

IS A FAST OR SLOW RATE OF WEIGHT LOSS ASSOCIATED WITH GREATER  
LONG-TERM WEIGHT LOSS MAINTENANCE? THE EFFECTS OF PRESCRIBING  
MILD OR MODERATE CALORIE RESTRICTION GOALS

By

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A DISSERTATION PRESENTED TO THE GRADUATE SCHOOL  
OF THE UNIVERSITY OF FLORIDA IN PARTIAL FULFILLMENT  
OF THE REQUIREMENTS FOR THE DEGREE OF  
DOCTOR OF PHILOSOPHY

UNIVERSITY OF FLORIDA

2012

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To everyone who supported me as a graduate student over the past five years

## ACKNOWLEDGEMENTS

I would like to thank my mentor, Dr. Michael Perri for his support, guidance, and wisdom. I would also like to thank the members of my supervisory committee, Dr. David Janicke, Dr. Tracey Barnett, and Dr. Stephen Anton for their time and assistance. Additionally, I would like to thank my colleagues in the UF Weight Management Program lab for their constant encouragement and support on this project, especially Kathryn Ross for her assistance with the statistical analyses. Finally, I would like to thank my family for providing unwavering love and support and for encouraging me to continue striving toward the finish line.

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Abstract of Dissertation Presented to the Graduate School  
of the University of Florida in Partial Fulfillment of the  
Requirements for the Degree of Doctor of Philosophy

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August 2012

Chair: Michael G. Perri  
Major: Psychology

Lifestyle interventions for obesity typically result in 7 to 10% reduction in body weight; however, these beneficial losses are rarely maintained. Controversy exists regarding whether small or large changes in caloric intake result in greater long-term weight reduction. This study examined the effects of mild versus moderate caloric restriction on weight loss. Additionally, the study assessed whether participants adhered to their caloric prescription. Participants included 125 obese women (mean BMI =  $37.9 \pm 3.9$  kg/m<sup>2</sup>; mean age =  $52.0 \pm 10.8$  yr) who were assigned either a 1,000 or 1,500 kcal/day goal. Results indicated that participants prescribed the 1,000 kcal/day goal lost more weight at Month 6 compared to those prescribed the 1,500 kcal/day goal ( $-10.8 \pm 6.8$  kg versus  $-6.3 \pm 6.8$  kg, respectively,  $p = .04$ ). From Months 6 – 12, the 1,000 kcal/day condition regained more weight than the 1,500 kcal/day condition so that weight change at Month 12 was not significantly different ( $-8.6 \pm 8.4$  kg versus  $-5.8 \pm 8.4$  kg, respectively,  $p = .212$ ); however, 61% of participants in the 1,000 kcal/day condition compared to 42% in the 1,500 kcal/day condition achieved a weight loss  $\geq$  5%. The majority of participants in both conditions adhered to their caloric

prescriptions, with the 1,000 kcal/day and 1,500 kcal/day participants consuming significantly different amounts ( $1,164 \pm 170$  versus  $1,518 \pm 222$  kcal/day, respectively,  $p < .001$ ). Treatment condition moderated the association between baseline caloric intake and weight regain; participants reporting higher caloric intake at baseline who were assigned the 1,000 kcal/day goal regained significantly more weight from Months 6 – 12 than those consuming higher baseline calories who were assigned the 1,500 kcal/day goal. Findings suggest that prescribing a 1,000 kcal/day goal results in greater short-term weight loss than a 1,500 kcal/day goal; however, larger caloric restriction may increase susceptibility to weight regain, especially for participants who consume greater amounts of calories at baseline. While power was inadequate to detect a significant long-term weight loss difference, results indicate that prescribing a 1,000 rather than 1,500 kcal/day goal increases the likelihood of achieving a 5% weight reduction.

## CHAPTER 1 INTRODUCTION

With its dramatic increase in prevalence and direct link to five of the ten leading causes of death in the United States, obesity (defined as a Body Mass Index, BMI,  $\geq 30$  kg/m<sup>2</sup>) has become one of the most significant public health epidemics (NHLBI, 1998; Flegal, Carroll, Ogden, & Curtin, 2010). Considerable research efforts have been placed on identifying interventions that result in a body weight reduction of a sufficient magnitude to improve health, found to be greater than 5% (IOM, 1995). Lifestyle interventions for obesity, consisting of 16 to 26 weekly group sessions, typically result in weight losses of 7 to 10% and reduced health-related risk factors (Jeffery et al., 2000; Perri & Fuller, 1995; Vetter, Faulconbridge, Webb, & Wadden, 2010; Wadden, Butryn, & Wilson, 2007); however, long-term weight maintenance is rarely achieved (Perri, 1998; Wadden et al., 2007). Research has suggested that early weight loss may serve as a predictor of long-term success in weight management; however, controversy exists regarding an ideal amount of initial weight reduction (Carels, Cacciapaglia, Douglass, Rydin, & O'Brien, 2003; Fogelholm, Kukkonen-Harjula, & Oja, 1999; Jeffery, Wing, & Mayer, 1998; Lutes et al., 2008; Sbrocco, Nedegaard, Stone, & Lewis, 1999; Wadden et al., 1992).

Recent initiatives promote the utilization of a small-changes approach, in which small, presumably sustainable, changes in caloric intake and physical activity may serve as an effective strategy for achieving and maintaining slow, yet steady reductions in body weight (Hill, 2009; Hill, Wyatt, Reed & Peters, 2003). Adopting this design in the context of lifestyle interventions may be effective for continued weight loss, reduced risk for weight regain, and successful long-term weight loss maintenance (Lutes, et al.,

2008; Sbrocco et al., 1999). Conversely, recent reviews and studies have coupled larger initial weight loss during lifestyle intervention with greater long-term body weight reductions (Astrup & Rössner, 2000; Carels et al., 2003; Elfhag & Rössner, 2005; Elfhag & Rössner, 2010; Jeffery et al., 1998; Nackers, Ross, & Perri, 2010; Wadden, et al., 1992). However, in some cases, larger initial weight loss has been associated with greater long-term weight regain (Jeffery et al., 1998; Sbrocco et al., 1999; Wadden, Foster, & Letizia, 1994), suggesting larger early weight reduction may serve as a risk factor for later weight regain (McGuire, Wing, Klem, Lang, & Hill, 1999; Weiss et al., 2007; Wing & Hill, 2001), and thus bringing to question the ability of participants to maintain large changes in diet and exercise following lifestyle intervention. However, with the use of continuous contact or extended care programs, maintenance of significant weight losses may be improved (Nackers, et al., 2010; NHLBI, 1998; Perri et al., 2008).

To our knowledge, only two studies have attempted to prospectively prescribe differing levels of caloric intake within the recommended range exceeding 1,000 kcal/day (Das et al., 2009; Toplak et al., 2005). While the majority of participants in both studies achieved weight losses of 5 to 10%, neither of these studies found differences in long-term weight loss between participants who either mildly or moderately restricted caloric intake. Furthermore, when assessing caloric intake, both studies found actual calories consumed were similar between conditions, with those who received prescriptions for mild caloric restriction consuming fewer calories than prescribed and those assigned to moderate caloric restriction consuming greater amounts of calories than prescribed (Das et al., 2009; Toplak et al., 2005). However, these studies were not

performed in the context of a lifestyle intervention with weekly group meetings that emphasized behavioral principles to attain energy goals.

In addition, it is unclear whether prescribing restrictive caloric goals prospectively results in adverse dietary events. Research on restrained eaters, or chronic dieters who restrict their intake of food with the goal of achieving or maintaining a lower weight (Heatherton, Polivy, & Herman, 1991), indicates that dietary restraint does not necessarily lead to successful weight loss due to vacillation between bouts of intense caloric restriction and disinhibition (i.e. a breakdown in the conscious control of food intake) (Heatherton, Herman, Polivy, King, & McGree, 1988). In fact, restrained eaters tend to binge eat (i.e. consume large quantities of food in short periods of time) when self-control is disrupted by critical events or disinhibitors (Marcus, Wing, & Lamparski, 1985; Ruderman, 1986). Binge eating, in turn, has been labeled a risk factor for increased body weight over time (Klesges, Isbell, & Klesges, 1992). Notably, reductions in disinhibition have consistently been linked to greater success in weight loss and weight maintenance (Niemeier, Phelan, Fava, & Wing, 2007; McGuire et al., 1999). It remains questionable then whether prospectively prescribing caloric intake goals that require greater dietary restraint will increase periods of disinhibition and adversely impact the extent and severity of binge eating than goals requiring lower dietary restraint.

Therefore, in sum, it is unknown whether prescribing goals of either mild caloric reduction so as to achieve a gradual, steady weight loss, or moderate caloric reduction so as to achieve a fast, large initial weight loss will result in greater long-term weight reduction for participants partaking in a lifestyle intervention. In addition, it is unknown

whether participants assigned to these energy restriction goals adhere to their prescribed levels of caloric intake and whether they experience altered levels of restraint or disinhibition or increases in binge eating episodes. This dissertation sought to answer these questions utilizing a 24-week lifestyle intervention and a 6-month extended-care program.

## **Obesity**

### **Prevalence**

Obesity results from an imbalance of the energy equation where energy intake (i.e. caloric intake) exceeds energy expenditure (i.e. metabolic rate and physical activity) (Tataranni & Ravussin, 2002). Reports from the National Health and Nutrition Examination Survey (NHANES) illustrate that rates of obesity in adults rose from 12.8% in 1960-1962 (Flegal, Carroll, Kuczmarski, & Johnson, 1998) to 33.8% in 2007-2008 (Flegal et al., 2010), with older adults, women, those from low socio-economic status, and inhabitants of rural areas exhibiting higher rates of obesity (Chang & Lauderdale, 2005; Flegal, Carroll, Ogden, & Johnson, 2002; Hedley et al., 2004; Flegal et al., 2010; Patterson, Moore, Probst, & Shinogle, 2004).

### **Health Conditions**

Evidence directly links excess weight with an increased morbidity. Obesity is associated with increased risk for cardiovascular disease (Flegal, Graubard, Williamson, & Gail, 2007; Gregg et al., 2005; Wilson, D'Agostino, Sullivan, Parise, & Kannel, 2002), hypertension (Mokdad et al., 2003), hypercholesterolemia (Brown et al., 2000; Mokdad et al., 2003), type 2 diabetes (Flegal et al., 2007; Mokdad et al., 2003), asthma, arthritis (Mokdad et al., 2003), gallbladder disease (Field et al., 2001), sleep apnea (Vgontzas et al., 1994), renal disease (Flegal et al., 2007), and breast, pancreatic, and prostate

cancers (Dumitrescu & Cotalra, 2005; Field et al., 2001; Freedland & Aronson, 2005). Obese individuals are also 2.8 times more likely to experience functional impairment (e.g. walking or lifting) than their normal weight counterparts (Alley & Chang, 2007).

Obesity is also related to an increased mortality and decreased life expectancy. Conservative estimates suggest 111,000 excess deaths per year are attributable to obesity (Flegal, Graubard, Williamson, & Gail, 2005), while others approximate numbers of deaths as high as 400,000 (Mokdad, Marks, Stroup, & Gerberding, 2004). Results from the Framingham Heart Study suggest that BMI at ages 30 to 49 predicts mortality in future decades, with five to seven years of life lost in obese individuals (Peeters et al., 2003).

In addition to adverse physical consequences, obesity negatively affects psychosocial outcomes. Stigmatization against obese persons in employment, education, and healthcare have been well documented (Puhl & Brownell, 2001), and close relationship partners (i.e. friends, parents, and spouses) serve as the worst sources of stigmatization (Puhl, Moss-Racusin, Schwartz, & Brownell, 2008). Obese individuals experience lower quality of life and higher levels of depression (Fontaine & Barofsky, 2001; Jia & Lubetkin, 2005; Wadden, Womble, Stunkard, & Anderson, 2002). Obese women are also at increased risk for suicidality (Carpenter, Hasin, Allison, & Faith, 2000).

Research demonstrates that weight loss can reverse many of the adverse effects associated with obesity. Even a modest reduction in body weight of  $\geq 5\%$  produces beneficial effects on glycemic control, hypertension, and hyperlipidemia (NHLBI, 1998). The Look AHEAD study is an ongoing multicenter randomized controlled trial that

compares lifestyle intervention to diabetes support and education on the incidence of cardiovascular disease morbidity and mortality in overweight or obese persons with type 2 diabetes (The Look AHEAD Research Group, 2010). Across four years, results indicate that individuals who received the lifestyle intervention lost a mean 6% bodyweight and experienced reductions in levels of HbA1c, systolic blood pressure, diastolic blood pressure, triglycerides, and LDL cholesterol. These values were significantly improved compared to those in the education condition who lost 0.9% body weight (The Look AHEAD Research Group, 2010). Other large scale lifestyle intervention trials have found similar health-related benefits in participants who lost weight compared to control conditions who do not achieve significant weight losses (Diabetes Prevention Program Research Group, 2002; Stevens et al., 2001; Tuomilehto et al., 2001). However, weight regain may also reverse these positive health outcomes and therefore, sustained weight loss remains an important goal (Moore et al., 2000; Stevens et al., 2001; Wadden, Anderson, & Foster, 1999).

### **Economic Factors**

The hazardous health consequences of obesity are accompanied by a significant financial burden. In the United States during 2008, the healthcare costs associated with obesity totaled about \$147 billion (Finkelstein, Trogon, Cohen, et al., 2009). In the year 2006, medical expenditures for obese people was \$1,429 (42%) greater than spending for someone of normal weight (Finkelstein et al., 2009). It has also been estimated that public-sector Medicare and Medicaid spending, in the absence of obesity, would be 8.5% and 11.8% lower, respectively (Finkelstein et al., 2009).

## **Lifestyle Intervention for Obesity**

With the increased prevalence and adverse outcomes associated with obesity comes a need for effective weight-loss treatments. Lifestyle interventions represent the first line of professional treatment for obesity (NHLBI, 1998). These programs teach participants to utilize cognitive-behavioral strategies to modify eating and activity patterns to produce a negative energy balance necessary to lose weight (Vetter et al., 2010). By applying the classical and operant learning theory to weight loss, participants learn to identify and modify the antecedents and consequences associated with their unhealthy eating patterns and low levels of physical activity and to alter their environment to increase and develop habits that promote healthy behaviors (Ferster, Nurnberger, & Levitt, 1962; Stuart, 1967; Vetter et al., 2010; Wing, 2002).

According to the NHLBI (1998), decreasing caloric intake serves as the most important element for weight reduction and maintenance. Whereas one pound is equivalent to 3,500 kcal, reducing daily caloric intake by 500 to 1,000 kcal typically results in a weight loss of 0.5 to 0.9 kg (i.e. 1 to 2 lbs) per week (NHLBI, 1998). Because requirements for maintaining the energy balance is not often known, researchers assume that resting energy expenditure approximates 1 kcal/kg\*h, and therefore often prescribe diets of 1,000 to 1,500 kcal/day for obese women to achieve the aforementioned weekly weight losses (Brownell, 2000; Wing, 1998). This level of energy intake has been shown to be safe and effective in women averaging 90.7 kg (i.e. 200 lbs) who aspire to lose weight (Jakicic, et al., 2001).

In addition to reduction of caloric intake, consumption of a balanced diet has been associated with weight loss. A balanced-deficit diet consists of caloric reduction while emphasizing consumption of all food groups and a variety of nutrients, (Melanson

& Dwyer, 2002). Lifestyle interventions typically encourage participants to adhere to a balanced-deficit diet in which they reduce their caloric and fat intake and increase amounts of fruits, vegetables, and whole grains (Wing, 2002). For example, lifestyle interventions, such as the Treatment of Obesity in Underserved Rural Settings (TOURS) project, set goals for participants to reduce caloric intake by 500-1,000 kcal/day, and modification of total fat intake to <25-30%, saturated fat to 7%, and protein to 15% of total caloric intake (Perri et al., 2008). In addition, participants were encouraged to increase fruit and vegetable consumption to at least 5 per day and whole grains to 3 or more servings per day (Perri et al., 2008).

On the other half of the equation, increasing physical activity to augment energy expenditure further creates a negative energy deficit. The most recent recommendations have suggested that overweight and obese adults participate in at least 150 minutes/week of moderate intensity physical activity (i.e. walking) to prevent weight gain, elicit modest reductions in body weight, and reduce risk factors for chronic disease (Donnelly, Blair, Jakicic, Manore, Rankin, & Smith, 2009). However, researchers have concluded that there exists a dose effect of physical activity where approximately 250 to 300 minutes/week (i.e. approximately 2,000 kcal/week) of moderate intensity physical activity produces greater weight loss and prevention of weight regain, suggesting overweight and obese adults progress to greater amounts of physical activity for larger benefits (Donnelly et al., 2009). In addition, reducing sedentary time by increasing every day, lifestyle, activities is encouraged (NHLBI, 1998). While adding 30-60 minutes of physical activity three times per week to a program of caloric restriction has only been shown to increase weight loss modestly by

approximately 2 kg, regular physical activity plays an important role in maintenance of weight loss (Blair & Leermakers, 2002).

In addition, cognitive-behavioral strategies utilized in lifestyle interventions are consistent with the social cognitive theory (Wadden & Foster, 1992). This theory describes how personal factors, such as cognitions and emotions, and environmental factors influence a person's behavior, while personal behavior in turn then may have a reciprocal influence on personal and environmental factors (Bandura, 1977, 1986). Therefore, lifestyle interventions target four key concepts of the social cognitive theory (Bandura, 1977, 1986; Wadden & Foster, 1992). First, they are used to increase knowledge of health behaviors, such as diet and physical activity, and their effects on weight and disease risk. Second, they enhance an individual's belief in his or her ability to perform positive behaviors and create positive outcome expectancies through promotion of successful eating and exercise experiences. Third, they increase one's ability to exert control over his or her behavior, cognitions, and environment through the use of goal-setting, self-monitoring of daily food intake and physical activity, self-reinforcement, stimulus control, and cognitive restructuring. And fourth, lifestyle interventions teach participants how to overcome barriers to performing specific behaviors through problem solving. National guidelines purport that a combined intervention utilizing the aforementioned cognitive-behavioral techniques, a caloric-restricted diet, and increased physical activity results in the most successful non-surgical treatment for weight loss and weight maintenance (NHLBI, 1998).

Lifestyle interventions have been found to be more effective when offered in groups versus individual treatment, regardless of preferred treatment modality

(Renjilian, Perri, Nezu, McKelvey, Shermer, & Anton, 2001). Additional studies of treatment preference have indicated that participants who are randomly matched to their preferred type of dietary treatment or to their preferred weight-maintenance treatment guidelines achieve no greater weight loss outcomes than those who are matched to their non-preferred treatment options (Burke et al., 2008; Vogels & Westerterp-Plantenga, 2005; Warziski, Sereika, Styn, Music, & Burke, 2008). Therefore, assigning participants to treatment of choice does not necessarily lead to improved adherence or greater weight maintenance.

### **The Maintenance Problem**

Reviews of randomized trials suggest that comprehensive behavioral modification programs, which typically consist of weekly group treatment sessions for four to six months, result in a 7 to 10% reduction of initial body weight, or a mean loss of 0.5 kg per week (Jeffery et al., 2000; Perri & Fuller, 1995; Wadden et al., 2007). Weight losses of this magnitude have been associated with reductions in adverse health conditions and risk factors associated with obesity (NHLBI, 1998). Unfortunately, long-term follow-up evaluations indicate that traditional behavioral treatment induced weight losses are not well maintained (Perri, 1998; Wadden et al., 2007). A review by Wadden et al. (2007) indicated that in the year following 20 to 30 weeks of group lifestyle modification treatment, patients regain 30% to 35% of their lost weight. Weight regain typically slows after the first year, but after 18 months following program entry, participants maintain only about 50% of the initial lost weight (Jeffery et al., 2000). Five years after treatment, 50% or more of patients return to their initial body weight (Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989). Another review found that only

13% to 22% of patients who initially lost  $\geq 5$  kg maintained this weight loss at five year follow-up (Wing & Hill, 2001). Thus, it appears that the pattern associated with behavioral treatment begins with successful initial weight loss followed by a reliable regain of lost weight (Jeffery et al., 2000).

### **Strategies for Improving Weight Maintenance**

Countless research efforts have sought to better understand the factors associated with the maintenance problem. Recent reviews found that personal characteristics, such as self-motivation, self-efficacy, autonomy, sufficient coping strategies for handling stress, and overall psychological stability, as well as fewer previous weight loss attempts served as predictors of successful weight-loss (Elfhag and Rössner, 2005; Teixeira, Going, Sardinha, & Lohman, 2005). In addition, results from the National Weight Control Registry, a group of over 3,000 people who have lost and maintained at least a 30 lb weight loss for one year, indicate that participating in high levels of physical activity, frequent self-monitoring of body weight and food intake, and eating a low-calorie and low-fat diet are associated with long-term weight maintenance (Wing & Hill, 2001). Conversely, factors that may increase the likelihood of weight regain include decreased restraint with dietary intake, increased hunger, disinhibited eating, binge eating, eating as a response to stress or negative emotions, passive reactions to problems, and a history of weight cycling (Elfhag & Rössner, 2005; McGuire et al., 1999).

Behavioral factors during weight management programs, such as higher rates of attendance (Carels et al., 2003; Wadden et al., 1992) and adherence, as measured by self-monitoring and recording daily dietary intake (Baker & Kirschenbaum, 1993;

Boutelle & Kirschenbaum, 1998), have also been correlated with long-term weight loss success. Perri and Corsica (2002) summarized the variety of strategies designed to improve lifestyle interventions and facilitate weight maintenance. These include increasing the initial treatment length, engaging participants in extended care programs via in-person or telephone sessions, utilizing exercise-focused programs or personal trainers, incorporating peer support, providing food or incentives, and creating multicomponent treatment programs. Of these, one of the most successful strategies appears to be offering extended care programs in which participants are encouraged to practice maintenance of the behaviors they learned in the initial lifestyle intervention (Vetter et al., 2010).

Perri and Corsica (2002) reviewed 13 studies that utilized extended care approaches spanning past six months of behavioral treatment. Participants who received extended care maintained 96% of their weight losses compared to 67% in those who did not receive extended follow-up care. Extended-care programs allow continuous practice of strategies and behaviors learned during initial treatment at a time when rate of weight loss begins to slow and participants struggle with maintaining lost weight (Perri & Corsica, 2002). Other reviews that support extended care treatment for weight maintenance raise the question of whether additional factors, such as level of energy prescription, for producing a specific rate of weight loss may result in augmented weight loss outcomes (Astrup & Rössner, 2000; Ayyad & Anderson, 2000). Current findings prove inconclusive and therefore, recent debates center around the role of rate of weight loss on long-term success in weight management.

## Caloric Restriction and Rate of Weight Loss

### Very Low Calorie Diets

Two decades ago, several studies assessed the effectiveness of severe dietary restriction, or very-low-calorie diets (VLCDs), consisting of an energy content of 400-800 kcal/day and often consumed in liquid formula (Wadden et al., 1994; Wadden & Stunkard, 1986; Wing, Blair, Marcus, Epstein, & Harvey, 1994; Wing et al., 1991). Because the energy deficit is often greater than that typically prescribed in conventional diets of 1,000-1,500 kcal/day (Brownell, 2000; Wing, 1998), initial rate of weight loss is often faster and larger with a mean loss of 20 kg over 12 weeks (Wadden, Stunkard, & Brownell, 1983). However, there is some evidence that prescribing faster initial weight loss may not produce better long-term outcomes. For example, Wadden and colleagues (1994) randomly assigned women to either a balanced deficit diet (1200 kcal/day) condition for 52 weeks of a behavioral treatment program or to a very-low-calorie diet (420 kcal/day) for the initial 16 weeks and a balanced deficit diet thereafter. At six months, women on the very-low-calorie diet experienced nearly twice the initial weight loss as those on the balanced deficit diet; however, during the following year of extended care, women who were prescribed the very-low-calorie diet regained significantly more weight. At 18 month follow-up, the groups no longer differed with regards to net weight loss.

Similarly, Toubro and Astrup (1997) prospectively randomized one group of obese women to eight weeks of VLCD (500 kcal/day) and another group to 17 weeks of a conventional hypocaloric diet (1200 kcal/day) to achieve similar weight losses at varying rates. Those on the VLCD experienced weight loss at approximately twice the

rate of the conventional dieters, but groups did not significantly differ in weight maintenance measured at one year follow-up. These results suggest that utilizing severe caloric restriction methods to attain fast initial weight losses may not lead to successful long-term weight maintenance and explains why VLCDs are not recommended for weight loss in most individuals (NHLBI, 1998).

### **Moderate Caloric Restriction**

Following the NHLBI guidelines (1998), a diet no lower than 1,000 kcal/day is recommended for obese women. Numerous studies of lifestyle interventions prescribing moderate caloric restriction (i.e. 1,000 to 1,500 kcal/day) have demonstrated that participants who lose at a faster rate in the short-term achieve greater weight reduction in the long-term (Carels et al., 2003; Jeffery et al., 1998; Nackers et al., 2010). Specifically, Nackers et al. (2010) conducted a secondary data analysis of the TOURS study in which 230 obese women who were prescribed a 1,200 kcal/day diet underwent 24 weeks of lifestyle intervention followed by one year of extended care follow-up were classified according to rate of weight loss during the first month of treatment. Results indicated that those who lost at the fastest rate achieved both greater short- and long-term weight reductions and were not at increased risk for weight regain than those who lost at a slower rate. In addition, those who decreased weight at a fast rate were 5.1 times more likely to achieve a 10% weight loss at 18 months than the slow losers. Nackers and colleagues (2010) theorized that, from a learning perspective, losing at a slow initial rate may be less reinforcing to participants than reducing weight at a fast rate. Reinforcers, such as improvements in quality of life factors (e.g. general appearance, body image, physical mobility, energy, and perceived health) achieved

early in behavioral treatment for obesity have been associated with greater long-term weight loss outcomes whereas consequences, such as unsatisfactory early weight loss, have been associated with poor treatment outcomes (Carels et al., 2003). This suggests that when shaping of healthy behaviors occurs slowly, the resulting small weight changes may not serve as sufficient reinforcers for learning and long-term habit change necessary to achieve and maintain long-term weight loss success (Nackers et al., 2010).

Similar to VLCDs, participants who are prescribed moderate caloric restriction and lose weight at a fast initial rate may also be susceptible to weight regain. Jeffery et al. (1998) conducted a randomized trial in which 130 men and women participated in an 18-month weight-loss treatment program with an additional 12-month follow-up. Participants were then categorized into tertiles according to the maximum amount of weight loss. Those participants in the highest maximum weight-loss category lost weight at more than twice the initial rate of those in the lowest tertile. The results indicated that 23% of those participants who achieved the highest rate of weight loss (i.e. highest tertile of maximum weight loss [mean loss of 0.68 kg/week]) attained a clinically significant 10% reduction in body weight at 30 months compared to only 9% of those who lost at a moderate rate (i.e. middle tertile [mean loss of 0.58 kg/week]) and 2% who lost the slowest (i.e. lowest tertile [mean loss of 0.29 kg/week]). However, the results also demonstrated that those who had the largest rate of initial loss experienced larger and more rapid weight regain than those who initially had slower, smaller losses. Similar findings have documented that a large initial weight loss is a risk factor for

weight regain (McGuire et al., 1999; Sbrocco et al., 1999; Wadden et al., 1994; Weiss et al., 2007; Wing & Hill, 2001).

### **Mild Caloric Restriction**

Hill and colleagues (2003) described the “energy gap” as an excess of 100 kcal/day, and thus suggest that small daily behavioral changes that decrease energy intake by this amount would be sufficient to prevent gradual weight gain and promote sustainable weight loss. This “small-changes” approach is based upon the idea that, in an environment that promotes increases in energy intake and decreases in physical activity, small behavioral changes are more feasible to achieve and sustain than larger ones. Theorists argue that not only are slight increases in physical activity (i.e. walking 2,000 extra steps to burn approximately 100 kcal) and small substitutions in food intake (i.e. diet soda instead of regular soda to save approximately 150 kcal per 12 oz serving) more sustainable, but these minor modifications can increase self-efficacy, promoting additional small changes that could eventually lead to larger maintainable changes (Hill, 2009; Hill et al., 2003).

Researchers have suggested that the small-changes approach may play an important role in weight regulation. Because it is often difficult to maintain the degree of caloric restriction promoted by traditional behavioral treatment programs for a prolonged period of time (Schlundt, Sbrocco, & Bell, 1989), Sbrocco and colleagues (1999) developed an alternate intervention called “behavioral choice treatment.” Based upon a decision-making model (Sbrocco & Schlundt, 1998), behavioral choice treatment teaches participants to use mild caloric restriction, reducing caloric intake from an estimated 2,500 kcal/day to 1,800 kcal/day, and to make healthy decisions regarding

eating choices without considering their eating patterns as dieting. Weight loss is therefore expected to be slower initially, but continuous as participants maintain new decision making regarding healthy eating patterns. Sbrocco et al. (1999) conducted a 13-week randomized trial where obese women took part in either a traditional behavioral treatment that encouraged significant caloric reduction so as to achieve a substantial initial weight loss, or a behavioral choice treatment that promoted mild caloric restriction and a slow, yet steady weight loss. Results indicated that at both mid- and post-treatment, those in the traditional behavioral treatment achieved significantly greater weight losses; however, at three-month follow-up, this difference was no longer apparent. The behavioral choice treatment group continued to lose weight and achieved significantly greater weight losses at both 6- and 12-month follow-up (-7.0 and -10.1 kg, respectively) than the traditional behavioral treatment group, which experienced continued weight regain from 6 to 12 months (-4.5 and -4.3 kg, respectively).

Similarly, Lutes and colleagues (2008) conducted a weight loss trial in which 59 adults participated in 16 weeks of either a standard treatment, *ASPIRE* program, or control condition. The two former conditions received 40 to 45 minute aerobic and resistance training twice per week while the control group was encouraged to make no changes in their usual exercise or dietary intake. The standard treatment group received weekly individual didactic education and behavioral counseling from a nutritionist, and they were encouraged to consume no more than 1,600 kcal/day for women and 2,200 kcal/day for men and participate in at least 30 minutes/day of physical activity on most days of the week. Those in the *ASPIRE* program met

individually on a weekly basis with a lifestyle coach and were encouraged to set nutrition and physical activity goals involving the small changes that were presented as choices each week (i.e. reducing caloric intake by 200 to 600 kcal/day and slowly increasing physical activity to reach 3,000 steps/day greater than baseline or a total of 10,000 steps/day).

Results demonstrated that participants in the *ASPIRE* program compared to the standard treatment and control conditions attained a greater initial weight loss ( $-4.5 \pm 3.4$  kg versus  $-1.1 \pm 2.7$  kg versus  $0.1 \pm 2.4$  kg, respectively) at 16 weeks (Lutes et al., 2008). In addition, the *ASPIRE* group sustained the loss and achieved superior weight reduction at 3-month follow-up compared to the standard treatment group ( $-4.1 \pm 5.8$  kg versus  $-1.3 \pm 2.5$  kg). Lutes and colleagues (2008) suggest that small changes used to induce a slow and steady initial weight loss produced larger long-term weight loss that was not susceptible to regain. However, this study did not incorporate a traditional lifestyle intervention program that utilized cognitive-behavioral techniques like goal setting, self-monitoring, and problem solving, which may explain the minimal amount of weight loss achieved by the standard treatment group. In addition, the researchers did not measure mean caloric intake at baseline, posttreatment, or 3-month follow-up, and therefore it remains unclear whether participants were consuming the actual caloric amount prescribed.

In summary, many behavioral treatment programs have proven effective in promoting clinically significant weight losses, but long-term weight reduction is difficult to maintain. Evidence suggests that initial weight loss may be associated with long-term

success; however, it remains unclear whether there exists an optimal initial weight loss for effective long-term weight management.

### **Caloric Intake Prescription**

Perhaps one of the issues in determining an optimal initial weight loss arises from the idea that adhering to a specific calorie goal in order to lose at a specific rate may prove difficult. Two studies have attempted to answer the question of whether prescribing a mild or moderate caloric restriction produces greater long-term success in weight management (Das et al., 2008; Toplak, et al., 2005). Das and colleagues (2008) assigned 46 participants to a group of either mild 10% energy restriction with the goal of producing a gradual weight loss or moderate 30% energy restriction to produce a faster rate and greater overall weight loss. Participants were provided an initial 24-week supply of food and were then asked to maintain their dietary regimen for an additional 24 weeks without food provision. Results indicated that, while the majority of participants achieved a 5 to 10% weight loss, there were no differences in mean percentage weight lost over the 12-month period. In addition, while conditions differed significantly in percent energy restriction during the first 24 weeks, groups did not differ in over the 12 months. This indicates that the 10% energy restricted group consumed less than prescribed while the 30% energy restricted group ate more than prescribed.

While the aforementioned study utilized the doubly labeled water method of tracking energy intake, similar results were found in a study utilizing self-reported dietary intake (Toplak et al., 2005). Toplak and colleagues (2005) assessed whether mild or moderate energy deficit in conjunction with pharmacotherapy would produce greater long-term weight loss. Participants (N=430) who were randomized to either a

500 kcal/day or 1,000 kcal/day energy deficit significantly differed in self-reported caloric intake at 6 months; however, the difference was only 111 kcal/day. At 12 months, the mildly and moderately restricted conditions were not consuming significantly different energy amounts. Results indicate that the majority of participants achieved a 5 to 10% weight reduction, but that groups did not differ in regards to weight loss. Toplak and colleagues (2005) suggested that participants tend to gravitate toward dietary intake they find manageable regardless of energy prescription.

### **Self-Efficacy and Quality of Life**

Low levels of self-efficacy may explain why participants find adherence to energy prescription difficult. Self-efficacy is based upon the idea that personal beliefs regarding accomplishment, mastery, and outcome expectancy determine whether a person begins a behavior, what goal she will attempt to attain, and the amount of effort exerted (Bandura, 1977). Therefore, estimation of capabilities to perform a behavior, or perceived self-efficacy, serves as a major determinant of performance independent of actual skill (Bandura, 1986).

Higher self-efficacy has been linked to greater success in weight-loss (Richman, Loughnan, Droulers, Steinbeck & Caterson, 2001) as well as behaviors associated with weight loss, such as dietary adherence (Linde, Rothman, Baldwin, & Jeffery, 2006). Warziski and colleagues (2008) examined self-efficacy in relation to eating behaviors to determine if changes in self-efficacy were associated with weight loss following an 18-month behavioral intervention. Using the Weight Efficacy Lifestyle questionnaire, a 20-item questionnaire measuring self-efficacy specific to eating behaviors (Clark, Abrams, Niaura, Eaton, & Rossi, 1991), the researchers found that self-efficacy increased over

the course of treatment and was associated with weight loss at 18 months (Warziski et al., 2008). Conversely, poor eating self-efficacy has been linked to weight cycling (Kensinger, Murtaugh, Reichmann, & Tangney, 1998). Improvements in quality of life have also been positively correlated with greater long-term weight loss outcomes (Carels et al., 2003; Kolotkin, Crosby, Williams, Hartley, & Nicol, 2001), while weight gain has been associated with reductions in quality of life (Engel et al., 2003).

### **Disinhibition, Restraint, Hunger, Depression, and Binge Eating**

Perhaps another reason participants experience difficulty adhering to prescribed calorie goals is the environmental pressure that promotes increased energy intake and decreased physical activity (Hill et al., 2009). Herman and Polivy (1980) characterize eating patterns as a balancing act between an innate physiological desire for food and efforts to resist that desire within the environment. They coined this cognitively-mediated effort used to avoid overeating as 'restraint' (Herman & Polivy, 1980). Studies have indicated that lower levels of cognitive restraint are often associated with higher energy intake (Stunkard & Messick, 1985), while higher levels of restraint are related to lower body weights (Foster et al., 1998). Researchers have argued that restrained eaters, or 'chronic dieters,' who have continual weight concerns, tend to vacillate between periods of dieting and overindulgence (Herman & Polivy, 1980; Ruderman, 1986). The latter period of overeating has been hypothesized to result from the cognitive, emotional, or pharmacological disruptions in dietary self-control, in which the physiological drive for food temporarily prevails (Polivy & Herman, 1983). In experimental conditions, this phenomenon has been termed disinhibition because disruptions in eating patterns disinhibit self-imposed cognitive restraint of eating

behavior (Herman & Polivy, 1980). In experimental settings, it has been well-established that restrained eaters who are forced to consume high-caloric foods subsequently increase laboratory consumption of food (Herman & Mack, 1975), potentially due to violation of an all-or-nothing attitude toward dieting in which one slip is indicative of abandoning the diet (Ruderman, 1986). Therefore, it is not surprising that lower levels of cognitive restraint have been linked to higher levels of disinhibition (d'Amore et al., 2001; Marcus et al., 1985; Wadden, Foster, Letizia, & Wilk, 1993).

Stunkard and Messick (1985) created the 51-item Eating Inventory, previously known as the Three Factor Eating Questionnaire, a well-validated measure of restraint (degree of conscious control over eating), disinhibition (susceptibility to loss of control over eating), and hunger (susceptibility to eat in response to hunger). Das and colleagues (2008) found no difference in reported hunger between the mild and moderate energy restricted groups, but noted that participants in the mild energy restricted group who reported greater disinhibition at six months experienced poorer weight outcome at 12 months. This suggests that a small-change approach to dietary restriction may still expose participants to discretionary foods high in caloric content that increase risk of disinhibition and non-adherence to the prescribed diet (Das et al., 2008). Hunger may also contribute to non-adherence to caloric diet. In obese participants prescribed a VLCD, those who endorsed the highest level of hunger consumed three times as many calories as those who endorsed the lowest level of hunger (LaPorte & Stunkard, 1990).

In addition to decreases in caloric intake adherence, restraint, disinhibition, and hunger have been examined in the context of weight management. Increases in dietary

restraint and decreases in disinhibition and perceived hunger have been linked with greater weight loss following treatment (Foster et al., 1998). Wing and colleagues (2008) recently investigated predictors of weight regain in successful weight losers and found that increases in disinhibition and hunger were related to greater weight regain. Also, those participants who did not receive in-person extended care follow-up experienced decreases in restraint and related weight regain. During follow-up, increases in reported depressive symptoms were associated greater weight regain, suggesting negative affect along with uncontrolled eating tendencies may result in difficulties with long-term weight loss maintenance (Wing et al., 2008).

In addition to reduced long-term maintenance, uncontrolled eating tendencies may also increase other adverse outcomes. For example, the experimental term disinhibition is often considered analogous to the clinical term of binge eating (Wardle & Beinart, 1981). Between 25 and 50% of obese persons have been found to binge eat (Bruce & Wilfley, 1996), and those who do have also been shown to demonstrate lower levels of self-efficacy and restraint during eating than obese non-binge eaters (Kensinger et al., 1998) as well as higher disinhibition and hunger (d'Amore et al., 2001) and greater levels of depression (Polivy & Herman, 1976; Polivy & Herman, 1985). Therefore, relationships have been illustrated between decreases in cognitive restraint, increases in disinhibition, hunger, and depressive symptoms, reduced dietary adherence, more frequent episodes of binge eating, and greater weight regain (d'Amore et al., 2001; Das et al., 2005; LaPorte & Stunkard, 1990; Wing et al., 2008).

## **Improving Caloric Intake Adherence**

Numerous approaches have been utilized to regulate uncontrolled eating tendencies in order to improve caloric adherence and long-term weight management outcomes. These include self-monitoring, partial meal replacements, portion-controlled meals, structured meal plans, and cognitive-behavioral strategies. Each approach is described in detail below.

### **Self-Monitoring**

Self-monitoring, or the systematic observation and recording of target behaviors (Kanfer, 1970), has been associated with reduced food intake and successful weight control (Baker & Kirschenbaum, 1993). In fact, self-monitoring has consistently been proven to be one of the most important components of weight management, with monitoring foods eaten, time of consumption, quantity eaten, and amount of fat grams consumed all correlated with weight loss (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998). As participants in lifestyle interventions improve the quality and consistency of self-monitoring, weight loss increases (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998). While self-monitoring may serve as one of the key behavioral strategies to observing caloric intake and improving weight outcomes, the validity of self-monitoring records remains questionable. Participants in lifestyle interventions tend to underreport dietary intake by approximately 27 to 46% when eating a diet of conventional foods (Johnson, Friedman, Harvey-Berino, Gold, & McKenzie, 2005; Lichtman et al., 1992; McKenzie, Johnson, Harvey-Berino, & Gold, 2002), a discrepancy that may be caused by lack of understanding of portion sizes or forgetfulness in recording foods and beverages (Blundell, J.E., 2000). Therefore,

additional behavioral strategies that reduce personal estimation of caloric intake and increase adherence to caloric prescriptions are warranted.

### **Partial Meal Replacements**

Partial meal replacements, or commercially available products fortified with minerals and vitamins sold as replacements for one or more meal, have been widely prescribed by both health professionals and researchers to improve weight loss success (Egger, 2006; Heymsfield, van Mierlo, van der Knaap, Heo, & Frier, 2003; Keogh & Clifton, 2005). These liquids, powders, or snack bars are often supplemented with fresh fruits and vegetables or at least one meal of normal food consumed as part of a low energy diet (Keogh & Clifton, 2005). In the Look AHEAD study, participants were able to accept or decline use of meal replacements. Results indicated that the number of meal replacements consumed in the first six months was significantly associated to weight loss at week 26, with participants in the highest quartile of meal replacement use experiencing a 4.1 times greater odds of reaching a 10% weight loss than those in the lowest quartile (Wadden et al., 2009). Meal replacements have also been shown to be as effective as medication (LeCheminant, Jacobsen, Hall, & Donnelly, 2005) and more effective than dieting alone (Vazquez et al., 2009) at maintaining weight loss over a one-year period.

Meal replacements offer known calorie content, a simplified choice of foods, little to no preparation, and an avoidance of problem foods (Wadden et al., 2007).

Participants have also rated meal replacements more favorably in terms of dietary compliance and convenience compared to participants consuming a conventional diet (Noakes, Foster, Keogh, & Clifton, 2004). In addition, partial meal replacements have

been associated with a lower risk of inadequate dietary intake of several vitamins and minerals compared to traditional food (Ashley et al., 2007) and hunger suppression for up to five hours following consumption (Rothacker & Watemberg, 2004). While meal replacements are convenient and provide consistent portion control, they also lack benefits of a balanced diet of real foods, such as non-traditional nutrients and phytochemicals that are essential for health (Hannum et al., 2004). Participants may also experience monotony in consuming similar products one or more times per day (Hannum et al., 2004) and therefore additional strategies to improve caloric adherence may be necessary.

### **Portion-Controlled Meals**

Another strategy utilized to increase dietary compliance involves prepackaged meals designed for specifically assigned calorie goals. Jeffery and colleagues (1993) conducted a 20-week lifestyle intervention program on 202 overweight and obese individuals to examine the impact of food provision on weight loss. Participants receiving reduced calorie prepackaged meals for five breakfasts and five dinners throughout the 18-month program in addition to the standard lifestyle intervention program achieved greater weight losses at 6, 12, and 18 months than those who only participated in the reduced calorie diet lifestyle intervention program. Use of frozen portion-controlled entrees in a study of 60 women achieved similar results (Hannum et al., 2004). Women who received at least two frozen meals in addition to set servings of foods from the Food Guide Pyramid experienced a 2.0 kg greater weight loss and greater reductions in metabolic risk factors for disease after only 8 weeks of the intervention than those who did not consume portion-controlled meals (Hannum et al.,

2004). Hannum et al. (2004) concluded that prepackaged frozen entrees may prove to be a key factor in weight control because of ease of preparation, known calorie content, and portion control. No additional weight-loss benefit has been found when portion-controlled meals are received free of charge compared to when participants purchase these meals on their own (Wing et al., 1996).

### **Structured Meal Plans**

Wing and colleagues (1996) also found that providing structured meal plans and grocery lists improves the outcome in behavioral treatment. Groups in a lifestyle intervention who received structured meal plans with or without food provision demonstrated greater adherence to self-monitoring, more regular eating patterns and increased ease in estimating portion size, finding time to plan meals, and restraining from eating when not hungry. Researchers concluded that menus with and without food provision lead to greater likelihood that low-calorie foods are available in the home, more structured eating patterns, increased knowledge of caloric content in commonly consumed foods, and greater ease of following a prescribed diet (Wing et al., 1996).

### **Cognitive-Behavioral Strategies**

Lifestyle interventions also include various cognitive-behavioral strategies to increase adherence and improve weight loss outcomes. Participants are taught to control eating and activity stimuli, change negative thoughts associated with eating habits, identify and plan ahead for situations that are high risk for slips, problem-solve for high-risk situations, and learn to cope with potential slips (Marlatt & Gordon, 1980; NHLBI, 1998). The restraint scale on Stunkard and Messick's Eating Inventory (Stunkard & Messick, 1985) includes items that inquire about control of caloric intake

and concerns of weight regain, questions that coincide with skills that are frequently taught in lifestyle intervention programs (Wing, Tate, Gorin, Raynor, & Fava, 2006). In a study of obese women, six-month of cognitive-behavioral weight loss treatment was linked to significant increases in restraint and decreases in disinhibition and hunger (Foster et al., 1998). In addition, larger increases in restraint achieved during treatment were associated with larger weight losses, suggesting training in cognitive-behavioral strategies increases cognitive control over eating and greater adherence to a low-calorie diet (Foster et al., 1998).

In summary, it remains unclear whether prescribing either a mild caloric restriction to induce a gradual initial weight loss or a moderate caloric reduction to generate a faster and larger initial weight loss results in greater long-term weight reduction for participants in a lifestyle intervention program. While previous studies have indicated somewhat poor adherence to prescribed calorie goals, there exist numerous strategies that can be utilized to improve caloric adherence in weight management programs; however, it is unknown if these strategies will be effective. In addition, no previous studies have assessed whether prescribing either mild or moderate caloric restriction will result in altered levels of dietary restraint, disinhibition, depression, or hunger, as well as changes in number of binge eating episodes.

### **Specific Aims and Hypotheses**

The present study examined the effects of prospectively prescribing two caloric intake goals on weight loss at six months and weight maintenance at 12 months in women ages 25-75 years who underwent a lifestyle intervention for obesity. The study first aimed to determine whether assigning participants to a moderate caloric restriction

(i.e. 1,000 kcal/day) was associated with larger weight loss at both 6 and 12 months than assigning a mild caloric restriction (i.e. 1,500 kcal/day). It was hypothesized that those women prescribed a moderate caloric restriction would achieve a greater weight loss at six months and greater maintenance and overall weight reduction at 12 months than those prescribed a mild caloric restriction. The study additionally assessed whether there existed a difference in the percentage of participants achieving a  $\geq 5\%$  weight reduction at both 6 and 12 months. It was hypothesized that a significantly greater percentage of participants within the 1,000 kcal/day condition would achieve a  $\geq 5\%$  loss at both time points, compared to the 1,500 kcal/day condition.

The second aim of this study examined whether participants adhered to their prescribed caloric intake goals of 1,000 or 1,500 kcal/day given this study's methodology that utilized self-monitoring, structured meal plans, and suggested meal replacements and portion-controlled meals. It was hypothesized that participants would adhere to their caloric prescription and that caloric intake between the two conditions would be significantly different.

Finally, exploratory analyses were conducted to assess the impact of the 1,000 and 1,500 caloric prescriptions on self-reported levels of dietary disinhibition, restraint, hunger, depression, self-efficacy, and quality of life, and to determine whether a mediation existed between these variables and frequency of binge eating episodes according to caloric assignment.

## CHAPTER 2 MATERIALS AND METHODS

### **Research Methods and Procedures**

The present study was a randomized trial that evaluated the effects of prescribing two calorie goals (1,000 versus 1,500 kcal/day) on weight loss at six months. Weight maintenance at one-year was also assessed. Approval was obtained from the University of Florida Institutional Review Board.

### **Participants**

This study included obese women between the ages of 25 to 75 years who weighed between 91 to 136 kg (i.e. 200 to 300 lbs). Weight limitations were imposed according to the energy requirements so that women who were prescribed a 1,500 kcal/day diet should have lost approximately 0.5 kg (1 lb) per week and women eating a 1,000 kcal/day diet should have lost 0.9 kg (2 lb) per week (NHLBI, 1998). Women were excluded if they lost an excess of 4.5 kg (10 lbs) within the preceding six months. In addition, participants were required to obtain written consent from their primary care physician stating they had no major medical complications that would limit their participation in a weight loss intervention or put them at risk for adverse events. Women also affirmed they were not pregnant and agreed to use proper contraception during the course of the study to prevent possible pregnancy. Interested participants were excluded for presence of a major psychiatric disorder or excessive alcohol intake, or if they were unavailable or unwilling to attend weekly group meetings, unwilling to self-monitor daily food and caloric intake, unwilling to adhere to the prescribed calorie goal, unwilling or unable to provide informed consent, unable to read English at a sixth

grade level, participating in another randomized research project, or have participated in a previous in a University of Florida weight loss program.

## **Procedure**

**Recruitment.** Participants in the study were recruited through the use of posted flyers and announcements in the Gainesville Sun newspaper classified section. Recruitment methods also included direct random mailings to female residents of Gainesville. Interested women were asked to telephone our office to undergo a brief telephone screening questionnaire. If women were eligible following the telephone interview, they were asked to attend an in-person assessment visit. At this visit, prospective participants received a detailed explanation of the study. Interested participants were asked to provide their informed consent. Measurements of height and weight, as well as questionnaires on demographic information, medical history, dietary intake and restraint, physical activity, and self-efficacy were completed. Potential participants were also be given a letter template and asked to obtain their physician's approval, indicating they had no medical contraindications to participating in a research study that required decreased caloric intake and increased physical activity and stating that they were not pregnant or planning on becoming pregnant in the next 16 months. Participants were then scheduled for a second assessment visit where they returned the physician consent letter and dietary intake questionnaire. Participants were again weighed at this visit to ensure they had not gained or lost  $\geq 10$  lbs since their first assessment visit.

All physical measures and questionnaires were then repeated at assessments at six months of the intervention and at study conclusion after a total of 12 months.

**Lifestyle Intervention.** The lifestyle intervention consisted of two phases. Phase I included 24 weekly group intervention sessions which were held at the University of Florida. Participants were randomized to a group of either 10 or 30 people.<sup>1</sup> Each session lasted 90 minutes and was designed to decrease caloric intake and increase moderate intensity physical activity. Dietary goals involved reducing energy intake to either 1,000 or 1,500 kcal/day so as to induce either a 0.90 kg or 0.45 kg weight loss, respectively. Participants were taught and encouraged to maintain a balanced diet according to recommendations from the U.S. Department of Agriculture and the National Institutes of Health's Dietary Approaches to Stop Hypertension, consisting of 22 to 29% total kcal from fat, 18 to 21% from protein, and the remaining 55 to 57% from carbohydrates (US Department of Health and Human Services, 2005). Participants were also encouraged to increase fruit and vegetable consumption to five servings per day and whole grains to three or more servings per day.

In order to increase adherence to caloric intake goals, a variety of strategies were utilized. Consistent with the conceptual model from the social cognitive theory (Bandura, 1977, 1986), participants first received education on strategies to control

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<sup>1</sup>The present dissertation was conducted in conjunction with dissertation research by Pamela J. Dubyak, M.S. She assessed whether participants assigned to a large group size (i.e. approximately 30 people) achieved similar weight losses to participants assigned to a smaller group size (i.e. approximately 10 people). Therefore, this study was comprised of four groups consuming 1,000 kcal/day (i.e. one group consisting of 30 participants and the remaining three groups consisting of 10 participants), and four groups consuming 1,500 kcal/day (i.e. again with one group of 30 participants and three groups of 10 participants). Analyses were conducted to assess for interactions between group size and caloric restriction levels. No interactions were found, and therefore results for the present study do not address group size.

caloric intake, including structured meal plans, examples of pre-packaged portion-controlled entrees, and suggestions for partial meal replacements (see Appendix A).

Second, self-efficacy and positive outcome expectancies were increased as participants were taught successful ways to modify eating behaviors through food tastings. Third, participants were guided in setting weekly goals, monitoring their progress, controlling negative stimuli, and restructuring maladaptive cognitions in order to improve self-regulatory skills. In addition to caloric intake, weekly goals included assignments that involved purchasing one new pre-packaged meal or planning a menu that incorporates more fruits and vegetables. Fourth, problem solving was utilized to overcome barriers to initiating and maintaining behavior change. Physical activity goals were also created each week based on recommendations of the American College of Sports Medicine (Donnelly, 2009). Pedometers were supplied as participants were encouraged to add 3,000 or more steps/day above baseline levels or attain 10,000 steps/day. To accomplish these goals, participants were instructed to maintain detailed daily written records of their dietary intake and physical activity.

Phase I also included cognitive and behavioral skills training for weight loss consisting of goal-setting, self-monitoring, self-reinforcement, stimulus control, cognitive restructuring, and increasing social support. Weekly sessions consisted of a private weigh-in, a review of participants' progress toward goals, a discussion of nutrition and exercise, feedback and encouragement from group leaders and other group members, and skills training related to the behavioral strategies for weight loss. Additionally, sessions included stress and depression coping strategies and techniques for eating away from home.

Phase II consisted of an extended care 6-month follow-up program in which participants were encouraged to maintain the new eating and exercise habits learned during the Phase I intervention. Participants were also encouraged to continue monitoring dietary intake and physical activity through the use of recording logs. During Phase II, all participants were asked to attend in-person group sessions once per month.

## **Measures**

**Body weight.** In the current study, body weight was used as the primary outcome measure. Weight was measured to the nearest 0.1 kg using a digital Tanita-BWB 800S scale. Participants were weighed at weekly group sessions and at assessments at Months 0, 6, and 12 while wearing light indoor clothing, without shoes, and with empty pockets.

**Caloric Intake.** Participants were asked to complete food records daily throughout Phase I and at least three times per week during Phase II of the study. Mean caloric intake was calculated by summing all daily values provided by participants from Months 0 – 6 and Months 7 – 12 for Phase I and II, respectively. Only self-monitoring logs that contained calorie values were included in this analysis. The total number of food records maintained serves as a better predictor of successful weight loss than actual content (Debraganza, 2010; Streit, Stevens, Stevens, & Rössner, 1991). For the present study, the total number of daily records completed from Months 0 – 6 and Months 7 – 12 was used as a measure of self-monitoring adherence. A completed record was operationally defined as having recorded at least two designated meals, regardless if caloric value was included.

**Adherence to Caloric Prescription.** Adherence to prescribed caloric intake goals was calculated by dividing the mean weekly amount consumed by the amount prescribed multiplied by 100. For example, if a participant consumed 900 kcal and her daily prescription was 1,000 kcal, she would be considered 10% below her prescribed goal. Adherence was then classified by the following categorization: 15% or more below the prescribed goal, within (+/-) 15% of the prescribed caloric intake goal, and 15% or more above the prescribed goal, based upon classifications utilized in the PREFER behavioral treatment weight-loss study, which assessed adherence to kilocalorie goals at baseline, 6, 12, and 18 months (Warziski et al., 2008).

**Physical activity.** Frequency and duration of levels of physical activity occurring within the previous week were measured utilizing the short-form, self-administered International Physical Activity Questionnaire (IPAQ) (Craig, et al., 2003). A study of reliability and validity demonstrated that the short-form IPAQ has reasonable measurement properties at least as good as established self-report measures of physical activity (Craig et al., 2003). We examined the change in minutes of moderate intensity walking rather than calculate a total score and convert to a metabolic equivalent of task (MET).

**Self-Efficacy.** The Weight Efficacy Lifestyle (WEL) questionnaire was used to measure self-efficacy specific to eating behaviors (Clark et al., 1991). This 20-item questionnaire utilizes a 10-point Likert scale assessing confidence in ability to avoid eating. The WEL contains one total score derived from totaling the scores from 20 items, has demonstrated good psychometric properties, and has proven to be an

acceptable measure of self-efficacy judgments for eating behaviors among obese individuals (Clark et al., 1991).

**Depressive Symptoms.** Symptoms of depression were measured by the BDI-II, a well-validated measure of depressive symptomatology (Beck, Steer, & Brown, 1996).

**Disinhibition, Hunger, and Self-Restraint.** The Eating Inventory/Three Factor Eating Questionnaire (EI) measures three dimensions of eating behavior: cognitive restraint of eating, disinhibition, and hunger (Stunkard & Messick, 1985). The EI is a 51-item questionnaire that has well-established reliability and validity (Gorman & Allison, 1995).

**Binge Eating Episodes.** The Binge Eating Scale (BES), a well-validated measure assessing binge eating severity in obese populations on a continuous scale, was utilized to classify binge eaters (Gormally, Black, Daston, & Rardin, 1982). The BES has been found to display good test-retest reliability (Greeno, Marcus, & Wing, 1995) and moderate associations with binge eating severity measured with food records (Timmerman, 1999).

**Quality of Life.** Quality of life was measured using the well-validated MOS Short-Form 36-Health Survey (SF-36; Ware, Kosinski, & Keller, 1994). The SF-36 assesses eight domains of health-related quality of life: role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. At least three studies (Fontaine & Barofsky, 2001; Jenkinson, Wright, & Coulter, 1994; Ware et al., 1994) have documented excellent psychometric properties for the SF-36 and validity has been well-established in populations of obese adults (Fontaine & Barofsky, 2001).

**Attendance.** Session attendance was recorded if the participant arrived at the treatment session and was weighed by a staff member.

**Group Preference.** A self-report measure designed for the present study assessed preference to either a 1,000 kcal/day goal in which rate of weight loss is expected to be faster, or to a 1,500 kcal/day goal where rate of weight loss is predicted to be slower (see Appendix B).

## Statistical Analyses

### Primary Aim

A sample size of at least 108 participants was selected to provide a statistical power of 0.80 to detect a 3.0% difference in weight regain between conditions using a 5.5% standard deviation within conditions (two-tailed testing with Bonferroni adjustments) as has been demonstrated in previous trials (Jeffery et al., 2000; Wadden, Berkowitz, Sarwer, Prus-Wisniewski, & Steinberg, 2001; Wadden et al., 2005). A missing-not-at-random (MNAR) approach was used to examine the data. Differences in weight between Months 0, 6, and 12 were analyzed using pattern mixture models (Little, 1994). A 0.3 kg/month was added to the last recorded intermittent weight for each participant who did not complete the assessment at 6 or 12 months. Based on this rate, 1.8 kg was added to the Month 6 weight for those who did not complete Phase II extended care or 12-month assessment. This scenario is based on the documented pattern of weight regain following lifestyle treatment (Jeffery et al., 2000; Perri et al., 2008; Wadden et al., 2001; Wadden et al., 2005).

An additional Chi-Square analysis was also conducted to assess whether treatment conditions differed in those achieving a  $\geq 5\%$  weight loss at both 6 and 12

months of the intervention. Percent weight change for participants at Month 6 was calculated using the following formula:  $((\text{Month 6 weight} - \text{Month 0 weight}) / \text{Month 0 weight}) * 100$ . Similarly, Month 12 percent weight change was calculated by the following:  $((\text{Month 12 weight} - \text{Month 0 weight}) / \text{Month 0 weight}) * 100$ .

### **Secondary Aim**

In order to examine whether participants first differed with respect to caloric intake goals, weekly reported caloric intake was averaged across Phase I of lifestyle intervention. Independent samples *t*-tests were conducted to assess whether the two treatment conditions differed in levels of caloric intake, according to mean values reported on self-monitoring logs.

Adherence to caloric prescription goals was also assessed for participants in both treatment conditions. Using mean reported calorie intake from self-monitoring records during Phase I, adherence was categorized by consumption 15% or more below prescribed amount, within (+/-) 15% of prescribed amount, and consumption 15% or more above prescribed amount. These values were based upon calculations dividing the amount consumed by the amount prescribed multiplied by 100. A Chi-Square analysis using an alpha level of 0.05 was conducted to assess whether the two treatment conditions significantly differed in categorized levels of adherence during Phase I.

### **Tertiary and Exploratory Aims**

Results of the Eating Inventory were utilized to calculate levels of disinhibition, restraint, and hunger. In addition, data from the BDI-II and Weight Efficacy Lifestyle questionnaire provided levels of depression and self-efficacy, respectively. To assess

whether differences between treatment conditions existed, three 3 x 2 repeated measures ANOVA were conducted to compare changes in ratings of these constructs from Months 0 to 6, Months 6 to 12, and Months 0 to 12. The between-condition variable was treatment condition, while the within-condition variable was time. Given the large number of statistical tests conducted, an alpha of 0.01 was used as a conservative balance between Type I and Type II error.

To assess whether treatment conditions differed in frequency of binge eating episodes, a 3 x 2 repeated measures ANOVA was also conducted utilizing results of the Binge Eating Scale as the between-condition variable and time as the within-condition variable. An alpha level of 0.01 was once again used for significance testing. To assess whether self-reported disinhibition, restraint, hunger, depression, and self-efficacy serve as mediators between treatment condition and frequency of binge eating episodes, the Baron and Kenny method (1986) was used. First, Pearson's correlations determined whether each of the variables in question was significantly associated with both treatment condition and frequency of binge eating episodes. If correlations were present, a multiple regression was conducted to determine whether a mediation existed. An alpha level of 0.05 was used for significance testing. Finally, to examine changes in quality of life factors across time, repeated measures ANOVA testing was employed as described above, with quality of life factors as between-condition variables.

Statistical analysis for the primary aim was conducted using SAS<sup>®</sup> statistical software (SAS Institute, 2008). Analyses for the secondary, tertiary, and exploratory aims were conducted using SPSS<sup>®</sup> statistical software, version 18.0 (SPSS, Inc., 2010).

## CHAPTER 3 RESULTS

### **Participants**

Of the original 182 participants assessed on location, 44 were initially excluded. The remaining 138 were potentially eligible for randomization; however, prior to initiation of lifestyle intervention, 13 of these individuals declined to participate. Therefore, the sample was composed of 125 obese women (mean  $\pm$  SD age = 52.0  $\pm$  10.8 years; unadjusted weight = 104.9  $\pm$  10.6 kg; BMI = 37.9  $\pm$  3.9 kg/m<sup>2</sup>). Of these individuals, 60 were assigned to the 1,500 kcal/day goal and 65 were assigned to a 1,000 kcal/day goal. Two women, one from each treatment condition, were removed from the study during Phase I due to exclusionary medical conditions and therefore were not included in the study analyses. Overall, 112 individuals completed the assessment at six months (90% of those who initiated treatment) and 111 finished the 12-month assessment (89% of those who initiated treatment). See Figure 3-1 for a Consolidated Standards of Reporting Trials (CONSORT) diagram, which documents participation. No significant differences in baseline age, weight, BMI, race/ethnicity, education, or household yearly income were found between the 1,000 or 1,500 calorie conditions (Table 3-1). There existed a difference in baseline level of physical activity, as measured by the IPAQ, with those women in the 1,000 kcal/day condition endorsing a lower level of physical activity than women in the 1,500 kcal/day condition,  $\chi^2(2) = 7.05$ ,  $p = .029$ , Cramer's  $V = .24$ . Therefore, analyses were run both with and without level of physical activity as a covariate. There were no differences in results when the covariate was included and so the following will present results without using physical activity as a covariate.

## Primary Aim

### Weight Change Outcomes

There existed a significant condition by time interaction effect across the course of the study,  $F(2, 122) = 8.39, p < .001$ , Figure 3-1. For those participants assigned the 1,000 kcal/day goal, there was a significant weight change from Month 0 – 6 ( $t(122) = 12.85, p < .001$ , Cohen's  $d = .96$ ) and Month 0 – 12 ( $t(122) = 8.27, p < .001$ , Cohen's  $d = .72$ ). This condition also experienced a significant weight regain from Month 6 – 12 of the trial,  $t(122) = -3.31, p = .001$ , Cohen's  $d = .17$ . Participants prescribed the 1,500 kcal/day goal also experienced a significant change in weight from Month 0 – 6 ( $t(122) = 7.17, p < .001$ , Cohen's  $d = .56$ ) and Month 0 – 12 ( $t(122) = 5.33, p < .001$ , Cohen's  $d = .49$ ); however, there was no significant time effect between Month 6 – 12 for this condition,  $p = .465$ . Adjusted and unadjusted weight change outcomes (means and SDs) for both the moderate and mild caloric restriction conditions from Month 0 – 6, Month 6 – 12, and Month 0 – 12 are presented in Table 3-2.

It was found that rates of dropout, eight women in the 1,000 kcal/day condition and six women in the 1,500 kcal/day condition, did not significantly affect the primary study outcomes ( $p = .360$ ). Participants attended a mean  $16.9 \pm 6.5$  sessions out of a total 24 possible during Phase I of the trial and  $3.0 \pm 2.3$  sessions out of a total 6 possible during Phase II. While higher rates of attendance were correlated with weight change from Month 0 – 6 ( $r = -.58, p < .001$ ) and Month 0 – 12 ( $r = -.25, p = .009$ ), there existed no significant differences in attendance rates between conditions during Phase I or Phase II,  $p = .377$  and  $p = .670$ , respectively (See Table 3-3). Attendance rates during Phases I and II of the study did differ significantly by group leader ( $15.6 \pm 6.8$  versus  $18.4 \pm 5.8$ ;  $F(1,121) = 6.153, p = .014, \eta^2_{\text{partial}} = .05$  for Phase I, and  $2.7 \pm 2.2$

versus  $3.5 \pm 2.2$ ;  $F(1, 121) = 4.706$ ,  $p = .032$ ,  $\eta^2_{\text{partial}} = .04$  for Phase II); however, there was no interaction effect when treatment condition was added to the model during either Phase I or Phase II,  $p = .744$  and  $p = .897$ , respectively. There was no effect for condition preference in that participants who were matched to their preferred caloric prescription goal did not achieve significantly different amounts of weight loss at 6 and 12 months than those who were matched to the goal they did not prefer,  $p = .128$  and  $p = .072$ , respectively; see Table 3-4. Again, there was no interaction effect when treatment condition was added to the model,  $p = .155$  at Month 6 and  $p = .111$  at Month 12.

### **Weight Change at Month 6**

At the conclusion of the initial six-month treatment period, the 1,000 kcal/day and 1,500 kcal/day conditions lost an estimated mean ( $\pm$  SD)  $-10.8 \pm 6.8$  and  $-6.3 \pm 6.8$  kg, respectively. At Month 6, the magnitude of these weight reductions significantly differed from each other,  $t(122) = 2.05$ ,  $p = .04$ , Cohen's  $d = .66$ . Of those women who completed the assessment at Month 6, 64% ( $n = 79$ ) attained a weight loss  $\geq 5\%$ . Within the 1,000 kcal/day condition, 72% ( $n = 46$ ) of participants reached this percentage of loss compared to 56% ( $n = 33$ ) in the 1,500 kcal/day condition. There existed no significant difference between treatment conditions in proportion of participants achieving a  $\geq 5\%$  weight reduction at Month 6,  $p = .065$ .

### **Weight Change at Month 12**

From conclusion of Phase I of behavioral treatment to 12-month follow-up, amount of weight regain was assessed by condition. Those women assigned the 1,000 kcal/day intake regained an estimated mean  $2.1 \pm 5.2$  kg body weight, while those

women assigned the 1,500 kcal/day goal regained  $0.5 \pm 5.1$  kg body weight. Therefore, overall those prescribed the 1,000 kcal/day intake lost an estimated total of  $-8.6 \pm 8.4$  kg at Month 12, while the women prescribed the 1,500 kcal/day intake lost  $-5.8 \pm 8.4$  kg. These weight losses no longer significantly differed at Month 12,  $p = .261$ . However, given our large standard deviation at Month 12 for the 1,000 and 1,500 kcal/day conditions, this study may not have been adequately powered to address differences of this effect size.

At Month 12, 52% ( $n = 64$ ) of the participants achieved a  $\geq 5\%$  weight loss. Within the 1,000 kcal/day condition, 61% ( $n = 39$ ) of participants reached this percent reduction compared to 42% ( $n = 25$ ) in the 1,500 kcal/day condition. Significantly more women in the 1,000 kcal/day condition achieved a weight change  $\geq 5\%$  at Month 12,  $X^2(1) = 4.239$ ,  $p = .04$ , Cramer's  $V = .19$ .

### **Secondary Aim**

Mean self-reported caloric intake for Phase I of the lifestyle intervention was calculated by averaging weekly reported caloric intake during the 24-week period. The participants prescribed a 1,000 kcal/day goal consumed a mean  $1,164 \pm 170$  calories, while those participants prescribed 1,500 kcal/day consumed a mean  $1,518 \pm 222$  calories. Mean caloric intake was found to be significantly different between conditions,  $t(122) = -10.01$ ,  $p < .001$ , Cohen's  $d = 1.80$ .

To assess whether participants in each condition were adherent to their prescribed caloric intake goals, caloric intake percentages were calculated by dividing participants' mean caloric intake by their prescribed goal and multiplying by 100. On average, participants in the 1,000 kcal/day condition consumed 16% more calories than

prescribed. Women who were prescribed the 1,500 kcal/day intake goal ate 1% more calories than prescribed.

Using adherence categories where participants were classified according to percent above or below their prescribed amount (e.g., 15% or more below prescribed goal, within (+/-) 15% of prescribed amount, and 15% or more above caloric intake goal), results indicated significant differences between the treatment conditions during Phase I,  $X^2(2) = 17.2$ ,  $p < .001$ , Cramer's  $V = .37$ . While 77% of the women prescribed the 1,500 kcal/day diet were classified as within 15% of their prescribed amount, 53% of those instructed to consume a 1,000 kcal/day diet were found to be within this range. In addition, 45% of participants in the 1,000 kcal/day condition were categorized as consuming  $\geq 15\%$  above their prescribed amount. Ten percent of the women on the 1,500 kcal/day prescription were categorized as consuming at least 15% below their prescribed amount. See Table 3-5 for categories based on percent adherence by condition. A trend was observed between participant adherence to caloric prescription and weight change, as those who adhered within (+/-) 15% of their caloric intake goal lost  $9.6 \pm 7.2$  kg compared to the  $7.0 \pm 6.8$  kg reduction achieved by those who did not consume within 15% of their prescribed calorie goal,  $p = .058$ .

An additional Independent Samples  $t$ -test was conducted to assess whether conditions differed in the number of self-monitoring records kept during Phase I. A self-monitoring log was considered complete if at least two designated meals were recorded in one day. Out of a potential 168 records, women in the 1,000 kcal/day condition turned in  $98.3 \pm 49.9$  food records, while those in the 1,500 kcal/day prescription turned

in  $98.7 \pm 57.4$  self-monitoring logs. The conditions did not differ in respect to adherence to maintaining self-monitoring logs,  $p = .973$ .

During Phase II of the trial, women were asked to maintain at least three days of food records per week. Therefore, the total number of weeks of records was used to assess differences in adherence to self-monitoring goals between conditions. Out of a total potential 24 weeks of self-monitoring logs, those prescribed 1,000 kcal/day returned  $4.7 \pm 7.2$  weeks of records, while those prescribed 1,500 kcal/day maintained  $6.8 \pm 9.7$  weeks of records,  $p = .182$ . While no between condition differences existed, this variable was significantly correlated to weight change from Months 6 to 12, with those participants maintaining a greater number of food records achieving greater weight loss success,  $r = -.44$ ,  $p < .001$ . During Phase II, participants were asked to maintain their prescribed caloric intake goals unless they had achieved a BMI of  $< 25$ , which pertained to one participant in the 1,000 kcal/day condition. During the extended-care period, participants within the treatment conditions continued to consume significantly different levels of caloric intake, with those prescribed 1,000 kcal/day reporting  $1,247 \pm 246$  kcal/day and those prescribed 1,500 kcal/day reporting  $1,488 \pm 208$  kcal/day,  $t(56) = -4.00$ ,  $p < .001$ , Cohen's  $d = 1.06$ .

### **Tertiary and Exploratory Aims**

#### **Restraint, Disinhibition, Hunger**

Table 3-6 outlines values of restraint, disinhibition, and hunger specific for the 1,000 kcal/day and 1,500 kcal/day conditions at Months 0, 6, and 12.

Restraint was found to increase from Month 0 to Month 6 and slightly decrease at Month 12. Mauchly's Test of Sphericity was significant ( $p < .01$ ) and therefore

Greenhouse-Geisser results were utilized. There existed a significant main effect for restraint across the three time points,  $F(1.78, 169.31) = 151.51, p < .001, \eta^2_{\text{partial}} = .70$ . However, the interaction effect of caloric prescription across time was not significant,  $p = .978$ , indicating the conditions did not differ in reported levels of restraint throughout the study period.

Levels of disinhibition decreased within the sample from baseline to end of Phase I and then slightly increase at the end of Phase 2. There existed a significant main effect for changes in level of disinhibition across time,  $F(2, 186), = 52.87, p < .001, \eta^2_{\text{partial}} = .55$ ; however, levels of disinhibition did not differ between conditions across the three time periods,  $p = .188$ .

Hunger also decreased from Month 0 to Month 6 and remained fairly stable at Month 12. Again, Mauchly's Test of Sphericity was significant ( $p < .01$ ) and therefore Greenhouse-Geisser values were used. The changes in hunger level was found to be significant across time, as indicated by a significant main effect,  $F(1.82, 169.38) = 56.28, p < .001, \eta^2_{\text{partial}} = .55$ . There was not a significant interaction effect of caloric prescription, indicating the conditions did not differ from each other across the study period with respect to levels of hunger,  $p = .346$ .

## **Depression**

Levels of depression at both 6 and 12 months did not meet the assumptions for normality with regards to skewness ( $z = 2.57$  at Month 6 and  $z = 2.34$  at Month 12). Because the depression variables were positively skewed, they were transformed using a square root ( $\sqrt{X_i + 1}$ ) for subsequent analyses. Participants exhibited minimal levels of depressive symptoms at the three assessment points. Trends from the overall

sample demonstrated a significant decrease in depressive symptoms during Phase I and a slight increase by Month 12. A significant main effect for depressive symptoms existed across time,  $F(2, 188) = 37.37, p < .001, \eta^2_{\text{partial}} = .45$ ; however, the interaction effect of time by condition was not significant, indicating conditions did not differ in levels of depression across Month 0, 6, or 12 of the study,  $p = .607$ ; see Table 3-6.

### **Self-Efficacy**

Levels of self-efficacy were found to increase from Month 0 to 6 and slightly decrease at Month 12. Table 3-6 outlines values specific for the 1,000 kcal/day and 1,500 kcal/day conditions. Mauchly's Test of Sphericity was significant for self-efficacy, and thus the Greenhouse-Geisser values were utilized for the results. A significant main effect indicates reported levels of self-efficacy differed across the three assessment points,  $F(1.72, 166.33) = 55.08, p < .001, \eta^2_{\text{partial}} = .49$ . Again, conditions did not differ significantly across the course of the study, as indicated by a non-significant interaction effect between time and treatment condition,  $p = .482$ .

### **Mediation of Binge Eating**

It was found at the three assessment points, the mean reported level of binge eating did not classify our sample as binge eaters (as demonstrated by a score  $\geq 17$  on the BES). Binge eating decreased from Month 0 to Month 6 and slightly increased at Month 12. This trend was consistent for both the 1,000 and 1,500 calorie conditions (see Table 3-6). Results demonstrated a significant main effect for time with respect to levels of binge eating,  $F(2, 190) = 51.32, p < .001, \eta^2_{\text{partial}} = .49$ ; however, the interaction of conditions across time was not significant,  $p = .072$ . Because conditions did not differ on levels of disinhibition, restraint, hunger, depression, self-efficacy, or with respect to

frequency of binge eating episodes, a mediation analysis of associations between these variables according to caloric assignment could not be conducted.

### **Quality of Life**

Quality of life was measured using the nine subscales of the SF-36: Reported Health Transition, Physical Functioning, Role Functioning-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Functioning-Emotional, and Mental Health. Table 3-7 provides values for the 1,000 kcal/day and 1,500 kcal/day conditions as well as the total sample on each of these subscales. Repeated measures 3 x 2 ANOVAs were conducted to assess for changes in reported levels of quality of life between treatment conditions. No significant main effect for time or significant interaction effects with treatment condition were observed for levels of Role Functioning-Physical, Bodily Pain, Social Functioning, or Role Functioning-Emotional.

Mauchly's Test of Sphericity was significant for Health Transition, Physical Functioning, General Health, Social Functioning, and Mental Health, and therefore the Greenhouse-Geisser results were utilized. There existed significant main effects across time for Health Transition,  $F(1.69, 153.86) = 43.17, p < .001, \eta^2_{\text{partial}} = .40$ , Physical Functioning,  $F(1.78, 170.70) = 17.57, p < .001, \eta^2_{\text{partial}} = .28$ , General Health,  $F(1.83, 175.84) = 16.29, p < .001, \eta^2_{\text{partial}} = .26$ , Vitality,  $F(2, 192) = 26.96, p < .001, \eta^2_{\text{partial}} = .36$ , and Mental Health,  $F(1.80, 172.48) = 9.82, p < .001, \eta^2_{\text{partial}} = .20$ . There existed no significant interaction effects between caloric prescription and time on any quality of life variables except Social Functioning. Results of an Independent Samples *t*-test indicated conditions significantly differed on reported levels of Social Functioning at Month 12,  $t(97) = 2.67, p = .009, \text{Cohen's } d = .54$ .

## Weight Regain

It was found that 28 participants regained  $\geq 4.5$  kg body weight from 6 to 12 months, thus contributing to the large standard deviation at Month 12. Sixteen of these women were prescribed a 1,000 kcal/day goal, while 12 were assigned the 1,500 kcal/day condition. Exploratory Analysis of Variance tests were conducted using Month 0 study measures to investigate whether baseline characteristics were associated with weight regain (Table 3-8). Participants who regained  $\geq 4.5$  kg from Months 6 to 12 reported higher levels of depressive symptoms ( $F(1, 116) = 4.439, p = .037, \eta^2_{\text{partial}} = .03$ ), disinhibition ( $F(1, 117) = 5.159, p = .025, \eta^2_{\text{partial}} = .04$ ), and greater caloric intake during the baseline week of the intervention ( $F(1, 121) = 4.232, p = .042, \eta^2_{\text{partial}} = .03$ ) compared to those who regained  $< 4.5$  kg. When treatment condition was added to the model, no interaction effects by caloric prescription were found for depression ( $p = .241$ ), disinhibition ( $p = .357$ ) or baseline caloric intake ( $p = .348$ ). No differences existed between regain categories with respect to baseline age, weight, restraint, hunger, binge eating, self-efficacy, or physical activity.

In additional exploratory analyses, weight regain was kept as a continuous variable and baseline levels of depressive symptoms, disinhibition, and caloric intake were categorized. Levels of depression were dichotomized as above or below the cutoff for mild depression (i.e., a score  $\geq 14$  on the BDI-II). It was found that 78 participants endorsed scores below the cutoff ( $n = 41$  in the 1,000 kcal/day condition and  $n = 37$  in the 1,500 kcal/day condition) and 40 participants reported mild depression or above ( $n = 21$  in the 1,000 kcal/day condition and  $n = 19$  in the 1,500 kcal/day condition). Given no clinical level exists for determining disinhibition (Stunkard &

Messick, 1985), this variable was categorized as either above or below the median level at baseline. According to answers on the Eating Inventory's 16 disinhibition questions, the median score was found to be 10. Finally, baseline caloric intake was also dichotomized according to the median of 1882.3 kcal/day, as no level of mean baseline energy intake for a population similar to the present study's was found. These potential moderators were again assessed by treatment condition and weight regain from Months 6 – 12 (Table 3-9). In the analysis including depressive symptoms, no significant main effects for treatment condition or depressive symptoms were found,  $p = .427$  and  $p = .167$ , respectively. In addition, no interaction effect existed between the two variables and weight change during Phase II,  $p = .698$ .

In the analysis of disinhibition x treatment condition x weight regain, no main effects existed for disinhibition, ( $p = .436$ ) or treatment condition ( $p = .053$ ). Additionally, there did not exist a significant interaction effect among these variables,  $p = .169$ . While no significant main effects existed for baseline caloric intake x treatment condition x weight regain from Months 6 – 12 ( $p = .144$  for treatment condition and  $p = .714$  for baseline caloric intake) a significant interaction effect was found among treatment condition x baseline caloric intake x weight regain during Phase II,  $F(1, 119) = 4.169$ ,  $p = .043$ ,  $\eta^2_{\text{partial}} = .03$ . Post-hoc testing indicated that participants with higher baseline caloric intake who were assigned the 1,000 kcal/day condition regained significantly greater amounts of weight than those with higher baseline caloric intake who were prescribed a 1,500 kcal/day diet,  $t(60) = 2.488$ ,  $p = .016$ , Cohen's  $d = .64$ .

Exploratory analyses were also conducted to assess for differences during the intervention between those who regained  $\geq 4.5$  kg and  $< 4.5$  kg (Table 3-10). No

significant differences were found with respect to completion of self-monitoring logs ( $p = .192$ ) or percent adherence to caloric prescription during Phase I of the intervention ( $p = .547$ ). There was, however, a significant difference in number of sessions attended during Phase I. Levene's test was significant ( $F(1, 121) = 8.408, p = .004$ ), indicating a violation of homogeneity of variances, and therefore, Brown-Forsythe results are shown. Those who regained large amounts of weight attended more sessions compared to those who did not regain a substantial amount of weight,  $F(1, 58.857) = 5.162, p = .027, \eta^2_{\text{partial}} = .03$ . No interaction effect by caloric prescription condition was found,  $p = .254$ . No significant differences were found between regain groups in attendance rates during Phase II,  $p = .296$ . With respect to number of calorie records completed during Phase II, Levene's test indicated unequal variances ( $F(1, 121) = 20.928, p < .001$ ), therefore the Brown-Forsythe test was utilized. Those participants who regained  $\geq 4.5$  kg returned significantly fewer weeks of calorie records compared to the group who did not regain 4.5 kg or more ( $F(1, 74.765) = 11.717, p = .001, \eta^2_{\text{partial}} = .05$ ) suggesting lower adherence to self-monitoring in the large regain group. Again, no interaction effect by treatment condition was found,  $p = .567$

At Month 6, regain groups did not differ on reported levels of depression ( $p = .924$ ), restraint ( $p = .129$ ), disinhibition ( $p = .987$ ), hunger ( $p = .985$ ), binge eating ( $p = .906$ ), and self-efficacy ( $p = .291$ ). Reported depressive symptoms at Month 12 were significantly different between regain groups. Levene's Test for equal variances was significant ( $F(1, 99) = 16.028, p < .001$ ) so the Brown-Forsythe test was used. Those who regained  $\geq 4.5$  kg reported greater depressive symptoms than those who regained less,  $F(1, 31.862) = 5.240, p = .029, \eta^2_{\text{partial}} = .08$ . In addition, all three variables

assessed by the Eating Inventory were also found to be different between regain groups, with those regaining more weight reporting significantly lower levels of restraint ( $F(1, 99) = 8.43, p = .005, \eta^2_{\text{partial}} = .08$ ) and higher levels of disinhibition ( $F(1, 99) = 7.674, p = .007, \eta^2_{\text{partial}} = .07$ ) and hunger ( $F(1, 99) = 8.425, p = .005, \eta^2_{\text{partial}} = .08$ ). Reported levels of self-efficacy were found to be significantly lower in those regaining  $\geq 4.5$  kg ( $F(1, 99) = 12.903, p = .001, \eta^2_{\text{partial}} = .12$ ), while endorsement of binge eating was significantly higher in the larger regain group compared to those who regained  $< 4.5$  kg,  $F(1, 99) = 12.574, p = .001, \eta^2_{\text{partial}} = .11$ . (See Table 3-11 for study measures at Months 6 and 12 according to weight regain category). Again, no interaction was significant for any aforementioned variables when caloric prescription treatment condition was added to assess for a moderation,  $p = .931$  for depression;  $p = .373$  for restraint;  $p = .599$  for disinhibition;  $p = .889$  for hunger;  $p = .858$  for self-efficacy; and  $p = .382$  for binge eating.

Table 3-1. Baseline values according to caloric prescription

	1,000 kcal/day <i>n</i> = 65		1,500 kcal/day <i>n</i> = 60		Total sample <i>N</i> = 125	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Age (years)	51.5	11.7	52.3	9.8	52.0	10.8
Unadjusted weight (kg)	105.0	10.6	104.7	10.7	104.9	10.6
BMI (kg/m <sup>2</sup> )	38.1	4.0	37.6	3.8	37.9	3.9
	<u><i>n</i></u>	<u>%</u>	<u><i>n</i></u>	<u>%</u>	<u><i>n</i></u>	<u>%</u>
Race/ethnicity						
Caucasian	48	73.8	44	73.3	92	73.6
African American	9	13.8	12	20.0	21	16.8
Hispanic American	4	6.2	0	0	4	3.2
Other	3	4.6	1	1.7	4	3.2
Declined to respond	1	1.5	3	5.0	4	3.2
Education						
12 years or less	3	4.6	3	5.0	6	4.8
13-15 years	33	50.8	28	46.7	61	48.8
16 years or more	29	44.6	29	48.3	58	46.4
Household yearly income						
< \$35,000	12	18.5	15	25.0	27	21.6
\$35,000 to \$49,999	10	15.4	12	20.0	22	17.6
\$50,000 to \$74,999	21	32.3	12	20.0	33	26.4
≥ \$75,000	18	27.7	18	30.0	36	28.8
Not reported	4	6.2	3	5.0	7	5.6

Table 3-2. Weight changes from Month 0 to Months 6 and 12 according to caloric prescription

	1,000 kcal/day				1,500 kcal/day			
	Unadjusted		Adjusted		Unadjusted		Adjusted	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Month 0 - 6	-11.6	7.3	-10.8 <sup>a,*</sup>	6.8	-6.7	6.1	-6.3 <sup>a,*</sup>	6.8
Month 6 - 12	2.5	4.9	2.1 <sup>b</sup>	5.2	0.5	4.7	0.5	5.1
Month 0 - 12	-9.5	7.8	-8.6 <sup>c</sup>	8.4	-6.3	8.7	-5.8 <sup>c</sup>	8.4

Note: <sup>a</sup>*p* < .001 for Month 0 – 6; <sup>b</sup>*p* < .001 for Month 6 – 12; <sup>c</sup>*p* < .001 for Month 0 – 12; <sup>\*</sup>*p* < .05 between treatment conditions for Month 0 – 6

Table 3-3. Attendance rates for Phase I and Phase II according to caloric prescription

	1,000 kcal/day		1,500 kcal/day	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Phase I (out of 24 total)	19.1	4.5	17.5	6.3
Phase II (out of 6 total)	3.7	1.8	3.3	2.3

Table 3-4. Weight changes according to matched and unmatched caloric prescription preference and assignment

	1,000 kcal/day				1,500 kcal/day				Total Sample			
	Matched		Unmatched		Matched		Unmatched		Matched		Unmatched	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Month 0-6	-9.2	6.5	-12.1	7.8	-6.5	6.4	-5.8	6.0	-7.7	6.5	-9.7	7.8
Month 0-12	-6.4	6.7	-10.9	7.9	-5.8	9.1	-5.4	8.2	-6.1	8.1	-8.8	8.3

Table 3-5. Percent adherence categorization for Phase I according to caloric prescription

	1,000 kcal/day		1,500 kcal/day	
	<i>n</i>	%	<i>n</i>	%
≥ 15% Below Caloric Prescription	1	1.6	6	10.0
Within (+/-) 15% of Caloric Prescription	34	53.1*	46	76.7*
≥ 15% Above Caloric Prescription	29	45.3*	8	13.3*

Note: \* $p < .001$  between conditions

Table 3-6. Restraint, disinhibition, hunger, self-efficacy, depression, and binge eating at Months 0, 6, and 12 according to caloric prescription

	1,000 kcal/day		1,500 kcal/day		Total Sample	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Restraint						
Month 0	7.3	3.7	8.3	3.9	7.7	3.8
Month 6	13.9	3.3	14.6	3.2	14.2*	3.2
Month 12	12.3	4.0	13.1	3.5	12.7*	3.8
Disinhibition						
Month 0	9.7	3.3	10.1	3.2	9.9	3.2
Month 6	6.4	3.0	6.8	3.8	6.6*	3.4
Month 12	8.3	3.8	7.8	4.0	8.1*	3.9
Hunger						
Month 0	7.3	3.6	7.3	3.1	7.3	3.3
Month 6	3.9	2.9	4.3	3.3	4.1*	3.1
Month 12	5.0	3.5	4.6	2.8	4.8*	3.1
Self-Efficacy						
Month 0	108.8	32.2	107.3	26.2	108.1	29.4
Month 6	138.9	21.8	137.9	19.8	138.4*	20.7
Month 12	126.9	31.1	127.8	26.1	127.4*	28.6
Depression						
Month 0	11.6	10.3	11.0	6.3	11.3	8.6
Month 6	6.0	7.6	5.2	5.8	5.6*	6.7
Month 12	5.7	7.2	6.5	7.6	6.1*	7.4
Binge Eating						
Month 0	16.4	8.3	16.1	6.8	16.2	7.6
Month 6	7.9	6.1	8.9	7.5	8.4*	6.8
Month 12	11.3	7.9	9.4	7.3	10.4*	7.6

Note: \*  $p < .001$  compared to Month 0 value

Table 3-7. Quality of life variables from the SF-36 at Months 0, 6, and 12 according to caloric prescription

	1,000 kcal/day		1,500 kcal/day		Total Sample	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Health Transition						
Month 0	3.1	1.0	3.1	1.2	3.1	1.1
Month 6	1.9	1.0	2.0	1.0	1.9 <sup>a</sup>	1.0
Month 12	2.1	0.9	1.9	1.1	2.0 <sup>b</sup>	1.0
Physical Functioning						
Month 0	69.9	20.6	72.7	21.9	71.2	21.0
Month 6	83.5	18.0	79.4	23.4	81.5 <sup>a</sup>	20.8
Month 12	80.2	23.7	79.6	24.3	79.9 <sup>b</sup>	23.9
Role Functioning (Physical)						
Month 0	73.5	34.8	71.3	35.6	72.4	35.0
Month 6	83.2	31.6	75.9	37.3	79.6	34.6
Month 12	85.5	29.9	75.0	38.8	80.3	34.9
Bodily Pain						
Month 0	68.8	25.3	62.5	23.5	65.5	24.5
Month 6	71.1	22.4	66.5	23.9	68.8	23.1
Month 12	67.9	22.0	67.0	24.3	67.4	23.1
General Health						
Month 0	64.3	22.3	66.2	17.9	65.2	20.3
Month 6	72.7	19.9	75.7	15.6	74.2 <sup>a</sup>	17.9
Month 12	69.9	19.5	73.3	18.6	71.6 <sup>b</sup>	19.0
Vitality						
Month 0	43.9	23.8	45.7	18.5	44.8	21.3
Month 6	61.7	20.5	60.8	15.1	61.3 <sup>a</sup>	18.0
Month 12	56.4	21.5	57.7	19.6	57.0 <sup>b</sup>	20.5
Social Functioning						
Month 0	72.9	25.8	73.9	24.4	73.4	25.1
Month 6	84.8	18.6	82.0	19.7	83.4	19.1
Month 12	88.5 <sup>*</sup>	19.7	76.0 <sup>*</sup>	26.4	82.2	24.0
Role Functioning (Emotional)						
Month 0	72.3	39.8	65.6	38.8	69.1	39.3
Month 6	73.9	40.4	75.3	35.6	74.6	37.9
Month 12	85.3	32.4	76.7	36.4	81.0	34.6
Mental Health						
Month 0	71.8	19.4	71.7	17.2	71.8	18.3
Month 6	79.3	15.9	80.7	12.5	80.0 <sup>a</sup>	14.3
Month 12	78.5	17.6	77.3	18.3	77.9 <sup>b</sup>	17.9

Note: <sup>a</sup> $p < .001$  for Month 0 – Month 6; <sup>b</sup> $p < .001$  for Month 0 – Month 12; <sup>\*</sup> $p < .01$  between treatment conditions at Month 12

Table 3-8. Month 0 study variables according to weight regain from Months 6 to 12

	Regain $\geq$ 4.5 kg (n = 28)		Regain < 4.5 kg (n = 95)	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Age	51.3	11.5	52.2	10.7
Weight	105.1	11.0	104.7	10.5
Depression	14.3*	10.7	10.3*	7.7
Restraint	7.4	3.9	7.8	3.9
Disinhibition	11.1*	2.4	9.5*	3.3
Hunger	7.6	2.7	7.1	3.5
Binge Eating	17.8	6.0	15.7	7.8
Self-Efficacy	98.8	29.6	111.1	28.9
Week 1 calorie mean	2016.0*	523.0	1712.7*	725.8

Note: \* $p < .05$  between categories

Table 3-9. Weight regain by Month 0 study variables according to treatment condition

	1,000 kcal/day		1,500 kcal/day	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Depression				
Score $\geq$ 14	1.8	7.2	1.4	4.1
Score < 14	1.8	4.3	0.6	4.4
Disinhibition				
Score $\geq$ 10	1.6	6.7	1.1	4.2
Score < 10	2.2	3.6	-1.0	5.2
Week 1 calorie mean				
Level $\geq$ 1882.3	3.1*	4.8	-0.0*	5.1
Level < 1882.3	0.9	5.7	1.5	3.5

Note: \* $p < .05$  for interaction of treatment condition, week 1 calorie mean, and weight regain

Table 3-10. Intervention variables according to weight regain from Months 6 to 12

	Regain $\geq$ 4.5 kg		Regain < 4.5 kg	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Ph I Attendance (# of weeks)	19.0*	5.0	16.4*	6.7
Ph I Weeks of calorie records	16.2	6.2	14.3	8.1
Ph I Caloric Adherence (%)	110.7	14.4	108.4	18.2
Ph II Attendance (#of weeks)	2.8	1.8	3.8	2.1
Ph II Weeks of calorie records	2.2**	5.4	6.9**	9.0

Note: \* $p < .01$  and \*\* $p < .001$  between categories

Table 3-11. Month 6 and 12 study variables according to weight regain from Months 6 to 12

	Regain $\geq$ 4.5 kg		Regain < 4.5 kg	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Month 6				
Depression	5.5	4.6	5.6	7.4
Restraint	15.0	2.6	14.0	3.4
Disinhibition	6.6	3.0	6.6	3.5
Hunger	4.1	2.8	4.1	3.2
Binge Eating	8.5	5.3	8.4	7.3
Self-Efficacy	134.8	22.0	139.6	20.3
Month 12				
Depression	9.5*	9.7	4.9*	6.0
Restraint	10.9*	3.3	13.3*	3.7
Disinhibition	9.8*	3.3	7.4*	3.9
Hunger	6.3*	3.3	4.3*	2.9
Binge Eating	14.7*	8.3	8.8*	6.8
Self-Efficacy	110.9*	28.0	132.9*	26.9

Note: \* $p < .01$  between categories

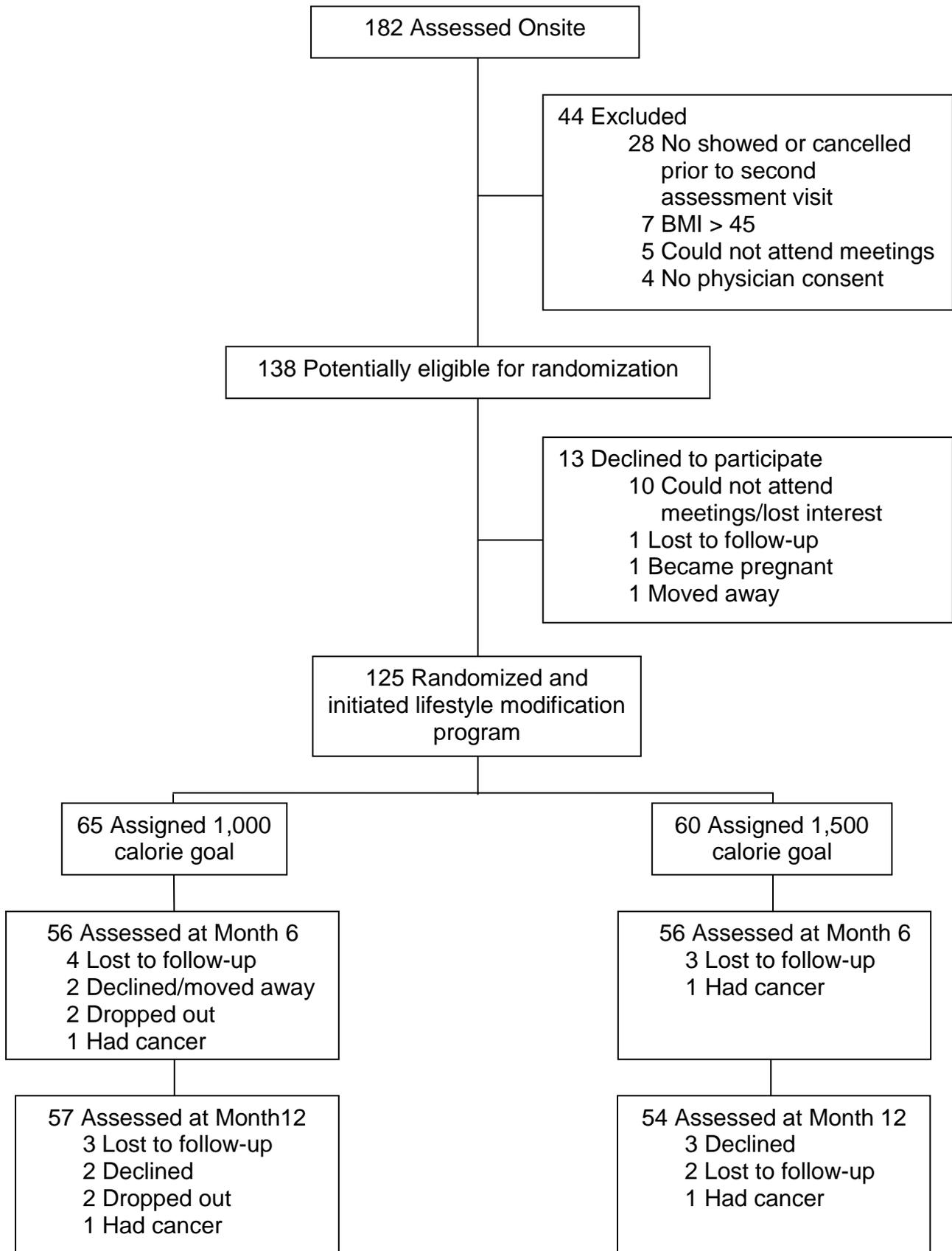


Figure 3-1. CONSORT diagram of participation rates during the 12-month program.

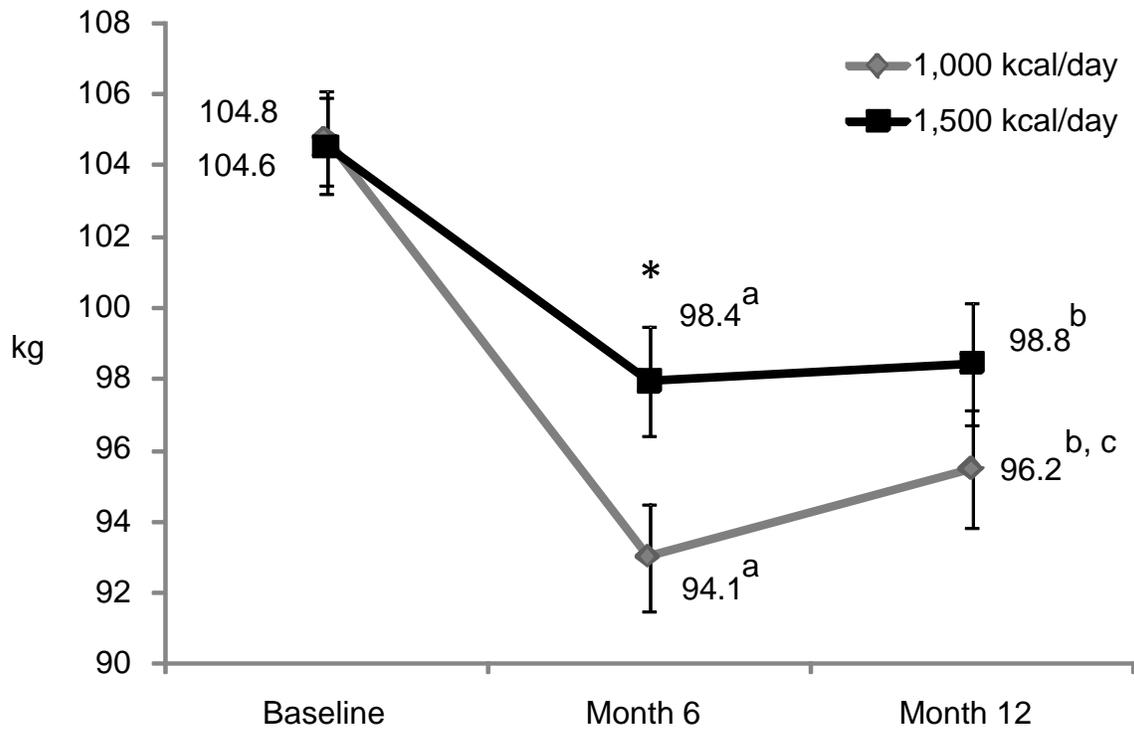


Figure 3-2. Adjusted weight changes according to treatment condition (Means and Standard Errors). \* $p = .04$  between treatment conditions at Month 6; <sup>a</sup> $p < .001$  for Month 0 – Month 6 for both conditions; <sup>b</sup> $p < .001$  for Month 0 – Month 12 for both conditions; <sup>c</sup> $p = .001$  for Month 6 – Month 12 for the 1,000 kcal/day condition.

## CHAPTER 4 DISCUSSION

### **Primary Aim**

The present lifestyle intervention trial examined whether prospectively prescribing a moderate caloric restriction of 1,000 kcal/day was associated with larger weight loss at six months and greater weight maintenance at 12 months than assigning a mild caloric restriction of 1,500 kcal/day. With regards to the primary aim, there were three key findings. First, while both conditions experienced a significant change in weight from baseline to six months, women who were assigned to the 1,000 kcal/day goal achieved a significantly greater weight loss than those women who were asked to consume 1,500 kcal/day ( $-10.8 \pm 6.8$  versus  $-6.3 \pm 6.8$ , respectively). When categorized according to those who achieved a  $\geq 5\%$  weight loss at Month 6, 64% of the sample achieved this level of weight reduction; however, no differences existed between treatment conditions in the percentage of participants reaching a  $\geq 5\%$  loss.

Second, it has been well documented that weight loss usually slows following six months of behavioral treatment (Jeffery et al., 2000; Wing, 2002), and weight regain begins (Perri, 1998; Wadden et al., 2007). Participants in the present study who were assigned a moderate caloric restriction of 1,000 kcal/day experienced a significant amount of weight regain between Months 6 – 12, while those assigned a mild caloric restriction of 1,500 kcal/day regained a nonsignificant amount of weight from end of treatment at six months to 12-month follow-up ( $2.1 \pm 5.2$  kg versus  $0.5 \pm 5.1$  kg, respectively).

The third key finding illustrates that both conditions experienced a significant change in weight from baseline to 12 months. However, as participants in the 1,000

kcal/day condition regained a significant amount of weight during the six-month extended-care period, at 12 months, weight changes were not significantly different between the 1,000 and 1,500 kcal/day conditions ( $-8.6 \pm 8.4$  versus  $-5.8 \pm 8.4$  kg, respectively). Of note, while participants in the 1,500 kcal/day condition did not regain a large amount of weight, they also did not continue to lose during Phase II of the study as is illustrated in other studies which utilized a small-change approach (Lutes et al., 2008; Sbrocco et al., 1999). This condition also remained 2.8 kg heavier than those prescribed the 1,000 kcal/day goal, which stands as a large clinical difference.

Our initial power analysis indicated a sample size of at least 108 participants to provide a statistical power of 0.80 to detect a 3.0% difference in weight regain between conditions using a 5.5% standard deviation within conditions. Given our large standard deviation at Month 12 for the 1,000 and 1,500 kcal/day conditions (8.4 and 8.4, respectively), this study may not have been adequately powered to address differences of this effect size. There did, however, exist a significant difference in the number of participants who achieved a weight loss  $\geq 5\%$  at Month 12. While 42% ( $n = 25$ ) participants in the 1,500 kcal/day condition reached this level of weight change, 61% ( $n = 39$ ) in the 1,000 kcal/day condition achieved this loss. From a clinical standpoint, maintaining a weight change  $\geq 5\%$  has been associated with reductions in glycemic control, hypertension, and hyperlipidemia (Diabetes Prevention Program Research Group, 2002; The Look AHEAD Research Group, 2010). Conversely, when weight is regained and net reduction is  $< 5\%$ , participants often lose the beneficial health effects associated with diabetes risk (Krebs et al., 2002), blood pressure (Stevens et al., 2001), and lipid control (Wadden, Anderson, and Foster, 1999). More participants in the 1,000

kcal/day prescription achieved and maintained a  $\geq 5\%$  weight reduction, which suggest potential clinical benefit of prescribing a greater caloric reduction and promoting greater initial loss in weight management programs.

Based upon classical and operant learning theory, greater initial changes in diet would result in larger reductions in body weight, which then reinforce habit change (Ferster et al., 1962; Stuart, 1967; Wadden et al., 2007; Wing, 2002). This appears congruent with 1,000 kcal/day condition where greater initial change in diet resulted in larger weight loss at six months compared to the 1,500 kcal/day condition. These results are similar to those found by Nackers and colleagues (2010) and Carels and colleagues (2003) where greater initial behavioral changes and a posited reinforcing initial weight loss was associated with improved weight-loss outcome following a six-month lifestyle intervention.

However, reducing calories so as to lose larger amounts of weight initially may also increase susceptibility to weight regain (McGuire et al., 1999; Sbrocco et al., 1999; Wadden et al., 1994; Weiss et al., 2007; Wing & Hill, 2001). This appeared especially true for those participants who consumed greater amounts of calories at baseline and who were then placed in the large caloric restriction condition of 1,000 kcal/day. These participants were asked to greatly restrain their dieting habits. According to the disinhibition hypothesis laid out by Herman and Polivy (1980), the level of dietary restraint required to sustain this reduction in caloric intake may have been too large to maintain, thus resulting in dietary violation. While the caloric prescriptions utilized in the current study did not fall under the classification of VLCDs, the weight regain trend seen from 6-12 months within the 1,000 kcal/day condition followed a similar pattern.

Wadden and colleagues (1994) utilized a VLCD of 420 kcal/day to initiate a large initial weight loss during the first 16 weeks of a 52 week behavioral treatment program. While these participants experienced nearly twice the initial weight reduction as those assigned a balanced deficit diet of 1,200 kcal/day at six months, they also regained significantly more weight (Wadden et al., 1994). Typically, VLCDs utilize meal replacements to achieve the prescribed energy content of 400-800 kcal/day, but participants are not asked to sustain this caloric intake level long-term (Wadden et al., 1994; Wadden & Stunkard, 1986; Wing, Blair, Marcus, Epstein, & Harvey, 1994; Wing et al., 1991). The current study differs in that participants were not prescribed a VLCD; however, reported caloric intake for participants in the 1,000 kcal/day condition did increase following the first six months, while the majority of participants within the 1,500 kcal/day group remained adherent to their caloric prescription.

In a review of participant weight loss during lifestyle interventions, Heymsfield and colleagues (2007) concluded that minimal weight changes associated with low-calorie diets are not likely due to biological adaptations, but more so attributed to difficulties with adherence to caloric intake. Kirschenbaum and Tomarken (1982) and Polivy and colleagues (1986) assessed restrained eaters and found that overeating reflected a disruption in self-monitoring of eating patterns. Applying this idea to the present study suggests that participants who highly restrained their eating (i.e., those assigned the 1,000 kcal/day goal) may have found it difficult to continuously monitor their eating behaviors in a strict manner. Hill and colleagues (2003) promote small daily reductions in energy intake that are thought to be more feasible to achieve and sustain than larger ones. This concept also supports the notion that, in the present study, those women

prescribed the 1,500 kcal/day goal may have been more likely to attain and maintain their energy prescription, while the women prescribed the 1,000 kcal/day may have initially achieved their energy intake goal, but were unable to sustain the behavioral change. These long-term results can be compared to those of Lutes and colleagues (2008) and Sbrocco and colleagues (1999), in which participants who were assigned greater behavioral changes experienced larger amounts of weight regain. Similar results of weight regain were found in a randomized trial where participants were categorized into tertiles according to maximum amount of weight loss (Jeffery et al., 1998). Participants who achieved the greatest amount of weight reduction in the short-term also experienced a larger and more rapid weight regain than those who initially demonstrated slower, smaller losses. Weiss and colleagues (2007) also found in an analysis of the 1999-2002 National Health and Nutrition Examination Survey that losing a greater percentage of maximum weight was associated with overall greater weight regain.

While this may have been true in the present study, the initial behavior change provided greater benefit as is illustrated by the significantly greater proportion of participants in the 1,000 kcal/day condition achieving and maintaining a  $\geq 5\%$  weight reduction at 12 months. In the aforementioned trial by Jeffery and colleagues (1998), participants who lost more weight initially also regained more weight; however, they continued to experience a greater reduction at 30 months compared to those who initially lost less. Unlike previous research that utilized the small-change approach (Lutes et al., 2008; Sbrocco et al., 1999) where participants who made small behavioral changes continued to lose weight, participants in the present study's 1,500 kcal/day

condition maintained, but did not continue to lose weight. This, along with the fact that less than half of the participants in this condition achieved a  $\geq 5\%$  reduction, suggests that the changes may not have been large enough to achieve beneficial results. Therefore, prescribing larger behavioral changes may still provide more benefits regardless of the greater weight regain.

This study included an extended-care program, which has been found to be one of the most successful strategies utilized to promote maintenance of learned behaviors as well as lost weight (Perri and Corsica, 2002; Vetter et al., 2010). Participants in the present study received extended care in the form of group meetings once per month. While it was posited that this extended care would promote continued use of cognitive-behavioral techniques (e.g., goal setting, self-monitoring, and problem solving), given the difficulties with attendance and adherence rates, it is questionable whether this approach served as the best method. Another form of extended care, as used in the TOURS project (Perri et al., 2008), provided participants with follow-up care twice per month in the year following initial treatment and found lower levels of weight regain. Others have utilized a step-down or tapered approach from treatment where participants receive sessions twice per month for three months followed by monthly sessions (Wadden et al., 2010). Perhaps these alternate methods would have provided additional group support, continued focus on cognitive-behavioral techniques, accountability, and reinforcement to result in lower weight regain for participants in the present study who were asked to maintain large behavioral changes.

## Secondary Aims

With regards to our secondary aim, the majority of participants in both the 1,000 and 1,500 kcal/day treatment conditions were found to be consuming within (+/-) 15% of their prescribed kcal/day amount (53% and 77% of participants, respectively) using classification from the PREFER behavioral treatment weight-loss study (Warziski et al., 2008). Unlike the two previous studies where participants were prospectively prescribed caloric intake goals (Das et al., 2008; Toplak, et al., 2005), participants in the present study consumed calorie amounts that were significantly different from each other during the first six months of the study, with the 1,000 kcal/day condition consuming a mean  $1,164 \pm 170$  calories and the 1,500 kcal/day condition consuming a mean  $1,518 \pm 222$  calories. These results could be attributed in part to this study's methodology that utilized a lifestyle intervention with components of self-monitoring, structured meal plans, and suggested meal replacements and portion-controlled meals. Following active treatment, caloric intake between treatment conditions remained significantly different by a margin of 242 calories. However, given the decreased rates of self-monitoring, it remains questionable whether this serves as an accurate measurement of actual caloric intake for the treatment conditions.

Conversely, two previous studies that prospectively prescribed energy intake amounts found that participants tended to gravitate toward a median dietary intake they find manageable regardless of energy prescription (Das et al., 2008; Toplak et al., 2005). Toplak and colleagues (2005) prescribed dietary restriction in combination with medication within a medical setting. While the investigators did provide dietary counseling, participants did not receive a behavioral lifestyle intervention where

techniques to modify eating habits were addressed. In addition, Das and colleagues (2008) provided food for 24 weeks and then asked participants to continue eating either a mild or moderate calorie restricted diet for an additional 24 weeks. The participants did meet throughout the study for support groups, individual nutritional counseling with a dietician, and safety monitoring; however, a lifestyle intervention utilizing behavioral techniques was not provided.

Results of the present study indicated, however, that the treatment conditions did differ in adherence to their respective calorie intake goals. While the mild caloric restriction condition was found to consume only 1% greater calories than their 1,500 kcal/day goal, participants within the 1,000 kcal/day condition consumed a mean 16% calories above their prescribed amount. Some 45% of the participants in the 1,000 kcal/day condition consumed  $\geq 15\%$  above their calorie goal. These results may provide additional support for the small-change approach (Hill et al., 2003), which suggests that mildly reducing calories to 1,500 kcal/day may be more feasible than moderately reducing calories to 1,000 kcal/day. Considering Herman and Polivy's (1980) disinhibition hypothesis, restraining eating as low as 1,000 kcal/day may lead to all-or-nothing thinking, and violations to dietary goals may result in overconsumption.

### **Tertiary and Exploratory Aims**

This study also assessed the impact of the 1,000 and 1,500 caloric prescriptions on reported levels of self-efficacy, dietary disinhibition, restraint, hunger, and depression. Results indicated that the two conditions did not differ at baseline, Month 6, or Month 12 on any of these factors. Trends for both conditions were consistent with previous findings (d'Amore et al., 2001; Marcus et al., 1985; Wadden et al., 1993;

Warziski et al., 2008; Wing et al., 2008). With regards to self-efficacy, women in the present study were found to significantly increase levels of self-efficacy from baseline to long-term follow-up. Levels of self-efficacy were associated with weight loss at 12-months, with those women displaying the highest levels of self-efficacy, regardless of treatment condition, achieving the greatest body weight reduction. These results are consistent with those of Warziski and colleagues (2008) who demonstrated that, with the use of a behavioral intervention, self-efficacy can be increased over the course of treatment and is associated with long-term weight management.

Wing and colleagues (2008) found that increases in disinhibition and hunger as well as decreases in restraint were related to greater weight regain; however, this was only found in participants who did not receive in-person extended care follow-up. The present study did utilize a six-month extended-care period, in which participants were encouraged to maintain use of strategies to manage these behaviors. Therefore, participants reported significant increases in levels of restraint and lower levels of disinhibition across the study period, a trend that appears similar to those found between these two variables in previous studies (d'Amore et al., 2001; Marcus et al., 1985; Wadden et al., 1993). Given both treatment conditions in the present study experienced overall long-term weight loss, this suggests that participants learned to control periods of overindulgence through increased dietary self-control (Foster et al., 1998). A discrepancy did exist, however, as it was found during Phase II that those participants who regained  $\geq 4.5$  kg reported greater disinhibition and hunger and decreased restraint regardless of treatment condition. Such changes in these variables have previously been linked to weight regain (Hays & Roberts, 2008; Wing et al., 2008).

Susceptibility to eat in response to hunger has been linked to decreased restraint and increased disinhibition (Stunkard & Messick, 1985). Participants within both treatment conditions endorsed reductions in levels of hunger over the course of treatment, with no differences existing between conditions. Previous findings of severe caloric restriction found that increased levels of hunger were associated with greater caloric intake (LaPorte & Stunkard, 1990). Participants in this study were taught strategies to manage their cravings and learned ways to consume a balanced diet to reduce levels of hunger. Therefore, these learned techniques may have counteracted the potential for increased hunger, specifically for participants in the moderate caloric restriction 1,000 kcal/day condition who may have been more likely to report greater hunger. At baseline, participants within both conditions, on average, endorsed only minimal levels of depression and did not fall within the classification of binge eaters. Throughout the course of treatment, levels of these two variables continued to decrease. It has previously been found that increases in reported depressive symptoms and uncontrolled eating tendencies may result in difficulties maintaining weight loss (Wing et al., 2008). Similar results were found in this study in those who regained  $\geq 4.5$  kg. Specifically, during Phase II, it was found that participants who regained a larger amount of weight reported greater uncontrolled eating and higher levels of depression, regardless of treatment condition, than those who regained  $< 4.5$  kg.

Taken together, it is therefore suggested that, using lifestyle interventions with a period of extended care like that used in the current trial may teach the majority of participants strategies to increase self-efficacy and restraint while lowering levels of disinhibition, hunger, depression, and episodes of binge eating. These results were

found regardless of prescribed caloric intake goal. Perhaps this is due to the fact that participants received the same intervention and learned similar strategies. Cognitive-behavioral techniques to modify eating and activity patterns teach participants methods not only to produce a negative energy balance necessary to lose weight, but also ways to identify and modify antecedents and consequences associated with unhealthy behavioral patterns as well as ways to modify the environment to develop healthy behavioral habits (Vettner et al., 2010; Ferster et al., 1962; Stuart, 1967; Wing, 2002). In line with the concepts of the social cognitive theory (Bandura, 1977, 1986; Wadden & Foster, 1992), lifestyle interventions not only increase knowledge of health behaviors, but they also enhance an individual's belief in his or her ability to perform these behaviors, thus explaining the present study's findings in overall increased levels of self-efficacy. Lifestyle interventions also increase one's ability to exert control over behavior, cognitions, and environment using behavioral techniques of problem solving, goal-setting, self-monitoring, self-reinforcement, stimulus control, and cognitive restructuring (Bandura, 1977, 1986; Wadden & Foster, 1992). Because participants in both caloric prescription conditions received the same lifestyle intervention, all learned these behaviors. Therefore, this structure may explain why, regardless of condition assignment, trends showed reductions in disinhibition, hunger, and depression, and increases in restraint.

The present study also found overall increases in six out of nine factors of quality of life. Across both treatment conditions, participants endorsed improvements in Health Transition, Physical Functioning, General Health, Vitality, Social Functioning, and Mental Health across the study period. Improvements in quality of life have previously

been linked to greater weight loss outcomes (Carels et al., 2003; Kolotkin et al., 2001) and may again result from the structure of the lifestyle intervention, which included a group format and utilized cognitive-behavioral techniques to overcome eating and exercise barriers. There existed a difference between caloric prescription conditions with respect to reported levels of Social Functioning at Month 12. Because no other variables of quality of life or levels of depression, binge eating, disinhibition, restraint, hunger, or self-efficacy varied between conditions, it remains questionable whether the difference in Social Functioning comes as a result of caloric prescription, or if there exist other non-study related variables that could account for this difference.

In further exploring potential reasons for the large standard deviations at Month 12, it was found that 28 women regained a significant amount of weight during Phase II. At baseline, these women reported greater levels of depression, disinhibition, and caloric intake. The link among these variables and weight regain appears congruent with theory outlined by Polivy and Herman (1983). These researchers suggested that affective states, such as depression, may decrease motivation to diet and result in disinhibition of eating. Similarly, a violation of intake goals (e.g. a restrained eater consuming excessive calories) may result in negative affect and an abandonment of eating patterns (Polivy & Herman, 1983). Given the participants who regained the most weight displayed higher baseline levels of depression, disinhibition, and caloric intake, deviations from caloric prescription goals during the intervention or changes in affective states may have instigated the habitual pattern of overeating and weight regain.

No interaction effects existed between depression or disinhibition and treatment condition with respect to weight regain during Phase II. This suggests that, regardless

of treatment placement, participants who exhibit greater depression and disinhibition at baseline may perform worse in the long-term. Treatment condition appeared to serve as a moderator between reported baseline caloric intake and weight regain during Phase II. Women who consumed more calories at baseline regained more weight if they were assigned to the 1,000 kcal/day group than those who were assigned to the 1,500 kcal/day group. This suggests that matching participants who initially consume a greater number of calories to a lower caloric intake prescription, thus requiring greater reductions in caloric intake, may be detrimental to long-term weight maintenance. The disinhibition hypothesis and restraint theory (Polivy & Herman, 1983; Ruderman, 1986) suggest that restrained eaters often view dieting as an all-or-nothing event, and the perception of having overeaten disinhibits these eaters. Given those women who consumed the most baseline calories and who were assigned the 1,000 kcal/day goal participated in the highest level of dietary restriction (compared to those assigned the 1,500 kcal/day goal), violations to dietary control may have led to abandonment of the calorie goal. Indeed, following Phase I of treatment, it was found that participants in the 1,000 kcal/day condition increased their caloric intake, which suggests difficulty in long-term adherence to the goal. Perhaps these participants who also experienced greater weight regain may have benefitted from a calorie goal range (e.g. 1,000 to 1,250 kcal/day) rather than attempting to maintain their restrictive goal from Phase I. In fitting with the restraint theory (Polivy & Herman, 1983), this may have reduced all-or-nothing perception of the dietary goal and lowered disinhibition of eating patterns and ensuing weight regain.

During the intervention, women who regained  $\geq 4.5$  kg attended a greater number of sessions compared to those who regained  $< 4.5$  kg. Perhaps the participants who regained the most weight utilized the group support and accountability during Phase I of the intervention, but when this was no longer available on a weekly basis, were unable to maintain their habit changes. Stunkard and Messnick (1985) posited that persons who score high on baseline disinhibition may respond well to the support associated with group approaches, especially when comorbid depression serves as an emotional disinhibitor. As these participants moved to Phase II, the monthly extended-care sessions may have been too few, the 1,000 kcal/day goal may have been too difficult to maintain, and the lack of group support may have made it hard to continue the behavioral changes necessary to maintain weight loss. Indeed, during Phase II, participants who regained  $\geq 4.5$  kg maintained significantly fewer self-monitoring records than those who regained  $< 4.5$  kg, a behavior that has been highly correlated with lower caloric intake and greater long-term weight-loss (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998).

In addition the large regainers reported significantly lower levels of restraint and higher levels of depression, disinhibition, uncontrolled eating, and hunger at Month 12 compared to those participants who regained  $< 4.5$  kg. These results mirror those of Wing and colleagues (2008), who found that greater disinhibition, uncontrolled eating, and hunger as well as lower restraint were related to greater weight regain. In the group who regained  $\geq 4.5$  kg, levels of self-efficacy were also found to be significantly lower than those who did not regain that magnitude of weight. While higher self-efficacy has been associated with greater weight-loss success (Richman et al., 2001; Warziski

et al., 2008), poorer self-efficacy has been linked to weight cycling (Kensinger et al., 1998). Bandura (1986) defined perceived self-efficacy as the estimation of capabilities to perform a behavior. As participants who regained larger amounts of weight lost weekly group support and accountability, they may have experienced a decreased capability to maintain the healthy behaviors learned during Phase I.

### **Limitations**

There are three potential limitations to the present study. First, participants self-reported caloric intake. When self-reporting energy intake, research suggests that people tend to underestimate consumption by 27 to 46% (Johnson et al., 2005; McKenzie et al., 2002). This inconsistency may result from the participant's desire to present herself in a positive, acceptable manner (McKenzie et al., 2002; Mertz, Tsui, Judd, et al., 1991) or from forgetfulness due to the inconvenience of record keeping (Macdiarmid & Blundell, 1997; Price, Paul, Cole, & Wadsworth, 1997). As previous research suggests, our sample of obese women tended to underreport caloric intake at a higher prevalence than other groups (Johnson, Goran, & Poehlman, 1994; Lichtman et al., 1992). Due to study constraints, utilization of doubly labeled water, which is often seen as the "gold standard" technique to measure energy expenditure and, in turn, energy intake (Livingstone, & Black, 2003; Trabulsi, & Schoeller, 2001), was not feasible to technically address the question of caloric intake.

Second, attendance and adherence rates, specifically during Phase II of the present study, were lower than those reported in other trials involving a lifestyle intervention and extended care (Perri et al., 2008; Wadden et al., 2009). Unlike the aforementioned studies, women in the present study were not provided factors of extrinsic motivation for participation or attendance, such as monetary incentives or meal

replacements, which may have impacted the rates of attendance. Given session attendance (Carels et al., 2003; Wadden et al., 1992) and adherence to self-monitoring records (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998) have been associated with amount of long-term weight loss, weight reduction results and amounts of regain may have been adversely impacted due to low rates of attendance and adherence.

Finally, the study is also limited by the population assessed; namely, only women between the ages of 25 and 75, weighing between 91 to 136 kg (i.e. 200 to 300 lbs), and having a BMI between 30 and 45 kg/m<sup>2</sup> were included in our sample. Generalizability therefore is limited by the exclusion of men and individuals of various weight and BMI groups. Additionally, those with serious health conditions who were unable to obtain permission from their physician were excluded from study participation, causing a truncated range that excludes individuals with uncontrolled comorbid medical conditions.

### **Clinical Implications**

The present study adds important clinical implications with regards to behavioral treatments for weight loss. While traditional behavioral treatment programs for obesity often result in a reduction of body weight that is associated with clinically significant benefits in health-related parameters, weight regain is considered “the single greatest challenge in the long-term management of obesity” (Perri, 1998). There exist two competing beliefs regarding prevention of weight regain, with some arguing for a small-changes approach that will lead to slow, yet steady reductions in body weight and attainable and sustainable healthy behavior changes (Hill, 2009; Hill, Wyatt, Reed &

Peters, 2003). Conversely, others support fast initial behavior changes and larger initial weight losses for greater long-term weight reduction (Astrup & Rössner, 2000; Carels et al., 2003; Elfhag & Rössner, 2005; Elfhag & Rössner, 2010; Jeffery et al., 1998; Nackers et al., Wadden, et al., 1992).

Results from the current study found that women prescribed a moderate caloric restriction of 1,000 kcal/day lost more weight initially, but experienced greater regain so that weight change did not differ from that of participants prescribed a 1,500 kcal/day goal at 12-month follow-up. This appears to be in accordance with the notion that larger initial weight loss are associated with greater long-term weight regain (Jeffery et al., 1998; Sbrocco et al., 1999; Wadden, Foster, & Letizia, 1994), suggesting larger initial weight reduction may serve as a risk factor for later weight regain (McGuire, Wing, Klem, Lang, & Hill, 1999; Weiss et al., 2007; Wing & Hill, 2001). This also raises the question of participants' abilities to maintain large changes in diet and exercise necessary to prevent weight regain following lifestyle intervention, even with this study's usage of a six-month extended-care period.

This study's prospective design provides unique evidence that suggests that large behavioral changes early in treatment may initially provide enough reinforcement value (i.e. fast weight loss) to result in short-term habit change; however, they may also be difficult to maintain long-term, thus resulting in larger weight regain. Clinically, these results also suggest that extended-care programs may need to be modified to continually reinforce healthy behavior changes achieved during the initial months of a lifestyle intervention program. The present study did find, however, that participants were able to adhere to their caloric prescriptions during active treatment, thus

suggesting that self-monitoring, structured meal plans, and suggested meal replacements and portion-controlled meals are useful methods to increase adherence.

Increased emphasis has been placed on clinical versus statistical differences. At Month 12, women in the 1,000 kcal/day condition maintained a 2.8 kg larger weight reduction than those in the 1,500 kcal/day condition. In addition, 61% of participants in the 1,000 kcal/day condition compared to 42% of those in the 1,500 kcal/day condition achieved a beneficial 5% weight reduction at 12 month. This study may not have been adequately powered to detect a significant difference at this time point. Therefore, while not statistically different, for clinical purposes of achieving an overall 2.8 kg larger weight loss and a greater likelihood of reaching a  $\geq 5\%$  weight change, a moderate caloric restriction goal of 1,000 kcal/day may be superior. Encouraging participants to make larger changes early on to result in greater initial weight loss may increase the likelihood of achieving a  $\geq 5\%$  reduction long term. This remains in accordance with the context of lifestyle interventions where cognitive-behavioral strategies are taught to safely achieve and maintain healthy eating and exercise behaviors and where food intake remains above 1,000 kcal/day.

Additional long-term follow-up of participants who are prescribed various levels of caloric intake are warranted. As participants in the 1,000 kcal/day condition were more likely to achieve a  $\geq 5\%$  weight reduction, they also experienced greater weight regain from Months 6 – 12. It remains unclear whether this rate of regain would continue so that conditions no longer differed in the proportion of participants achieving a  $\geq 5\%$  weight reduction. Future work should also provide special consideration to participants who endorse greater symptoms of depression, higher levels of disinhibition, and larger

caloric intakes at baseline. These baseline indicators were reported by participants in the present study who regained large amounts of weight in the long-term.

Treatment matching may prove an important strategy, specifically with participants reporting greater baseline caloric intake. Findings from this study demonstrated that prescribing participants who consumed more calories at baseline to the 1,000 kcal/day resulted in larger long-term weight regain than prescribing these participants to a 1,500 kcal/day goal. Therefore, matching participants with higher baseline calorie levels to a milder and more gradual caloric reduction may improve long-term weight loss outcomes. Another potential option of staging or providing a range of maintenance goals may reduce weight regain, specifically for those assigned to a 1,000 kcal/day goal who consume higher calorie levels prior to treatment. Rather than encouraging maintenance of a 1,000 kcal/day intake during extended care unless a normal BMI has been achieved, gradually moving participants from 1,000 to 1,250 to 1,500 kcal/day goals or allowing a range of 1,000 to 1,250 kcal/day may increase levels of self-efficacy and reduce all-or-nothing attitudes that could lead to abandonment of diet (Polivy & Herman, 1983; Ruderman, 1986). In addition, studies assessing various frequencies and lengths of extend-care periods may discover whether participants assigned to various caloric restriction goals respond differently to the cognitive-behavioral strategies required to maintain weight loss long-term. Future studies are warranted to assess whether additional personal and behavioral baseline characteristics not measured in this study predict who will adhere to and achieve success with a caloric restriction goal of 1,000 kcal/day.

In sum, findings suggest that, within the context of lifestyle treatment, prescribing a greater caloric restriction goal of 1,000 kcal/day may prove beneficial for initial short-term weight loss, but the behavioral changes required to sustain large initial changes may be too great for long-term maintenance when compared to a mild caloric restriction goal of 1,500 kcal/day. However, while not statistically different, at long-term follow-up those prescribed a 1,000 kcal/day goal continued to demonstrate a clinically larger weight loss. A significantly greater percentage of participants within this condition also achieved a beneficial weight reduction  $\geq 5\%$  than those in the 1,500 kcal/day condition. Given the potential health benefits associated with weight losses of this magnitude, these results suggest important advantages to prescribing a 1,000 kcal/day intake goal during lifestyle interventions. Regardless of caloric prescription, lifestyle interventions serve as important avenues to increase restraint and self-efficacy, and decrease disinhibition, depression, binge eating, and hunger. Emphasizing attendance and adherence to self-monitoring records also plays a role in achieving greater long-term weight loss. Finally, as treatment condition appeared to moderate the association between baseline caloric intake and weight regain, matching those participants with higher baseline caloric intake to more mild caloric restriction goals, or providing tailored extended care may result in greater long-term weight management success.

APPENDIX A  
SAMPLE METHODS TO MEET CALORIE INTAKE GOAL

SAMPLE MEAL PLANS: 1,000 CALORIES

<u>Sample Meal Plan</u>	Calories
<b>Breakfast:</b>	
1 cup sliced strawberries	53
1 tsp. sugar substitute	0
2 slices light whole-wheat toast	120
2 tsp. light margarine or butter	28
6 oz. fat-free, sugar free yogurt	100
<b>Total:</b>	<b>301</b>
<b>AM Snack:</b>	
10 fresh grapes	<b>35</b>
<b>Lunch:</b>	
2 oz. 98% fat-free sliced turkey breast	60
1/2 cup fresh spinach or romaine lettuce	12
2 tbsp. shredded parmesan cheese	41
2 tsp. yellow or dijon mustard	2
1 whole-wheat english muffin	150
10 baby carrots, raw	35
2 tbsp. fat-free ranch dressing	30
<b>Total:</b>	<b>330</b>
<b>PM Snack:</b>	
1/2 medium banana	<b>53</b>
<b>Dinner:</b>	
4 oz. baked salmon filet	100
1 medium baked sweet potato	130
1/2 tsp. light margarine	8
1 cup steamed green beans	45
<b>Total:</b>	<b>283</b>
<b><u>Total for Day:</u></b>	<b>1002</b>

<u>Sample Meal Plan 2</u>	Calories
<b>Breakfast:</b>	
1 medium orange	62
1/4 cup egg substitute	53
2 slices onion, chopped	15
1/4 cup bell pepper	10
1 slice light whole-wheat toast	60
1 tsp. peanut butter	31
<b>Total:</b>	<b>231</b>
<b>AM Snack:</b>	
1 small apple	<b>60</b>
<b>Lunch:</b>	
2 oz. skinless, grilled chicken breast	94
2 cups salad greens (not iceberg)	18
1 tbsp. reduced fat feta cheese	35
1 tsp. olive oil	39
1 tbsp. red wine vinegar	8
4 saltine crackers	48
1 peach	60
<b>Total:</b>	<b>302</b>
<b>PM Snack:</b>	
6 oz. fat-free, sugar-free yogurt	<b>100</b>
<b>Dinner:</b>	
3 oz. large shrimp, cooked w/o fat	131
1 cup broccoli, steamed	20
1/2 cup red bell pepper	20
1/2 cup summer squash	11
1/2 tsp. olive oil	19
1/3 cup brown rice, cooked	111
<b>Total:</b>	<b>312</b>
<b><u>Total for Day:</u></b>	<b>1005</b>

SAMPLE MEAL PLANS: 1,500 CALORIES

<u>Sample Meal Plan</u>	<b>Calories</b>
<b>Breakfast:</b>	
1 cup oatmeal	146
½ cup fat-free skim milk	45
2 tbsp. raisins	85
1 slice whole wheat toast	60
1 tsp. peanut butter	31
<b>Total:</b>	<b>367</b>
 <b>AM Snack:</b>	
1 oz. plain almonds	<b>164</b>
 <b>Lunch:</b>	
4 oz. tuna in water	132
2 slices whole grain bread	120
2 tsp. yellow or Dijon mustard	2
2 slices fresh tomato	5
½ cup fresh spinach or romaine	12
10 baby carrots, raw	35
2 tbsp. fat-free ranch dressing	30
<b>Total:</b>	<b>336</b>
 <b>PM Snack:</b>	
6 oz. fat-free, sugar-free yogurt	100
½ cup sliced strawberries	26
<b>Total:</b>	<b>126</b>
 <b>Dinner:</b>	
4 oz. pork tenderloin	185
1/3 cup brown rice	111
1/2 cup beets	37
½ cup zucchini	14
1 cup mixed salad greens	18
2 tsp. olive oil	40
1 tbsp. red wine or other vinegar	8
1 cup fat-free skim milk	91
<b>Total:</b>	<b>504</b>
<b>Total for Day:</b>	<b>1497</b>

<u>Sample Meal Plan 2</u>	<b>Calories</b>
<b>Breakfast:</b>	
1/3 cup egg substitute	71
¼ cup green pepper	10
2 slices onion, chopped	15
1 tsp. olive oil	39
1 slice light whole-wheat toast	60
1 tsp. peanut butter	31
1 medium banana	105
<b>Total:</b>	<b>331</b>
 <b>AM Snack:</b>	
2 cups fresh strawberries	106
6 oz. fat-free, sugar-free yogurt	100
<b>Total:</b>	<b>206</b>
 <b>Lunch:</b>	
2 cups fresh spinach	48
2 oz. skinless grilled chicken	94
1 tbsp. reduced fat feta cheese	70
1 tsp. olive oil	39
1 tbsp. red wine vinegar	8
1 whole wheat roll (1 oz.)	75
1 cup nonfat skim milk	91
<b>Total:</b>	<b>425</b>
 <b>PM Snack:</b>	
1 oz. plain almonds	<b>164</b>
 <b>Dinner:</b>	
4 oz. large shrimp, cooked	197
1 cup broccoli, steamed	20
1/2 cup red bell pepper	20
1/2 cup summer squash	11
1/2 tsp. olive oil	19
1/3 cup brown rice, cooked	111
<b>Total:</b>	<b>378</b>
<b>Total for Day:</b>	<b>1504</b>

EXAMPLES OF PORTION-CONTROLLED FOODS

**Lean Cuisine®**

**Calories**

 <p>Alfredo Pasta with Chicken &amp; Broccoli</p>	<p>300</p>
 <p>Angel Hair Pomodoro</p>	<p>250</p>
 <p>Asian-Style Pot Stickers</p>	<p>260</p>
 <p>Baja-Style Chicken Quesadilla</p>	<p>280</p>
 <p>BBQ Chicken Quesadilla</p>	<p>260</p>
 <p>Cheddar Potatoes with Broccoli</p>	<p>230</p>

EXAMPLES OF PARTIAL MEAL REPLACEMENTS

<u>Slim-Fast®</u>	<u>Calories</u>
 <p>Slim-Fast Creamy Milk Chocolate Shake</p>	190
 <p>Slim-Fast Chocolate Cookie Dough Meal Bar</p>	220

EXAMPLE OF PORTION-CONTROLLED EATING PLAN: 1,000 CALORIES

	<b>Calories</b>
<b>Breakfast:</b>	
Slim-Fast Milk Shake	190
1 medium banana	105
<b>Total:</b>	<b>295</b>
<b>Lunch:</b>	
Slim-Fast Meal Bar	<b>220</b>
<b>Dinner:</b>	
Lean Cuisine® Asian-Style Pot Stickers	250
1 whole wheat roll (1 oz)	75
1/2 cup beets	37
1/2 cup zucchini	14
1 cup mixed salad greens	18
1 tsp. olive oil	20
1 tbsp. red wine or other vinegar	8
1 small apple	60
<b>Total:</b>	<b>482</b>
<b>Total for Day:</b>	<b>997</b>

APPENDIX B  
GROUP PREFERENCE QUESTIONNAIRE

Please answer the following questions based on your preferences:

1. When you think about reducing the amount you eat, which would you prefer?

- I would prefer experience a rapid rate of weight loss, but eat fewer calories per day.
- I would prefer to experience a slower rate of weight loss, but eat more calories per day.

2. When you think about meeting in a group that discusses weight, nutrition, and physical activity, which would you prefer?

- I would prefer to meet in a group of approximately 10 members in which I would be expected to share my personal experiences and progress related to making changes in my diet and physical activity.
- I would prefer to meet in a group of approximately 30 members in which sharing my personal experiences and progress related to making changes in my diet and physical activity would be optional.

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## BIOGRAPHICAL SKETCH

Lisa Marie Nackers is originally from Wrightstown, Wisconsin and graduated summa cum laude from the University of Wisconsin—Eau Claire with a Bachelor of Arts in psychology. Prior to entering graduate school, she accepted a two-year Intramural Research Training Award fellowship at the National Institute of Diabetes and Digestive and Kidney Diseases and the National Center for Complementary and Alternative Medicine within the National Institutes of Health in Bethesda, Maryland. Following this research training, she enrolled in the doctorate program in Clinical and Health Psychology at the University of Florida. Under the mentorship of Dr. Michael G. Perri, she researched weight loss interventions for obesity, specifically in underserved rural counties. She earned her Master of Science degree in 2008 in clinical psychology. Concurrently while pursuing her doctorate, Lisa completed a master's in public health degree, with an emphasis in social and behavioral sciences, at the University of Florida in December 2010. To fulfill the final requirements of the Clinical and Health Psychology program, Lisa completed her internship in clinical psychology at Rush University Medical Center in Chicago. She obtained her Doctor of Philosophy degree in August 2012. Her clinical interests lie mainly in the area of behavioral medicine. Her research interests center around weight management, lifestyle interventions for obesity, and treatment dissemination.