Impact of a Medically Supervised Weight Management Program on Obese and Morbidly Obese Persons

Gemechu Abraham Kurfessa

Follow this and additional works at: https://scholarsrepository.llu.edu/etd

Part of the Preventive Medicine Commons

Recommended Citation
https://scholarsrepository.llu.edu/etd/886
LOMA LINDA UNIVERSITY
School of Public Health

IMPACT OF A MEDICALLY SUPERVISED WEIGHT MANAGEMENT
PROGRAM ON OBESE AND MORBIDLY OBESE PERSONS

By
Gemechu Abraham Kurfessa, MPA, RCP

A Dissertation in Partial Fulfillment of the Requirements for the
Degree of Doctor of Public Health in Preventive Care

March 2012
Each person whose signature appears below certifies that this dissertation, in his/her opinion, is adequate in the scope and quality as a dissertation for the degree of Doctor of Public Health.

Susanne Montgomery, Chair
Professor, Health Promotion & Education
Director, Center for Health Research

Serena Tonstad, MD, PhD, Co-chair
Professor, Health Promotion and Education
Professor, Preventive Medicine, School of Medicine
Coordinator for DrPH Preventive

Colwick Wilson, Committee Member
Associate Professor, Counseling & Family Sciences

Sylvia Cramer, DrPH, Committee Member
Executive Director, Lite-Weighs, Beaver Medical Group
ABSTRACT OF THE DISSERTATION

Impact of a Medically Supervised Weight Management Program on Obese and Morbidly Obese Persons

by

Gemechu Abraham Kurfessa, DrPH, MPA, RCP

Doctor of Public Health in Preventive Care

Loma Linda University, Loma Linda, California, 2011

Susanne Montgomery, PhD, MPH, Co-Chair
Serena Tonstad, MD, PhD, Co-Chair

Background: Overweight and obesity represent a major public health problem. While some studies indicate that a clinic-based, healthy-lifestyle program can result in significant weight loss, a systemic review of major commercial weight loss programs concluded that the evidence to support the use of such programs is minimal. While few argue for the need for weight loss in obese individuals it is important to identify factors associated with successful weight loss. These factors could include financial incentives, frequency of intervention sessions, use of adjunctive weight loss medications and supplemental diet products, and availability of group vs. individual therapy sessions. In addition, pretreatment levels of perceived and actual engagement in healthy lifestyle behaviors (self-monitoring, exercise and diet) and psychosocial factors could potentially influence weight loss success.

Purpose: The purpose of this study was to: (a) investigate whether an intensive weight management program that included funding for program expenses and use of a
patient contract was associated with clinically significant weight loss in obese and morbidly obese patients and, (b) identify environmental or psychological factors associated with successful weight loss.

**Methods:** We compared the amount of weight loss among patients who contracted to participate in a 26-week intervention including funding to offset program expenses and a signed participation contract (called the intervention group) to the results of patients who were offered the intervention without funding support or the contract requirement (called the comparison group). Patients in both groups were referred by their physician or self referred. Archived data from patient medical records was reviewed and analyzed. We included male or female patients, 21 to 75 years of age with BMI of ≥30 kg/m². The intervention group was offered funding for a wide spectrum of treatment classes except $25 material fee per 8 week class (total of $75) and signed an agreement to attend weekly treatment sessions for 26 weeks. This group also was asked to complete five questionnaires addressing psychosocial factors (Weight Loss Behaviors Perceived to be Important, Frequency of Engaging in Specific Behaviors, Social Readjustment Rating Scale, and The Hassles and Uplifts Scale). The comparison group was not offered the funding support or contract, and chose the frequency and type of intervention sessions depending on their willingness to pay and attend the treatment sessions. Assessments at baseline and end of follow-up (weeks 0 and 26) include demographic, anthropometric, lifestyle, and co-morbidity measures. During the programs, the number of therapy sessions attended, adjunctive medication use, and supplemental diet products purchased were assessed. The main outcomes were percent change in weight, BMI, and waist circumference.
Results: There were 23 men and 104 women in the intervention group (total N=127; mean BMI=40.5 ±8.7 (SD) and 36 men and 118 women (total N=154; BMI=39.3±7.1 (SD) in the comparison group. Both groups experienced significant decrease in weight (7.60 kg, or 6.68% from baseline for the intervention group vs. 6.23 kg or 5.84% for the comparison group) at 26 weeks using intent-to-treat analysis. Those who started with higher weight (p<0.0001), attended more sessions (p=0.0050) and used adjunctive weight loss medication (p=0.0144) lost more weight. There was no significant difference in percent weight loss (p=0.7686) and percent change in BMI (p=0.7686) between the intervention and comparison groups.

In the intervention group 100 of 127 (79%) participants completed the questionnaires. Multiple regression models showed that of five psychosocial and behavioral measures only frequency of engaging in weight loss-promoting behavior (self monitoring, diet, and physical activity) (p=0.0455) were significant and independent predictors of weight loss after adjusting for baseline weight. Major life change events, frequency and intensity of daily positive and negative events (uplifts and hassles), and perceived importance of weight loss promoting behaviors did not predict outcomes.

Discussion: We found that both weight management programs successfully promoted significant weight loss (≥5%) over a period of 26 weeks. The program that offered a financial incentive and required an attendance contract did not promote greater weight loss than a comparison program, but several predictors of success were identified.
TABLE OF CONTENTS

List of Tables ........................................................................................................ x
List of Figures ........................................................................................................ xi
Acknowledgements ................................................................................................ xii

CHAPTER 1 – INTRODUCTION .............................................................................. 1
   A. Statement of the Problem .............................................................................. 1
   B. Purpose of the Study .................................................................................... 5
   C. Research Questions ...................................................................................... 6
   D. Theoretical Justification .............................................................................. 7
   E. Significance to Preventive Care ................................................................... 10

CHAPTER 2 – REVIEW OF LITERATURE .............................................................. 11
   A. Overview .................................................................................................... 11
   B. Assessment of Adult Overweight and Obesity ........................................... 14
   C. Health Consequences of Obesity ............................................................... 15
      1. Hypertension ......................................................................................... 15
      2. Diabetes Mellitus .................................................................................... 16
      3. Cardiovascular Disease ......................................................................... 16
      4. Metabolic Syndrome ............................................................................. 17
      5. Orthopedic Disease .............................................................................. 17
      6. Respiratory Problems .......................................................................... 17
      7. Gastrointestinal Reflux ......................................................................... 18
      8. Depression ............................................................................................ 18
      9. Cancers .................................................................................................. 19
A. Study Design ......................................................... 45
B. Description of Study Participants ............................... 46
C. Participant Recruitment ........................................... 46
D. Intervention Procedures ......................................... 47
   1. Dietary Intervention ............................................ 47
   2. Physical Activity ............................................... 48
   3. Behavioral Therapy ............................................. 48
   4. Adjunctive Weight Loss Medication ........................... 48
   5. Intervention Classes ........................................... 49
   6. Measurements .................................................. 49
      a. Anthropometry ............................................... 49
      b. Questionnaires .............................................. 50
      c. Major Life Change Events ................................. 50
      d. The Hassles and Uplifts Scale ............................. 50
      e. Weight Management Behavior Questionnaires ......... 51
E. Data Collection ..................................................... 51
F. Data Analysis ....................................................... 52
G. Power Analysis ...................................................... 53
H. Ethical considerations ........................................... 54
I. Limitations ........................................................... 55

CHAPTER 4 – FIRST PUBLISHABLE PAPER

Grant-Supported, Contract-Based Versus Standard Weight Management for Treatment of Obese and Morbidly Obese Persons .......... 57
CHAPTER 5 – SECOND PUBLISHABLE PAPER

Psychosocial and Behavioral Predictors of Weight Management for Treatment of Obese and Morbidly Obese Persons ........................................... 90

CHAPTER 6 – CONCLUSION ................................................................. 117

A. Summary and Limitations ........................................................... 117
B. Future Studies ............................................................................. 119
C. Conclusions and Implications ....................................................... 120

REFERENCES .................................................................................. 121

APPENDICES

A. Weight Loss Behaviors Questionnaire ........................................... 144
B. Behavior Frequency Questionnaire ................................................. 146
C. Holmes and Rahe Life Events Scale .............................................. 147
D. The Hassles and Uplifts Scale ......................................................... 149
E. Proposed Budget .......................................................................... 152
F. Institutional Review Board Approval .............................................. 153
LIST OF TABLES

CHAPTER 4 – FIRST PUBLISHABLE PAPER

Table 4.1 Characteristics of Participants at Baseline Showing Number or Mean ± Standard Deviation ...................................................... 84

Table 4.2 Weight Loss Intervention During Treatment Period ...................... 85

Table 4.3 Change in Anthropometric Measures Using Intent-to-treat Analysis ...... 86

Table 4.4 Multiple Regression Analysis of Predictors of Change in Weight After 26-weeks ................................................................. 87

Table 4.5 Multiple Regression Analysis of Predictors of Changes in BMI change .............................................................................. 88

CHAPTER 5 – SECOND PUBLISHABLE PAPER

Table 5.1 Characteristics of Weight Loss in Lite Weighs Participants at Baseline ............................................................................. 112

Table 5.2 Pretreatment Scores for Psychosocial and Behavioral Variables ...... 113

Table 5.3 Change in Anthropometric Measures .................................................. 114

Table 5.4 Top 10 frequently reported Major Life Change Events, Daily Hassles and Daily Uplifts ............................................................. 115

Table 5.5 Multiple Regression Analysis for BMI Change Using Hassle/Uplift .... 116
LIST OF FIGURES

CHAPTER 1 – INTRODUCTION

Figure 1.1 The Association Between Stress and Weight ............................................. 4

CHAPTER 2 – REVIEW OF LITERATURE

Figure 2.1 Trends in Overweight, Obesity, and Extreme Obesity Among Adults Aged 20-74 Years: United States, 1960-2008 .................................................. 12

Figure 2.2 Prevalence of obesity among men aged 20 years and over, by race/ethnicity: United States, 1988-1994, 2007-2008 ..................................................... 13

Figure 2.3 Prevalence of obesity among women aged 20 years and over, by race/ethnicity: United States, 1988-1994, 2007-2008 ..................................................... 13

Figure 2.4 A Simplified Schematic Representation of the Central and Peripheral Components of the Stress System, Their Functional Interrelations, and Their Relations to Other Central Systems Involved in the Stress Response ........................................... 27

Figure 2.5 Detrimental Effects of Chronic Stress on Adipose Tissue Metabolism and Bone Mass ................................................................. 28

CHAPTER 4 – FIRST PUBLISHABLE PAPER

Figure 4.1 Scatter Plot of Percent Change in Weight vs. Baseline Weight by Group ................................................................. 89
ACKNOWLEDGEMENTS

First, I would like to thank God for the many blessings I have received in my life. I also would like to acknowledge and thank the members of my dissertation committee, Dr. Susanne Montgomery, Dr. Serena Tonstad, Dr. Sylvia Cramer, and Dr. Colwick Wilson. Dr. Montgomery’s time, patience, expertise, and generosity throughout my research period have made a significant contribution to my professional and personal development. She truly embodies the values of Loma Linda University. Dr. Tonstad’s insightful comments and constructive criticisms at different stages of my research were inspiring and helped me focus my ideas. I am grateful to her for holding me to a high research standard. Dr. Cramer, who granted me an access to her office and the relevant data, has generously given her time and expertise. I am also indebted to the rest of the staff of the Beaver Medical Group’s Lite-Weighs program, who provided various help with the research.

I would like to thank my wife Roman Beyene whose patience and support helped me stay the course throughout this endeavor, and my son, Kiya and daughter, Tia for their innocent cheerful smiles and love.

To my parents, Abraham Kurfessa and Zenebech Bedasso, I offer my thanks and deepest gratitude for the endless amount of love they have shown me throughout my life, I am forever grateful for their faith in me and providing me with unending encouragement and support. To my younger brother, Kila, and to my sisters Ayu and Asha, for always being proud of me and my academic achievements. I thank my friend and brother-in-law Dr. Gudata Hinika and my sister Wubitu Abraham and their sons;
their love, enthusiasm, and guidance have been pivotal to my success; no words can express my gratitude for their presence in my life.

I also thank Molly Dougherty and Jonathan Baumgarner for editing and formatting my work. Thanks also is due to Khaled Bahjri and Oda Keiji for their hard work, diligence and outstanding guidance with statistical analysis of the data.

My heartfelt thanks to my friends and extended family, who have been a constant source of love, concern, support and strength all these years. I greatly value their friendship and I deeply appreciate their belief in me. Above all, I am grateful to God for blessing me with a wonderful life, caring family, great friends, and supportive mentors to guide my way.

This dissertation is dedicated to the friendship and memory of my older sister, Demitu Abraham, who encouraged me to work hard and achieve my potential in life. She was my defender and counselor. We shared many childhood memories and grown up dreams, a golden thread to the meaning of life. In our last conversation she told me, “be strong” and “I love you.” Her sons Ebisan and Obsan are constant reminders of my beloved sister’s passion, spirit, sparkling eyes and bubbly smiles. Precious gifts she left behind. Bless you, our Dema, and you are always in our hearts.
CHAPTER 1
INTRODUCTION

A. Statement of the Problem

Obesity is a complex chronic disease that develops over years or decades. There is an urgent need to identify treatment approaches that may contribute to weight loss success. In the absence of genetic change, the increase in weight is attributed to behavioral, psychosocial, and environmental factors such as diet, exercise, stress, and other lifestyle pattern changes (Flegal, et al., 2001; Hill, et al., 1998). Most weight management programs focus on reducing caloric intake. However, it is clear that energy restriction alone is not sufficient. Predictors of weight management outcomes have been examined in the past (Brownell, 1984; Foreyt & Goodrick, 1991). These studies have concluded that predicting weight loss with certainty is difficult and complex. Potentially many factors are involved contributing only a fraction in the change in weight making it difficult to build a single predictive model (Foreyt & Goodrick, 1995; Weiss, 1997).

While few dispute the need for weight loss, it is important to identify factors associated with successful weight loss. These factors could include adjunctive therapies to dietary change (Astrup, et al., 2000; Jeffery, et al., 1993; Rolls, et al., 2002; Yu-Poth, et al., 1999), including increased physical activity (Ballard & Poehlman 1994; Jeffery, et al., 1984; Wadden, et al., 1997; Wing, 1999), increased intensity with more frequent intervention sessions (Butsch, et al., 2007; Jeffery, et al., 1993); financial incentives (Giuffrida & Torgerson, 1997; Janz, Becker, & Hartman, 1984; Kane, Johnson, Town, & Butler, 2004); contracting (Neal, 1991); use of adjunctive weight loss medication...
Behavioral and psychosocial factors could also influence the success of weight loss. Pre-treatment levels of perceived importance of engaging in weight loss enhancing behaviors (Becker, et al., 1975); social support (Wing, 1999); behavior therapy (Wadden & Foster, 2000); actual engagement in weight loss enhancing behaviors (Wadden, 1993; Wadden, et al., 1992; Wing, 2003); major life events (Homes & Rahe, 1976); and levels of daily hassles and uplifts (DeLongis, Folkman & Lazarus, 1988) could act as modifiers of health outcomes. We have utilized five different psychosocial and behavioral questionnaires to predict participant response to a medically supervised weight management program.

Many point to high out-of-pocket costs as a barrier to treatment (Bryant, 2001; Federal Trade Commission, 2006) since insurance coverage of obesity treatment is patchy in the U.S. (Tsai, Ash, & Wadden, 2006). Some studies have shown that financial incentives improve the effectiveness of obesity treatment programs (Hubbert, et al., 2003; Jeffery, Gerber, et al., 1983; Jeffery, Bjornson-Benson, et al., 1984) showed that among participants in a weight loss program, those receiving modest financial incentives (50% of a $300 weight loss program fee if participants attended 10-12 sessions and lost 6% of their initial body weight) had significantly higher chances of attending the recommended number of sessions and achieving successful weight loss. However, in meta-analysis the use of financial incentives did not promote successful weight loss or maintenance (Paul-Ebhohimhen & Avenell, 2008).
Failure to attend the required intervention sessions may be associated with failure to complete the treatment regimen or follow prescribed lifestyle changes and as a result, a failure to achieve weight loss benchmarks. A systemic review of medically supervised proprietary weight loss programs have shown 19-56% dropout rate during 26 weeks of treatment (Tsai & Wadden, 2005).

The World Health Organization (WHO) reports that for diseases associated with lifestyle, poor adherence to treatment is associated with worse health outcomes (WHO, 2003). Effective strategies need to be developed to improve patient adherence (Haynes, 2008). A written or verbal contract asking the patient to commit to adhere to the prescribed set of treatment components may improve patient adherence and overall outcomes (Bosch-Capblanch, et al., 2009; Neale, 1991).

Environmental factors (Price & Gottesman, 1991; Stunkard, et al., 1990) and unhealthy lifestyle behaviors (Flegal, et al., 2001; Hill, et al., 1998) could lead to stressors that greatly impact the homeostasis of the body (Table 1). When exposed to stress, the brain’s control center, the hypothalamus and brain-stem, stimulates neuronal circuits and endocrine pathways, leading to elevation of glucocorticoid levels. Under chronic exposure this can lead to behavioral and metabolic alterations which can increase energy intake and decrease energy expenditure, resulting in obesity (Tsigos & Chrousos, 2002). Major life events and the readjustment required to cope with changes have been correlated with increased risk of conditions such as obesity (Dohrenwend & Dohrenwend, 1974). This approach is based on the premise that major life changes lead to high levels of stress, which combined with inadequate coping skills can lead to chronic detrimental health outcomes (Holmes & Rahe, 1967). Thus a life event scale might be a
useful tool to assess the level of stress an individual is experiencing, possibly leading to overeating, weight gain, and subsequent health problems. In addition, daily negative events, or hassles, have been found to have an even greater impact on stress than major life events (Kanner, et al., 1981). Persons exposed to daily hassles such as irritating encounters, frustrations, or work pressures may experience negative health outcomes as a result of neurohormonal changes. This in turn increases stress, which may lead to less compliance with a weight loss regimen and limited success. In contrast, daily positive experiences such as social events and supportive encounters with friends and family (uplifts), may help to counter the effects of hassles, reducing stress and the risk of illness. Individuals with greater proportion of uplifts to hassles might be in a better position to achieve successful weight loss (see Figure 1.1).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Corticotropin-releasing hormone (CRH)</td>
<td>ACTH</td>
<td>Glucocorticoids (Cortisol in humans)</td>
<td>Visceral adiposity</td>
<td>GH, LH, FSH, TSH, sex steroids</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arginine-vasopressin (AVP)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 1.1** The Association Between Stress and Weight
B. Purpose of the Study

In 2007, the Institute of Medicine (IOM), reported identifying effective obesity management strategies was an essential priority, with evaluations of weight loss programs an important means of contributing to the evidence base (IOM, 2007).

In spite of an abundant body of literature on obesity, it is difficult to predict the outcomes of clinically-based weight-loss programs (Baker & Young, 2006). Bish et al., (2005) discovered that 46% of women and 33% of men in the U.S. reported trying to lose weight in 2000. Despite efforts to lose weight by a large majority of the population, many people are unable to prevent or reverse obesity. This calls for developing new solutions to confront the heart of the obesity epidemic (Blackburn & Waltman, 2005).

The National Heart, Lung, Blood Institute (NHLBI) defines successful long-term weight loss as an intentional reduction of 5-10% from baseline maintained for one year. Such weight loss, though modest, improves a host of cardiovascular risk factors (Blackburn, 1995; Goldstein, 1991; Oster, et al., 1999), prevents the development of type 2 diabetes, and is achievable in clinical practice. Clinical guidelines from The National Institutes of Health (NIH, 1998) indicate that decreased caloric intake, moderate physical activity, and behavioral therapy constitute vital elements of any effective weight loss and maintenance program. Furthermore, multidisciplinary programs that focus on positive lifestyle change and include expertise in health education, nutrition, exercise and behavior change are recommended.

Lite-Weighs is a medically supervised, multidisciplinary weight loss program located in Redlands, California. The program serves overweight, obese, and morbidly obese patients who are self referred or physician-referred. The program focuses on health
education, lifestyle skills development, behavior modification, nutrition, and physical activity. Lite-Weighs also provides options for diet supplements and medications to enhance weight loss.

In this study, we set out to investigate whether an intensive weight management program that included funding support to offset expenses and a client attendance contract was associated with clinically significant weight loss in obese and morbidly obese patients compared to one which contained all other program components but did not provide funding or require a contract. We also attempted to identify behavioral or psychological factors associated with successful weight loss.

C. Research Questions

When comparing patients who participated in a 26-week weight loss program which offered financial support for most program expenses and a participation contract (the intervention group) to patients who constructed and paid for their own program without a participation contract (the comparison group):

1. Were intervention group participants more successful in percent change in weight or BMI than the comparison group at 26 weeks post intervention?
2. For either intervention or comparison, was the percent change in weight or BMI associated with the quantity of supplemental diet products purchased?
3. For either intervention or comparison, was the percent change in weight or BMI associated with the number of weekly sessions attended?
4. Was the percent change in weight or BMI associated with use of adjunctive weight loss medication?
Among patients who contracted to participate in a 26-week intervention with financial assistance for program expenses and a participation contract (the intervention group):

1. Did pretreatment level of perceived importance of healthy lifestyle behaviors (self-monitoring, eating, physical activity) at baseline predict successful weight loss?

2. Did pretreatment level of engagement in weight loss promoting lifestyle behaviors (self-monitoring, eating, physical activity) predict successful weight loss?

3. Are baseline scores for major life change events and daily hassles vs. uplifts associated with successful weight loss?

D. Theoretical Justification

Effective weight management strategies are linked to the concept of energy balance. Obesity develops as a result of a cumulative excess of energy intake compared to energy expenditure. To remedy this imbalance, a person should reduce energy intake while increasing energy expenditure. Effective weight loss interventions should focus on developing the skills necessary for adopting and maintaining healthy lifestyle behaviors, leading to negative energy balance and improved health outcomes. Such interventions should include diet therapy, physical activity, and behavior therapy with or without pharmacotherapy (NHLBI, 1987).

Patients sometimes do not follow, or adhere to, recommended changes in diet, exercise, and behaviors. Adherence is the degree to which a patient’s behavior (such as eating and exercise) coincides with treatment guidelines (Evangelista, 2000). Poor adherence to treatment (i.e., number of sessions attended) may be due to difficulty in
changing entrenched personal habits, compromising the success of a weight management program. One intervention strategy that could improve adherence is a contract between the health care provider and the patient, in which both parties commit to a set of treatment features that lead to successful weight loss.

A theoretical model that can be utilized to improve compliance or adherence to weight loss treatment is called concordance theory. Concordance implies that patients and practitioners formulate a mutually agreed upon plan of care which respects the wishes of the patient (Jones, 2003). In this model, patients and providers act as partners to reach an agreement on treatment strategies (Cox, 2004). This process can help health care providers identify and address potential difficulties in treatment adherence (Townsend, 2003), ensuring that what has been agreed upon takes place and improves the likelihood of weight loss success. However, most contracts depend on a relationship model in which the health care provider designs a contract which places the responsibility of failure solely on the patient rather than as a shared outcome. Stevenson (2000) argues that unless patients and healthcare providers are mutually involved in the decision making process on developing a plan of care, there is no basis of agreement on the treatment. Creating a contract based on consensus between the patient and interventionist may enhance the likelihood of program success.

Another explanation for weight loss efforts could be provided by psychology and behavioral economics (Cawley & Price, 2009). The benefits of weight loss also may not be immediate. Improvements in obesity related health risks as well as social and economic disadvantages may not materialize for some time after weight loss (Ainsline, 1975). In addition, time-inconsistent preference (focusing on short-term interests instead
of long-term benefits) by patients may lead to repeated failure at weight loss. Some people can undercut their long range goal of weight loss by remaining in established maladaptive habits such as over eating and sedentary lifestyle. Decision making becomes a battle between farsighted planning and shortsighted actions (Thaler & Shefrin, 1981). High out-of-pocket costs may also be a barrier to enrolling in treatment programs and completing the recommended regimens.

Intervention programs that include financial support may provide a remedy to the problems of lack of financial resources, saliency, immediacy and time-inconsistency of weight loss. The amount and duration of financial support and the reasons for its use are clearly delineated. Financial support may also help people to stay committed to the long term goal (preference) of weight loss, especially if receiving the funds makes patients more committed to program adherence (Laibson, 1997).

We hypothesize that an intensive intervention with financial support for program costs may allow for a more effective dose of intervention by easing the financial burden and allowing patients to participate in more frequent intervention sessions. Adding the contractual agreement could further help improve patient program adherence by increasing frequency of provider encounters, monitoring participant progress, and adjusting the program to increase effectiveness. However, comparison group participants did not have financial support and were not required to sign a contract, paying for sessions based on their financial capacity. This precludes mandatory participation in weekly sessions, possibly decreasing program effectiveness and weight loss.
E. Significance to Preventive Care

Obesity is a significant public health problem, affecting a substantial number of people in the U.S. and other nations. Obesity is a major contributor to preventable lifestyle related diseases and premature death. Understanding intervention strategies for weight loss and identifying successful programs and the factors that contribute to their effectiveness will enhance the ability of both clinical and population health professionals to mitigate the devastating effect of the disease. The success of an obesity intervention is influenced by both physiological mediators and psychosocial variables. Attitudes (beliefs or feelings) about the importance of each behavior that will contribute to weight loss success and the baseline frequency of engagement in these behaviors may be used to better understand successful weight loss. Major life event changes and daily negative and positive experiences (hassles and uplifts) may impact the neurohormonal pathways that leading to stress and health conditions such as obesity. Preventive care specialists (PCS) employ therapeutic lifestyle interventions to help patients develop the coping skills necessary to reduce the prevalence of obesity and its health risks. As the prevalence of obesity continues to increase, so does the number of people seeking the help of weight loss programs and preventive care specialists. There are increasing numbers of commercial weight loss programs on the market, but few have been evaluated for their effectiveness, a necessary part of providing evidence-based intervention. Findings from this study may provide preventive care specialists with the necessary knowledge and skills to help them better educate and treat overweight and obese persons, thus lessening the pervasiveness of obesity and limiting its associated health risks.
A. Overview

The prevalence of obesity and overweight among adults has increased markedly over the last three decades, reaching epidemic proportions in the U.S (Figure 2.1). Obesity is defined as body mass index of 30kg/m² or greater and overweight is defined as BMI greater or equal to 25kg/m². Obesity and overweight varies by age, sex, and ethnic group (Figures 2.2 & 2.3). Evidence suggests that obesity trends will continue to rise (Ogden, et al., 2006; Wang & Beydoun, 2007; Wang & Zhang, 2006).

The current high prevalence of overweight and obesity is likely due to a combination of genetics and environmental interaction, in which already genetically vulnerable individuals respond to environments with an abundance of energy rich, calorically-dense foods coupled with limited opportunities for energy expenditure. Today’s low cost, high-calorie, readily available diets, combined with energy saving technological advances have promoted a lifestyle that increases the risk of being overweight or obese (Pi-Sunyer, 2002).

Overweight and obesity represents a major public health problem, leading to increased incidence of various health conditions such as diabetes mellitus, cardiovascular disease, non-alcoholic fatty liver, gallbladder disease, stroke, osteoarthritis, and increased risk of disability (Wolk, et al., 2003). It is also linked to increased risk of all cause mortality.

Age-adjusted by the direct method to the year 2000 U.S. Census Bureau estimates, using the age group 20-39, 40-59, and 60-74 years. Pregnant females were excluded. Overweight is defined as a body mass index (BMI) of 25 or greater but less than 30; obesity is a BMI greater than or equal to 30; extreme obesity is a BMI greater than or equal to 40.

B. Assessment of Adult Overweight and Obesity

In the past, health professionals used various methods of assessing and defining overweight and obesity. Some measures are based on the relationship between height and weight, while others depend on the measurement of body fat. According to the Metropolitan Life tables, overweight was defined as a body weight greater or equal to 20% of the midpoint of the weight range for a medium size frame.

Today, the body mass index (BMI) is the most frequently used method, derived by dividing an individual’s weight in kilograms by height in meters squared. The formula is weight (kg)/height (m²). To obtain BMI using pounds and inches, multiply weight in pounds by 704.5, divide the result by height in inches, and then divide the result by height in inches a second time (NHLBI, 1998). The expert panel convened by the NHLBI with the participation of the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) and the National Institutes of Health (NIH) defined overweight as a BMI between 25.0 and 29.9 kg/m²; obesity is defined as a BMI greater than or equal to 30kg/m², and morbid obesity is defined as a BMI greater or equal to 40kg/m² or 35 or greater with co-morbidities (NHLBI, 1998).

Weight classifications based on BMI vary by sex, age, ethnicity, and other variables (Baumgartner, et al., 1995). In general, women have more body fat than men, due to less muscle and bone mass. In women the larger percentile of fat is stored in subcutaneous tissue, while men tend to have fat deposits in visceral tissue. This pattern of difference in body composition results in an unequal proportion of body fat at a given body weight for men and women (Lemieux, et al., 1993). At the same BMI, an older adult person tends to have a higher body fat composition compared with younger
individuals. Therefore, a given value of BMI may represent different percentages of body fat and present different degrees of risk for obesity and other diseases (Ogden et al., 2006).

C. Health Consequences of Obesity

1. Hypertension

There is consistent epidemiologic data linking obesity and hypertension (Kannel, et al., 1967). Jones, et al., (1994) showed that in some populations, an almost linear correlation exists between BMI and systolic/diastolic blood pressure. Many cross-sectional studies have shown an association between hypertension and obesity. The Framingham Study demonstrated that the risk of developing hypertension increases with obesity. For every 10% increase in relative weight in men, systolic blood pressure increased by 6.5mm Hg. The study also suggested that 65% of the risk for hypertension in women and 78% in men could be related to obesity (Garrison, et al., 1987). In the Nurses’ Health Study, the relative risk for acquiring elevated blood pressure over a 16-year period increased from 1.0 for a BMI <23 to 1.67 for BMI 23-25, to 2.8 for BMI 26-28, to 3.86 for BMI of 29-31 and to 5.70 for BMI > 32 (Colditz, et al., 1990; Carey, et al., 1997). The association between obesity and hypertension is also confounded by various factors including race, gender, genetics, and other demographic factors. The pattern of fat distribution and type of obesity, especially increased visceral fat, is strongly associated with hypertension. Excess body weight damages the capacity of the heart to function properly, resulting in high blood pressure with potentially significant damage to the heart and other organs (Pi-Sunyer, 2009). Stevens, et al., (2001) found that severe hypertension is improved or even eliminated with weight loss.
2. *Diabetes Mellitus*

Overweight and obesity are among the strongest risk factors for type 2 diabetes. Obese individuals can develop a resistance to insulin, a hormone that regulates blood sugar levels. After compensatory mechanisms by the pancreas are overcome, high blood sugar levels damage the body. Extensive epidemiological evaluations have indicated that obesity is independently related to the risk of acquiring type-2 diabetes (Wing, et al., 2001). Data from the Nurses’ Health Study show that as obesity levels increase the risk of developing type 2 diabetes also increases (Carey, et al., 1997; Colditz, et al., 1990). In individuals at high risk for type 2 diabetes, weight loss may help prevent or delay the onset of the disease (CDC, 1997; Strum & Wells, 2001). Weight loss also has been shown to reduce insulin resistance and enhance glycemic control (Maggio & Pi-Sunyer, 1997; NHLBI, 1998).

3. *Cardiovascular Disease*

An American Heart Association report indicates that obesity is associated with cardiovascular disease (CVD), (Alpert, 2001; Klein, et al., 2004; Pascual, et al., 2003). The Nurses’ Health Study demonstrated an association between obesity and CVD (Manson, et al., 1995). The study also showed that relative risk of CVD death rose significantly with higher BMI (p < 0.001). In addition, the waist-hip ratio had a predictive risk of CVD death of 8.7 compared to those in the lowest quintile. Other epidemiologic data consistently show that CVD is associated with the duration and severity of obesity (Pascual, et al., 2003). These cardiovascular ailments include increased blood volume and cardiac output and decreased peripheral vascular resistance (Alpert, 2001; Kasper, et al., 1992), leading to elevated ventricular filling pressure, increased vascular wall stress,

4. **Metabolic Syndrome**

Metabolic syndrome is defined by multiple risk factors including central adiposity, low HDL levels, hypertension, high serum triglyceride levels, and impaired plasma glucose levels (Bary & Bellanger, 2006). Obesity and overweight are components of metabolic syndrome.

5. **Orthopedic Disease**

The excess weight placed on the joints, especially the knees and hips, result in rapid deterioration and wear and tear, causing pain and inflammation. Excess weight also affects the spinal column, resulting in degenerative disc disease and bone fractures (Creamer, 1997).

6. **Respiratory Problems**

Obese individuals are at high risk of developing obstructive sleep apnea (Wolk, et al., 2003). Several cross-sectional studies have consistently reported a link between obesity and the risk of sleep disorders (Young, et al., 2002). A significant proportion (40%) of obese people experience sleep apnea and about 70% of people with sleep apnea are also found to be obese (Vgontzas, et al., 1994). Other population-based studies showed that a 10% weight gain was associated with a six-fold increase in the odds of developing sleep apnea (Peppard, et al., 2000). According to a recent review by Romero-Corral (2009) there is also an association between the severity of obstructive sleep apnea and the extent of weight gain. Accordingly, weight loss has been shown to be
associated with a decrease in breathing problems. Several other case-control studies indicated weight loss in sleep apnea patients led to a significant decrease in apnea frequency (Schwartz, et al., 1991; Smith, et al., 1985). The mechanisms are thought to involve fat deposition on the airway such as increased tongue and neck tissue in tongue and neck causing the narrowing of the airway passage, which leads to intermittent obstruction of the air flow (Schwartz, et al., 1991). Sleep apnea leads to wakefulness, daytime drowsiness, and headaches. Increased weight also places a burden on the thoracic cavity.

7. **Gastrointestinal Reflux**

Chronic pressure on the valves of the gastroesophageal junction weakens the valves and result in the back flow of gastric acids into the esophagus. This reflex causes symptoms of heartburn and indigestion. If left untreated, approximately 10-15% of patients develop a pre-malignant change in the lining of the esophagus called Barrett’s esophagus, a pre-cursor of esophageal cancer (Sharma, 2004). Hampel et al., (2005) who conducted a meta-analysis of nine studies regarding the association of obesity and the risk for gastroesophageal reflux disease (GERD) and its complications, found a statistically significant increase in the risk for GERD symptoms, erosive esophagitis, and esophageal adenocarcinoma.

8. **Depression**

Morbidly obese patients face constant psychosocial challenges. Emotional disturbances may result from repeated failed attempts at dieting and the inability to maintain an ideal body weight. Other factors that lead to depression include disapproval by family and friends, remarks from complete strangers, discrimination at the work place
and inconveniences in public accommodations such as theater, airplane or bus seating (Simon, et al., 2006; Stunkard, Faith, & Allison, 2003).

9. Cancers

Overweight and obese individuals are at an increased risk for developing many cancers. An expert panel from the International Agency for Research on Cancer (IARC, 2002) concluded that some colon cancers, breast cancers, endometrial cancers, kidney cancers, and adenocarcinomas of the esophagus may be associated with adiposity. Recent studies suggested that more cancers including adenocarcinoma of the gastric cardia, gallbladder, liver, pancreas and prostate are associated with obesity and overweight (Calle, 2007; Calle & Kaak, 2004). According to American Cancer Society (ACS, 2002) estimates for cancer incidence, 51% of all new cancers among women in 2002 were linked to obesity. When analyzed to examine the association with different types of cancer the report indicated that 2% of thyroid cancers (15,800 new cases), 6% of uterine cancers (39,300 new cases), 12% of colorectal cancers (75,700 new cases), and 31% of breast cancers (203,500 new cases) among women were attributed to obesity risk. Among men, cancers linked to obesity comprised approximately 14% of new cancers: 3% of kidney cancers (19,100 new cases) and 11% of colorectal cancers (72,600 new cases), (ACS, 2002). In general, the mechanisms underlying the obesity and cancer link are not fully understood. The available evidence for mechanisms linking obesity and cancer risk involves the metabolic and endocrine effects of obesity and the alteration they create in the production of peptide and steroid hormones (Calle & Kaaks, 2004). With mounting evidence to support such an association it is important to recommend
maintaining a reasonable weight for its multiple health benefits, including decreasing the risk of cancer.

10. Mortality

Lew and Garfinkel (1979) showed that all-cause mortality has increased due to increase in body weight. The Nurses’ Health Study findings indicated obesity and mortality due to any cause had a J-shaped association; that is, women with lower BMI had lowest mortality while those with higher BMI saw a steady increase in mortality (Manson, et al., 1995). According to the American Cancer Society (2002), obesity-related cancers among women are estimated to comprise 28% of cancer-related deaths in 2002: 15% of breast cancers (39,600 deaths), 2% of uterine cancers (6,600 deaths), and 11% of colorectal cancers (28,800 deaths). Among men, obesity-related cancers are estimated to comprise 13% of cancer-related deaths in 2002: 10% of colorectal cancers (27,800 deaths) and 3% of kidney cancers (7,200 deaths).

D. Social Implications of Obesity

In a society that greatly values physical appearance and often associates likeability and attractiveness to slenderness, the resulting emotional burden for those who are obese can be overwhelming. Based on perceptions that they are lazy and insatiable, overweight and obese persons may be subjected to discrimination and prejudice among peers, at work, or other situations (Wellman & Friedberg, 2002). Rand and Macgregor (1991) examined self-perceptions among individuals who successfully maintained weight loss following a gastric restrictive surgery. The participants in their study viewed their previous state of obesity as extremely distressful. They also preferred normal weight over a major handicap such as deafness, dyslexia, diabetes, blindness, very bad acne,
heart disease, or limb amputation. They would choose to be poor and slim than wealthy and morbidly obese.

E. Economic Costs

The increase in the prevalence of overweight and obesity is also reflected in the rising cost of related health problems. The total cost of overweight and obesity is $117 billion (Weight-control Information Network [WIN], NIDDK, 2006), of which $61 billion accounted for direct health care costs and $56 billion accounted for indirect health care costs (WIN, 2006). Direct health care cost include preventive, diagnostic, and treatment services related to overweight and obesity. Another study estimated annual medical spending due to overweight and obesity alone (BMI>25) to be as much as $92.6 billion in 2002, corresponding to 9.1% of U.S. health spending (Finkelstein, Fiebelkorn, & Wang, 2003). The indirect cost category is reflected in the value of wages lost due to poor health or disability and the value of future income lost due to premature death. The effect on productivity related to overweight and obesity consists of workdays lost ($39.3 million), physician office visits ($62.7 million), restricted activity days ($239 million) and sick days ($89.5 million) The cost of care associated with cardiovascular disease, type 2 diabetes, and hypertension comprise the majority of these costs. Since the prevalence of overweight and obesity has dramatically increased since 1995, the actual costs are higher than the estimate provided.

F. Obesity Causes, Risks, and Contributing Factors

The causes of obesity are multi-factored and complex. Genes play an important role in determining how individuals control calorie intake, metabolize it, and deposit the excess calories. Environmental factors such as lifestyle and socio-cultural influences may
play a significant role. People have become more sedentary, resulting in fewer calories used than consumed. In addition, consumption of calorie-rich diets and total calories consumed has increased overall.

1. Genetic Factors

Overweight and obesity may be a result of a mismatch between today’s “obesogenic” environment and “energy-thrifty genes” that were designed to help our ancestors conserve (deposit) energy in period of famine for later use. This function is challenged by calorie-rich foods and less opportunity for physical activity. The variation in how different individuals respond to the same environment suggests genes play a role in the development of obesity.

The studies of resemblance and variation among twins and adoptees have provided indirect evidence of the genetic basis of obesity. The weights of adopted children did not show a correlation with the body weight of adoptive parents who provided them with food and other needs (Stunkard, et al., 1986; Sorenson, et al., 1992). On the other hand, even in cases in which adopted children never met their genetic parents, their weight showed an 80% correlation with their biological parents. When the weight of identical twins was compared to that of fraternal twins, the identical twins showed more similarity than the fraternal twins (Allison, et al., 1994; Allison, et al., 1996; Maes, Neal, & Eaves, 1997). Although a clinical link is not fully understood, there are more than 250 genes, markers, and chromosomal regions that have been implicated with human obesity (Rankinen, et al., 2002).

Direct evidence for obesity genes are due to single gene mutations. These extreme cases of obesity are rare and account for a small fraction of obese individuals. A mutation
in a single Melanocortin 4-receptor gene that is related to the control of feeding behavior has been found to be strongly associated with some obesity cases. The Human Obesity Gene Map showed single mutations in 11 genes which were implicated in cases of obesity. Fifty chromosomal locations relevant to obesity have been identified (Nirma, et al., 2008). Gathering family health history can provide health care specialists with important information on genetic susceptibilities shared by relatives, identifying those at high risk for obesity and obesity related disorders.

2. Environmental Factors

The strong influence of environment on the prevalence of overweight and obesity has been suggested by epidemiological studies (Flegal, et al., 1998). People of the same genetic background may have different rates of obesity resulting from a difference in their lifestyle. A study that compared the rate of obesity and other chronic disease among Pima Indians who live in rural Mexico and practice a traditional lifestyle (eat Pima diet and are physically active), with Pima Indians who live in live in the U.S. (are sedentary and consume a Western diet) found that the rate of obesity is higher in the U.S. Pima Indians (Ravussin, et al., 1994; Zimmer, et al., 1997). Even within the U.S. population, environmental factors have changed over the decades, including easy access to energy-rich, high-calorie food and the popularity of sedentary pastimes such as television and video games (Hill & Peters, 1998). Intervention studies have suggested that changing the unhealthful environment has a positive impact on modifying lifestyles, improving desirable eating behavior, encouraging physical activity, and increasing biological endpoints (Jeffery, 1995; Taylor, et al., 1991; Winkelby, 1994). Pima Indians
with a genetic predisposition to weight gain and living in an "obesogenic" environment in Arizona have difficult challenges to maintain a normal, healthy body weight.

3. Sedentary Lifestyle

The level of physical inactivity strongly influences obesity. A sedentary life, defined as engaging in less than 30 minutes of moderate physical activity each day, is strongly correlated with obesity and other preventable chronic diseases. The direct cost of physical inactivity is estimated to be as high as $24.3 billion (Colditz, 1999). Physical inactivity increases with age, is more common among females than males and among those with lower incomes and limited education (CDC, 1999). In the U.S, only 26% of adults engage in vigorous physical activity three or more times each week. That means about 59% of adults do not engage in any vigorous physical activity during their leisure hours (Lethbridge-Cejku & Vickerie, 2005). Jakicic, et al., (1997) reported a positive association between the amounts of exercise equipment at home and availability of exercise facilities in the neighborhood with levels of physical activity among adults. Adults living in homes or communities with greater access to exercise equipment were more likely to engage in physical activity. Similar findings were reported for children (Sallis, et al., 1990). Physical activity helps to manage weight and decreases the risk of developing and dying from various chronic diseases (Paffenbarger, et al., 1993).

4. Eating Behaviors

Portion size, the specific amount of food an individual eats during a given meal, is also a factor in obesity (Wellman & Friedberg, 2002). Although the U.S. Department of Agriculture (USDA) provides a guideline for portion sizes in its Food Guide Pyramid, most people eat in excess of the recommendations (USDA, 2011). A
study by Cheadle (1995) found a strong correlation between fat intake and the grades of milk and meat found in local grocery stores. In neighborhoods where the stores supplied higher grades of milk and meat, people were more likely to consume larger amounts of energy-rich fat. An individual’s preferences determine the types of food he or she eats; people tend to eat what they enjoy. This is partially determined by innate and experience factors (Drewnowski, et al., 1991).

5. Metabolism

Metabolic factors also are believed to contribute to the etiology of obesity. Energy intake that exceeds total body energy expenditure ultimately results in weight gain. Total energy expenditure includes resting energy expenditure (cellular processes necessary to sustain life), the thermic effect of food, and physical activity related expenditure. The relative contribution of each component differs, with about 10% coming from the thermic effect of food, about 60% during rest, and the remaining 30% from activity related expenditure. Genetics influence an individual’s resting energy expenditure (Bogardus, et al., 1986; Bouchard & Tremblay, 1990), the thermic effect of food (Bouchard & Tremblay, 1990) and adaptive body fat changes to overfeeding (Bouchard, et al., 1990). Low total daily energy expenditure has been found to be strongly associated with the rate of weight gain (Ravussin, et al., 1988). A study conducted among Pima Indians found that reduced activity-related energy expenditure may be a significant factor in developing obesity (Zurlo, et al., 1992). Activity related expenditure is the most variable factor and accounts for about 30% of the total (Carpenter, et al., 1995; Goran, 1995). Ravussin (1995) reported that the differences in metabolic rates are important factors in developing obesity and individuals with lower
metabolic rates had a greater incidence and magnitude of obesity. Energy intake and body weight are also influenced by the central nervous system’s influence on metabolism through its effects on behavior, on autonomic nervous system activity, and on neuroendocrine system, including secretion of hormones (Spiegelman & Flier, 2001).

6. Medical Conditions

Certain medical conditions such as insomnia, hypothyroidism, depression, eating disorders, Cushing’s disease, and polycystic ovary syndrome, and modifying behaviors such as smoking cessation can increase the risk of weight gain. Some medications such as antidepressants, corticosteroids, antipsychotics, antiepileptics, and medications for hypertension and diabetes are also known to increase the risk of weight gain.

Stress also is associated with being overweight or obese. Stress is linked to environmental cues like major life changing events (i.e., divorce or death of a family member) and more frequently experienced daily negative or positive encounters ("hassles and uplifts"). Selye (1956) and Moss (1973) hypothesized that the stress of constantly adjusting to both major and minor life events takes a physical toll on the body, including reduced resistance to disease.

Kanner et al. (1981) and DeLongis et al. (1982) found that minor but more frequent stressors (hassles) have a more profound effect and are more predictive of health outcomes than major life events. Stress cues parts of the brain, primarily the hypothalamus, to initiate a neurohormonal pathway to coping with stress known as the Hypothalamus-Pituitary-Axis (HPA), (Tsigos & Chrousos, 2002). When activated, this pathway elevates cortisol in the blood, which inhibits other energy demanding pathways
such as thyroid secretion, sex steroid production and growth inhibition, resulting in less bone and muscle mass growth (see Figures 2.4 and 2.5), and an increase in visceral adiposity (Chrousos, 1992; Tsigos, et al., 1994).

Figure 2.4 A Simplified Schematic Representation of the Central and Peripheral Components of the Stress System, Their Functional Interrelations, and Their Relations to Other Central Systems Involved in the Stress Response (Adapted from Chrousos and Gold, 1992). The CRH/AVP neurons and central catecholaminergic neurons of the LC/NE system reciprocally innervate and activate each other. The HPA axis is controlled by several feedback loops that tend to normalize the time-integrated secretion of cortisol, yet glucocorticoids stimulate the fear centers in the amygdala. Activation of the HPA axis leads to suppression of the GH/IGF-1, LH/testosterone/E2 and TSH/T3 axes; activation of the sympathetic system increases IL-6 secretion. Solid lines indicate stimulation; dashed lines indicate inhibition.
Figure 2.5 Detrimental Effects of Chronic Stress on Adipose Tissue Metabolism and Bone Mass (Adapted from Chrousos, 1998). G. P. Chrousos. Stressors, stress, and neuroendocrine integration of the adaptive response. The 1997 Hans Selve Memorial Lecture. Ann NY Acad Sci, 851, pp. 311-335). Solid lines indicate stimulation; dashed lines indicate inhibition.

7. Socioeconomic Factors

Disparities in socioeconomic status may contribute to the prevalence of obesity in lower income groups. The income gap contributes to the differences in access to healthy foods and opportunities for physical activity (Cheadle, et al., 1995; Hill & Peters, 1998). Sobal and Stunkard (1989) reviewed 144 published studies on the relationship between socioeconomic status (SES) and obesity. The authors reported a strong inverse relationship between SES and obesity in western societies; women with lower SES were far more likely to be obese (Sobal & Stunkard, 1989), though the relationship was inconsistent for men and children. On the other hand, in developing societies, a strong direct relationship was reported between SES and obesity among men.
women, and children (Sobal & Stunkard, 1989). A review of social attitudes toward obesity and thinness reveals values congruent with the distribution of obesity by SES in different societies. Factors that influence attitudes toward obesity and thinness among women in western societies include dietary restraint, physical activity, social mobility, and genetics.

8. Cultural Factors

Different cultures view obesity as either desirable or undesirable. For example, in North African countries obesity has become a growing problem, especially among those with resources, since fatness and specifically female fatness is viewed as a sign of social status and is a cultural symbol of beauty, fertility, and prosperity (Mokhtar, et al., 2001). In the U.S., studies indicate that obesity among Blacks and Hispanics is associated with lesser preoccupation with weight control, lower likelihood of perceiving oneself as overweight and related obesity tolerant behaviors and attitudes. These attitudes limit the motivation for weight loss or effectiveness of weight loss attempts (Dawson, 1988; Desmond, et al., 1989; Hazuda, et al., 1983; Kahn, Williamson, & Stevens, 1991; Kumanyika, Wilson, & Guilford-Davenport, 1993; Rand & Kuldau, 1990). However, cultures whose members equate thinness with beauty and health are more likely to weigh less or seek to maintain a desirable body weight. Cultures also determine diet and consumption patterns. In some cultures energy dense, fat-rich diets are preferred, creating conditions for energy excess and obesity, while in others a more health conscious approach is chosen.
G. Obesity Management and Interventions

The NHLBI Obesity Education Initiative Expert Panel recommends an initial goal for weight loss of up to 10% of baseline at the rate of 1-2 pounds per week. According to the guidelines, prevention of weight gain with lifestyle is indicated for patients with a BMI $\geq 25$kg/m$^2$, even without comorbidities, and weight loss is recommended for those with BMI of 25-29.9kg/m$^2$ plus with two or more comorbidities or with BMI of $\geq 30$kg/m$^2$. Pharmacotherapy is recommended for patients who fail to lose 1 pound per week after a 6-month trial of combined lifestyle intervention. Patients with BMI 27-29.9kg/m$^2$ and comorbidities or BMI $\geq 30$ may benefit from drug therapy. Weight loss surgical intervention can be an option for morbidly obese patients. Morbid obesity is defined as a BMI $\geq 40$ or BMI $\geq 35$ with other risk factors or disease.

Strategies for weight management in overweight and obese adults have three main components: dietary therapy, moderate physical activity, and behavioral therapy. Moderate weight loss achieved through sustainable lifestyle modification can mitigate some of the health risks associated with overweight and obesity. It takes most patients about six months to achieve a new equilibrium of energy balance (NIH, NHLBI, North American Association for the Study of Obesity [NAASO], 2000). To achieve additional weight loss after the initial six-month period, therapy goals must be revised to account for the decreased energy requirement. The next phase of weight loss should target weight maintenance. A regain of weight less than 6.6 pounds (3kg) in two years and a sustained decline in waist circumference of at minimum 1.6 inches represents successful weight maintenance.
1. Diet Therapy

The objective of dietary therapy is to reduce the total amount of caloric intake through diet modification. This can be achieved by creating a deficit of 500 to 1000 kcal/day, resulting in weight loss of 1 to 2 pounds per week. Low caloric diets (LCDs), also called Step I diets, reduce caloric intake by 500-1000 kcal/day. For women, diets containing 1,000-1200 kcal/day and for men 1200 to 1600 kcal/day may be appropriate.

The use of alcohol as a source of calories should be assessed and controlled. Total fat intake should be limited to 30% or less of total calories, saturated fatty acids to 8-10% of total calories, monounsaturated fatty acids up to 15% of the total calories, polyunsaturated fatty acids up to 10% of total calories, and cholesterol <300 mg/day. Protein derived from plant and lean sources of meat may be used to provide about 15% of total calories. Fifty-five percent or more of total calories should come from carbohydrates. Vegetables, fruits, and whole grains are excellent sources of carbohydrates, vitamins, minerals, and fiber. The recommended amount of fiber is 20 to 30 grams per day. Diets rich in fiber may be effective in reducing serum cholesterol levels and may promote weight loss and weight management by enhancing satiety at lower level of caloric intake (Butrum, et al., 1988; U.S. Public Health Service [USPHS], 1988; American Diabetes Association [ADA], 1998). Salt should be limited to no more than 100 mmol/day (approximately 2.4 g of sodium). Women who are at risk for osteoporosis are recommended to take 1,000 to 1,500 mg of calcium per day.

Patients with high serum cholesterol levels can be advanced to a Step II diet to further reduce LDL-cholesterol levels. In Step II diets, all nutrients are the same except
for saturated fats, which are reduced to fewer than 7% of total calories and cholesterol levels, which are limited to less than 200 mg/day. Very low calorie diets (VLCDs) are defined as less than 800 kcal/day and may be used in limited circumstances. Patients enrolled in a VLCD require supplementation and monitoring by trained staff (NHLBI, NIH, NAASO, 2000).

2. Physical Activity

The practical guidelines by the NHLBI (2002) recommend moderate levels of physical activity for 30 to 45 minutes on most and preferably all days of the week. This represents an expenditure of approximately 150 calories of energy per day or 1000 calories per week. Successful weight management programs make physical activity a vital part of their intervention (CDC, 2008). Although physical activity might not lead to more weight loss compared to diet alone, it helps in preventing weight regain (Pate, et al., 1995; NIH, 1996). Individual preferences should be considered when choosing the type of physical activity. Duration, intensity, and frequency can be adjusted to make physical activity a lifelong behavior.

3. Behavior Therapy

Often, individuals who are overweight or obese face barriers that hinder compliance with intervention. Behavior modification techniques such as self-monitoring, stimulus control, cognitive restructuring, goal setting, and relapse prevention can be used to help individuals change behaviors that contribute to being overweight or obese and adopt new dietary and physical activity behaviors that lead to weight loss (Wadden & Foster, 2000).
Self-monitoring involves recording and monitoring targeted aspects of behavior that impact weight loss, such as eating habits, daily weighing, exercise, or the measured outcome of the behavior such as weight lost, waist circumference, or other biomedical variables. This systematic accounting will lead to increased awareness of both desirable and undesirable behaviors, making it easier to review and adjust behaviors to achieve that goal. When a planned behavioral goal is met, the person may receive a reward that is desirable, timely, and consistent with achieving the goal.

Stimulus control involves recognizing environmental or socio-cultural cues that encourage the undesired behavior and then making an effort to modify those cues.

Weight loss efforts are often subverted by negative thoughts and beliefs. Cognitive restructuring skills help to identify and modify such distorted feelings by raising awareness, and eliminating or replacing them with positive and desirable thoughts that enhance the outcome of weight loss and maintenance (Wadden, et al., 1993).

Defining a specific, measurable, and achievable goal through realistic actions and behaviors helps achieve the desired amount of weight loss. In most cases 5-10% of initial weight loss at the rate of 1-2 lbs is recommended as a physiologically beneficial and achievable amount of weight loss (NIH, 1998). Patients set goals for calorie intake, diet composition, physical activity and other modifiable variables.

Relapse prevention teaches individuals to anticipate and cope efficiently with risky situations where relapse to a maladaptive habit is most likely to occur. This is accomplished by first identifying those factors that pose the greatest risk for relapse; second, by evaluating the processes that may have led to prior to the relapse; third, by assessing the reaction to the relapse and the extent to progression to full-blown relapse;
fourth, by strategies planned to intervene to prevent or manage relapse episode; and lastly, by learning from a relapse and developing more effective prevention skills (Larimer, Palmer, & Marlatt, 1999; Marlatt, Parks, & Witkiewitz, 2002).

4. **Adjunct Weight Loss Medication**

Medications may be used as a part of program that includes diet, physical activity, and behavior therapy in individuals with BMI ≥ 30 or ≥27 with other obesity related risk factors or disease. In the last two decades, many drugs were introduced and others withdrawn from the market due to unacceptable side effects (Cannolly, et al., 1997). However, in 1997 the Food and Drug Administration (FDA) approved Sibutramine until it was recently removed from the market, and in 1999, Orlistat for long term use. Selected patients may benefit from these long-term drugs to help reduce weight regain and maintain weight loss. The weight loss attributable to drugs is variable from person to person though the range is reported to be two to ten kilograms (4.4 to 22 pounds) loss.

Most of the drugs developed are appetite suppressants or anorexiants which function by affecting neurotransmitters in the brain via catecholamines (dopamine and norepinephrene), serotonin or by influencing a combination of these neurotransmitters. Sibutramine works by inhibiting the reuptake of norepinephrine and serotonin. Others work by modifying nutrient absorption from the GI tract. Orlistat is one such drug and functions by blocking the absorption of one-third of the available fat. Phentermine, Mazindol and others are approved for short-term use.
5. **Obesity Surgery**

Morbidly obese patients (BMI $\geq 40$ or a BMI $\geq 35$ with obesity related health risk) may benefit from bariatric surgery. Bariatric surgery provides medically significant weight loss over time. Most patients achieve reversal of diabetes, control of hypertension, improved mobility, fertility and overall improvement in quality of life. Effective surgeries target restricting gastric volume, altering digestion, or both. Banded gastroplasty and Roux-en-Y gastric bypass are surgical procedures in current use.

Some bariatric surgeries may have perioperative and postoperative complications. Patients should be assisted in dealing with new energy requirements through guidance on diet, physical activity, and psychosocial issues. Complications may include wound leak, infection, organ injuries, incision hernias, gallstones, dumping syndrome (rapid gastric emptying which occurs when the undigested contents of the stomach are transported or "dumped" into the small intestine too rapidly) or failure to lose weight. Deficiencies of vitamin B12, and iron deficiency with anemia are some additional complications of bariatric surgery. Flabby skin resulting from weight loss may be a source of emotional distress for some bariatric clients. In restrictive operations, failure to lose weight may result from failure to dietary compliance because high calorie intake is not prevented by the narrow outlet. Late failure or dilation of the pouch can also lead to increased intake and limited weight loss.

6. **Financial Support**

An explanation for weight loss failures could be provided by theory and evidence from psychology and behavioral economics (Cawley & Price, 2010). The physiological benefits of weight loss may not be readily apparent to the individual and
goes unrecognized. Improvements in obesity related health risks, and social and economic disadvantage may not materialize for some time after weight loss (Ainsline, 1975). In addition, time-inconsistent preference by patients (short-term gratification outweighing long-term planning) may lead to repeated failure at weight loss. People undercut their long range goal of weight loss by consistently failing victim to maladaptive behaviors of over eating and sedentary lifestyle (shortsighted interests) (Cawley & Price, 2010). Decision making becomes a battle between farsighted planning and shortsighted action (Thaler & Shefrin, 1981). High out of pocket costs may also be a barrier to enrolling in a treatment program and completing the recommended regimen.

There are high out of pocket costs involved in enrolling in weight loss programs and this could be a barrier to treatment (Bryant, 2001; Federal Trade Commission, 2006) as insurance coverage of obesity treatment is patchy in the U.S. (Tsai, Ash, & Wadden, 2006). Some studies have shown that financial incentives improve the effectiveness of obesity treatment programs (Jeffery, et al., 1983; Jeffery, et al., 1984). Hubbert et al., (2003) showed that among participants in a weight loss program, those receiving modest financial incentives (50% of $300 weight loss program fee if the participants attended 10-12 sessions and lost 6% of their initial body weight) had significantly higher chances of attending the recommended number of sessions and achieving successful weight loss. A review of 42 studies of the economic effects on health behaviors such as exercise, smoking cessation, and immunization by Kane et al. (2004) found that economic incentives were associated with behavior change in 73% of the studies. A meta-analysis of substance abuse treatment programs found that financial incentives improved compliance by an average of 30% (Lussier, et al., 2006). However, another meta-analysis
of nine randomized clinical trials (RCTs) that used financial incentives for weight loss found that the incentives did not promote successful weight loss or maintenance (Paul-Ebhohimhen & Avenell, 2008).

7. **Contracts**

The World Health Organization (WHO) reports that for diseases associated with lifestyle, poor adherence to treatment is associated with worse health outcomes (WHO, 2003). Adherence is the degree to which a patient’s behavior (such as eating and exercise) coincides with treatment guidelines (Evangelista, 2000). Sackett (1979) reported that adherence in keeping appointments may be as low as 10%. Effective strategies need to be developed to improve patient adherence (Haynes, 2008). A written or verbal contract asking the patient to commit to adhere to the prescribed set of treatment components may improve the patient’s adherence and overall outcome (Bosch-Capblanch, et al., 2009; Neale, 1991).

Patients often do not follow recommended changes in diet, exercise and behaviors. Poor adherence to treatment (i.e., number of sessions attended) may be due to difficulty in changing entrenched personal habits. This could compromise the success of a weight management program.

Concordance theory explains why it may be possible to improve compliance or adherence to recommended treatment regimens and achieve weight loss (Bosch-Capblanch, et al., 2009). The concordance model involves patients and practitioners formulating a mutually agreed upon plan of care which respects the wishes of the patient (Jones, 2003). Patients and providers work to reach an agreement on treatment strategies (Cox, 2004). This process will help health care providers identify and deal with potential
difficulties in adhering to treatment (Townsend, 2003), ensure that agreed-upon goals and milestones are met, and improve the likelihood of weight loss success. It also reinforces the mutual contribution of the patient and provider to a successful treatment (Maher, 2003).

A systematic review of strategies to improve adherence in general (Haynes, 2008), on tuberculosis treatment (Volmink, 2000, 2006), and HIV/AIDS treatment (Rueda, 2006) reported the association of adherence with desirable health outcomes. However, most health intervention contracts depend on a model in which the health care provider designs the contract and places the responsibility of failure solely on the patient rather than as a shared outcome. Stevenson (2000) argues that unless patients and health care providers are mutually involved in the decision making process when developing a treatment plan, there is no basis for reaching consensus on the treatment. Signing a treatment contract based on mutual agreement between the patient and interventionist may enhance the chance of program success.

Trials that addressed contract intervention for weight loss by Aragon, (1975) found participants who signed a contract lost more weight than those in the control group. Craighead (1989) reported that a supervised exercise group using contracts lost significantly more weight than those in the minimal care group both at 12 weeks and 12 months. However, Murphy (1982) did not find a statistically significant difference in weight loss between contracted and non-contracted groups. A study by Haber (1993) examined the effect of an intervention that included contracts to reduce specific dietary components, improve exercise, and manage stress. The contract group successfully modified some aspects of their diet.
H. Adult Obesity Treatment Program Outcomes

Although there are many weight management programs, the evidence demonstrating their effectiveness is mixed. Thus a need for a systemic approach to obesity management is essential for conquering obesity and improving the outcomes of patients seeking intervention.

A meta-analysis of 12 dietary intervention-controlled trials on body weight involving a total of 1,910 subjects reported that initiating an *ad libitum* low-fat diet resulted in an overall 10.8% decrease in total calories consumed as fat and 272 kcal/d decrease in energy intake as compared to control group (p=0.002) (Astrup, et al., 2000). Yu-Poth, et al., (1999) evaluated the results of 37 diet intervention studies involving 9,276 patients who were given the National Cholesterol Education Program’s Step I or Step II diets, which reduced energy intake from fat to ≤30%. The study showed that a 1% decline in energy consumed from fat was associated with a 0.28kg weight loss. A study that examined the result in weight loss at 6-months in five randomized clinical trials of low-fat vs. low-carbohydrate diets among adults (Brehm, et al., 2003; Foster, et al., 2003; Samaha, et al., 2003; Yancy, et al., 2003) reported that subjects randomized to low-carbohydrate, high protein, and low fat diet achieved more weight loss at six months than with the low fat diet alone.

Rolls, Morris, and Roe (2002) evaluated the effect of portion size on energy intake and reported a linear relationship between the two. Jeffery, et al., (1993) examined the effect of providing prepackaged meals with behavior change therapy on the success of a weight loss program. The authors concluded that participants who were provided with prepackaged meal replacements lost more weight than those prescribed only a self
chosen diet. Wadden, et al., (1990) evaluated the impact of very-low-calorie diets (VLCDs) and low-calorie diets (LCD) and found that VLCDs result in more weight loss in short term than LCD, but in the long term the VLCD resulted in weight gain and the total weight loss was similar for both groups.

Physical activity alone as a strategy for weight loss results in minimal weight loss (Wing, 1999). When comparing modified diet therapy to a modified diet therapy plus exercise weight loss does not appear to result in a significant difference in the short-term (Bertram, et. al, 1990; Blonk, et. al., 1994). However, the relationship between physical activity and weight loss maintenance is significant. Analysis of large cross-sectional case studies and prospective trials found that regular exercise was associated with successful long-term weight loss (Hartman, et al., 1993; Jeffery, et al., 1984; Kayman, et al., 1990; Marston & Criss, 1984). Studies suggest moderate physical activity is associated with successful long-term weight maintenance (Jakicic, et al., 1999; Jeffery et. al., 1998; Schoeller, et. al., 1997; Wing & Tate, 2000). Anderson et al. (1999) compared the effect of structured aerobic exercise programs and increasing daily lifestyle activities to be effective in maintaining long-term weight loss. This suggests that changing lifestyle activities is an acceptable alternative to programmed exercise for obese patients.

Providing patients with the skills, motivation, and support to change diet and exercise behaviors in order to avoid adverse health patterns has an impact on modifying health risks such as cardiovascular disease. A review of 29 trials with at least a one-year follow-up found that average weight change in diet or physical activity group was 1.9 to 8.8kg with a mean 3.3kg weight loss (NHLBI Obesity Education Initiative, 1998).

Counseling for low calorie diet (1000-1200kcal per day) reduced body weight by an
average of 8% from baseline over 3 to 12 months (NIH, 1996; Stevens, et al., 2002). A very low calorie diet produced the greatest weight loss but the outcomes were similar after one year. A review of 24 randomized clinical trials also showed that counseling for physical activity led to weight loss of 2-3% (NHLBI Obesity Education Initiative, 1998). Greater weight reduction was achieved when a combination of diet, physical activity, and behavior therapy was added as an adjunct modality (NIH, 1996). In a review of 24 studies of weight loss, when behavioral interventions were combined with diet or exercise the interventions were effective over the long-term (-3kg) 12 to 60 months. Another review by the Canadian Task Force on Preventive Health found that weight reduction was most effective with supervised dietary treatment (Douketis, Feightner, Attia, & Feldman, 1999). McTigue et al. (2003) identified 17 randomized clinical trials of counseling and examined weight loss maintenance trials separately and found attrition varied from 5-35%, with different rates of attrition for different treatments. Patterns of enrollment, random sampling, and poor gender and ethnic diversity resulted in limitations of the study outcomes.

Behavior therapy should involve developing specific realistic goals which can be measured with plans to achieve those incremental goals and prevent setbacks. Data from the National Weight Control Registry (NWCR) was analyzed for behaviors that were associated with successful long-term weight loss (Klem, et al., 1997; McGuire, et al., 1998; Wyatt et al., 2002). The study reported self-monitoring, low calorie intake, eating daily breakfast, and engaging in a regular exercise as a major behaviors practiced by those who had maintained successful weight loss.
Medically supervised commercial programs include physician monitoring to manage obesity related complications. Most of these programs use very-low-calorie diets (<800 kcal/d) with high protein intake, 70 to 100g/d to preserve lean mass. The VLCD diets resulted in mean weight loss of 3 lb weekly (NIH, 1998). The complications include elevated risk of gallstones, hair loss, cold intolerance, and change in bowel habits (NIH, 1993). OPTIFAST, Health Management Resources, and Medifast (Jason Pharmaceuticals, Inc., Owings Mills, MD) are reputable, medically supervised weight management programs. The programs focus on meal replacements and lifestyle modification involving 12 to 18 weeks of rapid weight loss, followed by a 3 to 8 week transition phase and long term maintenance program (OPTIFAST, Health Management Resources). Mandatory medical monitoring is provided in the first two phases.

A randomized clinical trial aimed at assessing the efficacy of proprietary-based programs involving meal replacement and other lifestyle interventions (Anderson, et al., 1994) found at the end of 12 weeks participants who received meal replacements lost 15.3% of their initial weight, while those who followed conventional diets lost 14.1% of their initial weight and maintained 8.4% in a one year follow up evaluation.

Multiple case series evaluations of OPTIFAST programs were conducted. One study held at 18 sites involving 12 weeks of VLCD showed those who completed treatment lost 21.8% of initial weight, compared with 11.3% for those who dropped out. A one-year follow up of 43% of the original sample found that these participants maintained a loss of 9% of their initial weight (Wadden, Foster, Letizia & Stunkard, 1992). Another single site OPTIFAST intervention study reported participants who
completed the program lost 19.9% of their initial weight after a 26-week intervention (Walsh & Flynn, 1995).

Similarly, a review of two case series of the Health Management Resources program at a single center with 12-17 week intervention period reported that participants lost 19.2% of their initial weight (Anderson, et al., 1991). Another single-center Health Management Resources study reported that morbidly obese participants who were treated for 26 weeks lost 27% of their initial weight. The results of these medically supervised commercial weight loss programs suggest that patients who complete a comprehensive intervention program can expect to lose 15 to 25% of their initial weight during 3 to 6 months of treatment and may maintain a weight loss of 8% after one year (Anderson, et al., 1994; Flynn & Walsh, 1993). These studies also reveal that morbidly obese patients lost the greatest percentage of their initial weight.

I. Conclusions

Contributing factors of obesity are both physiological and psychosocial. Attitudes towards and level of engagement in behaviors that promote weight loss can provide a hint about potential success of weight loss effort. Exposure to major life change events, daily hassles and buffering positive uplifts act impact the severity of stress and other health outcomes such as obesity. Providing coping skills and overcoming the burden of these psychosocial parameters can predict success of weight loss.

Obesity treatment is challenging. It is the one of the most difficult and frustrating health issues for patients and clinicians. An overwhelming amount of effort is spent on a variety of intervention strategies with limited beneficial outcomes. The most successful program results in about 8% weight loss. The absence of proven clinical success has
created an enormous demand for weight management resources. At any given time, thousands of men and women are attempting to lose weight. It is necessary to continue to investigate and identify factors and strategies associated with program success.
CHAPTER 3

METHODS

A. Study Design

The study used secondary archived patient data from the Lite-Weighs medical weight management program, operated by the Beaver Medical Group, to evaluate the effectiveness of a comprehensive long term weight loss program for obese or morbidly obese persons. Beaver Medical Group, an HMO type insurance plan, is prevention and lifestyle oriented, encourages their patients to engage in positive lifestyle behaviors, and offers them programs to support such choices if medically indicated. All variables were abstracted from the Beaver Medical Group patient database. The study focuses on the analysis of these archived data comparing the extent of weight loss among two groups of obese and morbidly obese patients. The first group (intervention) completed a behavioral contract to participate in a 26-week weight loss intervention and also received funding to offset most program costs. A second group (comparison) was made up of obese and morbidly obese Beaver Medical Group patients who were offered the regular Lite-Weighs program but without the contract element or financial support.

Patients were recruited from September 2009 to February 2010 and offered the 26-week Lite-Weighs program with funding for most costs, excluding meal replacements, physician visit co-pays, and material fees of $25 per 8-week program cycle for a total of $75 for 26 weeks. All patients who were referred to the weight loss clinic and met the inclusion criteria were offered this program. If they accepted they were required to sign a contract promising participation in 26 weekly treatment sessions. A total of 127 patients agreed to participate. The comparison group (N=154) consisted of patients who were
referred to the weight loss clinic from April 2008 to September 2010 and fit the inclusion criteria. This group was offered the same program as the intervention group without funding support and without the 26-week contract requirement. This group chose the frequency and type of intervention sessions based on their personal preference and ability to pay and attend the treatment sessions. All participating patients gave consent. Loma Linda University, Beaver Medical Group, and the Lite-Weighs program entered into a data use agreement prior the accessing the patient database.

B. Description of Study Participants

The study population consisted of obese and morbidly obese men and women with BMI >30kg/m². The age range of patients enrolled in the 26-week Lite-Weighs medically supervised weight loss program at chart abstraction time was 21-75 years. As part of their standard practice Beaver Medical Group excluded persons with medical contraindications for calorie restricted and fat reduced diets, moderate exercise, and those with active cancer and pregnancy. A medical clearance for participation was obtained prior to enrollment in the Lite-Weighs program. Consent to enroll in the program was obtained by the Beaver Medical Group. In addition, study approval was also obtained from the Loma Linda University Institutional Review Board (Appendix F).

C. Participant Recruitment

All participants were self-referred or physician-referred to the Lite-Weighs medically supervised weight loss program. Most referrals were from a local HMO (Beaver Medical Group Primary Care Service). The program was also offered to patients who had prior knowledge of the services provided by Lite-Weighs, either by previous attempts to enroll or those who had heard of the program but did not have financial
resources to enroll. Finally, patients who initially wanted to have bariatric surgery (Roux e Y or gastric banding), but were no longer interested in the surgical option were also invited.

D. Intervention Procedures

Potential participants attended a group orientation session which provided an overview of the program. The goal of the Lite-Weighs treatment program was to support patients in learning and practicing the lifestyle skills and health habits needed to lose weight, maintain weight loss, and improve overall health. The Lite-Weighs program consisted of interdisciplinary staff with specialized training in behavior modification, weight management, and exercise physiology. The team included physicians, preventive care specialists, health educators, medical assistants, and a personal trainer. Personalized attention and follow up care were central to this medically directed program.

Individual programs were designed in collaboration with the patient, supervising physician and a preventive care specialist during the initial consultation period. At subsequent weekly meetings, patients met with the intervention team as indicated. Patients also visited a physician every 3-4 weeks or more often if medically indicated.

The comparison group was offered a similar intervention program as the intervention group. However, no contract was signed, and this group paid for all of the sessions that they attended.

1. Dietary Intervention

Intensive or moderate individual nutrition plans were designed to meet participants’ needs. Patients who needed to lose 50 or more pounds were offered a very low calorie diet (VLCD), low calorie diet (LCD) or customized plan (calorie requirement
determined based on age, gender, height, and activity levels) in consultation with Lite Weighs team. Patients continued on this diet until one-half to three-quarters of the desired weight loss was achieved; after that a moderate eating plan allowing 1,000-1,200 calories per day was instituted to lose the remaining pounds. Moderate eating plans were recommended for desired weight loss of less than 50 pounds. In addition to individualized diets the program also provided options for nutritional shakes, bars, packaged meals, and other supplements. All purchases of such foods were noted in the patient’s file and were abstracted as part of the creation of the data set.

2. Physical Activity

Participants were asked to engage in regular exercise for a minimum of 60 minutes per day most of days, and asked to keep records of their activity. An exercise log was provided to each patient and reviewed during sessions.

3. Behavioral Therapy

Behavior therapy included instructing patients to set goals, self-monitor, employ stimulus control, solve problems, engage in cognitive restructuring, implement stress management skills learned through the program and use positive reinforcement to enhance adherence to prescribed physical activity, diet and other elements of weight loss program.

4. Adjunctive Weight Loss Medication

Each participant received individual consultation with the supervising physician to determine if adjunctive weight loss medication should be included. The weight loss medication Phentermine was made available for patients to use while in the Lite-Weighs program. Type and duration of medication use was recorded.
5. Intervention Classes

The intervention program provided weekly one hour sessions for 26 weeks. These sessions were divided into blocks of 8 weekly classes. For example, the General Pathway class focused on lifestyle transformation skills, details of dietary, exercise and behavioral elements, and methods of accounting for dietary and exercise behaviors. The Nutritional Pathway class focused on nutritional skills building, understanding carbohydrates, fibers, fat and proteins, food demonstrations, meal planning and calorie requirements. The Wellness Pathway class taught effective methods of behavior change, combined exercise and nutrition, journal keeping, and increasing fitness. Emotional Brain Training focused on changing the neuronal network which favors maladaptive behaviors such as cravings, emotional overeating, and mastering the skills needed to turn off those drives, to identify and to modify patterns which contribute to unhealthy choices. The outcomes of the initial assessment guided the type and sequence of classes suggested. Classes were offered during day and evening hours to accommodate patient schedules.

6. Measurements

a. Anthropometry Height was measured using a wall mounted stadiometer to the last completed 0.1 cm after keeping heels, buttocks, shoulders, and occiput in the vertical plane and head in the anatomic plane. Weight was measured using a digital weighing scale (Perspective Enterprise, Inc.) with minimal lightweight clothing to the closest 100 g. BMI was calculated as weight (kg)/height (m²). Waist circumference was measured with a tape placed around the bare abdomen just above the patient’s hipbone. The patient was instructed to relax and exhale prior to the measurement. Hip
circumference was measured same as the waist except for tape position. The tape was placed at the maximal circumference over the buttocks.

b. Questionnaires Participants in the intervention group also completed five psychosocial and behavioral questionnaires prior to the start of the treatment protocol. This was conducted in a quiet study room with an interventionist available to answer any questions.

c. Major Life Change Events The Life Event Scale (Appendix C) is designed to predict the likelihood of disease (obesity) and illness and the needed readjustment (weight loss) to return to homeostasis following exposure to stressful life events. Each life event was given a score that indicated the amount of readjustment a person had to make as a result of the event. Not all of the events in the scale were necessarily negative or positive.

Patients were asked to note events that occurred in the past such as death of a family member, job loss, divorce, etc., and whether these events were related to their current health condition. They were also asked to record a score for each of these events. In case an event occurred more than once the patient was instructed to multiply the score by the number of occurrences. A total score of 300 or more indicates that the patient is at major risk of illness; a score of 150-299 indicates moderate risk for illness (reduced by 30% from the previous risk), and a score of 150 and below has only a slight risk for illness. The higher the score (risk) the higher the burden and the more effort needed by the obese person to return to desirable weight state.

d. The Hassles and Uplifts Scale The Hassles and Uplifts Scale is an alternative method to the traditional life events approach to measuring stressors, and
assesses respondents' attitudes about daily situations. Instead of focusing on highly charged life events, the 53-item scale provides a comfortable way to evaluate positive and negative events that occur in each person's daily life, empowering clients to develop strategies for dealing with hassles and enhancing the occurrence of uplifts. The Uplifts scale suggests how positive aspects of daily life counteract the damaging effects of stress. It is graded 0 to 3 for none or not applicable, 1 for somewhat, 2 for quite a bit, and 3 for a great deal, respectively. It takes approximately 10 minutes to complete the scale (Appendix D).

e. Weight Management Behavior Questionnaires In addition to the questionnaires used to assess the impact of daily and major life events, two weight loss behavior questionnaires were used in this study. Patients were asked to quantify their perceived importance and actual frequency of engaging in 17 different weight loss promoting behaviors (Appendix A and B). The questions focused on three main categories of behaviors: self-monitoring, eating, and exercise. Self-monitoring questions captured data regarding use of food diaries, i.e., tracking calories, measuring food portions, logging exercise and weight values. Dietary habit questions include strictly following menu plans, smaller food portions, meal planning, restaurant eating, and thoughts about healthy eating. Physical activity questions covered whether participants exercised at least 60 minutes per day, participated in supervised sessions on changing the thoughts related to exercise, and exercised even when not in the mood.

E. Data Collection

Archived data from patient records was reviewed and analyzed. For the baseline characteristics, patient medical history questionnaire entries were reviewed and
demographics (age, race, marital status, employment, and education) and anthropometric data (height, weight, waist circumference and others) extracted. The presence of obesity-related medical illness (cardiovascular disease, type 2 diabetes, osteoarthritis, and endocrine disorders), and medication use were determined. Family history of obesity, cigarette smoking, physical activity and alcohol use were also recorded. Prior attempted dieting methods were recorded.

For the current program all treatment modalities were recorded including dietary prescription, use of weight loss medication, number of treatment sessions attended and use of diet supplements. At the end of treatment (26 weeks), or whenever the participant dropped out of the study, weight and waist and hip measurements were recorded.

The patients completed questionnaires were added to the data set and scored according to published guidelines. Data was also reviewed for 10 most frequently reported major life events, uplifts and hassles were identified.

Persons with medical contraindications for calorie restricted and fat reduced diets, moderate exercise, and those with active cancer and pregnancy were excluded.

F. Data Analysis

Abstracted data was entered using SAS version 9.2 software for Windows. A random 10% sample was re-entered. The dependent variables (changes in weight change, BMI, and waist circumference) were examined for normality; distributions were normal therefore did not require transformations. Descriptive analysis was completed for participants’ baseline variables and expressed as mean +/- standard deviations. An independent sample t-test was used to compare continuous variables in the intervention versus the comparison group. Chi square analysis was used for categorical variables.
Changes in weight, BMI, and waist circumference were calculated and compared between the intervention and comparison groups using the independent t-test (for some of the variables that appear in the descriptive statistics, the distribution was non-normal; for these variables, the Mann-Whitney test was used. Paired t-tests were used to examine changes in weight, BMI and waist circumference. Multiple linear regression was used to determine if changes in BMI or weight were associated with the psychosocial and behavioral questionnaire scale results; these variables were added to the model. The intent-to-treat approach was used to analyze data, with the last observation carried forward.

Multiple linear regressions were used to evaluate predictors of weight loss, adjusting for covariates. The dependent variables were changes in weight and BMI. Models were adjusted to the baseline value of the corresponding measure. Covariates were checked, and any variables that were significant or that changed the beta coefficient of the treatment variable by 10% were included in the model. Model selection was performed for each of the dependent variables. In addition variables that differed between groups at baseline and after the weight loss intervention were included in the models. The alpha (p-value) ≤ .05 was used as criteria for statistical significance.

Psychosocial correlate analyses: Multiple linear regression was used to determine if changes in BMI or weight were associated with psychosocial and behavioral questionnaire scale results. Significant variables were added to a final analytic model.

G. Power Analysis

The research questions concerning the intervention and comparison groups used multiple regression modeling to determine weight change on multiple (7 to 9) covariates.
With a sample size of 240 observations (participants?) provided 82\% power and a 0.05 (two-sided) significance level. We also determined that we had sufficient power with the 100 persons who completed the psychosocial questionnaire, noting that with a multiple regression we could model weight change on continuous independent variables (Xs) and achieve 85\% power at a 0.05 significance level (two-sided) to detect a change in R-squared of 0.08.

**H. Ethical considerations**

The Beaver Medical Group obtained participant consent at the beginning of patient enrollment. Participants were asked to provide consent for the investigator to access their patient data, including weight loss and health history, and evaluations performed by the physician, preventive care specialists, health educators, and for participation in the behavioral interventions. Participants in the intervention group also signed an agreement to attend 26 weekly sessions. They were asked to complete the psychosocial questionnaires, and to allow Lite-Weighs staff to collect anthropometric measurements. To reduce the undue burden that may be caused by the frequency of the visits, appropriate times and dates were chosen in consultation with the patient. Data were secured and kept in a locked file cabinet at Beaver Medical Group. Participant data was de-identified using ID numbers and the data set with the linking code was shredded at the completion of the study. Only de-identified data were used in the analyses.

While there may have been an initial risk such as divulging personal information with the intervention team and other participants during group discussions this was limited to the provider setting and since only de-identified data was used, did not affect the conduct of this study. Stringent medical provider standards regarding patient
confidentiality were followed throughout the study. Patients were informed that changes in diet and increased physical activity may alter baseline physiology such as resulting in hypo or hyperglycemia, joint pain, and others. The physician and the rest of the intervention team were available to adjust patients’ dietary intake, exercise regimen or medication in consultation with their primary care physician. During weekly meetings progress notes were taken to evaluate patients’ tolerance and adjustment to the behavior change approaches.

Patients were told that benefits could include acquiring skills necessary to lose weight through dietary modification, physical activity, and behavior change. They also could benefit from making connections with peers and developing confidence. The weekly obesity-related health assessments by a trained multi-disciplinary intervention team could identify other obesity related issues and help develop an appropriate plan for care. Patients in the intervention group also benefited from financial assistance to offset program costs associated with participation in an intensive weight management program.

I. Limitations

All study participants were self selected. Participants were free living and there was no control over other sources of information that may have affected the intervention. The questionnaires depended on the accuracy of self-reports by the patients. Patients may have overestimated their efforts to please the staff. Participants self-selected into the study, choosing either the intervention or comparison group, resulting in non-random group assignment. The questionnaires were somewhat lengthy and available only in English, although no patients asked for questionnaires translated into Spanish or any
other language. The study team who handled the secondary data analyses had no physical interaction with the participants.
CHAPTER 4
FIRST PUBLISHABLE PAPER

Title:
Grant-Supported, Contract-Based Versus Standard Weight Management for Treatment of Obese and Morbidly Obese Persons

Authors:
Gemechu Abraham Kurfessa, DrPH
Loma Linda University, School of Public Health
Department of Health Promotion and Education
24951 North Circle Drive, Nichol Hall 1511, Loma Linda, California 92350
gkurfessa01a@llu.edu
(818) 859-8454

Sylvia Cramer, DrPH
Lite-Weighs, Beaver Medical Group
1150 Brookside Avenue, Suite U, Redlands, California 92373
SCramer@epiclp.com
(909) 793-2506

Colwick Wilson, PhD
Loma Linda University, School of Public Health
Department of Counseling & Family Sciences
24951 North Circle Drive, Nichol Hall 1511, Loma Linda, California 92350
cwilson@llu.edu
(909) 558-4598

Susanne Montgomery, PhD, MPH, MS
Loma Linda University,
Behavioral Health Institute, 1686 Barton Road, Redlands, 92373
smontgomery@llu.edu
(909) 558-9586

Serena Tonstad, MD, PhD, MPH
Loma Linda University, School of Public Health
Department of Health Promotion and Education
24951 North Circle Drive, Nichol Hall 1511, Loma Linda, California 92350
stonstad@llu.edu
(909) 558-4741
ABSTRACT

Background and Aims: Engaging in a healthy lifestyle that includes diet, physical activity, and behavioral modification can influence weight loss. In addition, factors that promote weight loss could also include financial incentives, attendance at intervention sessions, adjunctive weight loss medication and supplemental diet products. The purpose of this study was to investigate whether an intensive weight management program was associated with clinically significant weight loss in obese and morbidly obese patients as well as predictors of weight loss.

Methods: We compared weight loss among patients who chose to participate in a 26-week intervention including an attendance contract and funding to offset most program costs (intervention group) to patients who were offered the program without the contract component or financial support (comparison group). Patients were self-referred or referred by their primary care physician. Archived data from patient medical records was reviewed and analyzed. Participants were men and women ages 21-75 years with a BMI ≥30 kg/m². The intervention group was offered the grant covering a wide spectrum of intervention classes and signed an agreement to attend weekly sessions for 26 weeks. The comparison group was not offered the grant, and chose the frequency and type of intervention sessions depending on their willingness to pay and attend. Assessments at baseline and end of follow-up (weeks 0 and 26) include demographics, anthropometric, lifestyle and co-morbidity measures. The number of therapy sessions attended, adjunctive medication use, and supplemental diet products purchased were recorded. The main outcome was percentage change in weight compared to baseline.
Results: There were 23 men and 104 women in the intervention group (BMI=40.5±8.7) and 36 men and 118 women (BMI=39.4±7.1) in the comparison group. Both experienced significant decreases (7.6±9.7 kg, or 6.7% from baseline for the intervention group vs. 6.2±6.3 kg or 5.8% for the comparison group) in weight using intent-to-treat analysis with no difference between groups. Those who started with higher weight (p<0.0011), attended more sessions (p=0.0395) and used adjunctive weight loss medication (p=0.0084) lost more weight. Depression was associated with lower weight loss.

Conclusion: Both programs induced clinically significant weight loss (≥5%) over 26 weeks, with no advantage observed between the intervention and comparison groups. Predictors of weight loss were in line with previous literature, and we were able to identify factors that should be addressed in weight intervention programs.
INTRODUCTION

Obesity is a complex chronic disease that develops over years or decades. There is an urgent need to identify treatment approaches that may contribute to weight loss success. Modest weight loss can lead to a significant reduction in co-morbidities associated with obesity. Risk factors for obesity have been attributed to genetic, behavioral, environmental, and physiological factors (Flegal, et al., 2001). Most weight management programs focus on reducing caloric intake. However, it is clear that energy restriction alone is not sufficient. Some studies indicate that a clinic-based, healthy-lifestyle program resulted in significant weight loss (Riebe, et al., 2003). However a systemic review of major commercial weight loss programs concluded that the evidence to support the use of such programs is minimal (Baker & Young, 2006; Tsai & Wadden, 2005).

While few dispute the need for weight loss it is important to identify factors associated with successful weight loss. These factors could include adjunctive therapies to dietary change (Astrup, et al., 2000; Jeffery, et al., 1993; Rolls, et al., 2002; Yu-Poth, et al., 1999), including increased physical activity (Ballard & Poehlman, 1994; Jeffery, et al., 1984; Wadden, et al., 1997; Wing, 1999), social support (Wing, 1999), behavior therapy (Wadden & Foster, 2000), increased intensity with more frequent intervention sessions (Butsch, et al., 2007; Jeffery, et al., 1993), financial incentives (Giuffrida & Torgerson, 1997; Janz, Becker, & Hartman, 1984; Kane, Johnson, Town, & Butler, 2004), contracting (Neal, 1991), use of adjunctive weight loss medication (Stanfford & Radley, 2003; Wirth & Krause, 2001) and supplemental diet products (Jeffery, et al., 1993). In its 2007 report, the Institute of Medicine (IOM) identified identifying effective
obesity management strategies as an essential priority action. It also emphasized that each evaluation can make an important contribution to the evidence base (IOM, 2007).

Many point to high out of pocket costs as a barrier to treatment (Bryant, 2001; Federal Trade Commission, 2006) as insurance coverage of obesity treatment is patchy in the U.S. (Tsai, Ash, & Wadden, 2006). Some studies have shown that financial incentives improve the effectiveness of obesity treatment programs (Jeffery, et al., 1983, 1984). Hubbert et al., (2003) showed that among participants in a weight loss program, those receiving modest financial incentives (50% of the $300 weight loss program fee if participants attended 10-12 sessions and lost 6% of their initial body weight) had significantly higher chances of attending the recommended number of sessions and achieving successful weight loss. However, in meta-analysis the use of financial incentives did not promote successful weight loss or maintenance (Paul-Ebhohimhen & Avenell, 2008).

Failure to attend the required intervention sessions may be associated with failure to complete the treatment regimen or follow prescribed lifestyle changes and as a result a failure to achieve weight loss benchmarks. A systemic review of medically supervised proprietary weight loss programs has shown a 19%-56% attrition rate during 26 weeks of treatment (Tsai & Wadden, 2005).

The World Health Organization reports that for diseases associated with lifestyle poor adherence to treatment is associated with worse health outcomes (WHO, 2003). Effective strategies need to be developed to improve patient adherence (Haynes, 2008). A written or verbal contract asking the patient to commit to adhere to the prescribed set of
treatment components may improve patient adherence (Bosch-Capblanch, et al., 2009; Neale, 1991).

According to the National Heart, Lung, Blood Institute (NHLBI), successful long-term weight loss is defined as an intentional reduction of 5-10% from baseline maintained for one year. Such weight loss, though modest, improves a host of cardiovascular risk factors (Blackburn, 1995; Goldstein, 1991; Oster, et al., 1999), prevents the development of type 2 diabetes, and is achievable in clinical practice. The 1998 National Institutes of Health (NIH) clinical guidelines indicate that decreased caloric intake, moderate physical activity, and behavioral therapy constitute vital elements of any effective weight loss and maintenance program. Furthermore, multidisciplinary programs that focus on positive lifestyle change and include expertise in health education, nutrition, exercise and behavior change are recommended.

Lite-Weighs is a medically supervised, multidisciplinary weight loss program located in Redlands, California. The program serves overweight, obese, and morbidly obese patients who are self referred or physician-referred. The program focuses on health education, lifestyle skills development, behavior modification, nutrition, and physical activity. Lite-Weighs also provides options for diet supplements and medications to enhance weight loss.

In the current study we investigated if offering financial support for program expenses and obtaining a signed contract committing the individual to attend a prescribed number of intervention sessions resulted in greater weight loss than the standard care provided by the Lite-Weighs program. We also sought to determine significant predictors of weight loss.
METHODS

A. Subjects

The study population consisted of obese and morbidly obese men and women aged 21-75 years with BMI >30 kg/m². All participants were self or physician-referred to the 26-week *Lite-Weighs* medically supervised weight loss program. Most referrals were from a local health maintenance organization Beaver Medical Group from September 2009 to February 2010 the Beaver Medical Group offered financial support covering most program expenses, with the exception of the cost of meal replacements, physician co-pays, and a $25 material fee per each 8 week class for a total of $75 during the 26 week program. All referrals in this time period were offered this program and were required to sign a contract promising participation in weekly treatment sessions.

Participants in this program are referred to as the intervention group. The comparison group consisted of patients who enrolled from April 2008 to September 2010 and were offered the identical treatment program to the intervention group without financial support and or the contract requirement. This group chose the frequency and type of intervention sessions depending on their willingness to pay for and attend the treatment sessions. Referred patients who had shown interest in bariatric surgery but decided against it were invited to participate in either program. Consent to enroll in the program was provided by Beaver Medical Group.

B. Treatment

Potential participants attended a group orientation session which provided an overview of the program. The goal of the Lite-Weighs treatment program was to support patients in learning and practicing the lifestyle skills and health habits needed to lose
weight, maintain weight loss, and improve overall health. The Lite-Weighs program consisted of an interdisciplinary program with staff with specialized training in behavior modification, weight management, and exercise physiology. The team included physicians, preventive care specialists, health educators, medical assistants, and a personal trainer. Personalized attention and follow up care were central to this medically directed program.

Individual programs were designed in collaboration with the patient, supervising physician and preventive care specialist during the initial consultation period. At subsequent weekly meetings, patients met with the intervention team as indicated. Patients also visited either the Lite-Weighs physician or their own personal physician every 3-4 weeks or sooner if medically indicated.

The comparison group was offered the same program as the intervention group, however, no contract was signed, and this group paid for all of the sessions they attended.

1. Dietary Intervention

Intensive or moderate individual nutrition plans were designed to meet participants’ needs. Patients who needed to lose 50 or more pounds were offered a very low calorie diet (VLCD), low calorie diet (LCD) or customized plan (calorie requirement determined based on age, gender, height, and activity levels) in consultation with the Lite Weighs team. Moderate eating plans were recommended for desired weight loss of less than 50 pounds. In addition to individualized diets, the program also provided options for nutritional shakes, bars, packaged meals, and other supplements.
2. Physical Activity

Participants were asked to engage in regular exercise for a minimum of 60 minutes per day most of days, and asked to keep records of their activity. An exercise log was provided to each patient and reviewed during sessions.

3. Behavioral Therapy

Behavior therapy included instructing patients to set goals, self-monitor, employ stimulus control, solve problems, engage in cognitive restructuring, implement stress management skills learned through the program and use positive reinforcement to enhance adherence to prescribed physical activity, diet and other elements of weight loss program.

4. Adjunctive Weight Loss Medication

Each participant received individual consultation with the supervising physician to determine if adjunctive weight loss medication should be included. The weight loss medication Phentermine was made available for patients to use while in the Lite-Weighs program. Type and duration of medication use was recorded.

5. Intervention Classes

The intervention program provided weekly one hour sessions for 26 weeks. These sessions were divided into blocks of 8 weekly classes. For example, the General Pathway class focused on lifestyle transformation skills, details of dietary, exercise and behavioral elements, and methods of accounting for dietary and exercise behaviors. The Nutritional Pathway class focused on nutritional skills building, understanding carbohydrates, fibers, fat and proteins, food demonstrations, meal planning and calorie requirements. The Wellness Pathway class taught effective methods of
behavior change, combined exercise and nutrition, journal keeping, and increasing fitness. Emotional Brain Training focused on changing the neuronal network which favors maladaptive behaviors such as cravings, emotional overeating, and mastering the skills needed to turn off those drives, to identify and to modify patterns which contribute to unhealthy choices. The outcomes of the initial assessment guided the type and sequence of classes suggested. Classes were offered during day and evening hours to accommodate patient schedules.

C. Data Collection

Archived data from patient records was reviewed and analyzed. For the baseline characteristics, patient medical history questionnaire entries were reviewed and demographics (age, race, marital status, employment, and education) and anthropometric data (height, weight, waist circumference and others) extracted. The presence of obesity-related medical illness (cardiovascular disease, type 2 diabetes, osteoarthritis, and endocrine disorders), and medication use were determined. Family history of obesity, cigarette smoking, physical activity and alcohol use were also recorded. Prior attempted dieting methods were recorded.

For the current program all treatment modalities were recorded including dietary prescription, use of weight loss medication, number of treatment sessions attended and use of diet supplements. At the end of treatment (26 weeks), or whenever the participant dropped out of the study, weight and waist and hip measurements were recorded.

The patients completed questionnaires were added to the data set and scored according to published guidelines. Data was also reviewed for 10 most frequently reported major life events, uplifts and hassles were identified.
Persons with medical contraindications for calorie restricted and fat reduced diets, moderate exercise, and those with active cancer and pregnancy were excluded.

D. Measurements

Height was measured using a wall mounted stadiometer to the last completed 0.1 cm after keeping heels, buttocks, shoulders, and occiput in the vertical plane and head in the anatomic plane. Weight was measured using a digital weighing scale (Perspective Enterprise, Inc.) with minimal lightweight clothing to the closest 100 g. BMI was calculated as weight (kg)/height (m²). Waist circumference was measured with a tape placed around the bare abdomen just above the patient’s hip bone. The patient was instructed to relax and exhale prior to the measurement. Hip circumference was measured same as the waist except for tape position. The tape was placed at the maximal circumference over the buttocks.

E. Data Analysis

Abstracted data was entered using SAS version 9.2 software for Windows. A random 10% sample was re-entered. The dependent variables (changes in weight change, BMI, and waist circumference) were examined for normality; distributions were normal therefore did not require transformations. Descriptive analysis was completed for participants’ baseline variables and expressed as mean +/- standard deviations. An independent sample t-test was used to compare continuous variables in the intervention versus the comparison group. Chi square analysis was used for categorical variables.

Changes in weight, BMI, and waist circumference were calculated and compared between the intervention and comparison groups using the independent t-test (for some of the variables that appear in the descriptive statistics, the distribution was non-normal; for
these variables, the Mann-Whitney test was used. Paired t-tests were used to examine changes in weight, BMI and waist circumference. Multiple linear regression was used to determine if changes in BMI or weight were associated with the psychosocial and behavioral questionnaire scale results; these variables were added to the model. The intent-to-treat approach was used to analyze data, with the last observation carried forward.

Multiple linear regressions were used to evaluate predictors of weight loss, adjusting for covariates. The dependent variables were changes in weight and BMI. Models were adjusted to the baseline value of the corresponding measure. Covariates were checked, and any variables that were significant or that changed the beta coefficient of the treatment variable by 10% were included in the model. Model selection was performed for each of the dependent variables. In addition variables that differed between groups at baseline and after the weight loss intervention were included in the models. The alpha (p-value) ≤ .05 was used as criteria for statistical significance.

F. Results

Baseline characteristics and measures were similar between participants in the intervention versus comparison groups as shown in Table 1. The dropout rate in the intervention group was 16 persons (12.6%) versus 25 persons (16.2%) for the comparison group.

There were no significant differences in weight, BMI, or waist circumference at baseline between the two groups. There was no significant difference between groups in the number of obesity related diseases (Table 1) except for cardiovascular disease. Slightly more intervention group participants had cardiovascular disease than comparison
participants. Lifestyle data (Table 1) revealed no significant differences in the level of physical activity and alcohol consumption between the two groups at the start of the program. However, more subjects in the comparison group had never smoked cigarettes compared to the intervention group. Similarly, more patients in the comparison group were employed than intervention group participants.

During the treatment period, there was a significant difference between the two groups in the number of sessions attended and use of adjunctive weight loss medication, with more participants in the comparison group using weight loss medications. The intervention group attended 12.7 more weekly sessions compared to the comparisons. Intervention group participants used more diet supplements than the comparison group (see Table 2).

There was clinically significant percent reduction in weight or BMI in both groups at 26 weeks. Figure 1 shows a scatter plot of the percent change in weight vs. baseline weight by group. As shown in Table 3, intent-to-treat analysis, those in the intervention group lost 6.68% weight/BMI change vs. 5.84% weight/BMI for the comparison group. However, the treatment effect was not significant in any of measures (percent weight /BMI change) adjusting for covariates (Table 3).

Table 4 shows multiple regression analysis for percent weight change at 26 weeks. Covariates were checked, and any variables that were significant or that changed the beta coefficient of the treatment variable by 10% were included in the model. In addition, monitored variables and baseline patient characteristics that had significant group differences were included in the model.
Baseline weight was predictive of weight loss success. The number of sessions attended was significantly associated with change in weight and change in BMI between baseline and 26 weeks. In addition, adjunctive medication usage was significantly associated with percent weight change, and percent BMI change. Those who attended more sessions or those who used weight medication achieved greater weight loss. Baseline weight and BMI were associated with greater weight loss; those with higher weight/BMI showed greater decrease in percent weight or BMI. There were no effects of quantity of supplement use. In terms of achieving medically significant weight loss 86 persons (55.8%) in the comparison group and 69 (54.33%) in the intervention group lost ≥5%, (p=0.7996), of baseline weight at 26 weeks (see Table 4).

G. Discussion

Findings from this study show no significant difference in percent weight loss between the intervention and comparison groups. The program that offered a financial incentive and required an attendance contract did not promote greater weight loss than the comparison program, but several predictors of success were identified. We found that both weight management programs successfully promoted significant weight loss (≥5%) over a period of 26 weeks. Comparison group participants lost about 6% of their total weight and the intervention group lost about 7%, however, the difference was not statistically significant. It appears that the groups used different strategies to achieve weight loss; the comparison group participants were more likely to use adjunctive weight loss medications, while the intervention group attended more sessions and relied more on program components.
Although the financial support and contractual agreement had no significant effect on weight loss (5.84% in the comparison group vs. 6.68% in the intervention group), there was a strong association between number of sessions attended, use of weight loss medication, initial BMI/weight and percent weight loss. Depression was associated with less success with weight loss.

Previous studies suggest that providing economic incentives improves weight loss program outcomes (Jeffery, et al., 1983; Jeffery, et al., 1984). Volpp, et al., (2008) reported that the use of financial incentives produced significant loss during 16 weeks of intervention. However, our findings are consistent with a meta-analysis of financial incentives on weight loss, which found no significant effect (Paul-Ebhohimhen & Avenell, 2008).

Similarly, a systemic review by Cochrane Database (2008) concluded that there is not enough reliable evidence to recommend the routine use of contracts to improve adherence in health care or other programs.

Weight management interventions that involved signing a contract (Aragona, 1975) reported that subjects in the contract group lost more weight than the control group. Craighead (1989) reported that subjects in the contract and supervised group lost more weight than those in the minimal care group. However, Murphy (1982) found no statistically significant differences in mean weight loss, percentage of excess weight loss and weight reduction index. Our study suggests that although there was no significant difference in percent weight loss between treatment groups which used signed contracts and those which did not, it was associated with higher session attendance.
A previous study by Tsai and Wadden (2005) concluded that weight loss programs should be evaluated for efficacy since many people seek out these programs without sufficient scientific evidence of program success. The study results suggested that the effectiveness of commercial weight loss programs was inconclusive. However, our study findings showed that participants in either the intervention or comparison group could expect to lose >5% of their initial weight, which is clinically significant weight loss.

Multidisciplinary obesity intervention programs that incorporate nutritional guidance (Astrup, et al., 2000; Brehm, et al., 2003; Samaha, et al., 2003; Yu-Poth, et al., 1999), physical activity (Bouchard, et al., 1990; Wing, 1999) and behavior therapy (Klem, et al., 1997; McGuire, et al., 1998; Wyatt, et al., 2002) reported successful levels of weight loss. The rate of weight loss in our study is less than the outcomes of OPTIFAST and Health Management Resources programs, which indicated that intensive multidisciplinary programs induced 15%-25% of the initial weight loss in persons who completed a 3 to 6 month intervention (Anderson et al., 1991, 1994; Wadden, et al., 1992; Walsh & Flynn, 1995). The Diabetes Prevention Program (DPP) trial showed that intensive supervised programs resulted in ≥7% body weight loss in 24 weeks (Diabetes Prevention Research Group, 2002). The results from our intervention group were similar to those found in the DPP study.

Results from our study show that a medically supervised weight loss program that offered financial support and required an attendance contract successfully facilitated a weight loss of about 7% of initial body weight and on average about a 17 lbs. weight loss. It also showed that a self-paced program without an attendance contract or financial
support resulted in clinically significant loss of about 6% (13.9 lbs) of initial weight in 6 months. Evidence from controlled randomized studies shows that weight loss of as little as ≥5% of initial body weight is considered clinically significant because it can improve associated comorbidities (Pi-Sunyer, 1996; Goldstein, 1992; American Diabetes Association [ADA] and National Institute of Diabetes, Digestive, and Kidney Disease [NIDDK], 2002). It takes about 6 months for most patients to achieve a new equilibrium of energy balance (National Institutes of Health [NIH], NHLBI, and the North American Association for the Study of Obesity [NAASO], 2000).

Attendance at intervention sessions and program adherence were related to weight loss success. This is consistent with findings of Jeffery et al. (1993) and Butsch et al. (2007) which indicated that attending more treatment sessions was associated with highest odds of meeting weight loss benchmarks. Wadden et al. (1992) and Perri et al. (1993) also reported similar findings. Our findings also are consistent with a study by Finley et al. (2006), which reported that commercial weight loss programs can be effective for individuals who attend more sessions. With 14-26 weeks of participation, Finley et al. reported about 7.3% (±4.5) weight loss. Participants with frequent contact with interventionists as indicated by number of sessions attended may have better support and compliance that translated into higher weight loss outcomes.

Large numbers of studies have addressed the association between baseline weight/BMI and change in weight/BMI after treatment (Foster, et al., 1998; Galdis, et al., 1998; IOM, 1995; Leibbrand & Fichter, 2002; Traverso, et al., 2000; Wing & Jeffery, 1999). Most studies reported a positive association between higher initial weight/BMI
and greater weight loss after treatment (Teixeira, et al., 2005). Our study supports these findings.

Use of Phentermine, an adjunctive weight loss medication, was strongly associated with weight loss success in both our intervention and comparison groups. In a randomized clinical trial, Munro, et al., (1968) attributed to phentermine therapy a weight loss of about 13% of initial weight compared with 5% for placebo. Weintraup, et al., (1992) in a controlled study reported weight loss success when using a combination of the drugs phentermine and fenfluramine, popularly known as “phen-fen,” when added to a program of diet, exercise and behavior modification. However, this combination of drugs later was associated with valvular heart disease (Connolly, Crary, McGoon, et al., 1997). The drug was removed from the market in 1997. Padwal, et al., (2009) reviewed pharmacotherapy for obese and overweight individuals and reported patients using drug therapy were significantly more likely to achieve >5% weight loss. Studies of the drug Sibutramine have also showed similar efficacy, producing significant weight loss (Bray, 2001). Our findings also show that those taking weight loss medications achieved a higher percent weight loss compared with those who did not. The NIH recommends that drugs should be used in combination with diet, physical activity, and behavior therapy.

In our study, more comparison group participants used weight loss medication (50%) than the intervention group 37%. Thus, a higher percentage of weight loss in comparison group may be attributable to medication use.

Some studies have reported a link between supplement use and weight loss (Metz, Stern, Kris-Etherton, et al., 2000; Wing & Jeffery, 2001). Jeffery et al. (1993) reported participants who used prepackaged meals with other components of weight loss
intervention lost more weight than those who used only a prescribed diet. In this study, there was no significant difference in weight loss between those who used a prescribed diet only vs. prescribed diet plus other supplements such as shakes, packaged meals, nutrition bars and others. These may be attributed to infrequent and minimal supplement use.

The NIH considers weight loss of $\geq 5\%$ of baseline weight in 6 months to be a good outcome for an obese person. By this standard, most participants in both programs achieved progress towards weight loss. Our current study showed that 55.8% of the comparison and 58% of the intervention group achieved $\geq 5\%$ weight loss, which is defined as clinically significant. Studies show that fewer than half of obese and morbidly obese persons attempting to lose significant weight achieve their goal. The current study suggests that weight loss programs such as Lite-weighs can be effective for individuals who attended prescribed intervention sessions and used adjunctive weight loss medication. Depression was found to be an obstacle to weight loss success.

H. Study Limitations

Participants self-selected to both study groups, therefore they could have had similar initial characteristics such as race, gender, dietary habits, and physical activity. This would decrease the heterogeneity of the sample size. The results may not be generalizable due to self-selection and lack of randomization.

The sample size was small and the study was powered to detect differences in weight change between groups rather than differences in physiological markers of weight change. The purpose of the study, which focused on the program as a whole and not the individual components, was to investigate whether an intensive weight management
program enhanced with a contract and financial support for most expenses was associated with clinically significant weight loss in obese and morbidly obese patients. The choice of the comparison group also affects the interpretation of the result. The two study groups may have not been sufficiently different. Controlled trials are needed to assess the efficacy of these weight loss intervention approaches.

In summary, the outcome of this study suggests that a multidisciplinary, medically supervised weight loss program was associated with clinically significant weight loss over a period of six months. The program that was enhanced with a financial incentive and required an attendance contract did not produce greater weight loss than a usual care comparison program. The study also demonstrated adjunctive use of weight loss medication, higher session attendance, and higher initial weight predicted weight loss success. On the other hand, depression was associated with a lack of weight loss success.
REFERENCES


Table 4.1 Characteristics of Participants at Baseline Showing number (percentage) or mean ± standard deviation

<table>
<thead>
<tr>
<th>Variables</th>
<th>Comparison (n = 154)</th>
<th>Intervention (n = 127)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, N (%)</td>
<td>118 (76.6)</td>
<td>104 (81.9)</td>
<td>0.2807</td>
</tr>
<tr>
<td>White, N (%)</td>
<td>96 (62.3)</td>
<td>93 (73.2)</td>
<td>0.0528</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>47.0 (+14.2)</td>
<td>49.8 (+15.6)</td>
<td>0.1212</td>
</tr>
<tr>
<td>Married, N (%)</td>
<td>100 (64.9)</td>
<td>79 (62.2)</td>
<td>0.6357</td>
</tr>
<tr>
<td>Weight, (kg)</td>
<td>105.9 (22.7)</td>
<td>112.0 (27.5)</td>
<td>0.1272</td>
</tr>
<tr>
<td>BMI (kg/m²), mean (SD)</td>
<td>39.4 (+7.1)</td>
<td>40.5 (+8.7)</td>
<td>0.3906</td>
</tr>
<tr>
<td>Waist, mean (SD)</td>
<td>111.2 (+15.5)</td>
<td>115.5 (+20.2)</td>
<td>0.1815</td>
</tr>
<tr>
<td>Hip, mean (SD)</td>
<td>124.3 (+14.9)</td>
<td>129.8 (+18.0)</td>
<td>0.0108</td>
</tr>
<tr>
<td>Waist/Hip ratio, mean (SD)</td>
<td>0.90 (+0.09)</td>
<td>0.89 (+0.09)</td>
<td>0.3194</td>
</tr>
<tr>
<td>Education, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High School or less</td>
<td>80 (52.3)</td>
<td>55 (44.0)</td>
<td>0.3835</td>
</tr>
<tr>
<td>Associate Degree</td>
<td>27 (17.7)</td>
<td>25 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Bachelor's Degree or more</td>
<td>46 (30.1)</td>
<td>45 (36.0)</td>
<td></td>
</tr>
<tr>
<td>Employment, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>125 (82.8)</td>
<td>68 (54.0)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Unemployed/Disabled/Retired</td>
<td>26 (17.3)</td>
<td>58 (46.0)</td>
<td></td>
</tr>
<tr>
<td>Past weight loss attempts*, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, new participants</td>
<td>104 (67.5)</td>
<td>75 (59.1)</td>
<td>0.1413</td>
</tr>
<tr>
<td>Yes, attended previously, N (%)</td>
<td>50 (32.5)</td>
<td>52 (40.9)</td>
<td></td>
</tr>
<tr>
<td>Physical Activity, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>45 (29.4)</td>
<td>25 (19.7)</td>
<td>0.0801</td>
</tr>
<tr>
<td>Mild</td>
<td>49 (32.0)</td>
<td>55 (43.3)</td>
<td></td>
</tr>
<tr>
<td>Moderate/Vigorous</td>
<td>59 (38.6)</td>
<td>47 (37.0)</td>
<td></td>
</tr>
<tr>
<td>Never smoked, N (%)</td>
<td>121 (79.1)</td>
<td>81 (63.8)</td>
<td>0.0045</td>
</tr>
<tr>
<td>No alcohol, N (%)</td>
<td>109 (71.7)</td>
<td>83 (65.4)</td>
<td>0.2537</td>
</tr>
<tr>
<td>Co morbidities* N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>31 (20.3)</td>
<td>26 (20.5)</td>
<td>0.9652</td>
</tr>
<tr>
<td>Thyroid</td>
<td>21 (13.7)</td>
<td>21 (16.5)</td>
<td>0.5121</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>15 (9.8)</td>
<td>27 (21.3)</td>
<td>0.0075</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>59 (38.3)</td>
<td>51 (39.3)</td>
<td>0.6723</td>
</tr>
<tr>
<td>Hypertension</td>
<td>76 (49.4)</td>
<td>58 (45.7)</td>
<td>0.5386</td>
</tr>
<tr>
<td>Depression</td>
<td>57 (37.0)</td>
<td>51 (40.2)</td>
<td>0.5897</td>
</tr>
</tbody>
</table>

* Medically supervised commercial weight loss program
Table 4.2  Weight Loss Intervention During Treatment Period

<table>
<thead>
<tr>
<th>Variables</th>
<th>Comparison (n = 154)</th>
<th>Intervention (n = 127)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet Prescription, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed diet only</td>
<td>51 (33.1)</td>
<td>32 (25.4)</td>
<td>0.1594</td>
</tr>
<tr>
<td>Prescribed diet + additional supplements</td>
<td>103 (66.9)</td>
<td>94 (74.6)</td>
<td></td>
</tr>
<tr>
<td>Weight loss medications, N (%)</td>
<td>77 (50.0)</td>
<td>47 (37.0)</td>
<td>0.0290</td>
</tr>
<tr>
<td>Sessions attended, mean (SD)</td>
<td>6.8 (3.3)</td>
<td>19.4 (6.8)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Number of Supplements*/whole treatment period, mean (SD)</td>
<td>12.9 (30.5)</td>
<td>47.3 (107.4)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

*Recorded in patient file during each purchase made
### Table 4.3 Change in Anthropometric Measures (after – before) using Intent-to-treat Analysis** (Last Observation Carried Forward-LOCF)

<table>
<thead>
<tr>
<th>Measures</th>
<th>Comparison (n = 154)</th>
<th>Intervention (n = 127)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight change (after - before)</td>
<td>-6.23 (6.3)</td>
<td>-7.58 (9.7)</td>
<td>0.5847</td>
</tr>
<tr>
<td>Weight change in percent</td>
<td>-5.84 (5.7)</td>
<td>-6.68 (7.7)</td>
<td>0.7686</td>
</tr>
<tr>
<td>BMI change (after - before)</td>
<td>-2.29 (2.3)</td>
<td>-2.74 (3.5)</td>
<td>0.7333</td>
</tr>
<tr>
<td>BMI change in percent</td>
<td>-5.84 (5.7)</td>
<td>-6.68 (7.7)</td>
<td>0.7686</td>
</tr>
<tr>
<td>Waist change (after - before)</td>
<td>-2.54 (8.7)</td>
<td>-7.19 (9.6)</td>
<td>0.5847</td>
</tr>
<tr>
<td>Waist change in percent</td>
<td>-1.85 (7.6)</td>
<td>-5.98 (7.6)</td>
<td>0.7686</td>
</tr>
</tbody>
</table>

*Change in Anthropometric measure is a negative number

** Mann-Whitney test
Table 4.4 Multiple Regression Analysis of Predictors of change in Weight* (after – before) after 26-weeks

<table>
<thead>
<tr>
<th>Variables</th>
<th>Beta</th>
<th>SE</th>
<th>lower</th>
<th>upper</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-5.552</td>
<td>1.446</td>
<td>-8.400</td>
<td>-2.703</td>
<td>0.0002</td>
</tr>
<tr>
<td>Baseline Weight</td>
<td>-0.079</td>
<td>0.019</td>
<td>-0.116</td>
<td>-0.043</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Treatment group:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention vs. comparison</td>
<td>1.865</td>
<td>1.537</td>
<td>-1.162</td>
<td>4.892</td>
<td>0.2262</td>
</tr>
<tr>
<td>Number of sessions attended</td>
<td>-0.257</td>
<td>0.091</td>
<td>-0.436</td>
<td>-0.078</td>
<td>0.0050</td>
</tr>
<tr>
<td>Weight Medication use vs. not</td>
<td>-2.282</td>
<td>0.927</td>
<td>-4.106</td>
<td>-0.457</td>
<td>0.0144</td>
</tr>
<tr>
<td>Physical Activity:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild vs. none</td>
<td>0.992</td>
<td>1.175</td>
<td>-1.322</td>
<td>3.307</td>
<td>0.3993</td>
</tr>
<tr>
<td>Moderate/vigorous vs. none</td>
<td>0.242</td>
<td>1.150</td>
<td>-2.022</td>
<td>2.506</td>
<td>0.8337</td>
</tr>
<tr>
<td>Employment:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired vs. employed</td>
<td>0.037</td>
<td>1.406</td>
<td>-2.731</td>
<td>2.806</td>
<td>0.9789</td>
</tr>
<tr>
<td>Unemployed vs. employed</td>
<td>0.034</td>
<td>1.274</td>
<td>-2.476</td>
<td>2.544</td>
<td>0.9789</td>
</tr>
<tr>
<td>Thyroid vs. none</td>
<td>1.831</td>
<td>1.256</td>
<td>-0.641</td>
<td>4.304</td>
<td>0.1459</td>
</tr>
<tr>
<td>Depression vs. none</td>
<td>3.656</td>
<td>0.927</td>
<td>1.829</td>
<td>5.482</td>
<td>0.0001</td>
</tr>
<tr>
<td>Quantity of supplements</td>
<td>0.005</td>
<td>0.006</td>
<td>-0.007</td>
<td>0.017</td>
<td>0.3787</td>
</tr>
<tr>
<td>Cardiovascular disease vs. none</td>
<td>2.169</td>
<td>1.332</td>
<td>-0.453</td>
<td>4.791</td>
<td>0.1046</td>
</tr>
<tr>
<td>Smoke: Ever smoker vs. never</td>
<td>-0.214</td>
<td>0.653</td>
<td>-1.500</td>
<td>1.071</td>
<td>0.7429</td>
</tr>
</tbody>
</table>

Cl, confidence interval
SE, standard error
*Change in weight is a negative number
This table will be added as addendum to the dissertation.

**Table 4.5 Multiple Regression Analysis of Predictors of Changes in BMI change** (after -before)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Beta</th>
<th>SE</th>
<th>lower</th>
<th>upper</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-2.057</td>
<td>0.530</td>
<td>-3.101</td>
<td>-1.013</td>
<td>0.0001</td>
</tr>
<tr>
<td>Baseline BMI</td>
<td>-0.069</td>
<td>0.022</td>
<td>-0.111</td>
<td>-0.026</td>
<td>0.0016</td>
</tr>
<tr>
<td>Treatment group:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention vs. comparison</td>
<td>0.616</td>
<td>0.560</td>
<td>-0.487</td>
<td>1.720</td>
<td>0.2724</td>
</tr>
<tr>
<td>Number of sessions attended</td>
<td>-0.091</td>
<td>0.033</td>
<td>-0.157</td>
<td>-0.026</td>
<td>0.0062</td>
</tr>
<tr>
<td>Weight Medication use vs. not</td>
<td>-0.824</td>
<td>0.338</td>
<td>-1.490</td>
<td>-0.158</td>
<td>0.0155</td>
</tr>
<tr>
<td>Physical Activity:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild vs. none</td>
<td>0.347</td>
<td>0.433</td>
<td>-0.506</td>
<td>1.200</td>
<td>0.4235</td>
</tr>
<tr>
<td>Moderate/vigorous vs. none</td>
<td>0.118</td>
<td>0.424</td>
<td>-0.717</td>
<td>0.953</td>
<td>0.7804</td>
</tr>
<tr>
<td>Employment:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired vs. employed</td>
<td>0.031</td>
<td>0.514</td>
<td>-0.982</td>
<td>1.044</td>
<td>0.9514</td>
</tr>
<tr>
<td>Unemployed vs. employed</td>
<td>-0.041</td>
<td>0.466</td>
<td>-0.958</td>
<td>0.877</td>
<td>0.9303</td>
</tr>
<tr>
<td>Thyroid vs. none</td>
<td>0.655</td>
<td>0.459</td>
<td>-0.249</td>
<td>1.559</td>
<td>0.1549</td>
</tr>
<tr>
<td>Depression vs. none</td>
<td>1.371</td>
<td>0.338</td>
<td>0.705</td>
<td>2.038</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Quantity of supplements</td>
<td>0.002</td>
<td>0.002</td>
<td>-0.003</td>
<td>0.006</td>
<td>0.4300</td>
</tr>
<tr>
<td>Cardiovascular disease vs. none</td>
<td>0.743</td>
<td>0.487</td>
<td>-0.216</td>
<td>1.701</td>
<td>0.1282</td>
</tr>
<tr>
<td>Smoke: Ever smoker vs. never</td>
<td>-0.055</td>
<td>0.238</td>
<td>-0.524</td>
<td>0.414</td>
<td>0.8179</td>
</tr>
</tbody>
</table>

CI, confidence interval  
SE, standard error  
*Change in BMI is a negative number
Figure 4.1 Scatter Plot of Percent Change in Weight vs. Baseline Weight by Group
CHAPTER 5
SECOND PUBLISHABLE PAPER

Title:
Psychosocial and Behavioral Predictors of Weight Management for Treatment of Obese and Morbidly Obese Persons

Authors:
Gemechu Abraham Kurfessa, DrPH, MPA
Loma Linda University, School of Public Health
Department of Health Promotion and Education
24951 North Circle Drive, Nichol Hall 1511, Loma Linda, California 92350
gkurfessa01a@llu.edu
(818) 859-8454

Sylvia Cramer, DrPH
Lite-Weighs, Beaver Medical Group
1150 Brookside Avenue, Suite U, Redlands, California 92373
SCramer@epiclp.com
(909) 793-2506

Colwick Wilson, PhD
Loma Linda University, School of Public Health
Department of Counseling & Family Sciences
24951 North Circle Drive, Nichol Hall 1511, Loma Linda, California 92350
cwilson@llu.edu
(909) 558-4598

Serena Tonstad, MD, PhD, MPH
Loma Linda University, School of Public Health
Department of Health Promotion and Education
24951 North Circle Drive, Nichol Hall 1511, Loma Linda, California 92350
stonstad@llu.edu
(909) 558-4741

Susanne Montgomery, PhD, MPH, MS
Loma Linda University,
Behavioral Health Institute, 1686 Barton Road, Redlands, 92373
smontgomery@llu.edu
(909) 558-9586
ABSTRACT

Background and Aims: The prevalence of obesity has more than doubled in the last few decades. Obesity is associated with many health problems. The purpose of this study is to evaluate psychosocial and behavioral predictors of weight loss success in obese and morbidly obese men and women enrolled in a medically supervised weight management program, Lite-Weighs.

Methods and Results: Participants were obese and morbidly obese men and women self-selected to the intervention group, a (n=127, BMI=40.5 ±8.7) comprehensive clinic based program which provided financial support to offset most program costs and required an attendance contract for 26 weekly one-hour sessions. Assessments at baseline and 26 weeks included demographics, anthropometric measures (weight, BMI, waist circumference) and a behavioral and psychosocial questionnaire aimed at exploring correlates of weight loss as measured at post test. Of the 127 patients only 100 (79%) completed the pre-treatment psychosocial and behavioral questionnaire. Participants experienced significant decreases in weight (-7.58kg) and BMI (-2.74 kg/m²) or 6.8%, (p<0.0001) at 26 weeks using intent-to-treat analysis. Multiple linear regression models identified baseline frequency of engaging in weight loss promoting behaviors (engaging in exercise, self-monitoring, eating; p=0.045) and depression (p=0.033) as significant and independent predictors of weight loss. Depression was negatively associated with weight loss. Major life change events, frequency and intensity of daily stressors, and perceived importance of weight loss promoting behaviors were not predictive of weight loss success.
Conclusions: Pretreatment frequency of engaging at various weight loss enhancing behaviors were confirmed as predictors of successful weight loss success while baseline depression was inversely related, suggesting a need for weight loss interventions to concurrently treat depression.
INTRODUCTION

In the last few decades the prevalence of obesity among adults in U.S. has sharply increased (CDC, 2009; Flegal, et al., 2009). In the absence of genetic change, the increase in weight is attributed to behavioral and environmental factors such as diet, exercise, and changes in other lifestyle patterns (Hill, et al., 1998). Predictors of weight management have been examined in the past (Brownell, 1984; Foreyt & Goodrick, 1991). These studies have concluded that predicting weight loss with certainty is difficult and complex. Potentially many factors are involved contributing only a fraction in the change in weight making it difficult to build a single predictive model (Foreyt & Goodrick, 1995; Weiss, 1977). Considering the difficulty of predicting outcomes in obesity treatment additional identification of pre-treatment predictors is essential (Teixeira, et al., 2002).

Studies show that a loss of 5-10% of baseline weight constitutes physiologically significant weight loss (Blackburn, 1995; Goldstein, 1992; Oster, et al., 1999). A review of clinic-based, healthy lifestyle interventions found some programs with significant weight loss (Riebe, et al., 2003). However, systemic reviews of major commercial weight loss programs (Tsai & Wadden, 2005) concluded that the evidence to support the use of such programs is minimal and that it is difficult to predict the efficacy of clinically-based weight-loss programs (Baker & Young, 2006). In 2000, Bish et al. (2005) reported that in the U.S., 46% of women and 33% of men are trying to lose weight. Despite such efforts a significant portion of persons appear unable to prevent or reverse obesity. This calls for developing new solutions to confront this epidemic (Blackburn & Waltman, 2005). Most weight management programs focus on lowering calorie intake. However, it is clear that
calorie reduction alone is not sufficient. Efforts also need to target psychosocial and behavioral factors that may predict failure or success of weight loss.

Successful long-term weight loss is defined as an intentional reduction of 5-10% from baseline maintained for one year (National Institutes of Health, [NIH] 1998). Modest weight loss is achievable in clinical settings and improves a host of health risk factors (Blackburn, 1995; Goldstein, 1992; Oster, et al., 1999), prevents the development of type 2 diabetes, and is achievable in clinical practice. The NIH clinical guidelines (1998) indicate that decreased caloric intake, moderate physical activity, and behavioral therapy constitute vital elements of any effective weight loss and maintenance programs. In addition, multidisciplinary programs that focus on positive lifestyle change and include expertise in health education, nutrition, exercise and behavior change are recommended.

Lite-Weights is a medically supervised, multidisciplinary weight loss program, operated by the Beaver Medical Group in Redlands, CA. The program serves overweight, obese, and morbidly obese patients who are self referred or physician-referred. The program focuses on health education, lifestyle skills development, behavior modification, nutrition, and physical activity. Lite-Weights also provides options for diet supplements and adjunct medications to enhance weight loss.

However, in addition to offering these proven program components it is also important to explore a variety of psychosocial variables which may influence participants’ weight loss as potential pretreatment modifiers, thus helping to identify individuals less likely to succeed at weight loss and match them to the program most appropriate for them to optimize the success of their treatment.
For instance, environmental factors (Price & Gottesman, 1991; Stunkard, et al., 1990) and baseline unhealthy lifestyle behaviors (Flegal, et al., 2001; Hill, et al., 1998) could lead to stressors that greatly impact the homeostasis of the body (Figure 1). When exposed to stress, the brain’s control center, the hypothalamus and brain-stem, stimulates neuronal circuits and endocrine pathways, leading to elevation of glucocorticoid levels. Under chronic exposure this can lead to behavioral and metabolic alterations which can increase energy intake and decrease energy expenditure, resulting in obesity (Tsigos & Chrousos, 2002). Major life events and the readjustment required to cope with changes have been correlated with increased risk of conditions such as obesity (Dohrenwend & Dohrenwend, 1974). This approach is based on the premise that major life changes lead to high levels of stress, which combined with inadequate coping skills can lead to chronic detrimental health outcomes (Holmes & Rahe, 1967).

Thus, a life event scale might be a useful tool to assess the level of stress an individual is experiencing, possibly leading to overeating, weight gain, and subsequent health problems. In addition, daily negative events, or hassles, have been found to have an even greater impact on stress than major life changes (Kanner, et al., 1981). Individuals exposed to daily hassles such as irritating encounters, frustrations, or work pressures may experience negative health outcomes as a result of neurohormonal changes. This in turn increases stress, which may lead to less compliance with a weight loss regimen and thus, limited success. In contrast, daily positive experiences (uplifts) such as supportive encounters with friends and family, may help to counter the effects of hassles, reducing stress and the risk of illness. Individuals with a greater proportion of uplifts to hassles might be in a better position to achieve successful weight loss.
To explore this, we used five different psychosocial and behavioral questionnaires to explore their predictive qualities on success from a medically supervised weight management program. These include measuring pre-treatment levels of perceived importance of engaging in weight loss enhancing behaviors (Becker, et al., 1975), prior engagement in weight loss enhancing behaviors (Wadden, 1993; Wadden, et al., 1992; Wing, 2003), major life events (Holmes & Rahe, 1967), and levels of daily hassles and uplifts (DeLongis, Folkman, & Lazarus, 1988) which might act as modifiers of weight loss success.

The purpose of this study was to investigate whether the outcomes of an intensive intervention program are predicted by pre-treatment identifiable psychosocial and behavioral variables.

METHODS

A. Subjects

Participants were obese and morbidly obese men and women aged 21-75 years with BMI >30 kg/m². Participants were self-referred or physician-referred to the 26-week Lite-Weighs medically supervised weight loss programs. From September 2009 to February 2010 financial support covering most program expenses was available. Support did not cover the cost of meal replacements, physician co-pays, or materials fees ($25 per 8 week class for a total of $75). All referrals in this time period were offered this program and were required to sign a contract promising participation in weekly treatment sessions, as well as the completion of a psychosocial and behavioral questionnaire. Consent to enroll in the study was obtained by the provider and approval for analyses of the de-
identified data base was given by Loma Linda University Institutional Review Board (Appendix F).

B. Treatment

Potential enrollees attended a group orientation session which provided an overview of the program. Those who chose to participate completed an array of medical history assessment forms and agreed to commit to the intervention, signed a behavioral contract to attend 26 weekly one-hour sessions, and completed the pre-treatment psychosocial and behavioral questionnaire. Program content was designed individually by the provider and the patient during the initial consultation period. At subsequent weekly meetings, patients met with the intervention team as indicated. Patients also visited either the Lite-Weighs physician or their own personal physician every 3-4 weeks or sooner if medically indicated.

The goal of the Lite-Weighs treatment program was to support patients in learning and practicing the lifestyle skills and health habits needed to lose weight, maintain weight loss, and improve overall health. The Lite-Weighs program is implemented by an interdisciplinary staff with specialized training in behavior modification, weight management, and exercise physiology. The team includes physicians, preventive care specialists, health educators, medical assistants, and a personal trainer. Personalized attention and follow up care are central to this medically directed program.

The medical weight loss treatment program included dietary modification, physical activity, behavioral therapy, and adjunct weight loss medication. In addition, intervention classes met weekly for one hour sessions for a total of 26 weeks. These sessions focused on wholesome lifestyle transformation skills, stressed exercise and
behavioral elements, and focused on nutritional skills building. The outcomes of the initial assessment guided the type and sequence of classes suggested. Classes were offered during day and evening hours to accommodate patient schedules.

C. Data Collection

Upon intake all information was entered into the patient files. Archived data was reviewed, coded, and analyzed. For the baseline characteristics, patient medical history questionnaire entries were reviewed and demographics (age, race, marital status, employment, and education) and anthropometric data (height, weight, waist circumference and others) were extracted. The presence of obesity-related medical illness (cardiovascular disease, type 2 diabetes, osteoarthritis, and endocrine disorders), and medication use were determined. Family history of obesity, cigarette smoking, physical activity and alcohol use were reviewed and recorded. Prior attempted dieting methods were recorded.

The pretreatment psychosocial and behavioral questionnaires were reviewed and scales constructed. Data was also reviewed for 10 most reported frequently experienced major life events, uplifts and hassles at baseline and at the end of treatment (26 weeks), or whenever the participant dropped out of the study, data was collected regarding weight, waist and hip measurements. In order to test if the change in BMI or weight were associated with psychosocial and behavioral questionnaire scale results, multiple linear regression was used and these variables were added to the model.

We excluded persons with medical contraindications for calorie restricted and fat reduced diets, moderate exercise, and those with active cancer and pregnancy. The main
outcome measure was percent change in weight, but change in BMI and waist circumferences was also calculated.

D. Measures

Participants completed psychosocial and behavioral questionnaires prior to the start of the treatment protocol. This was conducted in quiet study room with an interventionist available to answer any questions.

1. Major Life Change Events Questionnaires

The Life Event Scale (see Appendix C) is designed to predict the likelihood of disease (obesity) and illness and the needed readjustment (weight loss) to return to homeostasis following exposure to stressful life events. Each life event was given a score that indicates the amount of readjustment a person has to make as a result of the event. Not all of the events in the scale were necessarily negative or positive events.

Patients were asked to identify each event that occurred in the past and whether it is related to their current health condition and then record the corresponding score. In case an event has occurred more than once patients were instructed to multiply the score by the number of occurrences. A total score of 300 or more indicates that the patient was at major risk of illness; a score of 150-299 indicates moderate risk for illness (reduced by 30% from the previous risk), and a score of 150 and below has only a slight risk for illness. The higher the score (risk) the higher the burden and the more effort needed by the obese person to return to desirable weight.
2. The Hassles and Uplifts Scale

The Hassles and Uplifts Scale is an alternative method to the traditional life events approach to measuring stressors, and assesses respondents’ attitudes about daily situations. Instead of focusing on highly charged life events, the 53-item scale provides a comfortable way to evaluate positive and negative events that occur in each person's daily life, empowering clients to develop strategies for dealing with hassles and enhancing the occurrence of uplifts. The Uplifts scale suggests how positive aspects of daily life counteract the damaging effects of stress. It is graded 0 to 3 on scale of positive interactions; 1 for somewhat, 2 for quite a bit, and 3 for a great deal, respectively. It takes approximately 10 minutes to complete the scale (Appendix D).

3. Weight Management Behavior Questionnaires

In addition to the questionnaires used to assess the impact of daily and major life events, two weight loss behavior questionnaires were used in this study. Patients were asked to quantify their perceived importance and actual frequency of engaging in 17 different weight loss promoting behaviors (Appendix A and B). The questions focused on three main categories of behaviors: self-monitoring, eating, and exercise. Self-monitoring questions captured data regarding use of food diaries, i.e., tracking calories, measuring food portions, logging exercise and weight values. Dietary habit questions include strictly following menu plans, smaller food portions, meal planning, restaurant eating, and thoughts about healthy eating. Physical activity questions reported whether participants exercised at least 60 minutes per day, participated in supervised sessions on changing exercise-related thinking, and exercised even when not in the mood.
4. Anthropometry

Height was measured using a wall mounted stadiometer to the last completed 0.1 cm after keeping heels, buttocks, shoulders, and occiput in the vertical plane and head in the anatomic plane. Weight was measured using a digital weighing scale (Perspective Enterprise, Inc.) with minimal lightweight clothing to the closest 100 g. BMI was calculated by weight (kg)/height (m²). Waist circumference was measured using a measuring tape; the tape was placed around the bare abdomen just above the patient’s hipbone. The tape was placed snugly but not compressing patient’s skin and held parallel to the floor. The patient was instructed to relax, exhale, and measure their waist. For measuring hip circumference was the tape was placed at the maximal circumference over the buttocks.

E. Data Analysis

Data entry based on patient file abstraction was done by the first author using SAS version 9.2 software for Windows. A random 10% sample was re-entered. The dependent variables (weight change, BMI change, waist circumference change) were examined for normality and the distributions were normal and we did not need to apply transformations. Descriptive analysis was completed for participants’ baseline variables and expressed as mean +/- standard deviations. Paired t-test was used to evaluate the change in weight, BMI and waist circumference at 26 weeks. Chi square analysis was used for categorical variables. Changes in weight, BMI, and waist circumference were calculated. Analyses used the intent-to-treat approach (with last observation carried forward).
Multiple linear regression was utilized to evaluate predictors of weight loss adjusting for covariates. The dependent variable was weight loss. Models were adjusted for baseline weight. Covariates were examined using bi-variable analyses and any variables that were significant or that changed the beta coefficient of the treatment variable by 10% were included in the model. The alpha (p-value) ≤ .05 was used as criteria for statistical significance.

**F. Results**

Descriptive statistics for the study participants (n=127) are summarized in Table 1. The mean age was 51.4 (SD±13.3). At baseline the average weight was 112 kg (SD ±27.5), and average BMI was 40.5 (SD±8.7). Of the 127 participants, only 100 completed the psychosocial and behavioral questionnaires. However, all 100 of these completed the treatment and were thus included in the predictive model. Most participants were female (82%), white (73%), married (62%), had a high school education or less (44%), were employed (54%), had never attempted to lose weight (59%), noted mild activity levels (42%), and never smoked (64%). Mean BMI was 40.5 and many had co-morbidities such as hypertension (46%), depression (40%), high cholesterol (39%), as well as diabetes (21%), cardiovascular diseases (21%) and thyroid disease (17%).

Table 2 shows pretreatment test scores for psychosocial and behavioral factors. The average major life event score at baseline was 331.90 (±183.23) indicating major risk of illness and difficulty in achieving weight loss success. The average hassles intensity score was 1.89 (±0.45) and average uplifts score of 2 (±0.41), showing that intervention group participants experienced a great deal of both hassles and uplifts in daily lives.
Baseline perceived importance of weight loss enhancing behaviors score was on average 70.95 (±8.66) out of a maximum possible score of 119. The subscale scores for perceived importance of self-monitoring, eating, and exercise behaviors were 23.41 (±4.56) of maximum 30 points, 26.21 (±3.03) of maximum 30 points, and 21.59 (±2.58) of maximum 25 points respectively.

In contrast, the average score for frequency of engaging in weight loss enhancing behaviors prior to the start of the intervention was 51.27 (±21.76) out of a maximum possible score of 119. The scores for the subscales of actual engagement in weight loss promoting behaviors at base line were 14.65 (±9.78) of 42 possible for self-monitoring; 24 (±9.15) of 42 possible for eating, and 15.22 (±7.87) of 35 possible for exercise behaviors. Table 4 shows the 10 most frequently reported major life change events, daily hassles and daily uplifts.

There was clinically significant reduction in weight (-7.58kg) and BMI (-2.74 kg/m²) or 6.8%, (p<0.0001) at 26 weeks (Table 3). Among the psychosocial and behavioral scales only pre-treatment frequency of engaging in weight loss enhancing behaviors related to self-monitoring, exercise, and eating; lower scores on depression (Table 5) also were associated with successful weight loss (p=0.045). Scores for major life change events and frequency and intensity of daily hassles and uplifts did not predict weight loss success. Depression was negatively associated with weight loss (p=0.034).

G. Discussion

The aim of this study was to evaluate the association between several psychosocial pretreatment predictors and success in weight loss in obese and morbidly obese patients. The benefits of identifying moderators and mediators of weight loss could
lead to a new generation of interventions (Bauman, et al., 2002; Baranowski, et al, 1999).

Significant predictors of success included pre-treatment levels of engagement in weight loss-enhancing behaviors such as eating and self-monitoring of physical activity. The perceived importance of self-monitoring, eating and exercise behaviors did not show significant effect on outcomes. This is consistent with the findings of Mathur (2007). Similarly, levels of major life change events, hassles and uplifts frequency & intensity were not predictive of weight increase or decrease. Notably, baseline depression, which was highly prevalent (40%), was predictive of lack of weight loss success.

Researchers Tsai and Wadden (2005) have recommended that weight loss programs be evaluated for efficacy since many obese individuals seek them out without sufficient scientific evidence of program success.

Our findings regarding the association between pre-treatment levels of actual engagement in weight loss promoting behaviors and weight loss success is in harmony with previous studies. Engaging in behaviors that promote weight loss such as decreasing portions, monitoring calorie intake, or using nutritional supplements (Astrup, et al., 2000; Brehm, et al., 2003; Samaha, et al., 2003, Yu-Poth, et al., 1999), physical activity (Boucard, et al., 1990; Wing, 1999) and behavior therapy, (Klem, et al., 1997; McGiure, et al., 1998; Wyatt, et al., 2002) were found to be associated with successful weight loss outcomes. Clearly, those who had demonstrated engagement in weight loss behaviors by attempting to lose weight in the past were more successful, suggesting the need for participants to give even clinical weight loss programs multiple tries.

Teixeira, et al., (2002) showed that exercise related variables predicted weight loss success and the sub-scale analysis on exercise in our study also predicted weight
loss. However, in another study, Teixeira et al. (2004) found that exercise related variables did not predict weight loss.

There is ample evidence of a relationship between the number of stressful life events experienced by an individual and their effects on physical and psychosocial well-being. The Holmes-Rahe scale (Kale & Stenmark, 1983) measures life events in terms of the changes and readjustment required to return an individual to homeostasis. On average our study found that nearly all of our participants experienced severe levels of major life events which could have contributed to a ceiling effect, thus not showing this variable as important in a multi-variable model.

Additionally, when daily hassles and uplifts were explored by Kanner et al. (1981) and DeLongis et al. (1982), they found that hassles, defined as minor but more frequent stressors, have a more profound effect and are more predictive of health outcomes than major life events. While our study did not find an association between the frequency and intensity of daily hassles and uplifts and weight loss, data showed that individuals who were diagnosed with depression were less likely to achieve clinically significant weight loss.

Participant’s score on the Hassles and Uplifts scale indicates that they appear to understand the importance of weight loss promoting behaviors. However, this did not translate to practicing these behaviors as indicated by the lower test scores for the frequency of engaging in weight loss promoting behaviors compared to higher test scores for perceived importance of the behaviors. In addition, the list of the 10 most frequently reported major life events and daily hassles and uplifts provide a potential target for
interventions aimed at mitigating their effects by helping patients develop effective coping skills.

Overall, results from this study demonstrate that a medically supervised comprehensive obesity intervention program that incorporates nutritional, physical activity and behavior modification successfully facilitated a weight loss of about 7% of initial weight. This is considered clinically significant due to association in changes with obesity related health parameters.

There are large individual differences in obesity treatment outcomes. Attempts to identify predicting variables may be vital to improving treatment protocols. While several pre-treatment variables were evaluated as predictors of weight loss, only baseline level of engaging in weight loss promoting behaviors (eating, exercise, and self-monitoring) and depression were confirmed as a negative predictor of weight loss, suggesting that clinicians need to be aware of and build on past dieting and life style experiences, and address the effects of baseline depression on weight loss interventions.

H. Study Limitations

Participants were self-selected in the study and not randomly assigned to groups, affecting the generalizability of the results. However, this is the case in most clinical and commercial weight loss programs. Participants were free living and other influences on weight were not controlled. Patients may have exaggerated responses in order to elicit sympathy, while some respondents may be too embarrassed to reveal private details or may have under-reported the severity or frequency of health related information. The number of questions in the English-language only questionnaire may also have
influenced compliance with completing the questionnaires. The strength of this study is the a priori selection of variables to be analyzed as predictors and the low dropout rate.
REFERENCES


### Table 5.1 Characteristics of Weight Loss in Lite Weighs Participants at Baseline

<table>
<thead>
<tr>
<th>Variables</th>
<th>Intervention (n = 127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, N (%)</td>
<td>104 (81.9)</td>
</tr>
<tr>
<td>White, N (%)</td>
<td>93 (73.2)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>49.8 (±15.6)</td>
</tr>
<tr>
<td>Married, N (%)</td>
<td>79 (62.2)</td>
</tr>
<tr>
<td>Weight, (kg)</td>
<td>112.0 (27.5)</td>
</tr>
<tr>
<td>BMI ( kg/m²), mean (SD)</td>
<td>40.5 (±8.7)</td>
</tr>
<tr>
<td>Waist, mean (SD)</td>
<td>115.5 (±20.2)</td>
</tr>
<tr>
<td>Hip, mean (SD)</td>
<td>129.8 (±18.0)</td>
</tr>
<tr>
<td>Waist/Hip ratio, mean (SD)</td>
<td>0.89 (±0.09)</td>
</tr>
<tr>
<td>Education, N (%)</td>
<td></td>
</tr>
<tr>
<td>High School or less</td>
<td>55 (44.0)</td>
</tr>
<tr>
<td>Associate Degree</td>
<td>25 (20.0)</td>
</tr>
<tr>
<td>Bachelor’s Degree or more</td>
<td>45 (36.0)</td>
</tr>
<tr>
<td>Employment, N (%)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>68 (54.0)</td>
</tr>
<tr>
<td>Unemployed/Disabled/Retired</td>
<td>58 (46.0)</td>
</tr>
<tr>
<td>Past weight loss attempts*, N (%)</td>
<td></td>
</tr>
<tr>
<td>No, new participants</td>
<td>75 (59.1)</td>
</tr>
<tr>
<td>Yes, attended previously, N (%)</td>
<td>52 (40.9)</td>
</tr>
<tr>
<td>Physical Activity, N (%)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>25 (19.7)</td>
</tr>
<tr>
<td>Mild</td>
<td>55 (43.3)</td>
</tr>
<tr>
<td>Moderate/Vigorous</td>
<td>47 (37.0)</td>
</tr>
<tr>
<td>Never smoked, N (%)</td>
<td>81 (63.8)</td>
</tr>
<tr>
<td>No alcohol, N (%)</td>
<td>83 (65.4)</td>
</tr>
<tr>
<td>Co-morbidities* N (%)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>26 (20.5)</td>
</tr>
<tr>
<td>Thyroid</td>
<td>21 (16.5)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>27 (21.3)</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>51 (39.3)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>58 (45.7)</td>
</tr>
<tr>
<td>Depression</td>
<td>51 (40.2)</td>
</tr>
</tbody>
</table>

*Medically supervised commercial weight loss program
### Table 5.2 Pretreatment Scores for Psychosocial and Behavioral Variables

<table>
<thead>
<tr>
<th>Variables/ Behaviors</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Event Score</td>
<td>331.90</td>
<td>183.23</td>
</tr>
<tr>
<td>Hassle Intensity</td>
<td>1.89</td>
<td>0.45</td>
</tr>
<tr>
<td>Uplift Intensity</td>
<td>2.00</td>
<td>0.41</td>
</tr>
<tr>
<td>Hassle Frequency</td>
<td>21.35</td>
<td>9.64</td>
</tr>
<tr>
<td>Uplift Frequency</td>
<td>24.11</td>
<td>11.45</td>
</tr>
<tr>
<td>Perceived Importance of Weight Loss Behaviors (self-monitoring, eating and exercise)</td>
<td>70.95</td>
<td>8.66</td>
</tr>
<tr>
<td><strong>Sub-Scores</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived importance of Self-Monitoring</td>
<td>23.41</td>
<td>4.56</td>
</tr>
<tr>
<td>Perceived importance of Eating Behaviors</td>
<td>26.21</td>
<td>3.03</td>
</tr>
<tr>
<td>Perceived importance of Exercise Behaviors</td>
<td>21.59</td>
<td>2.58</td>
</tr>
<tr>
<td>Frequency of Weight Loss promoting Behaviors (self-monitoring, eating and exercise)</td>
<td>51.27</td>
<td>21.76</td>
</tr>
<tr>
<td><strong>Sub-Scores</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of Self-monitoring Behaviors</td>
<td>14.65</td>
<td>9.78</td>
</tr>
<tr>
<td>Frequency of Eating Behaviors</td>
<td>24.00</td>
<td>9.15</td>
</tr>
<tr>
<td>Frequency of Exercise Behaviors</td>
<td>15.22</td>
<td>7.87</td>
</tr>
</tbody>
</table>
Table 5.3 Change in Anthropometric Measures (after – before)

<table>
<thead>
<tr>
<th>Measures</th>
<th>Intervention (n = 127)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight change (after - before)</td>
<td>-7.58 (9.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Weight change in percent</td>
<td>-6.68 (7.7)</td>
<td></td>
</tr>
<tr>
<td>BMI change (after - before)</td>
<td>-2.74 (3.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>BMI change in percent</td>
<td>-6.68 (7.7)</td>
<td></td>
</tr>
<tr>
<td>Waist change (after - before)</td>
<td>-7.19 (9.6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Waist change in percent</td>
<td>-5.98 (7.6)</td>
<td></td>
</tr>
</tbody>
</table>

*Change in Anthropometric measure is a negative number
Base on Paired t-test analysis
### Table 5.4 Top 10 frequently reported Major Life Change Events, Daily Hassles and Daily Uplifts

<table>
<thead>
<tr>
<th>Rank</th>
<th>Life Change Events</th>
<th>F Hassles</th>
<th>F Uplifts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Change in eating habits</td>
<td>50 Your physical appearance</td>
<td>Home entertainment (e.g., 73 TV, music, reading)</td>
</tr>
<tr>
<td>2</td>
<td>Personal injury or illness</td>
<td>49 Exercise(s)</td>
<td>72 Exercise(s)</td>
</tr>
<tr>
<td>3</td>
<td>Death of close Family members</td>
<td>Taking care of paper work</td>
<td>Recreation and 66 entertainment outside the 64</td>
</tr>
<tr>
<td>4</td>
<td>Change in health of family member</td>
<td>44 Your health</td>
<td>61 Your child(ren) 62</td>
</tr>
<tr>
<td>5</td>
<td>Change in Finance</td>
<td>Enough money for necessities (e.g., food, clothing, etc)</td>
<td>59 Time spent with family 61</td>
</tr>
<tr>
<td>6</td>
<td>Mortgage over $100,000</td>
<td>38 Your physical abilities</td>
<td>Enough money for necessities (e.g., food, clothing, etc) 61</td>
</tr>
<tr>
<td>7</td>
<td>Change in sleeping habits</td>
<td>37 emergencies</td>
<td>57 Your friend(s) 60</td>
</tr>
<tr>
<td>8</td>
<td>Change in responsibilities at work</td>
<td>32 House work</td>
<td>55 Eating (at home) 60</td>
</tr>
<tr>
<td>9</td>
<td>Vacation</td>
<td>32 Being organized</td>
<td>54 Pets 59</td>
</tr>
<tr>
<td>10</td>
<td>Change in living condition</td>
<td>31 Being organized</td>
<td>53 Amount of free time 58</td>
</tr>
</tbody>
</table>

F=frequency
### Table 5.5 Multiple Regression Analysis for BMI change (after - before)-Using Hassle/Uplift, (n=100)

<table>
<thead>
<tr>
<th></th>
<th>Beta</th>
<th>SE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-2.350</td>
<td>3.496</td>
<td>0.5032</td>
</tr>
<tr>
<td>Baseline Weight</td>
<td>-0.074</td>
<td>0.042</td>
<td>0.0863</td>
</tr>
<tr>
<td>Number of Sessions attended</td>
<td>0.003</td>
<td>0.075</td>
<td>0.9735</td>
</tr>
<tr>
<td>Weight Medication use vs. not</td>
<td>-0.820</td>
<td>0.767</td>
<td>0.2877</td>
</tr>
<tr>
<td>Physical Activity: Mild vs. not</td>
<td>0.489</td>
<td>0.984</td>
<td>0.6207</td>
</tr>
<tr>
<td>Physical Activity: Moderate/vigorous vs. not</td>
<td>-0.002</td>
<td>1.059</td>
<td>0.9985</td>
</tr>
<tr>
<td>Thyroid vs. none</td>
<td>0.434</td>
<td>1.027</td>
<td>0.6739</td>
</tr>
<tr>
<td>Depression vs. none</td>
<td>1.613</td>
<td>0.748</td>
<td>0.0338</td>
</tr>
<tr>
<td>Life Event score</td>
<td>0.001</td>
<td>0.002</td>
<td>0.6341</td>
</tr>
<tr>
<td>Hassle Frequency score</td>
<td>-0.017</td>
<td>0.047</td>
<td>0.7133</td>
</tr>
<tr>
<td>Uplift Frequency score</td>
<td>0.064</td>
<td>0.039</td>
<td>0.1038</td>
</tr>
<tr>
<td>Perceived importance of weight loss behaviors</td>
<td>0.020</td>
<td>0.043</td>
<td>0.6420</td>
</tr>
<tr>
<td>Frequency of Weight Loss promoting Behaviors (self-monitoring, eating and exercise)</td>
<td>-0.040</td>
<td>0.020</td>
<td>0.0455</td>
</tr>
</tbody>
</table>

SE, standard error
CHAPTER 6
CONCLUSION

A. Summary and Limitations

Findings from this study suggest that both weight management approaches (the intervention group and the comparison group) successfully promoted clinically significant weight loss (≥5%) over a period of 26 weeks. The program that offered a financial support and required an attendance contract (intervention group) lost about 7% of their body weight and the usual care program (comparison) lost about 6%. This difference was not statistically significant. The program that offered a financial incentive and required an attendance contract did not promote statistically significant weight loss than the comparison usual care program, but several predictors of success were identified. It appears that both groups utilized different strategies (pathways) to achieve weight loss. Comparison group participants depended more on adjunctive weight loss medication use, while the intervention group attended more intervention sessions and depended more on behavior modification strategies.

Although the financial support and contractual agreement had no significant effect on weight loss, there was a strong association between the number of sessions, use of weight loss medication, BMI/weight at baseline and percent weight loss. Depression was associated with less success in weight loss.

The pretreatment evaluation of possible psychosocial and behavioral predictors identified baseline levels of engagement in weight loss enhancing behaviors such as self-monitoring, physical activity and diet as predictors of weight loss. However, perceived importance of self-monitoring, eating and exercise behaviors did not predict weight loss.
Similarly, levels of major life change events and the frequency and intensity of hassles and uplifts were not associated with weight loss. However, we did find that participants who were diagnosed with depression were less likely to achieve clinically meaningful weight loss. Interestingly, while this was not associated with weight loss, we found that participants had experienced severe levels of major life events and high levels of daily hassles in the past which may have contributed to their obesity. The study did not evaluate the improvement in the psychosocial and behavioral predictors post-intervention.

This study has several limitations. Participants were free living and other influences on weight were not controlled. The study may be partially limited due to self-reporting bias. Patients could have exaggerated responses in order to elicit sympathy, may have been too embarrassed to reveal private details, or may have under-reported the severity or frequency of health related information in order to minimize their problems. Participants self-selected into the study and chose the type of intervention they wanted resulting in non-random group assignment. The length of the questionnaire and language (English only) could have influenced compliance with completing the questionnaires. However, the clinical data and data on medication and product use were based on patient records and thus lacked self-reporting bias.

We did not evaluate specific intervention components such as physical activity, nutrition, behavior and other lifestyle modifying therapies. Only the outcomes of the overall program were examined as to the differences in the two approaches with respect to weight loss. The sample was powered to detect differences in percent weight change between groups rather than differences in physiological markers of weight change. The
purpose of the study was to investigate whether an intensive weight management program offered with financial support to offset program costs was associated with clinically significant weight loss in obese and morbidly obese patients.

B. Future Studies

Overall our patient population across the two groups was very homogeneous. Future studies should seek to address race and ethnicity as a factor in overweight and obesity. While obesity is prevalent in the general population, obesity rates are tend to be higher among minority populations. Randomization of participant’s conditions also was needed. Future studies should also evaluate the effect of components of treatment such as physical activity, behavior, diet, and cognitive and other types of therapy. We found that in our control group weight loss medication was associated with nearly as significant weight loss as in the intervention group. Future randomized studies comparing weight loss medication use with behavioral intervention alone could help evaluate the impact of these strategies of achieving weight loss. Appropriate power is recommended to capture adequate effect size of intervention features. In our case nearly 80% of participants completed the programs; however, power was still impacted as we did not recruit as many participants as originally hoped. Identifying psychosocial and behavioral predictors could help to match treatment components with individual needs and reduce variance of individual results in obesity treatment. Comparing pre-treatment and post-treatment levels of predicting factors for engaging in weight loss enhancing behaviors could help measure the association with outcomes due to intervention.
C. Conclusions and Implications

This study has shown that an intensive medically supervised contractual weight management program is effective in achieving clinically recommended weight loss. Nevertheless, control group members who designed their own program still achieved similar results as the intervention group, which had received financial support and an attendance contract. In general, commercially available weight loss program results are suboptimal. Thus, a clinically delivered but self-managed program can be as successful as a more structured intervention. The study also showed that pretreatment levels of engaging in weight loss enhancing lifestyle behaviors were associated with the success of the weight loss effort. Clearly, while patients in their past may have failed to achieve significant weight loss, their efforts were not in vain; previous attempts helped make the intervention more successful.

In sum, a weight loss program, whether structured or flexible, that is implemented with the aid of experienced weight loss staff helping guide the patient through the experience is effective in achieving weight loss. It is significant that while one does not need a structured (often quite costly) program, that the type of support given to our control group (standard care) that is covered by most insurance providers is nevertheless associated with significant weight loss success.
REFERENCES


Appendix A. Weight Loss Behaviors Questionnaire

Weight Loss Behaviors-Lite-Weighs

Name

Directions: The following items ask about what you believe to be important behaviors for successful weight loss and weight maintenance. Please read each statement carefully and answer all items. For each item, please indicate how important you believe or feel that each behavior will contribute to your weight loss success by using the following scale:

<table>
<thead>
<tr>
<th>Behaviors</th>
<th>Not at all Important</th>
<th>Somewhat Important</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To use a diary to write down everything I eat or drink every day.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. To follow menu plans when making food choices.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. To keep track of the number of calories I eat.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. To keep track of the amount of fat I eat.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. To measure my food portions using scales, spoons, cups, etc.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. To purposely eat smaller portions of food.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. To attend group weight loss meetings each week.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. To keep track of the exercise I do.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. To exercise at least 30 minutes every day</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. To take time to plan my meals.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11. To participate in supervised exercise sessions at the weight loss clinic.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12. To modify the way I cook and prepare food.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13. To eat out in restaurants less often than I currently do</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14. To change my schedule to make exercise time a priority.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15. To exercise even when I don’t feel like it</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16. To change my thoughts related to healthy eating and physical activity</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17. To weigh myself at least once a week.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix B. Behavior Frequency Questionnaire

Behavior Frequency Questionnaire-Lite Weighs

Name____________________

Directions: The following items relate to how often you engage in each of the specific behaviors. Please read each statement carefully and answer all items. For each item, please indicate on average how many days per week (0-7) you engaged in each specific behavior during the last four weeks.

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Circle the number indicating how many times per week you have engaged in the behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To use a diary to write down everything I eat or drink.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>2. To follow menu plans when making food choices</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>3. To record the number of calories I eat.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>4. To record the amount of fat I eat.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>5. To measure my food portions using scales, spoons, cups, etc.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>6. To purposely eat smaller portions of food.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>7. To attend group weight loss meetings.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>8. To record the exercise I do.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>9. To exercise at least 30 minutes at a moderate intensity</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>10. To take time to plan my meals.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>11. To participate in supervised exercise sessions at the weight loss clinic.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>12. To modify the way I cook and prepare food.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>13. To eat out in restaurants less often than I currently do.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>14. To change my schedule to make exercise time a priority.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>15. To exercise even when I don’t feel like it.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>16. To change my thoughts related to eating and physical activity.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
<tr>
<td>17. To weigh myself.</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
</tbody>
</table>

Adopted from: Mathur, M., Perceived Importance of and Willingness to Engage In weight loss behaviors among overweight adults. 2007.
Appendix C. Holmes and Rahe Life Events Scale

NAME ____________________________

Life Events Scale

Lite-Weighs, Beaver Medical Group

The "Life Events Scale" measures the amount of change, measured in life change units, a person has experienced and adjusted to in the past. The aim is to identify which of these events you have experienced in the past which may have affected your overall health.

Directions

Read each of the events listed on the next page, and circle the amount next to any event which has occurred in your life in the last two or more years. You may want to consider extending the timeline (e.g. 5yrs, 10yrs or more), if you believe it might be relevant to your current weight or other obesity related conditions. If an event occurred more than once, multiply the score for that event by the number of times that the event occurred.

<table>
<thead>
<tr>
<th>Life Events</th>
<th>Life Changes Units</th>
<th>Years since event</th>
<th>Life Events</th>
<th>Life Changes Units</th>
<th>Years since event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death of spouse</td>
<td>100</td>
<td></td>
<td>Son or daughter leaving home</td>
<td></td>
<td>29</td>
</tr>
<tr>
<td>Divorce</td>
<td>73</td>
<td></td>
<td>Trouble with in-laws</td>
<td></td>
<td>29</td>
</tr>
<tr>
<td>Martial separation</td>
<td>65</td>
<td></td>
<td>Outstanding personal achievement</td>
<td></td>
<td>28</td>
</tr>
<tr>
<td>Jail term</td>
<td>63</td>
<td></td>
<td>Wife begins or stops work</td>
<td></td>
<td>26</td>
</tr>
<tr>
<td>Death of close family member</td>
<td>63</td>
<td></td>
<td>Begin or end school</td>
<td></td>
<td>26</td>
</tr>
<tr>
<td>Personal injury or illness</td>
<td>53</td>
<td></td>
<td>Change in living conditions</td>
<td></td>
<td>25</td>
</tr>
<tr>
<td>Marriage</td>
<td>50</td>
<td></td>
<td>Revision in personal habits</td>
<td></td>
<td>24</td>
</tr>
<tr>
<td>Fired at work</td>
<td>47</td>
<td></td>
<td>Trouble with boss</td>
<td></td>
<td>23</td>
</tr>
<tr>
<td>Marital reconciliation</td>
<td>45</td>
<td></td>
<td>Change in work hours or conditions</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>Retirement</td>
<td>45</td>
<td></td>
<td>Change in residence</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>Change in health of a family member</td>
<td>44</td>
<td></td>
<td>Change in schools</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>40</td>
<td></td>
<td>Change in recreation</td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>Sex Difficulties</td>
<td>39</td>
<td></td>
<td>Change in church activities</td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>Gain of new family member</td>
<td>39</td>
<td></td>
<td>Change in social activities</td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>Business readjustment</td>
<td>39</td>
<td></td>
<td>Mortgage or loan less than $30,000</td>
<td></td>
<td>17</td>
</tr>
<tr>
<td>Change in financial state</td>
<td>38</td>
<td></td>
<td>Change in sleeping habits</td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>Death of close friend</td>
<td>37</td>
<td></td>
<td>Change in number of family get-togethers</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Change to different line of work</td>
<td>36</td>
<td></td>
<td>Change in eating habits</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Change in number of arguments with spouse</td>
<td>35</td>
<td></td>
<td>Vacation</td>
<td></td>
<td>13</td>
</tr>
<tr>
<td>Mortgage over $100,000</td>
<td>31</td>
<td></td>
<td>Christmas alone</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Foreclosure of mortgage or loan</td>
<td>30</td>
<td></td>
<td>Minor violations of the law</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>Change in responsibilities at work</td>
<td>29</td>
<td></td>
<td>TOTAL SCORE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Appendix D. The Hassles and Uplifts Scale

The Hassles and Uplifts Scale – Lite Weighs

NAME

HASSLES are irritants—things that annoy or bother you; they can make you upset or angry.

UPLIFTS are events that make you feel good; they can make you joyful, glad, or satisfied. Some hassles and uplifts occur on a fairly regular basis and others are relatively rare. Some have only a slight effect, while others have a strong effect.

This questionnaire lists things that can be hassles and uplifts in day-to-day life. You will find that during the course of a day some of these things will have been only a hassle for you and some will have been only an uplift. Others will have been both a hassle AND an uplift.

DIRECTIONS: Please think about how much of a hassle and how much of an uplift each item was for you today. Please indicate on the left-hand side of the page (under “HASSLES”) how much of a hassle the item was by circling the appropriate number. Then indicate on the right-hand side of the page (under “UPLIFTS”) how much of an uplift it was for you by circling the appropriate number. Remember, circle one number on the left-hand side of the page and one number on the right-hand side of the page for each item.

PLEASE FILL OUT THIS QUESTIONNAIRE TODAY

How much of a hassle was this item for you today?
How much of an uplift was this item for you today?
**HASSLES**

| Number | Description                                      | UPLIFTS
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None or not applicable</td>
<td>0 = None or not applicable</td>
</tr>
<tr>
<td>1</td>
<td>Somewhat</td>
<td>1 = Somewhat</td>
</tr>
<tr>
<td>2</td>
<td>Quite a bit</td>
<td>2 = Quite a bit</td>
</tr>
<tr>
<td>3</td>
<td>A great deal</td>
<td>3 = A great deal</td>
</tr>
</tbody>
</table>

**DIRECTIONS:** Please circle one number on the left-hand side and one number on the right-hand side for each item.

**HASSLES**  
[Numbers]  

**CATEGORIES**  
[Numbers]

1. Your child(ren)  
2. Your parents or parents-in-law  
3. Other relative(s)  
4. Your spouse  
5. Time spent with family  
6. Health or well-being of a family member  
7. Sex  
8. Intimacy  
9. Family-related obligations  
10. Your friend(s)  
11. Fellow workers  
12. Clients, customers, patients, etc.  
13. Your supervisor or employer  
14. The nature of your work  
15. Your work load  
16. Your job security  
17. Meeting deadlines or goals on the job  
18. Enough money for necessities (e.g., food, clothing, housing, health care, taxes, insurance)  
19. Enough money for education  
20. Enough money for emergencies  
21. Enough money for extras (e.g., entertainment, recreation, vacations)  
22. Financial care for someone who doesn't live with you  
23. Investments  
24. Your smoking  
25. Your drinking  
26. Mood-altering drugs  
27. Your physical appearance  

150
<table>
<thead>
<tr>
<th>HASSLES</th>
<th>Categories</th>
<th>UPLIFTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3</td>
<td>28. Contraception</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>29. Exercise(s)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>30. Your medical care</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>31. Your health</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>32. Your physical abilities</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>33. The weather</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>34. News events</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>35. Your environment (e.g., quality of air, noise level, greenery)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>36. Political or social issues</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>37. Your neighbourhood (e.g., neighbours, setting)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>38. Conserving (gas, electricity, water, gasoline, etc.)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>39. Pets</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>40. Cooking</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>41. Housework</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>42. Home repairs</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>43. Yardwork</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>44. Car maintenance</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>45. Taking care of paperwork (e.g., paying bills, filling out forms)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>46. Home entertainment (e.g., TV, music, reading)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>47. Amount of free time</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>48. Recreation and entertainment outside the home (e.g., movies, sports, eating out, walking)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>49. Eating (at home)</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>50. Church or community organizations</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>51. Legal matters</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>52. Being organized</td>
<td>0 1 2 3</td>
</tr>
<tr>
<td>0 1 2 3</td>
<td>53. Social commitments</td>
<td>0 1 2 3</td>
</tr>
</tbody>
</table>

## Appendix E. Proposed Budget

<table>
<thead>
<tr>
<th>Items</th>
<th>Justification</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAS software</td>
<td>Data Entry and Analysis</td>
<td>$250.00</td>
</tr>
<tr>
<td>Stationary</td>
<td>Supplies</td>
<td>$300.00</td>
</tr>
<tr>
<td>Computer Note book</td>
<td>Data collection and Entry</td>
<td>$1700.00</td>
</tr>
<tr>
<td>Travel</td>
<td>Travel to Beaver Medical Group</td>
<td>$500.00</td>
</tr>
<tr>
<td></td>
<td>Travel to LLU for conferences</td>
<td></td>
</tr>
<tr>
<td>Xerox</td>
<td>Questionnaires</td>
<td>$500.00</td>
</tr>
<tr>
<td>Statistician</td>
<td>Data Analysis</td>
<td>$600.00</td>
</tr>
<tr>
<td>Editing</td>
<td>Editing</td>
<td>$450.00</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>Food and other amenities</td>
<td>$350.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$4650.00</strong></td>
</tr>
</tbody>
</table>
Appendix F. Institutional Review Board Approval

INSTITUTIONAL REVIEW BOARD
Exempt Notice

Montgomery, Susanne B
Health Promotion & Education
Protocol: Impact of a medically supervised weight management program on obese and
morbidly obese persons: Lite-Weights, beaver medical group program

Your application for the research protocol indicated above was reviewed administratively on behalf of
the IRB. This protocol is determined to be exempt from IRB approval as outlined in federal regulations
for protection of human subjects, 45 CFR Part 46.101(b)(4)

Stipulations: Dr. Cramer will disclose relationship to Lite-Weights in publication,
presentation resulting from this study.

Please note the PI's name and the IRB number assigned to this IRB protocol (as indicated
above) on any future communications with the IRB. Direct all communications to the IRB c/o
the Office of Sponsored Research.

Although this protocol is exempt from further IRB review as submitted, it is understood that all
research conducted under the auspices of Loma Linda University will be guided by the highest
standards of ethical conduct.

Signature of IRB Chair/Designee.

Date:

IRB Chair:
Rhonda L. Riggsby, M.D.
Department of Medicine
Office of Sponsored Research

IRB Administrator:
Linda U. Hastedt, M.A., Director
Office of Sponsored Research

IRB Specialist:
Mark Tedeschi
Office of Sponsored Research

Loma Linda University, Department of Health Sciences Center
Loma Linda University Medical Center
Loma Linda, CA 92350

UNIVERSITY LIBRARIES
LOMA LINDA, CALIFORNIA

153