geq$ 25 kg/m^2) (Flegal, Carroll, Ogden, & Curtin, 2010). According to the National Center for Health Statistics, the national death rate from ischemic heart disease and prevalence of cardiovascular disease is higher in rural areas than in urban areas (National Center for Health Statistics, 2008). Obesity and physical inactivity are more prevalent in rural communities in the U.S. than in urban communities and is concentrated especially in the southern states (Bennett, Olatosi, & Probst, 2008).

In a recent study by Befort, Nazir, and Perri (2012) obesity prevalence was found to be 39.6% among rural adults and 33.4% among urban adults. This phenomenon maybe influenced by the infrastructure that rural counties have in terms of limited healthcare facilities, sport and recreational facilities, as well as grocery stores that provide adequate healthy food items (Bennett, Olatosi, & Pumkam, 2011). Moreover, socio-cultural factors that influence lifestyle further impact the health of rural communities. Factors such as high fat consumption (which is typical of the southern

cuisine), sedentary lifestyle, and the increased mechanization in the agricultural industry all contribute to the problem of obesity in rural areas (McIntosh & Sobal, 2004).

Rurality and Health

Geographic areas in the United States are classified in two main categories according to the National Center for Health Statistics Urban-Rural Classification Scheme for Counties (Ingram & Franco, 2012): urban or large metropolitan areas and rural or small non-metropolitan areas. Urban areas are counties with a population over 50,000; rural areas are counties with a population of 50,000 persons or less with some counties that may not have a city. This classification is associated with differential access to health services and differential impacts on health. While metropolitan areas may enjoy having large and advanced healthcare centers, rural areas may only have a small community primary healthcare center and individuals in need for healthcare may need to travel to metropolitan areas for tertiary care. Rural communities have a greater shortage of healthcare professionals, higher rates of poverty, lower educational attainment, and greater number of individuals without health insurance, which lead to decreased access to healthcare and contribute to the health disparities in these areas (Findeis et al., 2001).

Cooperative Extension Service Offices (CES)

The Cooperative Extension Service Offices were established by the USDA in 1914 to serve individuals in the rural areas. Since its inception, the CES's mission was to provide Americans in the rural areas public access to the latest advances in agricultural practices. CES adopted a more comprehensive approach to the health and welfare of rural citizens over the years. Nutrition education for example became a key element of CES services. Family and Consumer Sciences (FCS) agents were hired by

CES to help rural families live a healthier life physically and socially by teaching them about nutrition, food preparation, positive child care, family communication, financial management, and positive strategies to manage services within the healthcare system (National Institute of Food and Agriculture, 2007).

Behavioral Lifestyle Treatment for Obesity

Behavioral or lifestyle treatment for obesity had evolved over four decades of continuous scientific investigation and clinical trials. Behavioral treatment approaches to obesity are specifically geared towards teaching participants the necessary skills to lower their calorie intake, eat a healthier and more nutritious diet, and increase their physical activity. Strategies such as self-monitoring, goal setting, problem-solving, stimulus control, cognitive restructuring, and positive reinforcement are commonly used. Participants are typically asked to keep food logs of their daily food intake and physical activity as a form of self-monitoring and are coached by their clinical provider to learn the problem-solving skills that enable them to tackle their daily challenges with their lifestyle choices (Wing et al., 2011; Foster, Makris, & Bailer, 2005).

In a review of behavioral weight-loss studies from 1996 to 1999, Wing et al., (2002) found that participants achieved a mean short-term weight loss of 10.6% of their initial body weight during the treatment phase of 21 weeks and they maintained 8.6% at follow-ups of 18 months. Most studies provide their behavioral lifestyle treatment during an average of 18 to 24 weeks as standard treatment duration (Wing, 2002). However, these studies were all conducted in urban settings and large academic medical centers located in metropolitan areas. This recommended treatment duration may not usually be feasible in rural areas given the lack of resources, particularly specialized healthcare providers. Multiple studies on the duration of behavioral treatment for obesity have

indicated that increasing the duration of the treatment phase of a weight loss program will further increase the weight reductions achieved by participants and increase the percentage of that weight loss maintained at follow up after the maintenance phase (Perri, Nezu, Patti, & Mccann, 1989). However, some studies indicated that participants in low-dose behavioral treatment programs may not achieve or maintain clinically significant weight loss of 5% or greater (Wing, 2002; Foster, Makris, & Bailer, 2005).

Several studies indicated the efficacy and superiority of behavioral treatment over health education only interventions with obesity and overweight (Wadden, Crerand, & Brock, 2005; IOM Press, 1995). Nevertheless, weight-loss programs that are typically offered in community settings usually span over 8 to 10 weeks of group meetings that provide mainly health education regarding weight loss (without behavioral strategies such as self-monitoring and goal setting) and typically do not include maintenance programs in follow-up care. Moreover, few studies have investigated the effects of low-dose behavioral treatment programs compared to non-behavioral programs (Stern et al., 1995).

Defining Clinically Meaningful Weight Loss

A variety of studies show that achievement of body weight reductions of 5% or greater are associated with clinically meaningful changes in health status. In a recent study by Goodpaster et al. (2010), patients with severe obesity were offered a lifestyle intervention that included diet combined with initial physical activity or with delayed initiation of physical activity. The study found that participants achieved clinically significant weight loss of 5% or greater of their initial body weight in both groups. Additionally, weight loss produced positive changes in cardiometabolic risk factors and

significant reductions on the following: waist circumference, visceral abdominal fat, hepatic fat content, blood pressure, and insulin resistance (Goodpaster, et al, 2010).

Another study examined the association between the amount of weight loss and changes in cardiovascular risk factors at 1 year after a lifestyle intervention on participants with type 2 diabetes. The study aimed to see the participants' chances of meeting predefined criteria for clinically significant improvements in risk factors for individuals with type 2 diabetes. The study found that the amount of weight loss at 1 year was strongly associated with improvements in glycemic index, blood pressure, tryiglycerides, and HDL cholesterol but not with LDL cholesterol. Those who lost between 5 and < 10% of their body weight had increased chances of achieving a 0.5% point reduction in HbA1c, a 5-mmHg decrease in diastolic blood pressure, a 5-mmHg decrease in systolic blood pressure, a 5 mg/dL increase in HDL cholesterol, and a 40 mg/dL decrease in triglycerides. The findings further showed that the chances of clinically significant improvements in most of these risk factors were even greater for participants who lost 10–15% of their initial body weight (Wing et al., 2011).

Multiple studies have confirmed the strong relationship between the magnitude of weight loss and the improvement in critical anthropometric variables. In a lifestyle treatment study conducted (Matvienko & Hoehns, 2009) on individuals at risk for diabetes or diagnosed with diabetes, approximately 56% of patients lost 5% or greater of their initial body weight after 6 months of the intervention, and that lead to significant improvements in their diastolic Blood Pressure (-4.1 mm Hg), total cholesterol (-11.7%), LDL-C (-7.6%), HDL-C (-6.5%), Fasting glucose (-12%), and systolic BP (-8.4 mm Hg).

Moreover, 27% of the participants who were on diabetic medication had their drug discontinued after the lifestyle intervention (Matvienko & Hoehns, 2009).

Obesity and Health-Related Quality of Life

Several aspects of quality of life are impacted by obesity and overweight, including vitality, physical and mental health and social functioning. In studies examining the effect of obesity on individual's health-related quality of life (HRQL), which is the impact of a person's health condition on his/her quality of living, obese individuals reported significantly lower HRQL than those with normal weight. The quality of life domains that are often affected by obesity are physical functioning, general health, bodily pain and vitality (Han, Tijhuis, Lean, & Seidell, 1998; Kolotkin, Head, Hamilton, & Tse, 1995; Kruger, Bowles, Jones, Ainsworth, & Kohl, 2007; Doll, Petersen, & Stewart-Brown, 2000; Fontaine & Barofsky, 2001; Larsson, Karlsson, & Sullivan, 2002). Higher degrees of obesity are associated with lower quality of life. Jia and Lubetkin (2005) examined this relationship in a study and after the adjustment for other factors; health-related quality of life was negatively associated with higher levels of obesity. Individuals with severe obesity had significantly lower scores on the quality of life measures compared to their normal weight counterparts. The decrements in health related quality of life for those with severe obesity were similar to the decrements seen in individuals diagnosed with diabetes or hypertension (Jia & Lubetkin, 2005). Sedentary lifestyle (i. e. physical inactivity) was also found to be negatively associated with quality of life, independent of obesity or overweight status. Physically inactive individuals were more likely to report poor quality of life regardless of their body mass index (Andersen, Schnohr, Schroll, & Hein, 2000; Villeneuve, Morrison, Craig, & Schaubel, 1998; Kruger, Bowles, Jones, Ainsworth, & Kohl, 2007).

Weight Loss and Health-Related Quality of Life

Given the link between health-related quality of life and body weight, we would expect weight loss to be associated with improvements in quality of life. Fontaine, Barofsky, Bartlett, Franckowiak, and Andersen (2004) have observed that weight loss was associated with a significant increase in the quality of life domains such as physical functioning, role-physical, general health, vitality, and mental health scores from baseline to post-weight loss intervention. The greatest improvements on health-related quality of life were on the vitality, general health and role-physical SF-36 scales (Fontaine et al., 2004). One of the limitations of these studies is the lack of control group to examine for the difference and the effect of health education only and subsequent weight loss on quality of life. Studies have found that larger weight loss was associated with the greatest improvement in health-related quality of life; more specifically, weight losses of 5% to 10% were associated with 2-unit changes in the SF-36 general health scale (Samsa, Kolotkin, Williams, Nguyen, & Mendel, 2001; Karlsson, Sjötrö, & Sullivan, 1998; Kral, Sjostrom, & Sullivan, 1992; Weiner, Datz, Wagner, & Bockhorn, 1999). Furthermore, some studies have reported increases in health-related quality of life to be associated with increases in physical activity as an independent factor in weight loss (Ross, et al., 2009; Elavsky et al., 2005), thereby calling into question whether weight loss mediated the effect of treatment on quality of life (Imayama et al., 2011).

The Need to Study Low-dose Behavioral Treatments for Obesity

It is well-established that behavioral treatment for obesity delivered in 18 to 24 weeks will produce successful and clinically meaningful weight loss (Wadden, Crerand, & Brock, 2005; Wing, 2002; IOM Press, 1995; Perri et al., 1989); but few studies have examined the effects and clinical relevance of behavioral treatment delivered in lower

doses. Given the scope of the obesity problem in the United States, the unavailability of lower cost, low-dose treatments with documented clinical benefits would represent an important option particularly in resource-poor areas such as rural communities.

Specific Aims and Hypotheses

Specific Aim 1

Examine the effect of a low-dose behavioral lifestyle intervention on weight loss compared with a health education comparison group. We hypothesized that the participants in low-dose behavioral treatment group would experience greater weight loss than the participants in the health education only group. Furthermore, we hypothesized that there would be a larger proportion of participants achieving a clinically meaningful weight loss ($\geq$ 5% reduction in body weight) in the behavioral treatment condition than in the health education only condition.

Specific Aim 2

Examine the effect of a low-dose behavioral lifestyle intervention on health-related quality of life compared to a health education comparison group. We hypothesized that participants in the behavioral treatment group will report greater improvement on the health-related quality of life measure than participants in the health education only group. Moreover, we also hypothesized that the between-group difference in quality of life would be mediated by weight loss.

CHAPTER 2
METHODS

Rural LITE Study

This study is a secondary data analysis utilizing data driven from the Rural Lifestyle Intervention Treatment Effectiveness Trial (Rural LITE study), a single-blind, randomized controlled trial (RCT) in obese adults. Rural LITE was designed to examine the effects of three different doses of lifestyle treatment on changes in body weight, and several other outcomes such as quality of life, compared to a health education only condition over a two year period.

The study was carried out through the Cooperative Extension Service Offices in eight rural counties in Northern Florida. CES offices offered venues inside their buildings to conduct the groups; and several FCS agents were trained to join the current study as interventionists. The CES offices are funded by the state government, hence, their contribution to the current study with venues and FCS agents didn't add any costs to the study's expenses. The study was conducted in two phases; in the first phase (6 months), participants attended weekly sessions for a varied number of weeks depending on their randomized assignment. Eight weeks for the health education only and the low-dose behavioral treatment conditions, 16 weeks for the moderate dose behavioral treatment condition, and 24 weeks for the high dose behavioral treatment condition. These sessions focused on inducing weight loss by teaching participants how to reduce their calorie intake and increase engagement in safe physical activity for all the conditions. However, cognitive behavioral strategies such as self-monitoring and goal setting were integrated in the three behavioral treatment conditions only (Low, Moderate, and High) to test for the difference in treatment effects among all conditions

compared to the health education condition. The intervention program was a modified curriculum derived from the Diabetes Prevention Program (DPP) and the Look AHEAD study (Diabetes Prevention Program Research Group, 2002; Wadden et al., 2006).

Phase 2 (18 months) of the Rural LITE study focused on maintenance of behavior change and weight loss as an outcome and provided extended care to the participants. This extended care was provided according to the same dosing schedule as for the original intervention weekly sessions (8 extended care sessions for the health education and low-dose behavioral treatment conditions, 16 sessions for the moderate-dose behavioral treatment condition, and 24 sessions for the high-dose behavioral treatment condition). These extended care sessions focused on helping participants to deal with issues related to maintenance of lost weight and the adopted health behaviors such as regular physical activity.

Participants

The participants in this study were obese (BMI 30 to 45 kg/m^2) men and women between the age of 21 and 75 years old who resided in one of the eight rural counties in North Central Florida. These participants had a mean age of 51.7 years (SD = 11.5) and mean BMI of 36.2 kg/m^2 (SD = 3.9); 19.7% of the sample were classified as of an ethnic or racial minority origin and 80.3% were Caucasian; 78.9% were women and 21.1% were men (see Table 3-1). Exclusion from the study was limited to those with a life-limiting disease such as myocardial infarction, or congestive heart failure, those who might be subjected to an increased risk by participating in our study, or those with an uncontrolled chronic medical condition such as hypertension or diabetes. Individuals who reported using antipsychotic medications, human immunodeficiency antibiotics, monoamine oxidase inhibitors, systemic corticosteroids, chemotherapy treatments or

weight loss medications were excluded as well. Additionally, anyone reported a psychiatric disorder or excessive intake of alcohol, was unable or unwilling to accept random assignment or travel to the extension office for the weekly sessions, was unable to read English at a fifth-grade level, was planning to move out from the county during the period of the study, lost 10 or more pounds in the past 6 months, was currently participating in another research study, or had participated in TOURS, our lab's previous trial was also excluded. Two thousand eight hundred and seventy nine individuals made telephone inquiries about the study, 1366 of them were excluded based on the initial telephone screening, 441 didn't attend the first screening visit and 1072 attended. Three hundred eighteen out of those attended screening visit 1 were eventually excluded. Subsequently, 612 participants were randomized to the four treatment conditions. A sub-sample of 317 participants derived from the Rural LITE overall sample were included in the current study, of which 169 were in the health education only condition and 148 in the low-dose behavioral treatment condition.

Procedures

Participants in the current study were recruited utilizing a variety of recruitment methods such as direct mailings with the study's brochure to households and offices of healthcare providers, culturally-driven methods specifically to recruit ethnic minority participants, and presentations delivered by Extension agents at churches, social organization and community events. Those interested in the study underwent an initial telephone screening where they were interviewed to determine if they meet the basic study criteria to be deemed eligible for the study. Screening visit 1 was then conducted by the study's mobile clinical assessment team lead by the study registered nurse in each county's extension office. During this visit the participants learned about the study

details and were asked to sign the informed consent and fill in demographic and medication inventories. The assessment team then obtained the following measures for each participant: height, weight, girth, resting heart rate, blood pressure, blood analyses for lipids and other micronutrients, and physical performance. Data collected by the mobile clinical assessment team from screening visit 1 was then reviewed by the study Co-PI Marian Limacher, MD., to determine whether participants are eligible for the study. Those who were considered eligible were contacted and scheduled another appointment to attend the screening visit 2 less than four weeks before the intervention. During this visit the participants' were re-evaluated for possible changes in their medical status, their weight and blood pressure were measured again, and they completed a second walk test and asked to fill in a packet of self-report questionnaires that includes the quality of life measure used in this study. Those who reported rapid changes in weight or other changes that met the exclusionary criteria were excluded from the study.

Participants who passed the screening visit 2 were randomized to two treatment conditions, either the health education condition or the low-dose behavioral treatment condition. The study carried seven data collection visits, three main comprehensive assessments identical to the screening visit 2 assessment at month 0, 6, and 24; and four other assessments at Months 2, 4, 12, and 18 for weight and medical history updates only. For the purpose of this study, only data collected at month 0 and month 6 for participants in the two conditions were utilized.

Measures

Body weight: Weight was measured using a Tanita BWB-800S digital scale at month 0 before the intervention and was measured again at month 6. Participants' height was measured using a stadiometer at baseline for use in the calculation of

participant Body Mass Index (weight in kg / height in m^2). On both assessment occasions, the measurement was conducted by the study nurse who was masked to the treatment condition.

Health-Related Quality of Life: Health-related quality of life was assessed utilizing the MOS Short-Form 36-Health Survey (SF-36) which asks the participant to answer 36 questions clustered in eight domains of health-related quality of life, including: role limitations due to physical problems; bodily pain; general health perceptions; vitality; social functioning; physical functioning; role limitations due to emotional problems; and mental health. The SF-36 has been shown to have excellent psychometric properties in a variety of populations including obese adults. Most reliability and validity coefficients exceeded r = 0.70 with many exceeding 0.80 (McHorney, Ware, & Raczek, 1993). Participants in this study were asked to complete the SF-36 at month 0 and again at month 6. The standardized scores (on a scale of 0 to 100) on the eight domains were used in the analyses. A high reported score on any of the domains indicates a better reported quality of life or less impairment on the functioning domain measured.

Additional Outcome Measures

Program Satisfaction Questionnaire: Participants were asked to complete a satisfaction questionnaire that was designed by the study investigators for quality assurance purposes only. For the purposes of this study, only one Item from the questionnaire was incorporated to evaluate the overall satisfaction on the study. This measure was included to examine whether the participants satisfaction differed as a function of treatment condition.

Participants' Attendance Data: Participants attendance at the eight treatment sessions was calculated to determine whether exposure to treatment differed as a function of condition.

Treatment Conditions

There were two treatment conditions in this study, a health education control condition and a low-dose behavioral treatment condition. The health education condition used a curriculum that focused on health education geared to provide participants with latest government information about proper approaches to weight management. It consisted of eight weekly weight-loss treatment sessions during phase 1 (Months 0–6) and eight follow-up sessions during phase 2 (Months 7–24). The health education curriculum focused on providing advice related to healthy eating, nutritional tips, and recommendations on exercise safety following the recommendations of the Adult Treatment Panel III Report of the National Cholesterol Education Program along with the USDA's food guidance system, MyPyramid (The National Cholesterol Education Program, 2001; US Department of Health and Human Services, 2005). The goal was to help participants lower their calorie intake, increase their physical activity, and consume more healthy food. The low-dose behavioral treatment condition incorporated the use of behavioral strategies such as self-monitoring, goal-setting, stimulus control, and problem solving to help participants achieve changes in their eating and physical activity patterns (Wadden et al., 2006; Diabetes Prevention Program Research Group, 2002; Perri et al., 2001; Black, 1987). The use of the self-monitoring concept in weight management is done by maintaining food and exercise logs, and the goal-setting concept is typically accomplished by setting a calorie goal and a physical activity goal periodically, and trying to meet and/or maintain that goal. The study's interventionists

consisted of 2 person teams that included a masters' level graduate student in clinical psychology and an FCS agent employed by the extension offices. The interventionists underwent a thorough clinical training provided by the principal investigator through monthly face-to-face workshops and weekly telephone supervision.

Statistical Analyses

The statistical software package PASW SPSS® 20.0 for Windows by IBM was used to calculate the statistical analyses for this research study.

For the first aim an Independent t-test analysis was calculated to determine whether the change in body weight from month 0 to month 6 differed by condition. Percentages of participants in each condition who achieved body weight reductions of $\geq$ 5% and $\geq$ 10% were calculated with a chi-square test. T-tests were calculated to examine the between-group differences in attendance and treatment satisfaction.

The second aim was examined by using the Repeated Measures Multivariate Analysis of Variance test, (MANOVA) on the MOS – SF-36 Health Survey data. The Wilks' Lambda criterion was used to test whether there were differences between the means of the targeted groups on a combination of dependent variables and to test whether there were within-subjects differences pre and post the behavioral treatment.

The third aim was investigated by conducting a Repeated Measures Multivariate Analysis of Covariance, (MANCOVA) using the same variables in the second aim and adding weight change from baseline to month 6 as a covariate so as to determine whether the effect of treatment on quality of life was mediated by weight loss (Baron & Kenny, 1986).

Handling Missing Data: Forty of the 317 participants did not attend the 6-month assessment visit. Little's Missing Completely at Random test (MCAR) was used to test

the hypothesis that the missing values in the sample were missing completely at random before applying the missing data methods. Subsequently, Little's MCAR Chi square test statistics for all Expectation-Maximization (EM) estimated statistics were found not statistically significant at $p = 0.05$, therefore, the null hypothesis was accepted and the missing values were determined to be missing completely at random, ($X^2 = 52.444$, ($df = 190$; $p = 1.0$). Based on the results of Little's MCAR test, the Multiple Imputation method was used to complete missing values for these individuals. Missing values were predicted using existing values from other variables in the data set by performing ten separate imputations on the data set. Results from the ten separate imputations were pooled to provide the overall average for the t-statistics. Due to an administrative staff error, there were 90 missing SF-36 questionnaires at month 6. The Last Observation Carried Forward, (LOCF), was used to complete these missing values where participants' month 0 values were carried forward to complete missing data at month 6.

Table 2-1. Baseline characteristics for participants

Variable (Unit)	Low-Dose Behavioral Condition (n = 148)		Health Education (n= 169)	
Weight (kg)	M	SD	M	SD
	102	16.6	100.1	14.4
BMI (kg/m2)	36.1	4.2	36.3	3.9
Age (years)	51.5	12.3	52	10.8
Sex	n	%	n	%
Female	112	75.7	138	81.7
Male	36	24.3	31	18.3
Race/Ethnicity	n	%	n	%
Black, non-Hispanic	25	16.9	29	17.2
Hispanic	3	2	10	5.9
Caucasian	118	79.7	124	73.4
Other/Multiple	2	1.4	6	3.6

Note: BMI = Body Mass Index

CHAPTER 3
RESULTS

Sample Baseline Characteristics

A sub-sample of 317 participants from the Rural LITE overall sample were included in the current study, of which 169 were in the health education only condition and 148 in the low-dose behavioral treatment condition. The sub-sample included 317, 78.9% were women and 21.1% were men. The mean age was 51.7 years (SD = 11.5), and the mean BMI was 36.2 kg/m^2 (SD = 3.9). In the sub-sample, 19.7% of the participants described themselves as members of an ethnic or racial minority group and 80.3% as of having a Caucasian origin.

Effects of a Low-Dose Behavioral Lifestyle Intervention on Weight Loss

Results obtained from the independent t-test analysis on weight change revealed a statistically significant difference between the two conditions, t (315) = 4.378, $p < .001$. Participants in the low-dose behavioral treatment condition lost more weight (7.60kg ± 6.4) than those in the health education only condition, (4.46kg ± 4.9) (see Table 3-2). Moreover, there was a greater proportion of participants who achieved losses $\geq$ 5% and $\geq$ 10% in the low-dose behavioral treatment condition compared to the health education only condition. The difference between conditions was statistically significant for both the proportion of $\geq$ 5% weight loss, X^2 (1, 317) = 11.88, $p = .001$; and the proportion of $\geq$ 10% weight loss, X^2 (1, 317) = 15.47, $p < .001$ (see Figures 3-1 and 3-2). The analyses on the participants reported program satisfaction showed no statistically significant difference between the health education only condition and the low-dose behavioral treatment condition, t (222) = -1.173, $p > .05$. Participants in both conditions reported high overall program satisfaction: 92.5% and 89.9% respectively for the low-dose

behavioral treatment condition and the health education only condition (see Figure 3-3). Furthermore, the analysis of the participants' attendance data indicated no statistically significant difference between both conditions on the attendance rates for participants, $t(315) = .678$, $p > .05$. Participants' attendance rate in the health education only condition was similar to the attendance rate for participants in the low-dose behavioral treatment condition, 87% and 86% respectively.

Effects of a Low-Dose Behavioral Lifestyle Intervention on Health-Related Quality of Life

The Multivariate Analysis of Variance conducted on the participants' scores on the eight quality of life scales indicated that the entire sample in both conditions had a statistically significant within-subjects difference between their reported scores at month 0 and their reported scores at month 6 or after the intervention, $F(8, 276) = 428.487$, $p < .001$. This significant statistical difference was observed in three quality of life domains or scales, physical functioning ($F(1) = 3462.067$, $p < .001$), general health ($F(1) = 12.826$, $p < .001$), and vitality ($F(1) = 19.376$, $p < .001$). Participants' scores on these health-related quality of life domains in both conditions changed significantly from month 0 to month 6. Participants in both conditions reported improvement in their physical functioning, their general health and vitality. The analysis further revealed that there was a statistically significant difference between conditions on the quality of life domains of physical functioning, general health, and vitality with participants in the behavioral treatment condition reporting greater improvements on the three domains than those in the health education only condition (see Table 3-1).

Would Weight Loss Mediate the Effect of the Study's Behavioral Treatment on Quality of Life Scores

The mediation analysis was conducted according to Baron and Kenny model utilizing the Multivariate Analysis of Covariance test, (MANCOVA) with weight change as a covariate. The analysis demonstrated that weight change mediated the effect of treatment intervention on quality of life in both conditions. When adding weight change as a covariate in the MANOVA analysis, weight change clearly diminished the relationship between the treatment intervention and quality of life, (F (8, 276) = 525.103, p = .000, η_p^2= .938 before adding weight change as a covariate; versus, F (8, 279) = 2.119, p = .034, η_p^2= .057 when adding the covariate). In other words, the observed change in quality of life was partially mediated by change in body weight.

Table 3-1. Mean quality of life scores for both treatment conditions at baseline and month 6 (standard errors)

Quality of Life Subscales	Low-Dose Behavioral Condition (n = 148)		Health Education (n = 169)	
	Baseline	Month 6	Baseline	Month 6
Physical Functioning	77.7 (1.6)	85.9 (.18)	80.6 (1.5)	84.2 (.17)
General Health	68.7 (1.7)	72.3 (1.6)	67.9 (1.6)	69.8 (1.6)
Vitality	51.3 (1.9)	57.2 (1.9)	50.9 (1.8)	53.3 (1.8)

Note: Significant between-group effect at $p < .001$

Table 3-2. Mean body weight for both treatment conditions at baseline and month 6 (Standard Deviation)

	Low-Dose Behavioral Condition (n = 148)		Health Education (n = 169)	
	Baseline	Month 6	Baseline	Month 6
Weight (kg)	102 (16.6)	93.37 (15.6)	100.1 (14.4)	94.76 (15.1)

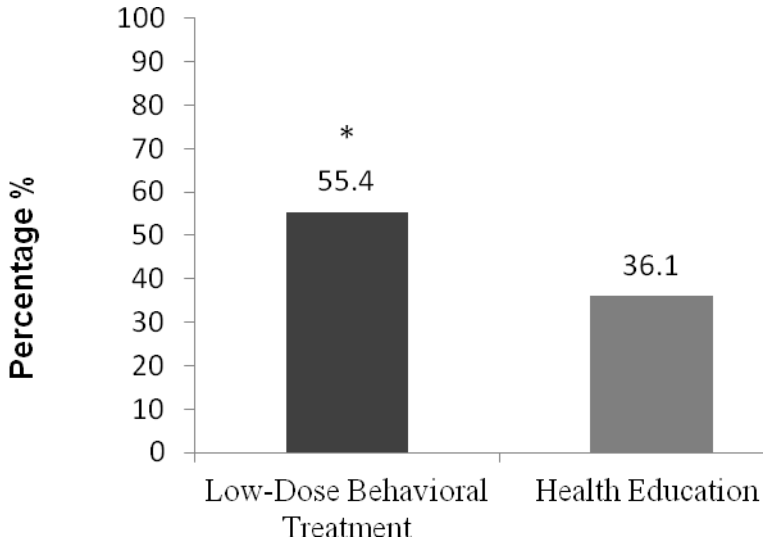

Figure 3-1. Proportion of participants achieved ≥5% weight loss in both groups. Note: (*) significant at p < .001

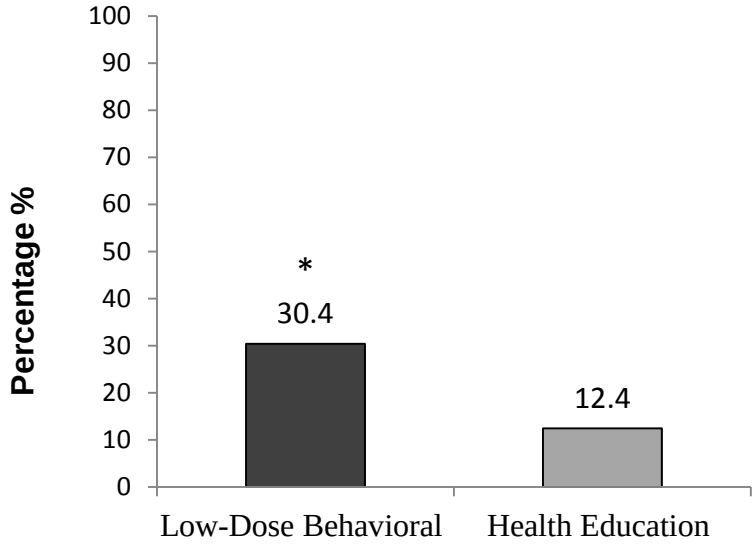

Figure 3-2. Proportion of participants achieved >10% weight loss in both groups.
Note: (*) significant at p < .001

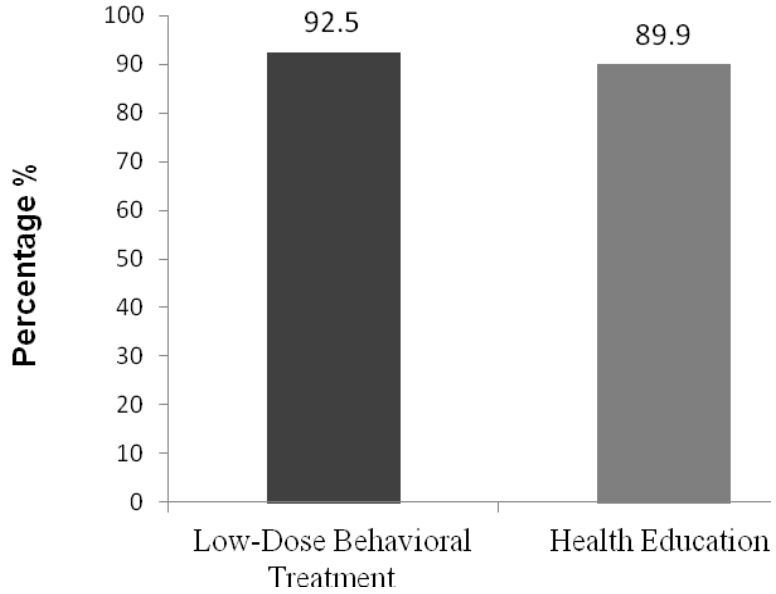

Figure 3-3**.** Percentage of participants' overall satisfaction with the weight-loss program between both groups

CHAPTER 4
DISCUSSION

The current study had several objectives; the first was to determine the effects of a low-dose behavioral lifestyle intervention on body weight in a sample of obese adults in a rural community. The second objective was to examine the effects of a low-dose behavioral lifestyle intervention on the health-related quality of life.

The major finding in this study was that participants in the behavioral treatment condition achieved a statistically significant mean weight loss that was greater than the mean weight loss achieved by those in the health education condition. On average, participants in the behavioral treatment condition lost 7.60kg (SD = 6.40) of their initial body weight compared to 4.46kg (SD = 4.9) in the health education only condition. Furthermore, a greater proportion of participants in the behavioral lifestyle treatment condition achieved clinically meaningful weight reductions ($\geq$ 5% of their initial weight) compared to the health education only condition. Approximately, 55% of the participants in the lifestyle behavioral treatment condition achieved 5% or greater weight loss from their initial weight. Moreover, around 30% of the participants achieved weight losses $\geq$ 10% of their initial body weight. In the health education only condition, only 36% of the participants achieved $\geq$ 5% weight reduction and only 12% achieved weight losses $\geq$10% of their initial body weight.

Weight losses of $\geq$ 5% of the initial body weight have been associated with greater improvements in several anthropometric indicators such as blood lipids, glycemic index, insulin resistance, and high blood pressure. Hence, weight loss of 5% or greater of initial body weight has been found to be clinically meaningful to the health outcomes of obese individuals. Furthermore, weight losses that are greater (i.e., 10% to

15% of the initial body weight) was linked to a greater improvement on the above physical health measures and general wellbeing.

While it is important to stress that the behavioral intervention was superior to the health education only intervention, it is equally important to highlight the notable weight loss observed with participants in the health education only condition. As noted previously, weight-loss programs based on health education without behavioral strategies such as self-monitoring are still the most common form of weight loss programs in the community settings (Stern et al., 1995).

The second main finding of this study was the significant improvement in the health-related quality of life for participants in the lifestyle behavioral treatment condition that was greater than that reported by participants in the health education only condition. An abundance of research has shown that weight loss is strongly associated with improvements in health related quality of life; furthermore, those who obtain greater weight losses consistently report greater improvements in health-related quality of life (Karlsson et al, 2007). In our study, participants in both conditions reported significant improvements in three domains of quality of life: physical functioning, general health, and vitality. As it was reported in previous research, physical domains of quality of life are the most affected by obesity treatment than the mental and social domains (Doll et al., 2000; Fontaine et al., 2004). Given that the improvement was observed in domains that are related to the physical component of the quality of life, we suspected that this effect occurred most likely due to the weight loss obtained in the groups.

We further investigated the effect of our treatment intervention on the health-related quality of life by exploring the possible meditational effects that weight loss could

have as an important contributor to the improvements in health and quality of life. We found that weight loss partially mediated the effect that treatment had on the quality of life domains. These findings highlight the impact of weight loss alone on quality of life (Ross et al., 2009; Imayama et al., 2011).

Previous research on the effect of body weight on quality of life in the context of pain has indicated that improvement in body joint pain and other comorbidities attenuated the relationship between Body Mass Index and health related quality of life. That is if an obese individual with joint pain loses weight, the relief in pain likely caused by weight loss will lead to improvements in the individual's quality of life (Heo, Allison, Faith, Zhu, & Fontaine, 2003). One potential explanation is that this improvement was mainly due to the increased mobility and positive change in anthropometric indices. To our knowledge however, no previous studies investigated this meditational relationship and effect on quality of life in the context of low-dose behavioral treatment.

Quality of life is an important indicator of success for clinical programs as well as for healthcare consumers; significant improvements in quality of life along with successful weight loss in this study could make this low-dose (8 session) treatment option more attractive to policy makers than programs with the costly standard behavioral treatment consisting of 16 to 24 sessions. However, regardless of the well-established efficacy for lifestyle behavioral interventions for weight loss, the issue of whether these individuals are going to maintain this weight loss long-term remains unresolved. In fact, multiple studies have indicated that this success is not well maintained over time and most participants regain the weight initially reduced.

Therefore, the role of extended follow-up care after weight loss programs in enabling the participants to maintain the improvement in quality of life should be investigated.

This study had important limitations that should be addressed in future or subsequent research, one of which is the issue of cost-effectiveness of our program. In a recent survey conducted by the University of Florida Weight Management Lab asking the administrators of the extension offices in the rural counties regarding the likelihood of funding these weight loss programs, more than 91.6% have indicated that a treatment program of 16 weeks (8 sessions of treatment and 8 sessions of extended care) would be “moderately” or “highly” feasible. Despite the abundance of research indicating the effectiveness of behavioral lifestyle treatment for obesity, these services are often not provided due to cost. There was no empirical data in current research on the effectiveness of “low” dose behavioral treatment compared to health education in a rural community setting and our study’s findings are the first step in this line of research. According to the Center of Medicaid and Medicare Services guidelines, Intensive Behavioral Therapy for Obesity, (IBT) is to be covered and billed for if it was offered in primary care centers by primary care physicians and specialized providers. Unfortunately, most rural areas experience a shortage in specialized healthcare providers and facilities and this still represents a barrier to their access to these services. However, providing weight-loss programs via non-traditional settings utilizing the community’s own grass root organizations and community workers would optimize access to these services by obese individuals in rural areas (Centers of Medicaid & Medicare Services, 2012). Additionally, questions regarding the long-term maintenance of the weight loss achieved or the health-related quality of life obtained through this

program should be further investigated, along with examining participants' age as a potential moderator for the relationship between the treatment and the study's outcomes. Moreover, the study's exclusion of individuals with significant health problems limits the generalizability of its findings.

In summary, the findings from this study demonstrate the potential benefits of low-dose behavioral intervention for weight loss. Low-dose treatment may represent an effective and less costly option to traditional high-dose weight loss interventions.

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BIOGRAPHICAL SKETCH

Manal Alabduljabbar attended the University of Jordan–Amman and graduated in 2003 with a bachelor's degree in psychology. She worked in Saad Specialist Hospital, Saudi Arabia in 2005 and developed a psychological service for bariatric surgery patients. Soon after, Manal started her post-graduate studies in Boston University and graduated in 2009 with a master's degree in mental health and behavioral medicine. In 2011, Manal joined the Clinical & Health Psychology doctoral program and became a graduate assistant in the Weight Management Lab at the University of Florida, Gainesville. In 2013, Manal earned her Master of Science degree in clinical health psychology from the College of Public Health and Health Professions at the University of Florida.