

**FEASIBILITY OF A CAMPAIGN INTERVENTION
COMPARED TO A STANDARD BEHAVIORAL WEIGHT LOSS INTERVENTION
IN OVERWEIGHT AND OBESE ADULTS**

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Overweight and obesity are a significant public health concern. Behavioral treatment is considered the first line of intervention for individuals attempting to lose weight. Behavioral weight loss interventions are capable of producing an 8-10% weight loss of initial body weight at six-months. However, not all individuals achieve this magnitude of weight loss. Therefore, the development of alternative approaches to standard behavioral weight loss programs is needed to improve weight loss and weight maintenance efforts. **PURPOSE:** The purpose of this study was to examine a stand-alone campaign as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention. **METHODS:** Twenty six sedentary, overweight and obese adult men and women (Age: 43.1 ± 8.9 years; BMI: 33.3 ± 3.7 kg/m²) participated in a behavioral weight loss intervention and were randomized to one of two groups: Standard Behavioral Weight Loss Intervention (SBWL) or Campaign Intervention (CI). Participants in the SBWL attended weekly group meetings, were prescribed 1200-1800 kcal/day, and 200 minutes of moderate intensity physical activity per week. Participants randomized to the CI received the same SBWL components described previously, in addition to an incentive-based point system, a lottery system, and an e-mail based self-monitoring and intervention delivery. Body weight was assessed at week 0 and 12. **RESULTS:** Both groups achieved significant weight loss from week 0 to week 12 (SBWL group: -5.6 ± 2.9 kg; CI group -3.1 ± 3.4

kg) ($p<0.001$). There were no significant differences between groups ($p=0.603$) or a group X time interaction ($p=0.052$) from baseline. **CONCLUSION:** The current investigation demonstrated that participants in the CI group achieved modest yet clinically meaningful weight loss at week 12. This is of importance as standard behavioral weight loss interventions can be intensive, costly, and require substantial time commitments from the participants. Therefore, the CI may provide an alternative approach to disseminate an effective behavioral weight loss program to assist a larger proportion of individuals with weight loss and weight maintenance efforts. This may also result in a more positive net impact on the overall health of the population. Future studies should evaluate the effectiveness of the CI long-term to determine whether these findings can be sustained beyond 12 weeks.

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PREFACE

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1.0 INTRODUCTION

The increasing prevalence of overweight and obesity in the United States is a significant public health concern due to the fact that approximately 69% of adults in the United States are classified as overweight (Body Mass Index (BMI) $\geq 25.0 \text{ kg/m}^2$) and 36% obese (BMI $\geq 30.0 \text{ kg/m}^2$)¹. Overweight and obesity are associated with higher rates of mortality² and a multitude of negative health consequences such as: hyperinsulinemia, insulin resistance, type 2 diabetes, hypertension, dyslipidemia, coronary heart disease, and gall bladder disease³. As a result, annual health care costs associated with obesity related health outcomes is well over \$147 billion dollars⁴. This evidence suggests that improved strategies to manage weight are critically important for the prevention and treatment of obesity.

The National Heart, Blood and Lung Institute (NHLBI) promotes using behavioral interventions as a strategy to help individuals modify eating and exercise behaviors to manage weight⁵. The goal of these interventions is to assist individuals in restructuring their lifestyle and environment to monitor and reduce behaviors known to contribute to obesity⁶. These interventions incorporate several behavioral strategies such as goal setting, self-monitoring, stimulus control, problem solving, and relapse prevention in combination with dietary modifications and increased physical activity to elicit approximately an 8-10% weight loss over the course of 6 months⁷. Unfortunately, not all participants achieve or sustain this magnitude of weight loss long-term⁸. Furthermore, while a modest weight loss of 3-5% can significantly

reduce health risks⁹, weight loss programs can be intensive, costly, and require substantial time commitments from the participants¹⁰. Thus, it is crucial to examine alternative strategies in obesity treatment to improve success rates for individuals attempting to lose and maintain weight.

1.1 SIGNIFICANCE

One potential alternative strategy is the implementation of a campaign. Campaigns target specific behaviors (e.g., diet, physical activity) to improve weight loss and weight maintenance efforts within a thematic framework (e.g., Reach the Beach). Campaign session content and targeted behavior goals tie into this overall theme (e.g., walking 10,000 steps a day to reach a beach destination) to increase an individual's motivation and self-efficacy for attaining the targeted goals. Throughout the campaign, participants have the opportunity to earn tangible incentives (e.g., beach towel) to reinforce positive behavior changes.

Various clinical trials have integrated campaigns into weight loss programs to assist individuals in changing their dietary and physical activity habits to induce and maintain weight loss. For example, both the Diabetes Prevention Program (DPP) and the Look AHEAD (Action for Health in Diabetes) trials have incorporated campaigns into the lifestyle intervention to assist participants' in the attainment of lifestyle study goals^{7,11}. The intensive lifestyle intervention (ILS) in the DPP showed weight loss to be effective at reducing diabetes incidence by 58% for those at high risk for the disease when compared to a control group¹². More recently, the intensive lifestyle intervention (ILI) of Look AHEAD has shown that weight loss is associated with improved fitness, glycemic control, and cardiovascular risk factors in individuals with type

2 diabetes^{13,14}. However, the ILI did not reduce the rate of cardiovascular events in overweight and obese adults with type 2 diabetes¹⁴. While these trials have both been highly successful lifestyle interventions, the feasibility of solely using a campaign intervention to promote healthy eating and physical activity behaviors for weight loss and weight maintenance has not been examined in a systematic manner. Therefore, it is not currently known the degree to which campaign interventions alone impact weight loss, diet and physical activity behaviors, in addition to self-efficacy and motivation.

1.2 THEORETICAL RATIONALE

The National Institutes of Health and the World Health Organization recommend that overweight and obese adults with comorbid conditions lose 10% of their initial body weight^{5,15}. A comprehensive lifestyle modification program focused on caloric restriction, physical activity, and behavior therapy is considered the first option for achieving this goal⁵. Key strategies of behavior therapy to produce weight loss include goal setting, self-monitoring, feedback on goal achievement, and reinforcement^{16,17}. For example, typically within lifestyle interventions individuals are given specific goals for daily caloric intake and weekly minutes of physical activity and instructed to self-monitor these behaviors. To assess progress and compliance towards these goals, participants are encouraged to keep detailed records of their food intake, physical activity, and body weight. These records are used by interventionists to provide regular feedback on goal attainment, in order to increase participant motivation and self-efficacy¹⁸. In addition, self-monitoring allows the participant to be aware of current behaviors and adjust these behaviors as needed to achieve goals. Upon the successful achievement of goals, reinforcement

through incentives can motivate individuals to continue to set and accomplish future goals¹⁹. Thus, a conceptual model was constructed to demonstrate the proposed relationship between a campaign intervention and the above strategies for modifying physical activity, dietary, and weight loss related behaviors (Figure 1). This primary aim of this study was to examine the feasibility of a stand-alone campaign intervention as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention.

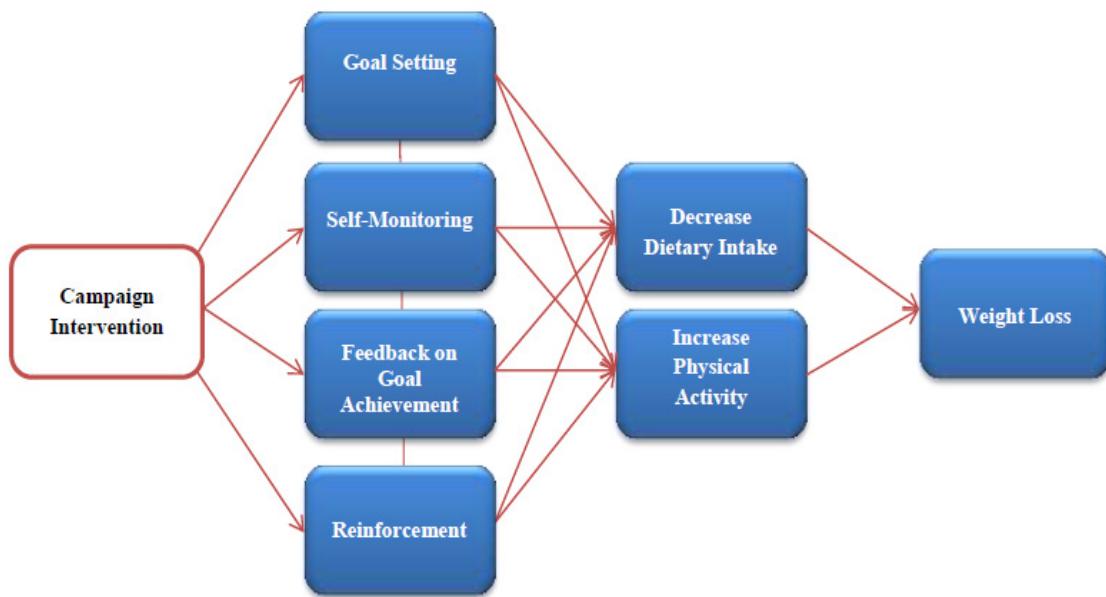


Figure 1. Conceptual Model for How a Campaign Intervention May Induce Weight Loss

1.3 GOAL SETTING

Goal setting is an essential component of behavioral weight loss interventions. This strategy designates setting clear goals that are detailed, easily measured, and assessed regularly to assist individuals with self-regulation toward a particular behavior change^{16,20,21}. When formulating goals, goal specificity plays a significant role in attainment of health behaviors. For example,

Nothwehr and Yang²² found that individuals who set specific dietary and physical activity goals achieved greater weight loss when compared to those who set weight only goals. Conversely, a ‘do your best goal’ is less likely to be obtained given the absence of measureable properties and inability to determine outcomes²¹. This can impact an individual’s ability to perform or set future goals²¹. The effectiveness of goal setting is also directly related to the length of time to achieve the goal. Short term goals, if achieved, can enhance motivation and encourage participants to continue to take action towards behavior changes²⁰. Dubbert and Wilson²³ found that individuals who reported following either daily or weekly specific goals lost significantly more weight over a 19-week period than those who did not set goals. Thus, it is important that individuals set detailed and timely goals to change behaviors and ultimately, outcomes such as weight change. In addition, frequent physical activity and dietary goals should be set by individuals to continue to engage in health related behavior changes and manage weight long-term.

1.4 SELF-MONITORING

Self-monitoring is considered a cornerstone of behavioral weight loss interventions¹⁶. Social Cognitive Theory identifies self-monitoring as a main strategy to assist individuals in the self-regulation of behaviors²⁴. During weight loss treatment, participants record the types, amounts, and caloric value of foods eaten with a goal of decreasing caloric intake by approximately 500-1000 kilocalories per day¹⁶. They also record minutes of physical activity with a goal of increasing moderate physical activity to 200-300 minutes per week to assist with weight loss and the prevention of weight regain⁹. This allows participants to be more aware of eating and

activity patterns, including time of day, environmental settings, and social and psychological correlates¹⁷. Therefore, successful self-monitoring depends on truthfulness, consistency, and timeliness in relation to the performance of the targeted behavior²⁵.

Consistent self-monitoring of diet and activity behaviors is a significant predictor of both short-term and long-term weight loss²⁶⁻²⁸. Research has also shown that individuals who are successful at losing weight and maintaining weight loss often exhibit more consistent self-monitoring habits, such as frequent self-weighing²⁶. For example, Butryn et al.²⁶ examined the association between self-weighing and weight change in a large sample of successful weight losers in the National Weight Control Registry (NWCR). They found 36% of participants who maintained successful weight loss at 1 year of follow-up weighed-in daily and 79% weighed themselves weekly. One way to improve consistency for self-monitoring in weight loss programs is through encouragement and reminders. Boutelle and colleagues²⁹ examined the efficacy of enhancing a weight loss program with an 8-week self-monitoring intervention during the holiday season. Participants were asked to self-monitor 3 weeks before the holiday period (pre-holiday), 2 weeks during the holiday period (1 week before Christmas through New Year's), and 3 weeks after the holiday period (post-holiday). The authors found that additional reminders via phone and mail encouraged self-monitoring more consistently during the holiday period, resulting in improved weight control. Thus, consistent self-monitoring is critically important to improve behaviors related to weight loss and weight maintenance.

1.5 FEEDBACK ON GOAL ACHIEVEMENT

Feedback regarding dietary intake, physical activity, and overall weight loss is necessary during a behavioral weight loss intervention. Feedback can be helpful in measuring progress, setting or evaluating goals, overcoming barriers, and maintaining high levels of motivation. For instance, Burke and colleagues³⁰ found that individuals given a personal digital assistant (PDA) with customized daily feedback messages, dependent on goal attainment, significantly reduced energy and saturated fat intake and improved self-monitoring adherence compared to those using a paper diary. Individualized feedback on progress towards goal attainment can also impact weight loss. Tate and colleagues³¹ found participants who were given a structured behavioral treatment program with weekly contact and individualized feedback from interventionists had better weight loss than those given links to education web sites. More recently, Wing et al.³² found that when instruction video sessions including information regarding nutrition, physical activity, and behavior change were supplemented with self-monitoring and computer generated feedback within a community weight loss campaign, the average weight loss more than doubled (3.5 ± 3.8 kg vs. 1.4 ± 2.7 kg) ($p<0.01$) and the proportion of individuals achieving a weight loss of 5% or more tripled (40.5% vs. 13.2%) ($p<0.01$) when compared to a standard control group. Thus, it appears adding feedback in some form is an important component to improve weight loss behaviors and outcomes.

1.6 REINFORCEMENT

Incentives have been used within behavioral weight loss interventions to reinforce positive behavior changes. The use of incentives as tangible rewards for weight loss behaviors is based on theoretically sound concepts. For instance, the antecedents-behavior-consequences (ABC Model) model of behavior change is based on the premise that after a behavior occurs the consequences of that behavior will help to determine whether or not the individual continues to engage in this behavior³³. By offering incentives as a consequence of behavior change, the likelihood that the individual will continue to engage in this behavior may be increased. Incentives may serve as cost effective, convenient, easy to administer, and enjoyable promoters of behavior change that can assist individuals in changing behaviors and losing weight, thus improving their overall health. Several examples of incentives include, but are not limited to; cash payments, lottery prizes, coupons for free or reduced price goods or services, gifts (e.g., t-shirts, blankets, coffee mugs, etc.), gift certificates, vouchers, contingency contracts, free or reduced price of medical insurance, or a reduction in cost of healthcare services. Incentives related to weight loss are typically dependent on weight change^{11,34-37}, but can also be dependent on other factors such as attendance at intervention or exercise sessions³⁸, an increase in physical activity steps or minutes reported¹¹, self-reported caloric intake³⁹, or completion of self-monitoring diaries¹¹. The most effective incentive strategies have resulted from monetary contracts where participants deposit their own money and receive funds contingent upon weight loss³⁷. Volpp et al.¹⁹ have shown that participants in a lottery incentive group and deposit contract group who earned chances to win money for achieving a weekly weigh-in goal (1 lb. per week) lost more weight (-5.9 kg and -6.3 kg, respectively) than those in a control condition (-1.8 kg) over the course of a 16-week study. Jeffery and colleagues³⁶ have also demonstrated that

monetary rewards for self-reported attainment of behavioral goals was as effective as rewarding weight change in producing weight loss. Thus, using incentives as a strategy within interventions to reinforce behavior changes and keep participants engaged has resulted in significant positive health outcomes.

1.6.1 Motivation

Self Determination Theory (SDT) suggests that for a behavior to be instigated and continued, an individual must feel they are doing a behavior to better themselves and that they are inspired to carry out the behavior of their own will, also known as autonomous motivation⁴⁰. In contrast, controlled motivation is associated with a need to comply with feelings of pressure and tension the individual has internalized or by external contingencies such as incentives or expected negative consequences from a behavior⁴¹. Incentives and reinforcement have also been used as strategies within weight loss programs to motivate participants to initiate and continue healthy behaviors. However, there is controversy that providing external rewards for behavior will lead to a reduction in autonomous motivation⁴². Crane and colleagues⁴³ found no significant differences in autonomous or controlled motivation between participants offered a financial incentive for weight loss compared to individuals not offered an incentive. In addition, increases in autonomous motivation were associated with greater weight losses. The authors concluded that small incentives did not lead to increases in controlled motivation and did not undermine autonomous motivation. Therefore, research is needed to examine the relationship between incentives and motivation for weight loss including the magnitude and timing of the incentive.

Behavioral weight loss interventions can produce significant weight loss. However, this treatment can be intensive, costly, and require substantial time commitments from the

participants. In addition, not all participants achieve significant weight loss or maintain this loss long-term. Thus, it is crucial to examine alternative strategies in obesity treatment to improve success rates for individuals attempting to lose and maintain weight. One possible strategy is the use of a stand-alone campaign weight loss intervention. To our knowledge, there is no published data on the effectiveness of a stand-alone campaign as an alternative weight loss intervention. Therefore, the primary aim of this study was to examine a stand-alone campaign as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention.

1.7 SPECIFIC AIMS

The primary specific aims of this study were:

1. To examine the effect of a 12-week campaign intervention (CI) on weight loss compared to a standard behavioral weight loss intervention (SBWL).
2. To examine the effect of a 12-week CI on moderate to vigorous intensity physical activity compared to a SBWL.
3. To examine the effect of a 12-week CI on dietary intake compared to a SBWL.
4. To examine the effect of a 12-week CI on self-monitoring of dietary intake and physical activity compared to a SBWL.

The exploratory aims of this study were:

1. To examine the effect of a 12-week CI for weight loss self-efficacy compared to a SBWL.
2. To examine the effect of a 12-week CI for autonomous and controlled motivation compared to a SBWL.

1.8 HYPOTHESES

The specific hypotheses for the primary aims of this study were:

1. The CI would achieve a similar weight loss when compared to the SBWL.
2. The CI would achieve a similar increase in moderate to vigorous intensity physical activity when compared to the SBWL.
3. The CI would achieve a similar reduction in dietary intake when compared to the SBWL.
4. The CI would achieve a similar number of days that dietary intake and physical activity would be self-monitored when compared to the SBWL.

The specific hypotheses for the exploratory aims of this study were:

1. The CI would achieve similar changes for weight loss self-efficacy when compared to a SBWL.
2. There would be no significant difference in autonomous and controlled motivation between the SBWL and the CI at week 12.

2.0 REVIEW OF THE LITERATURE

2.1 INTRODUCTION

Overweight and obesity is a significant public health concern in the United States affecting both children and adults^{1,44}. Weight loss treatment is recommended for individuals with a body mass index (BMI) of 30 kg/m² or higher, in addition to those with a BMI of 25 kg/m² or higher who have weight-related comorbidities⁵. While there are many treatments available for overweight and obese individuals including behavior therapy, pharmacotherapy and weight loss surgery, behavioral treatments are largely considered the first line of intervention⁵.

Behavioral weight loss interventions are effective in producing a weight loss of approximately 8-10% of initial body weight by incorporating key components such as goal setting, self-monitoring, stimulus control, problem solving, and relapse prevention to modify eating and exercise behaviors⁷. Despite this success, nearly 20% of participants do not complete treatment⁴⁵. Furthermore, of the participants who do complete treatment, one-third of lost weight is regained within 1 year of treatment ending and nearly one-half of participants return to their original weight within 5 years^{45,46}. Thus, alternative strategies are needed to assist individuals attempting to lose and maintain weight. It is not currently known the degree to which campaign interventions alone impact diet and physical activity behaviors and weight loss. Therefore, the primary aim of this study was to examine the feasibility of a stand-alone campaign intervention

as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention.

2.2 OVERWEIGHT AND OBESITY

2.2.1 Overweight and Obesity Prevalence

Overweight and obesity are characterized by an excess in body weight and are determined by body mass index (BMI), which is calculated as weight in kilograms divided by height in meters squared (kg/m^2)⁵. A BMI of 25.0-29.9 kg/m^2 is considered overweight and a BMI equal to or greater than 30.0 kg/m^2 is classified as obese¹. The classification of obesity can be further divided with a BMI of 30.0-34.9 kg/m^2 classified as Class I Obesity, a BMI of 35-39.9 kg/m^2 as Class II Obesity, and a BMI greater than or equal to 40 kg/m^2 as Class III obesity¹. Based on data from the National Health and Examination Survey (NHANES), the prevalence of overweight and obesity in adults aged 20 years and older showed little change between 1960 and 1980, followed by a marked increase of almost 8% between the 1976-1980 survey and the 1988-1994 survey⁴⁷. A similar increase of nearly 8% was observed in the 1999-2000 survey⁴⁸. It is now estimated that 69.2% of adults in the United States, ages 20 years or older, are classified as overweight or obese¹.

2.2.2 Consequences of Overweight and Obesity

The rising prevalence of overweight and obesity negatively impacts the health and longevity of the population. Overweight and obesity are linked to cardiovascular disease, metabolic syndrome, type 2 diabetes, hypertension, dyslipidemia, osteoarthritis, sleep apnea, gall stones, and certain forms of cancer^{3,5,49}. The risk of developing these comorbid conditions is positively associated with increasing BMI. For instance, Field and colleagues⁵⁰ found that participants whose BMI was 35 or greater were about 20 times more likely to develop diabetes, 2 times more likely to develop heart disease or stroke, 2.5 times more likely to develop hypertension, 3 times more likely to develop gall stones, and 1.5 times more likely to develop colon cancer compared to participants who were in the healthy BMI range of 18.9 to 24.9. Subsequently, obesity is associated with increased mortality (e.g., an excess of 112,000 deaths per year) relative to the healthy BMI category⁵¹.

The rising prevalence rates of overweight and obesity also have an adverse impact on the economy. For instance, in 1998 Finkelstein and colleagues showed that the costs of overweight and obesity were approximately \$78.5 billion, with roughly half financed by Medicare and Medicaid⁵². In 2008, that number nearly doubled as the medical cost of obesity was estimated to be \$147 billion, accounting for almost 10% of all medical spending⁴. Obesity imposes additional medical costs on an individual level with obese individuals paying \$1,429 higher out-of-pocket medical expenses per year, or 42 percent higher, than for someone of normal weight⁴. Furthermore, compared to the cost for normal weight beneficiaries, Medicare costs are over \$600 per beneficiary per year greater⁴. These costs extend into the workplace as financial and productivity costs for employers are substantially impacted by absenteeism, sick leave, disability, injuries, and health-care claims are substantially impacted⁵³⁻⁵⁵.

2.2.3 Causes and Contributing Factors to Overweight and Obesity

To understand the obesity epidemic, it is helpful to examine how body weight is regulated⁵⁶. Energy balance is determined by the amount of energy consumed (caloric intake) in relation to the amount of energy expended in physical activity and metabolism⁵⁷⁻⁵⁹. To lose weight, individuals must obtain a negative energy balance in which energy expenditure exceeds energy intake. Whereas, weight gain is a result of a positive energy balance in which energy intake exceeds energy expenditure. Finally, to maintain a stable body weight, energy expenditure must equal energy intake over time.

While energy balance appears to be straightforward, overweight and obesity result from a complex interaction between biologic, genetic, environmental, and psychosocial factors⁶⁰. For instance, genes can affect each component of energy balance and can explain some of the variance between individuals' BMI and body composition⁶¹. However, genes are not the primary cause of the gradual weight gain of the population⁵⁶. Our environment promotes the consumption of energy dense foods and sedentary lifestyles⁶². Thus, it has been suggested that maintaining a healthy body weight requires cognitive effort focused on the combination of changing individual behaviors and the environment to facilitate healthy behavior changes^{56,59}.

2.3 STANDARD BEHAVIORAL WEIGHT LOSS INTERVENTIONS

The National Heart, Blood and Lung Institute (NHLBI) suggests that a behavioral intervention which combines calorie restriction, increased physical activity, and behavior therapy is the most effective strategy to help individuals lose and maintain weight⁵. Behavior therapy refers to a set

of principles and techniques to assist obese individuals in modifying eating, activity, and thinking habits that contribute to their excess weight⁴⁵. This approach recognizes that weight is affected by factors other than behavior, including genetic, metabolic, and hormonal influences, which may predispose some individuals to obesity⁴⁵.

Standard behavioral weight loss interventions are typically provided on a weekly basis for an initial period of 16 to 26 weeks¹⁶. Interventions focused on weight loss maintenance may continue after this period with biweekly sessions⁶³. Treatment is often provided in 60 to 90 minute group and/or individual sessions lead by professionals with degrees in nutrition, psychology, exercise physiology, or a related field⁶³.

Sessions begin with a measurement of the participants' weight and once the group assembles participants discuss their success and/or barriers in achieving behavioral goals⁶³. This is followed by the delivery and discussion of a behavioral lesson which includes topics such as self-monitoring, problem solving, nutrition, physical activity, stimulus control, goal setting, social support, cognitive restructuring, and relapse prevention^{16,17,63}. Lecturing is minimal as participants are encouraged to ask questions or discuss progress in completing assignments¹⁶. Sessions conclude with a discussion of the homework assignment for the coming week¹⁶. The overarching goal of treatment is to modify a participant's lifestyle behaviors thought to contribute to obesity (e.g., inappropriate diet and inactivity), in addition to close monitoring of those behaviors⁶⁴.

2.3.1 Dietary Modification

Dietary modification is a key component of behavioral weight loss interventions. To induce a weight loss of 1-2 pounds per week, it is recommended that adults reduce caloric intake by 500-1,000 kcal

per day⁵. To produce this amount of weight loss, men in behavioral weight loss programs are recommended to consume a diet of 1,500-1,800 kcals and women a diet of 1,200-1,500 kcal per day¹⁶. Dietary recommendations within programs are also consistent with the 2010 Dietary Guidelines for Americans⁶⁵, limiting fat intake to 20-30% of total caloric intake.

Behavioral weight loss interventions promote flexible and modest dietary changes that may be maintained long term. However, more restrictive and structured diets such as very low calorie diets (VLCD), meal replacements, and food provisions have been used within behavioral treatment to induce larger weight losses^{16,20}. VLCDs produce a weight loss of 20% of initial body weight within 12 to 16 weeks of treatment with participants consuming approximately 800 kcals per day¹⁶. While this weight loss is nearly double the amount experienced with the conventional energy-restricted diet, previous studies have shown no differences in weight loss after a year of treatment as participants prescribed a VLCD regained their lost weight⁶⁶.

Meal replacement diets combine two or more servings a day of a liquid diet with a meal of conventional foods to have participants consume 1,000-1,200 kcals per day. Dietschuneit et al.⁶⁷ have shown that participants who replaced two snacks and two meals a day with a liquid supplement (e.g., Slimfast) lost 7.1 kg in 3 months compared to a weight loss of 1.3 kg for those prescribed the same amount of calories (1200-1500 kcal per day) but who consumed a diet of conventional foods. Furthermore, participants who continued to replace one meal and one snack a day with a liquid supplement maintained a weight loss of 10.4 kg at 27 months⁶⁸. A meta-analysis by Heymsfield et al.⁶⁹ found participants who followed a partial meal plan (e.g., 1-2 meal replacements per day) lost approximately 2.5 kg and 2.4 kg greater at 3 months and 1 year, respectively, compared to those who followed a conventional diet. Meal replacements allow individuals to simplify food choices, limit contact with problem foods, and require little preparation which appears to facilitate adherence to targeted calorie goals¹⁶.

Food provisions have also been used to improve weight loss efforts in behavioral weight loss interventions. Jeffery et al.³⁵ examined the impact of food provision on weight loss outcomes in overweight adults. Individuals who received a standard behavioral treatment program plus food provisions lost significantly more weight at 6 months (10.1 kg vs. 7.7 kg), 12 months (9.1 kg vs. 4.5 kg) and 18 months (6.4 kg vs. 4.1 kg) compared to those who received a standard behavioral weight loss program with a reduced calorie diet. In a follow up study, Wing et al.⁷⁰ examined the contribution of food provision components on weight loss in a behavioral treatment program: the food itself; the fact that food was provided free; and specific meal plans indicating what foods to eat affected weight loss. Participants were randomized to one of four conditions: standard behavioral weight loss program (SBWL), SBWL plus structured meal plans and grocery lists, SBT plus meal plans plus food provision, with participants sharing cost, or SBT plus meal plans plus free food provision. Weight loss was greater in the groups that received food and meal plans compared to the group that received standard behavioral treatment at 6 months (-12.0, -11.7 and -11.4 kg vs. 8.0 kg) and 18 months (-6.9, -7.5 and -6.6 kg vs. -3.3 kg). However, there were no significant differences observed between the groups that were provided food and the group that received meals plans and grocery lists. The authors concluded that the component of food provision responsible for its success is the provision of structured meal plans and grocery lists. Therefore, providing structured meal plans and grocery lists may improve outcomes in behavioral weight loss interventions; however it is not necessary to provide the foods.

2.3.2 Physical Activity

Physical activity is a central component of weight management in the prevention of weight gain, weight loss, and the prevention of regain after weight loss. It is defined as any bodily movement produced by skeletal muscle that results in energy expenditure⁷¹. It is recommended to be performed at 3-4 METS, comparable to the intensity of a brisk walk at 3-4 miles per hour⁷². Regular physical activity can positively affect health outcomes, such as coronary heart disease, hypertension, type 2 diabetes, osteoporosis, colon cancer, anxiety, and depression⁷². Furthermore, physical activity is the most variable and modifiable component of the energy balance equation with 10-30% of total daily energy expenditure resulting from activities of daily living and structured exercise⁷³. Consequently, weight loss interventions incorporating an exercise component, in addition to dietary instruction, are more effective than dietary instruction alone^{9,74-78}.

To examine the effect of physical activity alone on weight loss, Miller and colleagues⁷⁹ conducted a meta-analysis of weight loss research using diet, exercise, or diet plus exercise intervention. The authors concluded that exercise alone produces a weight loss of 2.9 kg in comparison to diet alone (-10.7 kg) and diet plus exercise (-11.0 kg). Similarly, Wing⁸⁰ has reported weight losses of approximately 1-2 kg in weight loss interventions due to exercise alone. A study by Sletz and colleagues⁸¹ underlines the modest effect of exercise alone for weight loss. Participants who jogged/ran the equivalent of 20 miles per week without dietary restriction lost only 3.5 kg at the end of 8 months of training. In contrast, participants who walked 12 miles per week at a moderate intensity (approximately 30 minutes, 6 days per week) lost only 1.1 kg.

While physical activity has been shown to have a modest effect on body weight in short-term weight loss interventions, there is evidence to suggest physical activity plays a more significant role in weight maintenance^{9,74}. Jeffery and colleagues⁸² showed that individuals in a behavioral weight control program who were prescribed high levels of physical activity (2500 kcal per week) maintained significantly greater weight losses compared to individuals with a lower physical activity goal (1,000 kcal per week) at 18 months (-6.7 kg vs. -4.1 kg). Jakicic et al.⁸³ have shown that participants who exercised 275 minutes per week (1,835 kcal per week) maintained weight losses of 10% or more of initial body weight at 24 months compared to those maintaining a weight loss of less than 10% of initial body weight. These results suggest that a higher level of physical activity that results in energy expenditure of 1835-2500 kcal per week promotes long-term weight loss. This level of physical activity is consistent with the American College of Sports Medicine (ACSM) guidelines suggesting that 150-250 minutes of moderate intensity physical activity per week is needed to induce modest weight loss and prevent weight gain with moderate diet restriction and that weight maintenance is improved with physical activity levels greater than 250 minutes per week⁹.

2.3.3 Goal Setting

Goals are the object or aim of an action such as attaining a specific standard of proficiency within a particular time frame²¹. According to Locke and Latham²¹, goals affect performance through four mechanisms: 1) goals direct effort and attention towards activities that are goal relevant and away from those that are irrelevant; 2) goals serve in an energizing capacity in that higher but realistically attainable goals lead to greater effort and better performance than lower set goals; 3) goals impact persistence with more difficult goals resulting in a prolonged effort;

and 4) goals can affect actions indirectly through the discovery and/or application of task-related strategies and knowledge. These mechanisms assist individuals in acquiring skills to enable them to adjust their plans and actions to achieve optimal goal attainment.

Goal setting is a key behavioral strategy in promoting dietary and physical activity behavior change among adults⁸⁴. Schneider et al.⁸⁵ examined the effects of a 10,000 steps per day exercise prescription on body composition and cardiovascular disease risk factors in sedentary, overweight and obese adults. Participants who averaged greater than 9,500 steps per day (adherers) had significant improvements in walking volume (+3994 steps per day), body weight (-2.4 kg), waist circumference (-1.8 cm), hip circumference (-1.9 cm), and high density lipoprotein (3 mg/dl) compared to participants who did not adhere to the step goal. Schnoll and colleagues⁸⁶ have shown that participants who set goals to increase dietary fiber intake consumed 91% more fiber than participants who did not set goals.

During behavioral weight loss interventions, participants are given specific goals that can be easily measured such as a target for average daily calorie intake, weekly minutes of physical activity, and number of days for which foods should be recorded⁶³. Nothwehr and Yang²² examined whether changes in goal setting frequency predicted changes in behavioral strategies over time. They found that frequent goal setting that focused on specific diet or physical activity behaviors was more predictive of using dietary and physical activity strategies than goal setting focused on weight loss overall. Therefore, frequent goal setting in behavioral weight loss interventions is important to allow participants to work towards behavior changes rather than focusing solely on weight related goals.

The effectiveness of goal setting is also directly related to the length of time to achieve the goal. Previous research has shown individuals who set short-term goals are more likely to

have greater success than individuals who set long-term goals⁸⁷. Dubbert and Wilson²³ examined the effect of setting short-term or long-term goals for energy expenditure and calorie intake on weight loss. They found individuals who reported following either daily or weekly specific goals lost significantly more weight over a 19-week period than those who did not set goals. These findings suggest that it is important to provide individuals with detailed and timely goals to change diet and physical activity behaviors to impact weight.

2.3.4 Self-Monitoring

Self-monitoring is largely considered the most important component of behavioral weight loss interventions¹⁶. It is the systematic observation and recording of behaviors to assist individuals in the self-regulation of behaviors^{16,24}. For instance, during behavioral weight loss programs participants record caloric intake, physical activity, and weight so they are aware of current behaviors²⁰. This process could help participants identify a pattern that they are unaware of, such as snacking in the evening¹⁶. It also allows participants to set goals accordingly to modify behaviors and improve progress towards a targeted behavior or health outcome¹⁸.

Previous research has shown that participants who monitor their diet and activity behaviors consistently have better weight control short-term and long-term than participants who do not self-monitor, or are not consistent monitors²⁶⁻²⁸. Helsel and colleagues²⁷ examined the influence of self-monitoring on weight control. Participants were randomized to a traditional detailed method of self-monitoring or an abbreviated method of self-monitoring. The authors found that participants in the abbreviated method group returned significantly more entries than the traditional method. While there was no significant difference in weight loss between the groups, weight loss was significantly associated with the number of self-monitoring diaries

completed. Similarly, Boutelle and Kirschenbaum⁸⁸ examined the percentage of participants who self-monitored consistently and the relationship between the variability in self-monitoring and weight change. Participants from two long-term behavioral weight control programs, involved in treatment an average of 17 months, self-monitored for a total of 8 weeks. Both treatment programs had already incorporated the use of self-monitoring booklets and were given the same treatment. By week 8, participants lost an average of 0.11 pounds, in addition to the mean of 33.17 pounds they lost prior to this sub study. While 45.6% of the participants monitored all foods eaten between 75 and 100% of the days; 28.1 % monitored all foods eaten between 50 and 74% of the days or more; 15.8 % monitored all foods eaten between 25% and 49% of the days; and 10.5% monitored foods eaten on 24% or fewer days. The results demonstrated that average self-monitoring consistency was significantly associated with average weight change. Furthermore, participants lost significantly more weight during their most consistent weeks (according to counselor ratings) of self-monitoring compared to their least consistent weeks. Thus, the authors concluded that self-monitoring food intake consistently, at least 75% of the time, can be a reasonable target for consistency to improve success for weight control during treatment.

One way to improve consistency of self-monitoring in weight loss programs is through encouragement and reminders. Encouragement and reminders to improve self-monitoring consistency can also impact weight outcomes. For example, Boutelle and colleagues²⁹ examined the efficacy of enhancing a behavioral weight loss program with a self-monitoring intervention during the high risk holiday season. Participants in a long-term behavioral weight loss program were randomly assigned to an 8-week self-monitoring intervention or a comparison group. During holiday weeks (Christmas and New Year's), the self-monitoring intervention group

received daily mailings to remind them to self-monitor. The mailings included reminder letters, information on self-monitoring, and comics about weight control. Participants also received 1-2 phone calls per week to remind them to self-monitor. If the participants reported they had stopped monitoring, staff would review their recent eating and exercise behaviors over the phone and encourage them to self-monitor in their booklets. The authors found that the intervention group self-monitored more consistently (75.5% vs. 53%) and managed their weight better (0 lbs. vs. +1.2 lbs.) than the comparison group during the holidays. While these results were not statistically significant, they suggest encouragement and reminders may improve self-monitoring consistency to improve weight outcomes.

Self-monitoring weight allows individuals to notice how situations or patterns of eating and physical activity behaviors relate to body weight. Accordingly, individuals who are successful at losing weight and maintaining weight loss often exhibit more frequent self-monitoring habits²⁶. For example, Butryn et al.²⁶ examined the association between self-weighing and weight change in a large sample of successful weight losers in the National Weight Control Registry (NWCR). Participants were members of the NWCR who lost greater than or equal to 30 lbs. and kept it off for greater than or equal to 1 year and completed the self-weighing frequency assessment at baseline and at the 1-year follow-up assessment. They found 36% of participants who maintained successful weight loss weighed-in daily and 79% weighed themselves weekly. Furthermore, participants who significantly decreased their frequency of self-weighing gained weight at the 1-year follow-up (4.0 kg) compared to those whose frequency increased (1.1 kg) or remained the same (1.8 kg). Linde et al.⁸⁹ also examined cross-sectional and longitudinal associations between the self-weighing frequency and weight in two groups. One group was enrolled in a weight gain prevention trial and the other group was enrolled in a

weight loss trial. The authors concluded that regular weekly weighing was significantly associated with less weight gain and greater weight loss at 24 months, respectively. Thus, self-monitoring weight, in addition to diet and physical activity behaviors, is an effective strategy to improve weight loss and weight maintenance efforts.

2.3.5 Feedback on Goal Achievement

Providing feedback at various time points through personal or technological methods has been identified as an integral component of successful goal attainment^{21,90}. In order to promote behavior changes during behavioral weight loss interventions, participants need feedback and encouragement with regard to accuracy and progress relative to their goals and achievements. Upon receiving this feedback, participants can evaluate their efforts and adjust their performance accordingly²¹.

Feedback has the potential to increase adherence to self-monitoring which may also enhance goal attainment. Burke and colleagues³⁰ examined if self-monitoring diet using a personal digital assistant (PDA) only or a PDA with customized daily feedback (PDA+FB) was superior to using a paper record (PR) at six-months in a behavioral weight loss program. They found that individuals in the PDA+FB significantly reduced energy and saturated fat intake and improved self-monitoring adherence compared to those using a paper diary. Interestingly, while the use of the PDA improved adherence to self-monitoring in both groups (90% in the PDA+FB and 80% in the PDA), the greatest weight change was observed in the PDA+FB group. The authors suggest individualized feedback may play a central role in goal attainment.

The Internet is a viable method to provide individualized feedback within behavioral weight loss interventions. Tate and colleagues³¹ examined whether an Internet behavior therapy

group produced greater initial weight loss compared to an Internet education only group. All participants were given 1 face-to-face group session and access to a website with links to Internet weight loss resources. Participants in the behavior therapy group received 24 weekly behavioral lessons via e-mail, weekly online submission of self-monitoring diaries with individualized therapist feedback via e-mail, and an online bulletin board. The authors found participants who were given a structured behavioral treatment program online with weekly contact and individualized feedback from interventionists had better weight loss than those given links to education web sites (-4.1 kg vs. -1.6 kg, respectively).

Tate et al.⁹¹ also examined the short-term efficacy of a self-directed Internet weight loss program compared with the same program supplemented with behavioral counseling from a human counselor or computer automated tailored system. All participants received 1 weight loss group session, coupons for meal replacements, and access to an interactive Website. In addition, the e-mail counseling group received weekly e-mail feedback from a counselor, and the computer-automated group received automated, tailored messages. At 3 months, weight losses for the computer-automated group (-5.3 kg) and human e-mail counseling (-6.1 kg) were significantly greater compared to the no counseling group (-2.8 kg). However, there was no significant difference between the computer-automated group and the human e-mail counseling group. At 6 months, weight losses were significantly greater in the human e-mail counseling group (-7.3 kg) than in the computer-automated feedback (-4.9 kg) or no counseling (-2.6 kg). Thus, it appears individualized feedback from a counselor is an important component to improve weight loss outcomes.

Wing et al.³² examined whether adding behavioral weight loss strategies to a 12-week Internet-based community weight loss campaign could improve outcomes. Participants were

randomly assigned to one of two groups: standard Shape Up Rhode Island or enhanced Shape Up Rhode Island. Participants in the standard Shape Up Rhode Island group were given access to the intervention website components and received an e-mail with a directory of publicly available Web sites that had information regarding nutrition, physical activity, and behavior change. There was no additional contact until the follow-up assessment. Conversely, participants in the enhanced Shape Up Rhode Island group were given access to a set of instruction video sessions including information regarding nutrition, physical activity, and behavior change. In addition, they reported daily weight, calories and fat grams, steps, and exercise minutes on the study website. Computer-automated feedback was provided weekly in response to these data and commented on the participant's weight loss, calorie intake, and exercise minutes relative to the set goals. If the participant was not meeting the set goals, the messages included suggestions to help him/her reach that goal. The authors found that when instruction video sessions were supplemented with self-monitoring and computer generated feedback, the average weight loss more than doubled (3.5 ± 3.8 kg vs. 1.4 ± 2.7 kg) ($p<0.01$) and the proportion of individuals achieving a weight loss of 5% or more tripled (40.5% vs. 13.2%) ($p<0.01$) when compared to the standard control group. Thus, adding behavioral strategies within Internet programs may improve weight loss outcomes.

The above studies suggest that the Internet may be a feasible method to provide feedback and behavioral weight loss strategies within interventions. While there is a valid concern that participation in Internet-based programs are limited to those with access to computers with Internet capability, nearly 77% of households contain a computer with access to the Internet⁹². While a proportion of African-American households that currently have Internet access is lower than for White households (63.4% vs. 80.7%, respectively), previous research has shown

that it is possible to recruit a diverse population to participate in a long-term Internet weight management program⁹³. This may be due to the fact that 36.7% of African Americans have access to the Internet from some location outside their home⁹². Thus, using the Internet to deliver behavioral weight loss interventions can be a practical delivery method which may also reduce cost associated with in-person weight loss interventions.

2.3.6 Reinforcement

Tangible rewards of weight loss for participants such as wearing smaller clothes and compliments from others can be very reinforcing in the early stages of weight loss treatment¹⁷. However, there is evidence to suggest that motivation for health behaviors and participation decreases as treatment continues. For example, adherence to self-monitoring starts at a high level and significantly drops over time²⁵. Furthermore, only approximately 80% of participants who begin weight loss treatment complete it⁴⁵. Thus, methods to encourage participants to maintain motivation to continue health behaviors and stay engaged in weight loss treatment are important.

To increase motivation and self-efficacy for behavior changes, behavioral weight loss programs advocate participants making small sustainable changes rather than large unrealistic changes through frequent goal setting¹⁶. Once the goal is achieved, incentives can serve as a tangible reinforcer for positive behavior changes¹⁷. Examples of incentives include cash payments, lottery prizes, coupons for free or reduced price goods or services, gifts (e.g., t-shirts, blankets, coffee mugs, etc.), gift certificates, vouchers, free or reduced price of medical insurance, or a reduction in cost of healthcare services. Financial incentives have been used as direct payment to the individual, repayment from deposits provided by the individual (deposit

contracts), and within lotteries⁹⁴. These methods are contingent upon specific goals or outcomes, such as achieving weight loss or increasing physical activity⁹⁴.

Finkelstein and colleagues⁹⁵ tested the ability of two levels of modest financial incentives to encourage weight loss among overweight employees. Participants were randomized to one of three groups: no financial incentives, \$7 per percentage point of weight lost, and \$14 per percentage point of weight loss. Payments were structured so that all participants had the equal opportunity to earn the incentives during the study time frame. At 3 months, participants in the \$14 group lost significantly more weight (-4.7 lbs.) compared to those who received no financial incentives (-2.0 lbs.). However, differences in weight loss between the \$14 group (-4.7 lbs.) and \$7 group (-3.0 lbs.) were not statistically significant. These findings suggest that short-term weight loss was associated with the magnitude of payment. Thus, the authors concluded that modest financial incentives can be effective in motivating overweight individuals to lose weight.

Volpp et al.¹⁹ examined if participants who earned chances to win money achieved or lost more than the target weight compared to a deposit contract condition in which participants invested their own money, which they lost if they failed to achieve set weight goals. Participants were randomized to one of three groups: a control group (monthly weigh-ins), a lottery incentive group, or deposit contract group. All participants were given a weight loss goal of one pound per week for 16-weeks. Participants in the deposit contract group chose to contribute between \$0.01 and \$3.00 for each day of the month that was refunded at the end of the month if they met or exceeded their weight loss goal. As an additional incentive, the authors matched the amount the participants' contribution to deposit contracts and added a fixed payment of \$3.00 per day. Participants accumulated money each day they called in and reported a weight at or below their weight loss goal. They were also provided feedback via a text message including the amount of

money they had earned that day. Participants in the lottery incentive group were eligible for a daily lottery drawing prize of \$3.00 per day if they reported weight at or below their weight loss goal prior to the drawing. The lottery also provided infrequent large payoffs (e.g., a 1 in 100 chance at \$100) and frequent small payoffs (e.g., a 1 in 5 chance at \$10). The authors found that participants in the lottery incentive group and the deposit contract group lost significantly more weight (13.1 lbs. and 14 lbs., respectively) compared to those in the control condition (3.9 lbs.) over the course of the 16-week study.

Prize-based reinforcement has been used as a promising approach to enhance weight loss efforts. Petry and colleagues⁹⁶ evaluated the efficacy of a low-cost 12-week reinforcement intervention to produce weight loss. Participants were randomized to one of two treatments: a standard treatment program with supportive counseling or the same treatment plus opportunities to win prizes ranging from \$1 to \$100 for losing weight and completing weight loss activities (e.g., self-monitoring). Participants receiving reinforcement prizes lost significantly more weight (-6.1 kg) compared to the non-reinforcement condition (-2.7 kg). Furthermore, 64.3% of participants in the reinforcement group achieved a weight loss of 5% of initial body weight compared to 25% of those in the non-reinforcement condition. These findings suggest using small and frequent incentive reinforcers combined with a chance to win an incentive of higher value can significantly affect behaviors and result in weight loss.

2.3.6.1 Motivation

The Self Determination Theory (SDT) suggests that for a behavior to be instigated and continued, an individual must feel they are doing a behavior to better themselves and that they are inspired to carry out the behavior of their own will (autonomous motivation)⁴⁰. In contrast,

controlled motivation is associated with a need to comply with feelings of pressure and tension the individual has internalized or by external contingencies such as incentives or expected negative consequences from a behavior⁴¹. While motivation appears to play a role in weight loss behaviors, a limited number of studies have examined individuals' motives for initiating weight loss attempts or the impact of initial motivation on treatment outcomes⁹⁷. Williams et al.⁹⁸ have shown that perceived autonomy support predicted autonomous reasons to continue to participate in treatment, which also resulted in higher attendance and improved weight loss within a 6-month weight control intervention.

Within the context of a behavioral weight loss program, incentives and reinforcement have been used as strategies to encourage participants to initiate and continue healthy behaviors. However, these strategies could potentially be observed as controlling by the participant, thereby undermining their autonomous motivation for participating in the weight loss program. Crane and colleagues⁴³ were the first to examine the effect of incentives on motivation. They examined if changes in autonomous or controlled motivation for participation in a weight loss program differed between participants offered a financial incentive for weight loss compared to individuals not offered an incentive. The same relationships were examined among participants who lost weight and either received or did not receive an incentive. Data were analyzed from 594 participants in the Worksite Activities for You (WAY) research study; a year-long worksite-based intervention trial. The WAY trial examined the effects of a low-intensity weight loss program compared to the same program plus small financial incentives for weight loss (\$5.00 per percentage of initial weight lost). The results demonstrated no significant difference in motivation between the groups during the study. However, increases in autonomous motivation were associated with greater weight losses. The authors concluded that small incentives did not

lead to increases in controlled motivation and did not undermine autonomous motivation. These results suggest further research is needed to examine the relationship between incentives and motivation for weight loss including the magnitude and timing of the incentive.

2.4 CAMPAIGNS AND BEHAVIORAL WEIGHT LOSS INTERVENTIONS

The Diabetes Prevention Program (DPP) and the Look AHEAD (Action for Health in Diabetes) trials have incorporated the use of campaigns as part of the lifestyle intervention to assist participants' in the attainment of lifestyle goals^{7,11}. Nationwide centers, local teams, and individuals have competed on best attendance, regular self-monitoring, weight loss, minutes of physical activity, or steps measured by a pedometer in a variety of 6 to 10 week campaigns in DPP and Look AHEAD^{7,11}. For example, data from the DPP National Lifestyle Lottery demonstrated increases in the average percent of weight loss, average minutes of physical activity, percent of participants at weight goal, and percent of participants at their physical activity goal during the time the campaign was implemented as part of the larger intervention⁹⁹. Postcards, magnets, weight graphs, newsletters, t-shirts, and other small incentives are examples of incentives used to reflect the overall content and theme during the various campaigns^{7,11}. While it appears campaigns within behavioral interventions may be effective for improving weight loss behaviors, data from other DPP and Look AHEAD campaigns have not been published or made available to the public.

Otto et al.¹⁰⁰ examined the effect of a campaign on body weight and physical activity in overweight women participating in a behavioral weight loss program. The 12-week campaign was introduced four months into the study and focused on increasing physical activity using a

pedometer. The campaign gave subjects an opportunity to earn incentives, such as exercise tapes, clothing, and gift certificates. By achieving specific exercise and eating goals participants were able to earn additional points toward attaining incentives. Significant correlations were shown between total steps taken and weight loss during the campaign. These results held true even after controlling for weight loss from baseline to pre-campaign.

Other support for incentives and campaigns comes from a study conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh¹⁰¹. Within the context of a standard behavioral weight loss intervention, one group received a 12-week pedometer, incentive-based campaign during months 12-18, while another group did not. The group that received the campaign went from a 10.9% weight loss at month 12 to a 10.2% weight loss at month 18. In comparison, the group that did not receive a campaign had a weight loss of 9.3% at month 12 and went to a 7.0% weight loss at month 18. Significant differences were observed for change in weight and percent change in weight between the two groups at 18-months. These results suggest that additional incentives as part of a campaign, added to a standard behavioral weight loss intervention, may improve weight loss.

2.5 SUMMARY

Overweight and obesity are a significant public health concern. Behavioral treatment is considered the first line of intervention for individuals attempting to lose weight. Behavioral weight loss interventions are capable of producing an 8-10% weight loss of initial body weight at six-months. However, not all individuals achieve this magnitude of weight loss. Of those who do, approximately one-third of lost weight is regained within 1 year of treatment ending and

nearly one-half of participants return to their original weight within 5 years^{45,46}. Therefore, the development of alternative approaches to standard behavioral weight loss programs is needed to improve weight loss and weight maintenance efforts. One possible solution is the use of a stand-alone campaign in combination with the strategies described above. To our knowledge, there is no published data on the effectiveness of a stand-alone campaign intervention. Therefore, the primary aim of this study was to examine the feasibility of a stand-alone campaign as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention.

3.0 METHODOLOGY

3.1 SUBJECTS

We recruited twenty six (N=26) sedentary, overweight and obese adult men and women to participate in a behavioral weight loss intervention at the University of Pittsburgh Physical Activity and Weight Management Research Center. To be considered eligible for this study, participants were 18-55 years of age, with a body mass index (BMI) ranging from $\geq 25.0 \text{ kg/m}^2$ to 45.0 kg/m^2 . Additional inclusion and exclusion criteria for participation are listed in Table 1.

Table 1. Study Eligibility Requirements

Inclusion Criteria:
<ul style="list-style-type: none">• Male or Female• 18 to 55 years of age• Body Mass Index (BMI) between $\geq 25.0 \text{ kg/m}^2$ to 45.0 kg/m^2• Ability to provide informed consent
Exclusion Criteria:
<ul style="list-style-type: none">• Regular exercise participation of at least 20 minutes per day on at least 3 days per week during the previous six months.• Participation in a previous physical activity or weight management research project in the previous 6 months.• Weight loss of $\geq 5\%$ of current body weight in the previous 6 months.• For women, those currently pregnant, pregnant during the previous 6 months, or plan on becoming pregnant in the next 6 months.• History of myocardial infarction, coronary bypass surgery, angioplasty, or other heart-related surgeries.• History of orthopedic or physical complications that would prevent participation in exercise.• Currently taking any prescription medication that may affect metabolism and/or body weight (e.g., synthroid).• Currently being treated for any condition that could affect body weight, such as coronary heart disease, diabetes mellitus, uncontrolled hypertension, cancer, depression, and anxiety.• Currently being treated for any psychological issues or problems, taking any psychotropic medications, or receiving treatment with psychotropic medications within the previous 6 months.• Resting systolic blood pressure $\geq 150\text{mmHg}$ or diastolic blood pressure $\geq 100\text{mmHg}$. Subjects with controlled hypertension were allowed to participate if they obtained a medical doctor's written consent to ensure that it is safe to participate in a weight loss intervention.• Currently do not have access to a computer and the Internet.

3.2 RECRUITMENT AND SCREENING PROCEDURES

Subjects were recruited from flier postings (Appendix A), Craigslist advertisements, and the Clinical and Translational Science Institute (CTSI) Research Participant Registry. Letters were

also sent to interested participants in the Obesity and Nutrition Research Center database (Appendix B). Additionally, fliers were mailed to University of Pittsburgh Faculty and Staff. Potential subjects were instructed to call the University of Pittsburgh Physical Activity and Weight Management Research Center where trained staff conducted a telephone screening to determine initial eligibility. The telephone screening included a detailed description of the study and its' potential risks and benefits (Appendix C). Upon the participants' verbal consent, staff asked questions regarding medical history and other pertinent questions related to exclusion/inclusion criteria (Appendix D).

All eligible participants, determined by the initial telephone screening, were invited to attend a 60 minute orientation session where complete details of the study were given. During this time, participants were encouraged to ask questions about the study's procedures. Interested participants provided written informed consent (Appendix E) and completed a Physical Activity Readiness Questionnaire¹⁰² (PAR-Q) (Appendix F) and provided a medical history (Appendix G) as recommended by the American College of Sports Medicine to detect those at high risk of participating in regular physical activity. Furthermore, participants were required to obtain a medical doctor's written consent (Appendix H) to ensure that it is safe to participate in a weight loss intervention. The cost of obtaining this consent was the responsibility of the participant.

Eligible participants, who obtained this consent, underwent baseline assessments. Assessment procedures and measures included obtaining height, body weight, body composition, physical activity, and dietary intake. Participants were also given questionnaires to complete at home prior to the assessment. The questionnaires were returned the day of the assessment. Eligible subjects who completed all assessment procedures were randomized to one of two groups (Figure 2) using a stratified randomized block design. Participants were stratified by

gender (e.g., male and female) and ethnicity (e.g., Non-Hispanic White and African American). All study procedures were approved by the University of Pittsburgh Institutional Review Board (Appendix I).

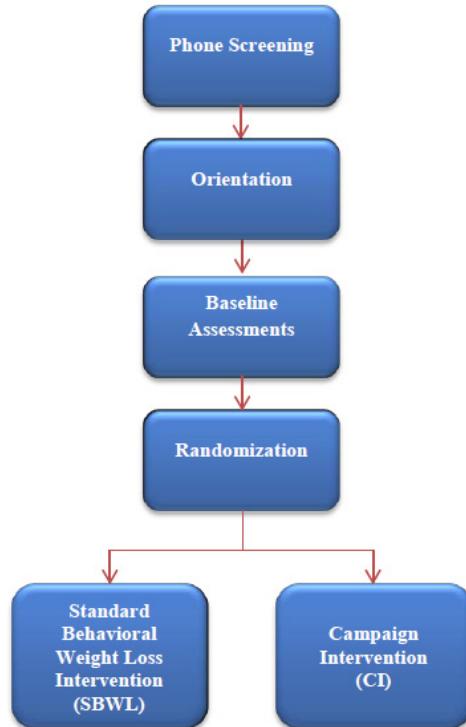


Figure 2. Study Progression

3.3 EXPERIMENTAL DESIGN

This study was a 12-week randomized controlled trial (RCT) to examine the feasibility of a stand-alone campaign intervention (CI) as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention (SBWL). This intervention was conducted at the University of Pittsburgh's Physical Activity and Weight Management Research Center. Upon successful completion of baseline assessments, eligible subjects were randomly

assigned to one of two groups using a stratified randomized block design: 1) standard behavioral weight loss intervention (SBWL) or 2) campaign intervention (CI). Participants were stratified by gender (e.g., male and female) and ethnicity (e.g., Non-Hispanic White and African American). The interventions are discussed in greater detail below. Assessments were completed at 0 and 12-weeks. The study timeline is illustrated in Figure 3.

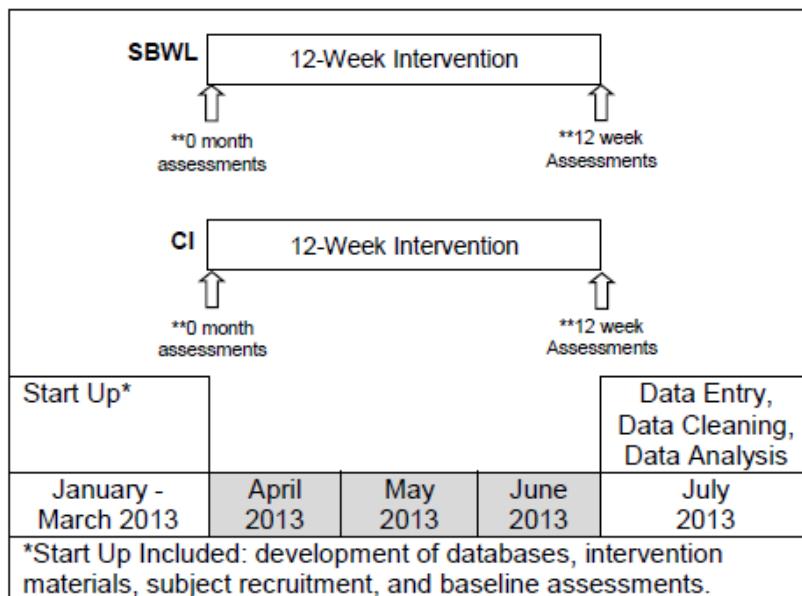


Figure 3. Study Timeline

3.4 STANDARD BEHAVIORAL WEIGHT LOSS PROGRAM (SBWL)

The 12-week SBWL was conducted at the University of Pittsburgh Physical Activity and Weight Management Research Center. Participants attended group meetings weekly. Group meetings lasted approximately 45-60 minutes in duration and were guided by a qualified nutritionist or exercise physiologist with prior experience teaching behavioral lessons. These lessons focused on behavioral strategies for adopting and maintaining eating and physical activity behaviors

based on Social Cognitive Theory²⁴ and Problem Solving Theory¹⁰³. Subjects also weighed in each week prior to their group meeting to assist interventionists with weight counseling and goal-setting. Participants who do not attend the weekly group meeting were contacted via a telephone call to reschedule for an individual weigh-in and make-up session with an interventionist prior to the next group meeting. If an individual make-up session could not be scheduled, an interventionist provided a brief counseling session by telephone and the written materials were mailed. The duration of the group and individual make-up sessions were recorded to determine how much time participants spent in intervention sessions.

3.4.1 Dietary Component

Subjects were prescribed a calorie and fat gram goal to reduce total energy intake to approximately 1200-1800 calories per day dependent on their initial body weight (Table 2). The goal for total fat intake was 20-30% of total caloric intake, which is consistent with the 2010 Dietary Guidelines for Americans⁶⁵.

Table 2. Recommended Daily Caloric and Fat Intake by Body Weight

Initial Body Weight	Kcal/Day	Fat Grams
<200 lbs.	1200	26-40
≥200-250 lbs.	1500	33-50
≥250 pounds	1800	40-60

Participants were given sample meal plans, menus, and recipes in order to assist them with making healthy eating choices. In addition, a copy of the 2013 edition of The CalorieKing® Calorie, Fat, and Carbohydrate Counter book¹⁰⁴ was given to each participant as a reference. Group lessons included dietary information such as lowering calorie and fat intake, reading food labels, portion control, eating out, and self-monitoring food intake. To facilitate

healthy eating, subjects recorded their daily dietary intake in a weekly food diary. The diaries allowed participants to keep track of the calorie and fat grams of food items consumed throughout the day, including all meals and snacks. The diaries were turned in weekly to be reviewed by trained staff to determine if subjects were adherent to the recommended guidelines and accomplished set goals. Upon review, interventionists provided constructive and positive feedback written on the diaries before returning them back to the participants the following week. If for any reason the participant was not demonstrating eating behaviors that were consistent with the study recommendations, they were counseled by the staff dietitian. Furthermore, if a participant was not recording dietary behaviors for seven consecutive days, an interventionist spoke with the participant at the next group session or contacted the participant by telephone (if they missed that session) to determine why the individual stopped self-monitoring.

3.4.2 Exercise Component

Participants were prescribed weekly exercise goals starting with 75 minutes a week (e.g., 15 minutes per day, 5 days a week) and progressed to 200 minutes a week (e.g., 40 minutes per day, 5 days a week) by week 12 (Table 3). Aerobic exercise, similar to a brisk walk, was recommended as the primary mode of exercise. It was recommended that goals be completed in long bouts or several short bouts that were at least 10 minutes in duration. Non-aerobic activities such as resistance training and yoga were also encouraged to supplement physical activity levels. However, participants were instructed that these activities should not replace aerobic exercise as their primary mode of exercise. Participants were also be instructed to use the Borg Ratings of Perceived Exertion¹⁰⁵ (RPE) scale to exercise at a moderate intensity (e.g., RPE of 11-13), equivalent to 60-70% of age predicted maximal heart rate. Group exercise lessons focused on

strategies to overcome barriers to physical activity and increase structured and lifestyle physical activity.

Table 3. Recommended Exercise Progression

Weeks	Minutes/Day	Days/Week	Minutes/Week	Intensity/RPE
1-2	15	5	75	11-13
3-4	20	5	100	11-13
5-6	25	5	125	11-13
7-8	30	5	150	11-13
9-10	35	5	175	11-13
11-12	40	5	200	11-13

Participants were also instructed to record their exercise behaviors including the time of day, type, duration, and RPE in a weekly diary. The diaries provided a space for participants to list the reasons for not exercising (e.g., lack of time or lack of motivation). These behaviors were reviewed weekly by an interventionist. If a participant demonstrated exercise behaviors that were not consistent with the study recommendations, they were counseled by the staff exercise physiologist. In addition, participants had the opportunity to participate in a supervised exercise session before or after their behavioral group session beginning in week 2. The exercise session took place at the University of Pittsburgh Physical Activity and Weight Management Research Center where treadmills, stationary cycles, elliptical machines, and adaptive motion trainers (AMT) were available for use.

3.4.3 Weight Loss Goal

SBWL programs typically produce an 8-10% weight loss over the course of 6 months⁷. Therefore, participants were given a target weight loss goal of 5% of initial weight due to the 12-week duration of the study. This magnitude of weight loss is associated with significant reductions in health risks⁹.

3.5 CAMPAIGN INTERVENTION (CI)

Participants randomized to the CI received the same SBWL components described previously. Additional CI features such as the incentive-based point system, the lottery system, and self-monitoring and intervention delivery procedures are described in further detail below.

3.5.1 Thematic Framework

The thematic framework of the CI was a race car cup theme based on the professional auto racing point system concept. Therefore, the Weight Loss, Diet, and Activity (W.L.D.A.) Cup was designed to have participants “race” towards achieving dietary, physical activity and weight loss goals. This thematic framework was incorporated into behavioral lesson content, targeted campaign goals, and feedback on progress. Furthermore, the classroom was decorated to reflect this theme at the in-person group sessions.

3.5.2 W.L.D.A. Cup Point System

To reinforce positive behavior changes and motivate participants to achieve diet, physical activity, and weight loss goals, the W.L.D.A. Cup featured an incentive-based point system (Table 4). W.L.D.A. cup points were accumulated from week 2 to week 11 (e.g., 10-weeks of data collection). Participants had the opportunity to earn points by self-monitoring their diet and physical activity behaviors, and body weight. For example, participants earned one point if they self-reported their food intake five out of seven days, one point if they reported body weight at least once during the week, and one point if they achieved the weekly physical activity goal. To

minimize participant burden, interventionists tracked points for participants and informed them of their weekly totals.

Table 4. W.L.D.A. Cup Point System

W.L.D.A. Cup Point System	
	Points
Food Intake Reported <i>(5 out of 7 days)</i>	1
Body Weight Reported <i>(at least once during the week)</i>	1
Weekly Physical Activity Goal Achieved	1

Points for the outcome measure (weight loss) were awarded at the final in-person group session at week 12. Points were based on total percent weight loss from the initial in-person group session. Therefore, all W.L.D.A. participants had the same time allotment to work towards attaining the weight loss goal. Weight loss points were weighted more heavily than self-monitoring diet and physical activity behaviors and body weight (Table 5). Higher reinforcement for weight loss was intentional as it was the primary outcome of the study. However, the point system was structured in a way that promoted a safe, healthy rate of weight loss.

Table 5. W.L.D.A. Weight Loss Point System

Total Weight Loss (%)	Points
1-1.9	5
2-3.9	10
4-4.9	15
≥ 5	20

3.5.3 W.L.D.A. Cup Lottery Ticket System

Participants had the opportunity to earn chances to win incentives during the W.L.D.A. Cup. W.L.D.A. Cup “lottery tickets” were awarded at the end of week 12 based on individual point totals (Table 6). The lottery drawing occurred at week 12 and all participants had an opportunity to win an incentive if they achieved a minimum of 5 points. For example, if a participant achieved the weekly physical activity goal 7 times throughout the W.L.D.A. Cup, reported food intake 5 out of 7 days 8 times, and reported their body weight once per week 6 times, he/she earned 21 points. Thus, this participant was eligible to receive 10 lottery tickets for the drawing. The participant increased their chances to win an incentive based on their total percent weight loss. For example, if this same participant lost 7% of their initial body weight throughout the campaign, they would now have earned 41 points and were eligible to receive 25 lottery tickets for the drawing.

Table 6. W.L.D.A. Cup Lottery Ticket System

W.L.D.A. Cup Lottery Ticket System					
Total Points Awarded	5-9	10-19	20-29	30-39	40-50
Lottery Tickets Earned	3	5	10	15	25

3.5.4 W.L.D.A. Lottery Drawing and Incentives

Lottery tickets were drawn for incentives based on individual point totals at week 12. To facilitate this process, interventionists had an excel spreadsheet in the weigh-in room at the final in-person group session with the accumulated point totals throughout the W.L.D.A. Cup for each participant. It also included the most recent self-reported body weight and projected point totals

for each level of percent weight loss that could be achieved by the participant. Upon weighing-in, final point totals were determined and interventionists awarded participants the corresponding number of lottery tickets they earned. Preprinted perforated raffle tickets were used to allow participants to hold a copy of their number during the drawing.

Participants had the opportunity to win incentives including a water bottle, pedometer, stability ball, Apple I-Pod Shuffle, and Apple I-Pod Nano. Incentives were placed on a table in the classroom with a brown paper bag in front of each. Participants were instructed to put as many tickets as they like in the bags that go with the prizes they would like to win. Once all participants were weighed-in, the lottery drawing occurred. Designated staff members conducted the drawing. They shook up each bag, drew out one ticket, and called the number out loud. The participants were asked to hold up their matching ticket. Interventionists confirmed the match and distributed the incentive to the winner. Participants were eligible to win only one lottery drawing prize. However, all participants who achieved the overall weight loss goal of approximately 5% of initial body weight were awarded an incentive (e.g., gym bag and certificate for successful weight loss efforts). A variety of other incentives and certificates were given to recognize different levels of participation (e.g., best self-monitoring effort, biggest % of weight loss, and highest level of physical activity).

3.5.5 Intervention Delivery Procedures: In-Person Group Sessions

W.L.D.A. Cup participants attended two in-person group sessions at weeks 0 and 12. Participants weighed in prior to each group session. At these sessions, the classroom was decorated accordingly to reflect the thematic framework of the intervention (e.g., race car cup theme). To minimize potential problems of confounding by contamination, the SBWL group

sessions occurred in a separate area within the center. The duration of the sessions were recorded to determine how much time participants spent in the intervention sessions. This information was also used to compare the exposure times between the SBWL and CI.

The initial 60 minute in-person group session reviewed the core components of the overall intervention and then the additional features of the CI such as the W.L.D.A. Cup incentive-based point system, the W.L.D.A. Cup lottery drawing and incentives, and the intervention delivery format procedures for e-mail messages. Participants were also given an overview document which stated the rationale of the program, weekly goals, intervention calendar, and a clear explanation of how they can earn chances to win incentives. Participants who did not attend the first weekly group meeting were contacted via a telephone call to reschedule for an individual weigh-in and make-up session with an interventionist prior to the next intervention contact. If an individual make-up session could not be scheduled, an interventionist provided a brief counseling session by telephone and the written materials were mailed. For the purpose of the incentive-based point system, participants must have weighed in no later than week 2 to be included in the lottery drawing for incentives. The final session, at week 12, was a 60 minute summary session on how the participants did in the campaign intervention. The individual and group W.L.D.A. cup point standings were also revealed followed by the lottery drawing for incentives. Participants also reviewed what steps they should take to continue to move forward with weight loss and weight maintenance.

3.5.6 Intervention Delivery Procedures: E-mail

During the weeks participants were not scheduled to attend in-person group sessions (week 1-11), the CI group received one tailored e-mail message including the behavioral lesson, goal assignments, and feedback on group progress per week.

For example:

“It looks like we are going to get some rain during the race this week. Don’t let that stop you from achieving the physical activity goal of 100 minutes. Please review the attached lesson to learn how to overcome weather as a barrier to physical activity. Achieving your diet and physical activity goals will continue to help you lose weight and earn points for campaign lottery tickets and the prize drawing. As a group, you have earned 200 of 216 cup points thus far. Don’t forget to enter your diary information this week and keep up the great job!”

Each participant also received one e-mail message per week including individualized feedback personally from the interventionist. This feedback included recommendations and reinforcement based on dietary intake, physical activity, and weight loss progress assessed from the self-monitoring diary.

For example:

“Hi Sarah, you did an excellent job crossing the physical activity finish line this week. You earned three points! It appears you drove over some diet speed bumps along the way. What do you think you can do differently this week to avoid the “bumps” and stay full throttle while on the weight loss track? For example, you may plan meals in advance to ensure you stay within your 1200 calorie goal each day. Keep up the great efforts and have a wonderful race week!”

E-mails were sent from a secured study e-mail address. The frequency and duration spent drafting the e-mails was recorded. In addition, the investigators reviewed the e-mails to ensure they included behavioral lesson content, goal assignments, and appropriate feedback on individual and group progress. E-mail messages were copied and monitored by investigators. Return receipt was used to monitor opening of the email messages and all messages that were sent were printed and filed weekly. Participants were instructed not to respond to an e-mail message. However, any replies from participants were printed and filed accordingly. Any deviations from protocol with regard to number, length, and frequency of contacts were recorded.

3.5.7 Self-Monitoring Procedures

CI participants were instructed to report their self-monitoring information (e.g., food intake, physical activity minutes, and body weight) each week via an e-mail (Figure 4). To ensure participants had a sufficient level of computer and Internet knowledge, e-mail procedures were reviewed at the first group session and any questions were addressed. In addition, a detailed written guideline outlining e-mail procedures was given to each participant. Participants were instructed to report their diet and physical activity behaviors and body weight by a specific date and time each week (e.g., Thursday by 5:45 PM) to be awarded W.L.D.A. Cup points. In the event a participant did not meet this deadline, they were still able to report their information to assist interventionists with counseling; however they were not awarded W.L.D.A. Cup points for that week.

Week 1 Example:

Calories: 1200, 1309, 1409, 1200, 1400, 1500, 1200 Fat Grams: 45, 30, 25, 30, 35, 33, 32 Weight (Pounds): 188.2, 188.0, 187.0, 186.0, 186.3, 186.4, 187.2 Physical Activity (Minutes): 15, 0, 15, 0, 15, 20, 20

If did not complete any physical activity, what were the reasons:

Lack of Time for Exercise: 1 Day

Exercise Was Inconvenient:

Lack of Motivation for Exercise: 1 Day

Other:

Additional Comments:

It was a great week! I lost 1 lb. and earned all 3 points! I did have some trouble with late night snacking. Any thoughts?

Figure 4. CI Participant Self-Monitoring Example

3.5.8 Engagement and Retention

If a participant did not e-mail their self-monitoring information for one week, he or she was called by the investigator to be encouraged to monitor and continue with the program. If the participant had not responded to telephone calls before the start of next intervention week, an e-mail was sent by the investigator. If the participant had not responded to either contact attempts, an official letter was sent to the participant to determine their participation status.

3.5.9 Intervention Fidelity Plan

To monitor and enhance the reliability and validity of the CI, we developed a treatment fidelity plan described in Table 7. This plan was based on best practices and recommendations from the National Institutes of Health Behavior Change Consortium (BCC) for enhancing treatment fidelity in health behavior change studies¹⁰⁶. It addressed the design of the study, monitoring the

delivery of the intervention, receipt of the treatment by the participant, and enactment to ensure that the participant performed the skills and strategies as intended by the intervention.

Table 7. Intervention Fidelity Plan

Study Component	Fidelity Plan
Design	<ul style="list-style-type: none"> • Behavioral lesson content identical between intervention groups • Individual and group feedback on progress provided at fixed intervals (once per week) • Fixed duration of in-person group sessions (60 minutes) • Any deviations from protocol with regard to number, length, and frequency of contacts were recorded • Guidelines for e-mail content established
Monitoring	<ul style="list-style-type: none"> • Recorded frequency and duration spent drafting e-mail responses
Intervention Delivery	<ul style="list-style-type: none"> • Emails messages copied to and monitored by investigators • Email messages sent and received were printed and filed weekly • During the two in-person group sessions, the SBWL group sessions occurred in separate area within the center to minimize potential problems of confounding by contamination
Intervention Receipt	<p>Monitoring of CI participants:</p> <ul style="list-style-type: none"> • Diet and physical activity behaviors, and body weight were recorded <p>Monitoring of counseling via e-mail:</p> <ul style="list-style-type: none"> • Return receipt was used to monitor opening of email messages • Replies from participants were printed and filed (if needed)
Enactment	<ul style="list-style-type: none"> • Collected self-monitoring data for diet and physical activity behaviors, and body weight to observe attainment of goals • Assessed outcome measures: weight, dietary intake, physical activity, and self-efficacy and motivation for weight loss at week 0 and 12

3.5.10 Summary

In summary, Table 8 illustrates the dietary and physical activity components common to the two randomized groups, plus the alternative treatment components received by the CI group.

Table 8. Treatment Components of the SBWL and CI Groups

	Standard Behavioral Weight Loss Program	Campaign Intervention
Frequency and Type of Contact		
Weekly In-Person Group Sessions (Weeks 1-12)	X	
In-Person Group Sessions (Weeks 1 & 12)		X
Group and Individual E-mails (Weeks 2-11)		X
Dietary Component		
Reduced Calorie Diet (1200-1800 kcals/day)	X	X
Fat Intake at 20-30% of Total Intake	X	X
Meal Plans and Recipes	X	X
Recorded Food Intake in a Paper Diary	X	
Reported Food Intake via E-mail		X
Physical Activity Component		
Progressed to 200 min/week	X	X
Supervised Physical Activity Weekly	X	
Recorded Physical Activity in a Paper Diary	X	
Reported Physical Activity via E-mail		X
Additional Components		
Thematic Framework (W.L.D.A. Cup Race Car Theme)		X
Incentive-Based Point System		X
Lottery Drawing and Incentives		X

3.6 ASSESSMENT PROCEDURES

Assessments were conducted at week 0 and 12 of the intervention at the University of Pittsburgh Physical Activity and Weight Management Research Center. Assessments occurred Monday thru Saturday between the hours of 7:00 AM and 7:00 PM. Each assessment took approximately 30 minutes to complete and included height, body weight, and assessment of physical activity, dietary intake, self-efficacy for weight loss, and motivation.

3.6.1 Height, Body Weight, and Body Mass Index

Height was measured to the nearest 0.01 centimeter (cm) at week 0 and 12 using a wall-mounted stadiometer (Perspective Enterprises; Portage, MI) with participants removing their shoes prior to the measurement. Two measurements were taken. A third measurement was taken if the first two measurements differed by more than 0.5 cm. The average of the two measurements which meet the criteria above was recorded for data collection. Body weight was measured to the nearest 0.1 kilogram (kg) on a Tanita WB-110A digital scale (Tanita Corporation; Arlington Heights, IL) at week 0 and 12 with subjects in a lightweight hospital gown. Two measurements were taken. A third measurement was taken if the first two measurements differed by more than 0.2 kg. The average of the two measurements which meet the criteria above were recorded for data collection. BMI was calculated using body weight in kilograms divided by squared height in meters (kg/m^2).

3.6.2 Anthropometric Measurements

Resting blood pressure and heart rate were measured on the participants left arm using a DINAMAP V100 (GE Healthcare) automated blood pressure system. Using a Gulick measuring tape, an arm measurement was performed on the lateral aspect of the left arm at the midpoint between the acromion process to the olecranon process to determine the appropriate cuff size. The cuff size was determined from the arm circumference measurement according to the following chart:

	Cuff Size
17.0 to <24.0 cm	Small Adult
24.0 to <33.0 cm	Adult
33.0 to <41.0 cm	Large Adult
>41.0 cm	Thigh or Large Adult Long*

*(If a participant's upper arm circumference would indicate use of the thigh cuff, but the arm was too short for the cuff, or the cuff did not remain secured when inflated, the Large Adult Long arm cuff was used.)

Upon a five-minute resting period with the participant in an upright position with feet flat on the floor, two blood pressure measurements were taken with a one-minute time period between each measurement. A third blood pressure was taken if the mean difference between the systolic blood pressure measurements differed by 10 mmHg or greater and/or the diastolic blood pressure measurements differed by 6 mmHg or greater. The average of the two measurements which meet the criteria above were recorded for data collection. If the measurements did not meet the criteria, the average of all three were recorded for data collection. In addition, if the mean resting systolic blood pressure was ≥ 150 mmHg or average diastolic blood pressure was ≥ 100 mmHg at baseline, the subject was excluded from participation and referred back to their physician.

Waist and hip circumferences were obtained using a Gulick measuring tape recorded to the nearest 0.1 cm. Waist circumference was measured in the horizontal plane directly at the umbilicus. Hip circumference was taken at the largest circumference in the horizontal plane at the largest part of the hips above the gluteal fold. Two measurements were taken at each site. A third measurement was taken if the first two measurements differed by more than 2.0 cm. The average of the two measurements closest to each other were recorded for data collection. In addition, the average waist measurement was divided by the average hip measurement to derive the waist-to-hip-ratio (WHR).

3.6.3 Dietary Intake and Eating Behaviors

To estimate energy intake (kilocalories per day) and macronutrient composition, dietary intake was measured at week 0 and 12 using the Block Food Frequency Questionnaire (FFQ) (Block, 2005, Dietary Data Systems, Berkeley, CA)^{107,108} (Appendix J). This questionnaire assesses subjects' portion sizes and routinely eaten foods. The Eating Behavior Inventory (EBI) (Appendix K) measured the adoption of weight loss eating behaviors at week 0 and 12. The EBI is a 26-point checklist that assesses behaviors that are associated with weight loss such as: self-monitoring of food intake and of weight, refusing offers of food, eating at only one place, and eating in response to emotions. It is considered a valid tool for measuring changes in weight related behaviors as a result of behavioral weight management interventions¹⁰⁹.

3.6.4 Physical Activity

Physical activity was assessed using the Paffenbarger Physical Activity Questionnaire¹¹⁰ (Exercise Habits) (Appendix L) at week 0 and 12. This self-reported questionnaire is a valid and reliable measure of structured and lifestyle physical activity¹¹¹. The Exercise Habits Questionnaire was administered via interview by the investigator to determine the daily average number of flights of stairs walked up and the number of city blocks walked for the sole purpose of exercise. In addition, any sport, recreational, or fitness activities the participant engaged in over the previous week was reported. These values were converted into self-reported physical activity minutes and self-reported kilocalories expended per week from physical activity (with stairs and without stairs)^{112,113}.

3.6.5 Self-Efficacy for Weight Loss

Self-efficacy is a main construct of Social Cognitive Theory. It has been shown to be associated with success for weight loss. Therefore, self-efficacy for weight loss was assessed at week 0 and 12 using a 20-item Weight Efficacy Lifestyle Questionnaire (WEL) (Appendix M) developed by Clark and colleagues¹¹⁴. This questionnaire consists of five situational factors such as: negative emotions, availability, social pressure, physical discomfort, and positive activities. Internal consistency coefficients for the subscales are 0.88 for negative emotions, 0.83 for availability, 0.89 for social pressure, 0.84 for physical discomfort and 0.79 for positive activities. The total WEL has been estimated an interval coefficient of 0.92¹¹⁵.

3.6.6 Motivation

Motivation was assessed using the autonomous and controlled regulation subscales of the Treatment Self-Regulation Questionnaire (TSRQ)¹¹⁶ for participating in weight loss treatment at week 0 and 12. The TSRQ represents participants' reasons for starting or continuing participation in a weight loss program via participants' endorsement of statements of autonomous and controlled motivation. For example, an autonomous subscale item statement is "I have remained in this program because I feel like it is the best way to help myself." The controlled subscale included items such as "I have remained in the program because others would have been angry at me if I did not." Responses are given using a 7-point Likert scale (1 = not at all true to 7 = very true). At baseline, participants completed the full 18-item TSRQ (6 autonomous items and 12 controlled items) (Appendix N) assessing motivation to begin a weight loss program. At week 12, participants completed the 13-item TSRQ (5 autonomous items and 8 controlled items) (Appendix O) to assess motivation to continue to participate in the program. Crane and colleagues¹¹⁷ have shown the internal consistency of the autonomous subscale at four time points ranged from 0.63 to 0.78, whereas the internal consistencies of the controlled motivation subscale ranged from 0.66 to 0.88.

3.6.7 Treatment Satisfaction

At week 12, participants in the SBWL and the CI groups were asked to rate their overall satisfaction (Appendix P) with the intervention and if they would recommend the program to others¹¹⁸. Participants were also asked questions regarding their effort following the intervention including satisfaction with overall progress and satisfaction for changing dietary and physical

activity habits, and weight¹¹⁹. Each item was rated on a Likert scale with higher scores indicating greater program favorability.

3.7 STATISTICAL ANALYSES

Statistical analyses were performed using the Statistical Package for the Social Sciences (IBM-SPSS, version 21.0). Statistical significance was accepted at the p<0.05 level of confidence. Analyses were performed to examine normality and appropriate transformations were used for data that were not normally distributed. The following analyses were conducted using individuals who completed assessments at week 0 and 12, with intent-to-treat (ITT) analysis carrying the baseline data forward:

- Descriptive analyses examined the mean baseline characteristics (e.g., age, weight, BMI, systolic and diastolic blood pressure, resting heart rate, waist and hip circumferences, waist-to-hip ratio), eating behaviors, weight loss self-efficacy, dietary intake, motivation, and self-reported physical activity. Independent samples t-test examined any differences in the mean baseline characteristics between the groups. For data that were not normally distributed, Mann-Whitney U tests examined any differences in the mean baseline characteristics between the groups.
- 2 X 2 repeated measures ANOVA were performed on weight loss, self-reported physical activity, dietary intake, and weight loss self-efficacy as a function of group and time to determine differences between the variables. The main effect of time was examined between 0 and 12 weeks; the main effect of group examined any differences between randomized groups. The group X time interaction was examined to determine patterns of

difference between groups for weight loss, physical activity, dietary intake, and weight loss self-efficacy at 0 and 12 weeks. For data that were not normally distributed, nonparametric tests (Mann Whitney U and Wilcoxon Signed Rank Test) were performed to examine changes between groups and across time. Statistical significance values for the nonparametric tests did not change the interpretation of results when compared to statistical significance values from parametric tests. Therefore, the completers analysis and ITT analysis were conducted using the parametric two-factor repeated measures (group X time) ANOVA.

- Descriptive analyses were used to examine self-monitoring of dietary intake, physical activity, and treatment satisfaction. Independent samples t-tests were performed to examine differences between groups for the number of diet days recorded, self-reported calorie intake, self-reported physical activity (days and minutes/week), and self-weighing days per week. When normality tests assumptions were violated, Mann-Whitney U Tests were performed.
- Pearson correlation coefficients were also calculated as secondary analyses to determine the relationship between changes in weight, physical activity, eating behaviors, and weight loss self-efficacy at 0 and 12 weeks. Spearman Rank Order correlations were computed for skewed data.

3.8 POWER ANALYSES

The primary aim of this study was to examine the feasibility of a stand-alone campaign intervention (CI) as an alternative strategy for weight management when compared to a standard

behavioral weight loss intervention (SBWL). However, there was limited data in the literature to provide an estimate of the effect of a CI on weight loss compared to a SBWL. Therefore, we assumed that the variance estimates from other weight loss studies were representative of what we would observe in this study (standard deviation = 2.8 kg in a recent study conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh). Based on these assumptions, it was proposed that 48 subjects be recruited and complete the intervention, with 24 subjects in each treatment condition. This would have provided a sufficient sample to detect a 2.5 kg difference between groups with a type I error rate of 0.05 at 88% power. To allow for an attrition rate of 20%, 20 subjects per treatment condition (40 total participants) were needed to complete the intervention to detect a 2.5 kg difference between groups with a type 1 error rate of 0.05 at 80% power. However, only 26 individuals completed baseline assessments and were eligible to be randomized to one of the two treatment groups (SBWL, CI). Results from this study will serve as a pilot data that will be used to estimate sample sizes for a CI in a larger clinical trial in the future.

4.0 RESULTS

The primary aim of this study was to examine the feasibility of a stand-alone campaign intervention (CI) as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention (SBWL). The study was a pretest-posttest randomized controlled weight loss trial with assessments performed at week 0 and 12. The results from this study are presented below:

4.1 SUBJECT CHARACTERISTICS

Twenty-six (N=26) overweight and obese adults between the ages of 18-55 years with a Body Mass Index (BMI) between $\geq 25.0 \text{ kg/m}^2$ to 45.0 kg/m^2 were randomized to this study. Physical assessments and intervention procedures were conducted at the Physical Activity and Weight Management Research Center (PAWMRC) at the University of Pittsburgh. Descriptive statistics for all subjects in this study are shown in Table 9. Independent samples t-tests revealed no significant differences between randomized groups at baseline for age, weight, BMI, systolic and diastolic blood pressure, waist and hip circumference, waist-to-hip ratio, eating behaviors, weight loss self-efficacy, motivation, and dietary intake.

Self-reported physical activity (kcals/week with stairs, kcals/week without stairs, and minutes per week) and percent protein intake did not meet assumptions of normality at baseline. Therefore, nonparametric Mann-Whitney U tests were performed and revealed no significant differences between the randomized groups. Pearson Chi-Square analyses revealed no significant differences in gender ($p=1.000$), race ($p=1.000$), and blood pressure medication use ($p=0.352$) at baseline.

Table 9. Differences in Baseline Characteristics by Treatment Group

Characteristics	Total (N=26) (mean±s.d.)	SBWL (N=13) (mean±s.d.)	CI (N=13) (mean±s.d.)	p-value
Age (years)	43.1±8.9	42.5±9.1	43.8±9.0	0.715
Weight (kg)	92.2±13.1	91.5±13.0	92.9±13.7	0.787
Body Mass Index (kg/m ²)	33.3±3.7	33.4±3.8	33.2±3.8	0.874
Systolic Blood Pressure (mmHg)	121.1±10.8	120.2±11.1	122.0±10.8	0.690
Diastolic Blood Pressure (mmHg)	71.0±9.00	72.0±8.8	70.0±9.4	0.567
Resting Heart Rate (beats/min)	75.5±10.0	75.2±8.8	75.9±11.5	0.871
Waist Circumference (cm)	114.7±11.9	113.1±11.2	116.3±12.7	0.499
Hip Circumference (cm)	117.7±8.8	118.0±8.1	117.3±9.8	0.841
Waist-to-Hip Ratio	0.97±0.06	0.96±0.1	0.99±0.1	0.187
Gender				
% Males	15.4% (N=4)	15.4% (N=2)	15.4% (N=2)	
% Females	84.6% (N=22)	84.6% (N=11)	84.6% (N=11)	1.000
Race				
% African-American	15.4% (N=4)	15.4% (N=2)	15.4% (N=2)	
% Caucasian	84.6% (N=22)	84.6% (N=11)	84.6% (N=11)	1.000
Taking Blood Pressure Medication				
% Yes	23.1% (N=6)	15.4% (N=2)	30.8% (N=4)	0.352
% No	76.9% (N=20)	84.6% (N=11)	69.2% (N=9)	
Eating Behavior Inventory	61.9±9.2	60.5±10.0	63.2±8.5	0.466
Weight Loss Self-Efficacy	110.5±38.2	114.2±34.9	106.9±42.3	0.635
Motivation (TSRQ)				
• Autonomous	5.7±0.8	5.7±0.7	5.7±0.9	0.935
• Controlled	2.6±1.0	2.7±0.9	2.6±1.0	0.817
Food Frequency Questionnaire:				
• Dietary Intake (kcal/day)	1891.2±718.5	1868.5±767.5	1913.9±696.7	0.876
• Percent Fat Intake (%)	35.9±6.9	36.4±7.2	35.3±6.8	0.681
• Percent Carbohydrate Intake (%)	46.2±9.5	45.9±8.9	46.6±10.4	0.857
• Percent Protein Intake (%)†	14.9±3.5	14.9±3.6	14.9±3.5	0.801†
Paffenbarger Exercise Habits Questionnaire:				
• Self-Reported Physical Activity with stairs (kcals/week)†	724.9±635.1	726.5±657.8	723.3±638.5	0.920†
• Self-Reported Physical Activity without stairs (kcals/week)†	512.7±581.7	543.4±659.4	482.1±517.8	0.960†
• Self-Reported Physical Activity (mins/week)†	92.4±95.3	98.4±109.4	86.3±82.9	0.960†

s.d. = standard deviation

†Mann-Whitney U Test performed for nonparametric data

Note: % Fat, Carbohydrate, and Protein Intake does not include alcohol in the denominator

4.2 STUDY RECRUITMENT AND RETENTION

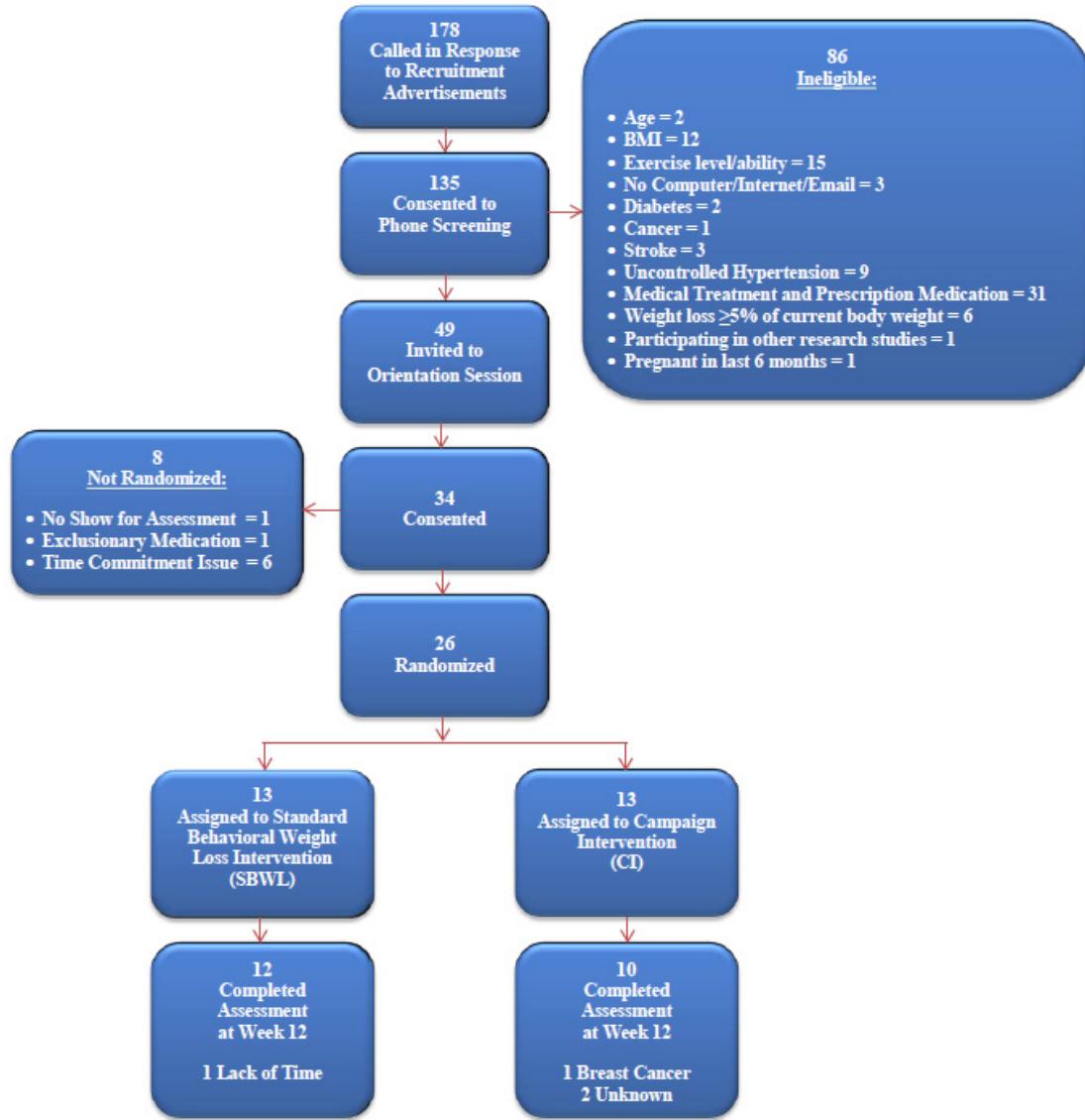


Figure 5. Study Recruitment and Retention Between Groups

Figure 5 illustrates subject recruitment, randomization, retention, and reasons for withdrawal. Twenty-six (N=26) subjects were randomized to one of two treatment groups (SBWL, CI). A total of 22 participants (84.6%) completed assessments at week 0 and 12 and will be referred to as “completers.” Participants who did not complete the assessment at week 12

(N=4) will be referred to as “non-completers.” Overall retention rates for each group were as follows: 92.3% for SBWL and 76.9% for CI. A Pearson Chi Square analysis revealed no significant difference ($p=0.277$) in retention rates between treatment groups.

Baseline characteristics between completers and non-completers are presented in Table 10. Independent samples t-tests revealed a significant difference between completers and non-completers in age (completers > non-completers, $p=0.044$) and controlled motivation (completers < non-completers, $p=0.016$) at baseline. No significant differences were observed in any of the other baseline characteristics. Self-reported physical activity (kcals/week with stairs, kcals/week without stairs, and minutes per week), dietary intake (kcal/day), and percent protein intake were not normally distributed at baseline for completers and non-completers. Therefore, nonparametric Mann-Whitney U tests were performed and indicated there were no significant differences.

When baseline characteristics were examined for completers and non-completers by treatment group (Table 11), independent t-tests revealed no significant differences between CI completers and non-completers at baseline. Self-reported physical activity (kcals/week with stairs, kcals/week without stairs, and minutes per week), dietary intake (kcal/day), percent carbohydrate intake, and percent protein intake did not meet assumptions of normality for CI completers and non-completers. Therefore, nonparametric Mann-Whitney U tests were performed and revealed no significant differences.

Table 10. Differences in Baseline Characteristics by Completers and Non-Completers

Characteristics	Total (N=26) (mean±s.d.)	Completers (N=22) (mean±s.d.)	Non- Completers (N=4) (mean±s.d.)	p-value
Age (years)	43.1±8.9	44.6±6.6	35.0±15.7	0.044*
Weight (kg)	92.2±13.1	93.1±12.4	87.1±18.0	0.414
Body Mass Index (kg/m ²)	33.3±3.7	33.7±3.3	30.9±5.3	0.166
Systolic Blood Pressure (mmHg)	121.1±10.8	122.3±11.2	114.4±3.7	0.179
Diastolic Blood Pressure (mmHg)	71.0±9.00	72.3±9.2	64.0±1.9	0.091
Resting Heart Rate (beats/min)	75.5±10.0	74.9±9.9	78.9±11.3	0.476
Waist Circumference (cm)	114.7±11.9	116.4±10.2	105.7±17.6	0.097
Hip Circumference (cm)	117.7±8.8	118.4±8.6	114.0±10.0	0.374
Waist-to-Hip Ratio	0.97±0.06	0.98±0.1	0.92±0.1	0.068
Gender				
% Males	15.4% (N=4)	18.2% (N=4)	0% (N=0)	
% Females	84.6% (N=22)	81.8% (N=18)	100.0% (N=4)	0.354
Race				
% African-American	15.4% (N=4)	18.2% (N=4)	0% (N=0)	
% Caucasian	84.6% (N=22)	81.8% (N=18)	100.0% (N=4)	0.354
Taking Blood Pressure Medication				
% Yes	23.1% (N=6)	27.3% (N=6)	0% (N=0)	
% No	76.9% (N=20)	72.7% (N=16)	100.0% (N=4)	0.234
Eating Behavior Inventory	61.9±9.2	61.2±8.6	65.8±12.6	0.371
Weight Loss Self-Efficacy	110.5±38.2	111.3±39.1	106.0±32.6	0.803
Motivation (TSRQ)				
• Autonomous	5.7±0.8	5.6±0.8	6.2±0.6	0.150
• Controlled	2.6±1.0	2.5±0.8	3.7±1.3	0.016**
Food Frequency Questionnaire:				
• Dietary Intake (kcal/day)†	1891.2±718.5	1882.1±710.8	1941.4±436.5	0.706†
• Percent Fat Intake (%)	35.9±6.9	35.8±5.7	36.4±13.0	0.868
• Percent Carbohydrate Intake (%)	46.2±9.5	46.4±9.3	45.5±11.9	0.865
• Percent Protein Intake (%)†	14.9±3.5	15.2±3.3	13.7±4.5	0.515†
Paffenbarger Exercise Habits Questionnaire:				
• Self-Reported Physical Activity with stairs (kcals/week)†	724.9±635.1	707.8±649.8	819.0±625.8	0.706†
• Self-Reported Physical Activity without stairs (kcals/week)†	512.7±581.7	490.1±594.0	637.0±570.8	0.656†
• Self-Reported Physical Activity (mins/week)†	92.4±95.3	88.2±93.8	115.0±115.1	0.758†

s.d. = standard deviation

*completers > non-completers

**completers < non-completers

†Mann-Whitney U Test performed for nonparametric data

Note: % Fat, Carbohydrate, and Protein Intake does not include alcohol in the denominator

Table 11. Baseline Characteristics by Completers and Non-Completers by Treatment Group*

Characteristics	SBWL		CI	
	Completers (N=12) (mean±s.d.)	Non- Completer (N=1) (mean±s.d.)	Completers (N=10) (mean±s.d.)	Non- Completers (N=3) (mean±s.d.)
Age (years)	44.3±6.7	21.0	45.0±6.8	39.7±15.5
Weight (kg)	92.2±13.3	83.0	94.2±11.7	88.5±21.8
Body Mass Index (kg/m ²)	33.9±3.4	27.1	33.4±3.4	32.2±5.7
Systolic Blood Pressure (mmHg)	121.0±11.2	111.0	123.9±11.5	115.5±3.6
Diastolic Blood Pressure (mmHg)	72.9±8.6	61.5	71.5±10.3	64.8±1.0
Resting Heart Rate (beats/min)	74.2±8.3	87.5	75.8±12.0	76.0±12.0
Waist Circumference (cm)	114.6±10.3	95.5	118.5±10.2	109.0±19.8
Hip Circumference (cm)	118.6±8.2	111.7	118.1.0±9.6	114.8±12.2
Waist-to-Hip Ratio	0.97±0.06	0.85	1.0±0.04	0.94±0.1
Gender				
% Males	16.7% (N=2)		20.0% (N=2)	0% (N=0)
% Females	83.3% (N=10)	100.0% (N=1)	80.0% (N=8)	100.0% (N=3)
Race				
% African-American	16.7% (N=2)	0% (N=0)	20.0% (N=2)	0% (N=0)
% Caucasian	83.3% (N=10)	100.0% (N=1)	80.0% (N=8)	100.0% (N=3)
Taking Blood Pressure Medication				
% Yes	16.7% (N=2)	0% (N=0)	40.0% (N=4)	0% (N=0)
% No	83.3% (N=10)	100.00% (N=1)	60.0% (N=6)	100.0% (N=3)
Eating Behavior Inventory	60.8±10.4	57.0	61.6±6.4	68.7±13.7
Weight Loss Self-Efficacy	113.1±36.2	127.0	109.2±45.5	99.0±36.1
Motivation				
• Autonomous	5.7±0.7	5.5	5.5±0.9	6.4±0.4
• Controlled	2.6±0.8	4.2	2.3±0.8	3.5±1.5
Food Frequency Questionnaire:				
• Dietary Intake (kcal/day)†	1963.8±716.7	724.1	1783.9±728.9	2347.2±394.0†
• Percent Fat Intake (%)	37.5±6.2	23.1	33.6±4.2	40.8±11.7
• Percent Carbohydrate Intake (%)†	45.8±9.3	46.6	47.0±9.9	45.1±14.6†
• Percent Protein Intake (%)†	15.5±3.2	8.7	14.8±3.7	15.4±3.7†
Paffenbarger Exercise Habits Questionnaire:				
• Self-Reported Physical Activity with stairs (kcals/week)†	655.4±632.8	1578.9	770.6±698.4	565.7±449.9†
• Self-Reported Physical Activity without stairs (kcals/week)†	478.1±643.3	1326.9	504.6±563.0	407.1±414.1†
• Self-Reported Physical Activity (mins/week)†	83.3±99.0	280	94.2±92.1	60.0±41.6†

s.d. = standard deviation

*no significant differences between completers and non-completers, p>0.05

†Mann-Whitney U Test performed for nonparametric data

Note: % Fat, Carbohydrate, and Protein Intake does not include alcohol in the denominator

4.3 OUTCOME DIFFERENCES BETWEEN TREATMENT GROUPS

Two-factor repeated measures ANOVA were performed on weight loss, self-reported physical activity, dietary intake, and weight loss self-efficacy as a function of group and time to determine differences between the variables. The main effect of time was examined between 0 and 12 weeks; the main effect of group examined any differences between randomized groups. The group X time interaction was examined to determine patterns of difference between groups for weight loss, physical activity, dietary intake, and weight loss self-efficacy at 0 and 12 weeks. For data that were not normally distributed, nonparametric tests (Mann Whitney U and Wilcoxon Signed Rank Test) were performed to examine changes between groups and across time. Statistical significance values for the nonparametric tests did not change the interpretation of results when compared to statistical significance values from parametric tests. Therefore, the completers analysis (Table 12) and ITT analysis (Table 13) were conducted using the parametric two-factored repeated measures (group x time) ANOVA.

Table 12. Outcome Differences Between Treatment Groups at Week 12: Completers Analysis

Outcome Variable	SBWL (N=12) (mean±s.d.)	CI (N=10) (mean±s.d.)	Group Effect	p-values	
				Time Effect	Group X Time
Weight (kg)					
Baseline	92.2±13.3	94.2±11.7			
Week 12	86.1±13.0	90.2±11.7	0.569	<0.001	0.111
Body Mass Index (kg/m ²)					
Baseline	33.9±3.4	33.5±3.4			
Week 12	31.8±3.0	32.1±3.6	0.960	<0.001	0.141
Systolic Blood Pressure (mmHg)					
Baseline	121.0±11.2	123.9±11.5			
Week 12	113.5±10.2	115.6±5.2	0.493	0.003	0.866
Diastolic Blood Pressure (mmHg)					
Baseline	72.9±8.6	71.5±10.3			
Week 12	68.0±10.9	65.3±4.3	0.578	0.002	0.664
Resting Heart Rate (beats/min)					
Baseline	74.2±8.3	75.8±12.0			
Week 12	64.9±5.3	69.1±9.4	0.399	<0.001	0.493
Waist Circumference (cm)					
Baseline	114.6±10.3	118.5±10.2			
Week 12	108.1±9.0	114.2±10.8	0.250	<0.001	0.139
Hip Circumference (cm)					
Baseline	118.6±8.2	118.1±9.6			
Week 12	113.6±7.9	114.7±8.6	0.909	<0.001	0.153
Waist-to-Hip Ratio					
Baseline	0.97±0.06	1.0±0.04			
Week 12	0.95±0.04	1.0±0.04	0.081	0.021	0.666
Eating Behavior Inventory					
Baseline	60.8±10.4	61.6±6.4			
Week 12	71.3±104	69.2±5.3	0.840	<0.001	0.337
Weight Loss Self-Efficacy					
Baseline	113.1±36.2	109.2±45.5			
Week 12	141.3±24.8	125.5±26.6	0.434	0.009	0.444
Food Frequency Questionnaire:					
Dietary Intake (kcal/day)					
Baseline	1963.8±716.7	1783.9±728.9			
Week 12	1449.4±598.4	1468.7±586.5	0.747	0.008	0.448
Percent Fat Intake (%)					
Baseline	37.5±6.2	33.6±4.2			
Week 12	34.0±5.8	33.6±5.8	0.316	0.141	0.142
Percent Carbohydrate Intake (%)					
Baseline	45.8±9.3	47.0±9.9			
Week 12	46.5±7.2	48.2±9.3	0.693	0.493	0.860
Percent Protein Intake (%)					
Baseline	15.5±3.2	14.8±3.7			
Week 12	16.2±3.0	15.4±3.0	0.538	0.255	0.850
Paffenbarger Exercise Habits Questionnaire:					
Self-Reported Physical Activity with stairs (kcal/week)					
Baseline	655.4±632.8	770.6±698.4			
Week 12	1720.7±577.5	1779.7±1260.5	0.765	<0.001	0.890
Self-Reported Physical Activity without stairs (kcals/week)					
Baseline	478.1±643.3	504.6±563.0			
Week 12	1494.3±549.3	1457.7±1202.9	0.985	<0.001	0.877
Self-Reported Physical Activity (mins/week)					
Baseline	83.3±99.0	94.2±92.1			
Week 12	236.8±97.6	285.0±222.5	0.516	<0.001	0.619

s.d. = standard deviation

Note: Total % Fat, Carbohydrate, and Protein Intake does not include alcohol in the denominator

Table 13. Outcome Differences Between Treatment Groups at Week 12: ITT Analysis

Outcome Variable	SBWL (N=12) (mean±s.d.)	CI (N=10) (mean±s.d.)	p-values		
			Group Effect	Time Effect	Group X Time
Weight (kg)					
Baseline	91.5±13.0	92.9±13.7			
Week 12	85.8±12.5	89.8±13.5	0.603	<0.001	0.052
Body Mass Index (kg/m ²)					
Baseline	33.4±3.8	33.2±3.8			
Week 12	31.4±3.2	32.1±3.9	0.872	<0.001	0.067
Systolic Blood Pressure (mmHg)					
Baseline	120.2±11.1	122.0±10.8			
Week 12	113.3±9.8	115.6±4.8	0.525	0.003	0.896
Diastolic Blood Pressure (mmHg)					
Baseline	72.0±8.8	70.0±9.4			
Week 12	67.5±10.6	65.2±6.4	0.495	0.002	0.912
Resting Heart Rate (beats/min)					
Baseline	75.2±8.8	75.8±11.4			
Week 12	66.7±8.1	70.7±10.0	0.504	<0.001	0.304
Waist Circumference (cm)					
Baseline	113.1±11.2	116.3±12.7			
Week 12	107.1±9.3	113.0±12.6	0.318	<0.001	0.066
Hip Circumference (cm)					
Baseline	118.0±8.1	117.3±9.8			
Week 12	113.5±7.6	114.7±8.8	0.914	<0.001	0.073
Waist-to-Hip Ratio					
Baseline	0.96±0.06	0.99±0.06			
Week 12	0.95±0.06	0.98±0.05	0.131	0.019	0.516
Eating Behavior Inventory					
Baseline	60.5±10.0	63.2±8.5			
Week 12	70.2±10.7	69.1±7.2	0.817	<0.001	0.205
Weight Loss Self-Efficacy					
Baseline	114.2±34.9	106.9±42.3			
Week 12	140.2±24.0	119.4±29.7	0.226	0.007	0.313
Food Frequency Questionnaire:					
Dietary Intake (kcal/day)					
Baseline	1868.5±767.5	1913.9±696.7			
Week 12	1393.6±607.2	1671.4±657.5	0.507	0.007	0.347
Percent Fat Intake (%)					
Baseline	36.4±7.2	35.3±6.8			
Week 12	33.2±6.3	35.3±7.6	0.851	0.107	0.108
Percent Carbohydrate Intake (%)					
Baseline	45.9±8.9	46.6±10.4			
Week 12	46.5±6.9	47.5±10.1	0.813	0.498	0.909
Percent Protein Intake (%)					
Baseline	14.9±3.6	14.9±3.5			
Week 12	15.7±3.5	15.4±3.0	0.902	0.243	0.767
Paffenbarger Exercise Habits Questionnaire:					
Self-Reported Physical Activity with stairs (kcal/week)					
Baseline	726.5±657.8	723.3±638.5			
Week 12	1709.8±554.26	1499.6±1228.3	0.687	<0.001	0.578
Self-Reported Physical Activity without stairs (kcals/week)					
Baseline	543.4±659.4	482.1±517.8			
Week 12	1481.5±517.8	1215.3±1151.5	0.494	<0.001	0.578
Self-Reported Physical Activity (mins/week)					
Baseline	98.4±109.4	86.3±82.9			
Week 12	240.1±94.2	233.1±217.1	0.822	<0.001	0.940

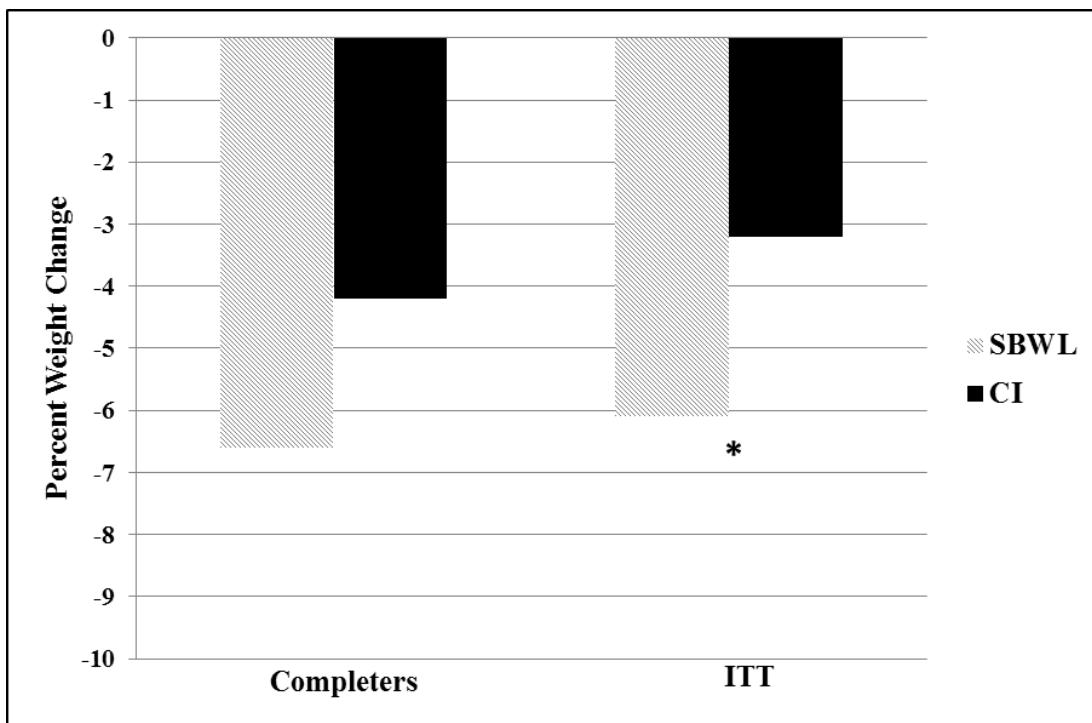
s.d. = standard deviation

Note: Total % Fat, Carbohydrate, and Protein Intake does not include alcohol in the denominator

4.3.1. Changes in Body Weight and BMI

A two-factor repeated measures (group X time) ANOVA was performed to examine changes in body weight and BMI from week 0 to week 12 between the treatment groups (Table 12). Results of the completers analysis revealed a significant decrease in body weight from week 0 to week 12 for completers in the SBWL group (-6.1 ± 2.5 kg) and the CI group (-4.0 ± 3.4 kg) ($p<0.001$). There were no significant differences between groups ($p=0.569$) or a group X time interaction ($p=0.111$) from baseline. Similarly, BMI significantly decreased from week 0 to week 12 for completers in the SBWL group (-2.2 ± 1.2 kg/m²) and the CI group (-1.4 ± 1.2 kg/m²) ($p<0.001$). There were no significant differences between groups ($p=0.960$) or a group X time interaction ($p=0.141$) from baseline. The total weight loss percentage for completers was $5.5 \pm 3.4\%$, with no significant differences between groups (SBWL: $6.6 \pm 2.6\%$; CI: $4.2 \pm 3.8\%$) ($p=0.097$) (Figure 6).

Changes in body weight and BMI were also examined for all randomized participants using ITT with baseline data carried forward when week 12 data was missing (Table 13). A two-factor repeated measures (group X time) ANOVA revealed a significant decrease in body weight from week 0 to week 12 in the SBWL group (-5.6 ± 2.9 kg) and in the CI group (-3.1 ± 3.4 kg) ($p<0.001$). There were no significant differences between groups ($p=0.603$) or a group X time interaction ($p=0.052$) from baseline. Similarly, BMI significantly decreased from week 0 to week 12 in the SBWL group (-2.0 ± 1.3 kg/m²) and the CI group (-1.1 ± 1.2 kg/m²) ($p<0.001$). There were no significant differences between groups ($p=0.872$) or a group X time interaction ($p=0.067$) from baseline. The overall total weight loss percentage was $4.7 \pm 3.7\%$, with significant differences between the groups (SBWL: $6.1 \pm 3.1\%$; CI: $3.3 \pm 3.8\%$) ($p=0.046$) (Figure 6).



*p=0.046 for difference between percent weight change in the SBWL and CI groups

Figure 6. Weight Loss Percentage Between Treatment Groups (Completers and ITT)

A weight loss of 5% can significantly reduce weight related health risks⁹. Therefore, SBWL and CI participants were grouped by percentage of weight loss less than 5% and greater than 5% (Table 14). A Pearson Chi-Square analysis indicated no significant difference between the SBWL group and the CI group for distribution in these categories (p=0.116). Figure 7 illustrates the individual percent weight changes for participants in the SBWL and the CI groups.

Table 14. Distribution of Participants by Percentage of Weight Loss: <5% and >5%

Group	Number (%) of Participants by Percentage of Weight Loss Category		
	<5%	>5%	p-value
SBWL	5 (38.4)	8 (61.6)	0.119
CI	9 (69.2)	4 (30.8)	

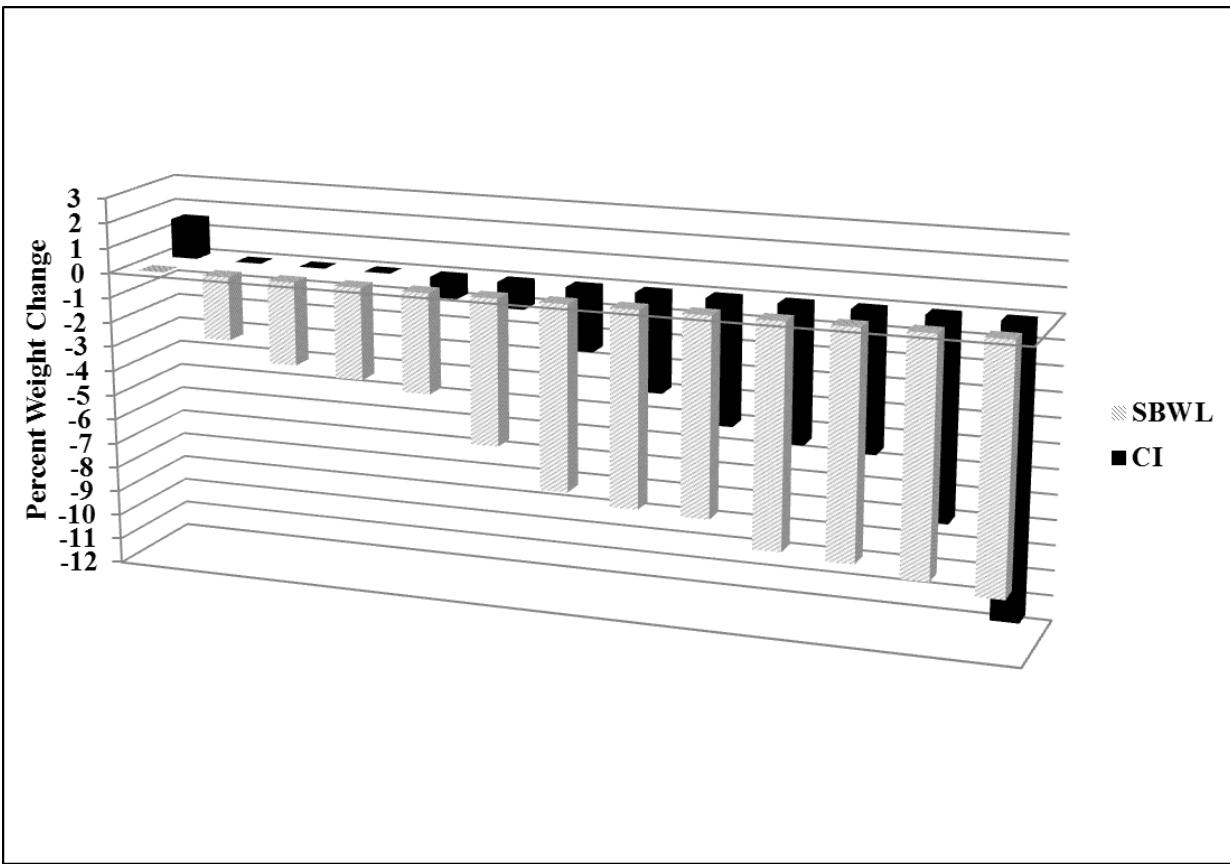


Figure 7. Individual Percent Weight Changes for Participants in the SBWL and CI groups

4.3.2. Changes in Physical Activity

Self-reported physical activity (kcals/week with stairs, kcals/week without stairs, and minutes per week) did not meet assumptions of normality for the both the completers analysis and the ITT analysis. Therefore, nonparametric tests (Mann Whitney U and Wilcoxon Signed Rank Test) were performed to examine changes in moderate-to-vigorous physical activity (MVPA) between groups and across time. Statistical significance values for the nonparametric tests did not change the interpretation of results when compared to statistical significance values from parametric tests. Therefore, the completers analysis and ITT analysis were conducted using the parametric two-factor repeated measures (group X time) ANOVA.

A two-factor repeated measures (group X time) ANOVA was performed to examine changes in self-reported physical activity (kcals/week with stairs, kcals/week without stairs, and minutes per week) from week 0 to week 12 between the treatment groups (Table 12). Results of the completers analysis revealed significant increases in self-reported physical activity with stairs (1065.2 ± 506.2 kcal/week), without stairs (1016.2 ± 510.8 kcal/week), and minutes per week (153.5 ± 80.7 mins/week) ($p<0.001$) (Table 12) from week 0 to week 12 for the SBWL group. Likewise, the CI group significantly increased self-reported physical activity with stairs (1009.2 ± 1281.5 kcal/week), without stairs (953.1 ± 1277.8 kcal/week), and minutes per week (190.8 ± 241.1 mins/week) ($p<0.001$) (Table 12). There were no significant differences between groups in self-reported physical activity with stairs, without stairs, and minutes per week ($p=0.765$, $p=0.985$, and $p=0.516$, respectively) from baseline. There was also no group X time interaction in self-reported physical activity with stairs, without stairs, and minutes per week ($p=0.890$, $p=0.877$, and $p=0.619$, respectively) (Table 12) from baseline.

The ITT analysis revealed similar results (Table 13). Self-reported physical activity with stairs (983.3 ± 567.6 kcal/week), without stairs (938.1 ± 564.4 kcal/week), and minutes per week (141.7 ± 88.3 mins/week) ($p<0.001$) significantly increased from week 0 to week 12 in the SBWL group (Table 13). Similarly, the CI group significantly increased self-reported physical activity with stairs (776.3 ± 1194.8 kcal/week), self-reported physical activity without stairs (733.2 ± 1182.9 kcal/week), and physical activity minutes per week (146.8 ± 224.9 mins/week) ($p<0.001$) (Table 13) from week 0 to week 12. There were no significant differences between groups in self-reported physical activity with stairs, without stairs, and minutes per week ($p=0.687$, $p=0.494$, and $p=0.882$, respectively) from baseline. There was also no group X time

interaction in self-reported physical activity with stairs, without stairs, and minutes per week ($p=0.578$, $p=0.578$, and $p=0.940$, respectively) (Table 13) from baseline.

4.3.3. Changes in Dietary Intake and Eating Behaviors

Dietary intake (kcals/day) and percent protein intake did not meet assumptions of normality for the completers analysis. Percent protein intake was also not normally distributed for the ITT analysis. Therefore, nonparametric tests (Mann Whitney U and Wilcoxon Signed Rank Test) were performed to examine changes in dietary intake and percent protein take between groups and across time. Statistical significance values for the nonparametric tests did not change the interpretation of results when compared to statistical significance values from parametric tests. Therefore, the completers analysis and ITT analysis were conducted using the parametric two-factor repeated measures (group X time) ANOVA.

A two-factor repeated measures (group X time) ANOVA was performed to examine changes in dietary intake (kcals/day) from week 0 to week 12 between the treatment groups (Table 12). Results of the completers analysis revealed a significant decrease in dietary intake from week 0 to week 12 for completers in the SBWL group (514.4 ± 510.3 kcal/day) and the CI group (315.2 ± 803.3 kcal/day) ($p=0.008$). There were no significant differences between groups ($p=0.747$) or a group X time interaction ($p=0.448$) from baseline. The ITT analysis revealed similar results (Table 13).

Two-factor repeated measures (group X time) ANOVA were also performed to examine changes in percent fat, percent carbohydrate, and percent protein from week 0 to week 12 between the treatment groups (Table 12). Results of the completers analysis revealed no significant improvement in percent fat ($p=0.141$), percent carbohydrate ($p=0.493$), and percent

protein ($p=0.255$) from week 0 to week 12 for completers in the SBWL group and the CI group. There were no significant differences between groups in percent fat, percent carbohydrate, and percent protein ($p=0.316$, $p=0.693$, and $p=0.538$, respectively) from baseline. There was also no group X time interaction in percent fat, percent carbohydrate, and percent protein ($p=0.142$, $p=0.860$, and $p=0.850$, respectively) from baseline. The ITT analysis revealed similar results (Table 13).

A two-factor repeated measures (group X time) ANOVA was also performed to examine changes in the adoption of eating behaviors from week 0 to week 12 between the treatment groups (Table 12). Higher scores indicate greater adoption of weight loss eating behaviors. Results of the completers analysis revealed a significant increase in weight loss eating behaviors from week 0 to week 12 for completers in the SBWL group (10.5 ± 7.9) and the CI group (7.6 ± 7.0) ($p<0.001$). There were no significant differences between groups ($p=0.569$) or a group X time interaction ($p=0.111$) from baseline. The ITT analysis revealed similar results (Table 13). Weight loss eating behaviors significantly increased from week 0 to week 12 in the SBWL group (9.7 ± 8.1) and the CI group (5.8 ± 7.0) ($p<0.001$). There were no significant differences between groups ($p=0.817$) or a group X time interaction ($p=0.205$) from baseline.

4.3.4. Changes in Self-Efficacy for Weight Loss

A two-factor repeated measures (group X time) ANOVA was performed to examine changes in self-efficacy for weight loss from week 0 to week 12 between the treatment groups (Table 12). Results of the completers analysis revealed a significant increase in self-efficacy for weight loss from week 0 to week 12 for completers in the SBWL group (28.3 ± 35.7) and the CI group (16.3 ± 35.8) ($p=0.009$). There were no significant differences between groups ($p=0.434$) or a group X

time interaction ($p=0.444$) from baseline. The ITT analysis revealed similar results (Table 13). Self-efficacy for weight loss significantly increased from week 0 to week 12 in the SBWL group (28.3 ± 35.7) and the CI group (16.3 ± 35.8) ($p=0.007$). There were no significant differences between groups ($p=0.226$) or a group X time interaction ($p=0.313$) from baseline.

4.3.5. Motivation

At baseline, participants completed the Treatment Self-Regulation Questionnaire (TSRQ) to assess their motivation to begin a weight loss program. At week 12, participants completed the TSRQ to assess their motivation to continue to participate in the program if given the opportunity. Therefore, only completers are used within this analysis. Autonomous motivation was not normally distributed between the groups. Therefore, a nonparametric Mann-Whitney U test was performed and revealed no significant difference between the groups ($p=0.107$) (Table 15). Furthermore, an independent samples t-test was performed to determine if there was any difference in controlled motivation between the SBWL and CI groups. The results indicated there was no significant difference between the groups ($p=0.993$) (Table 15).

Table 15. Differences in Autonomous and Controlled Motivation Between Treatment Groups at Week 12

	SBWL (N=12) (mean±s.d.)	CI (N=10) (mean±s.d.)	p-value
Autonomous Motivation†	6.3 ± 0.9	5.3 ± 1.5	0.107†
Controlled Motivation	2.9 ± 1.1	2.9 ± 1.0	0.993

†Mann-Whitney U Test performed for nonparametric data

4.4 PROCESS MEASURES

Descriptive analyses were used for the SBWL group to examine weekly group attendance, self-monitoring of dietary intake, physical activity, self-weighing, treatment satisfaction, and intervention delivery time. Similar descriptive analyses were also used for the CI group. However, group attendance was omitted from the analysis due to the design of the study. In addition, self-monitoring of dietary intake, physical activity, and self-weighing was submitted via e-mail. Independent samples t-tests were performed for the completers analysis (Table 16) and ITT analysis (Table 17) to determine if there were any differences between treatment groups for diet days recorded, self-reported calorie intake, self-reported physical activity (days and minutes/week), and self-weighing days per week. When normality tests assumptions were violated, Mann-Whitney U Tests were performed.

Table 16. Differences in Process Measures Between Treatment Groups at Week 12: Completers Analysis

Characteristics	SBWL (N=12) (mean±s.d.)	CI (N=10) (mean±s.d.)	p-value
Group Attendance (%)	95.8±9.7	----	----
Diaries Completed (%)	96.2±7.2	----	----
Diaries Completed Per Person (total # diaries)	10.6±0.8	----	----
Diaries Completed via E-Mail (%)	----	71.8±35.2	----
Diaries Completed Per Person via E-mail (total # diaries)	----	7.9±3.9	----
Diet Days Recorded (days/week) ^{a†}	6.1±1.8	5.4±1.9	0.254†
Self-Reported Calorie Intake (kcal/day) ^a	1125±473.9	965.4±521.4	0.460
Self-Reported Physical Activity ^{a†}			
• Days/Week ^{a†}	4.2±1.9	3.7±2.3	0.497†
• Minutes/Week ^{a†}	178.2±92.4	174.8±177.4	0.456†
Self-Weighed (days/week) ^a	3.7±2.6	4.5±2.6	0.471

s.d. = standard deviation

^a Data obtained from paper diary logging (SBWL) and diaries submitted via e-mail (CI)

†Mann-Whitney U Test performed for nonparametric data

Table 17. Differences in Process Measures Between Treatment Groups at Week 12: ITT Analysis

Characteristics	SBWL (N=13) (mean±s.d.)	CI (N=13) (mean±s.d.)	p-value
Group Attendance (%)	91.6±17.7	----	----
Percent Diaries Completed (%)	91.6±18.0	----	----
Diaries Completed Per Person (total # diaries)	10.1±2.0	----	----
Diaries Completed via E-Mail (%)	----	60.1±38.5	----
Diaries Submitted Per Person via E-mail (total # diaries)	----	6.6±4.2	----
Diet Days Recorded (days/week) ^{a†}	5.8±2.0	4.0±2.5	0.057†
Self-Reported Calorie Intake (kcal/day) ^a	1067.8±498.9	808.0±550.9	0.220
Self-Reported Physical Activity ^{a†}			
• Days/Week ^{a†}	4.0±2.0	3.1±2.3	0.264†
• Minutes/Week ^{a†}	170.4±92.8	141.3±166.7	0.169†
Self-Weighed (days/week) ^a	3.6±2.5	3.7±2.7	0.920

s.d. = standard deviation

^a Data obtained from paper diary logging (SBWL) and diaries submitted via e-mail (CI)

†Mann-Whitney U Test performed for nonparametric data

4.4.1. Attendance and Diaries Completed

Attendance at weekly group sessions was $95.8 \pm 9.7\%$ among SBWL completers with $96.2 \pm 7.2\%$ of self-monitoring food and activity diaries completed across the 12 weeks (Table 16). ITT analysis revealed $91.6 \pm 17.7\%$ of SBWL participants attending weekly group sessions and $91.6 \pm 18.0\%$ of self-monitoring food and activity diaries completed (Table 17). Participants in the CI group did not attend weekly group meetings. Instead, participants in the CI group submitted summary information (calories/day, fat grams/day, physical activity minutes/day, and daily body weight) from the food and activity diary via e-mail each week. Overall, CI completers submitted this information $71.8 \pm 35.2\%$ across the 12 weeks (Table 16). ITT analysis revealed $60.1 \pm 38.5\%$ of summary information from the food and activity diary was submitted via e-mail (Table 17).

4.4.2. Self-Monitoring of Dietary Intake

A nonparametric Mann-Whitney U test revealed no significant difference between SBWL and CI completers in the number of days dietary intake was recorded (SBWL: 6.1 ± 1.8 days/week; CI: 5.4 ± 1.9 days/week) ($p=0.254$) (Table 16). The ITT analysis indicated similar results (SBWL: 5.8 ± 2.0 days/week; CI: 4.0 ± 2.5 days/week) ($p=0.057$) (Table 17).

An independent samples t-test examined differences between SBWL and CI completers in daily self-reported caloric intake recorded. The results indicated there were no significant differences between the SBWL group (1125 ± 473.9 kcals/day) and the CI group (965.4 ± 521.4 kcals/day) ($p=0.460$) (Table 15). Similarly, ITT analysis revealed no significant differences were observed between the groups ($p=0.220$) (Table 17).

4.4.3. Self-Monitoring of Physical Activity

Differences between SBWL and CI completers in the number of days physical activity recorded was examined with a nonparametric Mann-Whitney U test. The results indicated there were no significant differences between the groups, with the SBWL group reporting physical activity 4.2 ± 1.9 days per week compared to 3.7 ± 2.3 days per week for the CI group ($p=0.497$) (Table 16). The ITT analysis revealed similar results, with the SBWL reporting physical activity 4.0 ± 2.0 days per week compared to 3.1 ± 2.3 days per week for CI group ($p=0.264$) (Table 17).

A Mann-Whitney U test also examined differences between SBWL and CI completers in self-reported physical activity minutes per week. The results revealed there were no significant differences between the SBWL group (178.2 ± 92.4 minutes/week) and the CI group (174.8 ± 177.4 minutes/week) ($p=0.456$) (Table 16). The ITT analysis also demonstrated no significant

differences between the SBWL group (170.4 ± 92.8 minutes/week) and the CI group (141.3 ± 166.7 minutes/week) ($p=0.588$) (Table 17).

4.4.4. Self-Weighing

An independent samples t-test examined differences between SBWL and CI completers in the number of days body weight was recorded. There were no significant differences between the groups, with the SBWL completers self-weighing 3.7 ± 2.6 days per week compared to 4.5 ± 2.6 days per week for the CI completers (Table 16). The ITT analysis revealed similar findings with no significant differences observed between the groups ($p=0.920$) (Table 17).

4.4.5. Treatment Satisfaction

At week 12, completers in the SBWL and the CI groups were asked to rate their overall satisfaction with the intervention they received. Participants were asked questions regarding their effort following the intervention, including satisfaction with overall progress and satisfaction for changing dietary and physical activity habits, and weight. Each item was rated on a Likert scale with higher scores indicating greater program favorability. Table 18 illustrates the participant responses to a treatment satisfaction survey, overall and by group. Mann-Whitney U tests revealed participants in the SBWL group were more satisfied overall with the weight management program ($p=0.030$) (Table 18). There were no other significant differences between the SBWL group and the CI group. In the event participants were not satisfied or would not recommend the weight management program, they had the opportunity to provide comments (Appendix O).

Table 18. Participant Responses to Treatment Satisfaction Survey

Question	Total (N=22) (mean±s.d.)	SBWL (N=12) (mean±s.d.)	CI (N=10) (mean±s.d.)	p-value
1. How satisfied are you overall with the weight management program? ^{†‡}	3.6±0.6	3.8±0.4	3.2±0.6	0.030*†
2. Would you recommend the weight management program you received to others? ^{†§}	3.6±0.6	3.8±0.5	3.4±0.7	0.283†
3. Given the effort you put into following the weight management program, how satisfied are you overall with your progress over the past 12 weeks? ^{†°}	2.0±1.8	2.4±1.4	1.4±2.1	0.283†
4. Given the effort you put into following the weight management program over the past 12-weeks, how satisfied are you overall with your progress on...				
• Changing your weight ^{†°}	1.8±2.2	2.1±1.9	1.4±2.6	0.628†
• Changing your dietary habits ^{†°}	2.1±1.7	2.1±1.8	2.0±1.6	0.821†
• Changing your physical activity habits ^{†°}	2.9±1.2	3.1±1.1	2.6±1.4	0.418†

s.d. = standard deviation

*SBWL > CI group

†Mann-Whitney U Test performed for nonparametric data

‡ (1 = very dissatisfied and 4 = very satisfied)

§ (1 = definitely not and 4 = definitely would)

° (-4 = very dissatisfied and 4 = very satisfied)

4.4.6. Intervention Delivery Time

A treatment fidelity plan was developed to monitor and enhance the reliability and validity of the CI. Therefore, the SBWL and CI group interventions were closely monitored to ensure that the participants performed the skills and strategies intended by the intervention. Furthermore, the time spent delivering the intervention was recorded to ensure that the intervention contact was not biased. Figure 8 illustrates the total time, in minutes, spent delivering the intervention for

participants in the SBWL group and the CI group. Overall, the SBWL group intervention time was 1382 minutes, including group sessions, individual make-up sessions, telephone make-ups (in the event they were unable to come in-person), and commenting on food and activity diaries. In comparison, the CI group total intervention time was 1003 minutes, including group sessions at week 1 and week 12, individual make-up sessions, retention phone calls (in the event diary information was not e-mailed by the specified deadline), and drafting individual and group e-mails.

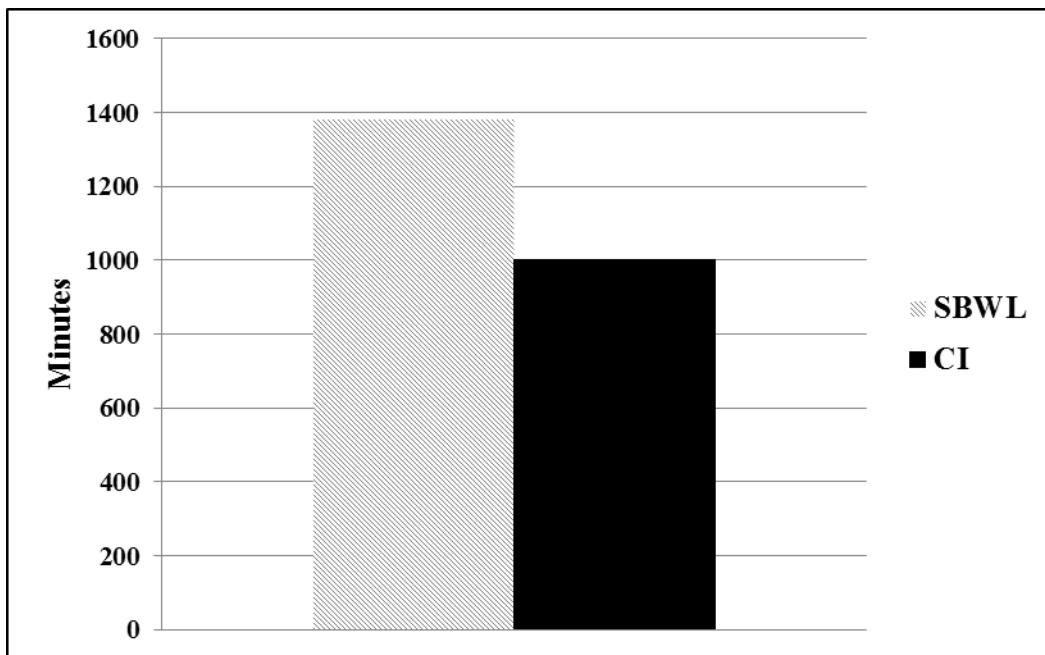


Figure 8. Intervention Delivery Time for the SBWL and CI Group

4.5 CORRELATES OF WEIGHT CHANGE

Pearson correlation coefficients were conducted to examine the relationship between changes in body weight, physical activity, eating behaviors, weight loss self-efficacy, and dietary intake at 0 and 12 weeks for completers. Changes in body weight and outcome measures were calculated

by subtracting the week 12 value from week 0. Therefore, a negative correlation indicates body weight decreased as eating behaviors, weight loss self-efficacy, and self-reported physical activity improved. Conversely, a positive correlation indicates body weight decreased as dietary intake improved. Spearman Rank Order correlations were computed for skewed data.

Table 19. Correlations Between Weight Change and Outcome Measures at Week 12: Completers

Outcome Variable	TOTAL (N=22)	SBWL (N=12)	CI (N=10)
Eating Behaviors	-0.433*	-0.529	-0.280
Weight Loss Self-Efficacy	-0.119	-0.350	0.192
Dietary Intake (kcal/day)	0.125	0.331	-0.069
Self-Reported Physical Activity with stairs (kcal/week)	-0.418	-0.426	-0.461
Self-Reported Physical Activity without stairs (kcal/week)	-0.393	-0.430	-0.419
Self-Reported Physical Activity (mins/week)‡	-0.519**‡	-0.661*	-0.514

*significant at p<0.05

‡Spearman Rank Order correlation was performed

4.5.1 Eating Behaviors and Body Weight Change

Completers analysis revealed a significant correlation between changes in eating behaviors and body weight when groups were combined ($r=-0.433$, $p=0.044$). However, there was no significant correlations among groups (SBWL: $r=-0.529$, $p=0.077$; CI: $r=-0.280$, $p=0.432$).

4.5.2 Self-Efficacy for Weight Loss and Body Weight Change

Completers analysis did not reveal any significant correlations between changes in self-efficacy for weight loss and body weight when groups were combined ($r=-0.119$, $p=0.598$) and among groups (SBWL: $r=-0.350$, $p=0.264$; CI: $r=0.192$, $p=0.594$).

4.5.3 Dietary Intake and Body Weight Change

Completers analysis did not reveal a significant correlation between changes in dietary intake (kcals/day) and body weight when both groups were combined ($r=0.125$, $p=0.578$) and among groups (SBWL: $r=0.331$, $p=0.294$; CI: $r=-0.069$, $p=0.850$).

4.5.4 Physical Activity and Body Weight Change

Completers analysis did not reveal any significant correlations between changes in self-reported physical activity (kcals/week with stairs) and body weight when both groups were combined ($r=-0.418$, $p=0.053$) and among groups (SBWL: $r=-0.426$, $p=0.167$; CI: $r=-0.461$, $p=0.180$). Similarly, completers analysis did not reveal any significant correlations between changes in self-reported physical activity (kcals/week without stairs) and body weight when both groups were combined ($r=-0.393$, $p=0.070$) and among groups (SBWL: $r=-0.430$, $p=0.163$; CI: $r=-0.419$, $p=0.228$). Self-reported physical activity (minutes/week) for the group combined was skewed. Therefore, a Spearman Rank Order correlation was performed and revealed a significant correlation for changes in self-reported physical activity (minutes/week) and body weight change ($\rho=-0.670$, $p<0.001$). Changes in self-reported physical activity (minutes/week) were significantly correlated with change in body weight for the SBWL group ($r=-0.661$, $p=0.019$), but not the CI group ($r=-0.514$, $p=0.129$).

5.0 DISCUSSION

Overweight and obesity are a significant public health concern. Behavioral treatment is considered the first line of intervention for individuals attempting to lose weight. Face-to-face behavioral weight loss interventions are capable of producing a 5% (~4.8 kg) weight loss of initial body weight at 12-weeks¹⁶. This magnitude of weight loss results in significant reductions in weight related risks⁹ such hyperinsulinemia, insulin resistance, type 2 diabetes, hypertension, dyslipidemia, coronary heart disease, and gall bladder disease³. Despite the implications of these findings, not all individuals achieve this magnitude of weight loss during in-person behavioral treatment. Furthermore, in-person behavioral programs can be intensive, costly, and require substantial time commitments from the participants¹⁰. Lastly, they are also limited in reach as they often exclude individuals with health related risks (e.g., hypertension) from participation and are not easily accessible to rural populations⁶³. Thus, it is crucial to examine alternative strategies in obesity treatment to improve approaches and success rates for individuals attempting to lose and maintain weight. Therefore, the purpose of this study was to examine a stand-alone campaign as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention.

5.1 PARTICIPANT ATTRITION

Twenty-six overweight and obese adults were randomized to this study. The overall attrition rate of this investigation was 15.4%, with 22 of 26 participants completing assessments at week 12. Participants were lost at follow-up due to lack of time (N=1), a medical reason (N=1), and unknown reasons (N=2). Previous research has shown that approximately 20% of participants who begin treatment in behavioral weight loss interventions do not complete it at 6-months¹⁶. While the overall attrition rate was lower than what is normally observed in behavioral weight loss programs at 6-months, it is unclear if it would be maintained beyond 12-weeks.

Attrition rates were not significantly different between groups with 7.7% for the SBWL group and 23.1% for the CI group. The attrition rate in the CI group is comparable to previous e-mail based weight loss programs^{31,91,120}. Unknown or lack of interest accounts for the majority of individuals lost at follow-up in e-mail based programs^{31,91,120}. Based on comments from the treatment satisfaction survey in this investigation, difficulties with self-monitoring, lack of effort and lack of support appeared to be major barriers for participants for completers in the CI group. Therefore, the participants in the CI group lost at follow-up due to unknown reasons (N=2) may have experienced similar difficulties.

5.2 BODY WEIGHT AND BMI

This investigation demonstrated that the SBWL and CI produced significant weight loss from week 0 to week 12 for completers (SBWL: -6.1 ± 2.5 kg; CI: -4.0 ± 3.4 kg) and ITT (SBWL: -5.6 ± 2.9 kg; CI: -3.1 ± 3.4 kg), with no significant difference between groups. These findings

support the hypothesis that the CI group would achieve similar changes in body weight compared to the SBWL group.

The weight loss observed in the SBWL group was consistent with weight loss produced in face-to-face behavioral weight loss interventions at 12-weeks¹⁶. However, currently there is no published data on the effectiveness of a stand-alone campaign as an alternative weight loss intervention. Weight loss achieved in the CI is similar to previous studies that have examined the use of e-mail counseling to deliver a behavioral weight loss intervention. For example, Tate et al.³¹ have shown that participants in an online structured behavioral treatment program which included weekly contact and individualized feedback from an interventionist achieved significantly better weight loss compared to those just given links to education web sites at 12-weeks (-4.0 ± 2.8 kg vs. -1.7 ± 2.7 kg, respectively) and 24-weeks (-4.1 ± 4.5 kg vs. -1.6 ± 3.3 kg, respectively). Additionally, Gabriele et al.¹²¹ have also shown that a minimal contact e-mail intervention can result in an average weight loss of 3.4 kg over the course of 12-weeks, with over 35% of participants achieving a 5% weight loss. In comparison, the current investigation resulted in 30.8% of participants in the CI group achieving a 5% of weight loss.

The CI included an incentive-based point system to reinforce positive behavior changes to achieve diet, physical activity, and weight loss goals. The CI did not appear to enhance weight loss efforts above and beyond what is typical of a SBWL. This is not consistent with previous research findings. Petry and colleagues⁹⁶ have shown that participants receiving reinforcement prizes in 12-week weight loss program lost significantly more weight (-6.1 kg) compared to a non-reinforcement standard weight loss program condition (-2.7 kg). Volpp et al.¹⁹ have shown that participants in an lottery incentive group and deposit contract group who earned chances to win money for achieving a weekly weigh-in goal (1 lb. per week) lost more

weight (-5.9 kg and -6.3 kg, respectively) than those in a control condition (-1.8 kg) over the course of a 16-week study. One possible explanation may be due to the magnitude and frequency of the incentive. The studies by Petry⁹⁶ and Volpp¹⁹ gave participants the opportunity to earn incentives weekly, whereas participants in the CI group earned points towards chances to win incentives at one time point (week 12).

Overall, the findings of this investigation demonstrated that both groups can produce significant weight loss and there were no differences between groups. While the weight loss in the CI group did not approach the same magnitude of weight loss as a face-to-face intervention; it may provide a low-intensity and potentially cost-effective approach to expand the reach and audience of weight loss treatment programs. This could have a substantial impact on health outcomes for overweight and obese individuals at risk for developing chronic diseases who cannot participate in face-to-face treatment due to the many constraints of this type of program.

5.3 PHYSICAL ACTIVITY

The results of this investigation demonstrated that self-reported physical activity significantly increased from baseline for completers in the SBWL group with stairs (1065.2 ± 506.2 kcal/week), without stairs (1016.2 ± 510.8 kcal/week), and minutes per week (153.5 ± 80.7 mins/week). Likewise, the CI group significantly increased self-reported physical activity with stairs (1009.2 ± 1281.5 kcal/week), without stairs (953.1 ± 1277.8 kcal/week), and minutes per week (190.8 ± 241.1 mins/week). There were no significant differences between groups. These findings support the hypothesis that the CI group would achieve similar increases in moderate-to-vigorous physical activity compared to the SBWL group.

Overall, participants in SBWL group self-reported 240.1 ± 94.2 (minutes/week) of moderate to vigorous physical activity and the CI group self-reported 233.1 ± 17.1 (minutes/week) at week 12. These results are consistent with the level of physical activity recommended by the American College of Sports Medicine (ACSM) suggesting that 150-250 minutes of moderate intensity physical activity per week is needed to induce modest weight loss and prevent weight gain with moderate diet restriction⁹. The overall increases in self-reported physical activity observed in this study are similar to previous in-person behavioral weight loss interventions¹⁰ and slightly higher than previous e-mailed based programs^{31,91} at 12 weeks. For instance, Jakicic et al.¹⁰ observed a change in physical activity of 1204 kcals/week (95% CI, 987 to 1422 kcals/week) in 12-weeks of a SBWL in which physical activity was progressed to 300 minutes by 6-months. Tate and colleagues³¹ have shown that an e-mail based program increases physical activity to 1500 ± 1513 kcal/week over the course of 12-weeks. Therefore, a CI can be used as an alternative strategy to increase moderate to vigorous physical activity consistent with current recommendations.

It is also important to note that 6 participants with controlled hypertension completed this study. This suggests that with proper screening, individuals with health related risks can safely participate in physical activity to improve weight loss and weight maintenance efforts and reduce health risks.

5.4 DIETARY INTAKE AND EATING BEHAVIORS

The results of this investigation demonstrated a significant decrease in dietary intake from week 0 to week 12 for completers in the SBWL group (514.4 ± 510.3 kcal/day) and the CI group

(315.2 ± 803.3 kcal/day). There were no significant differences between groups. Reductions in dietary intake were combined with significant improvements in weight loss eating behaviors measured for completers in the SBWL group (10.5 ± 7.9) and the CI group (7.6 ± 7.0) at week 12. There were no significant differences between groups. Weight loss eating behaviors significantly increased from week 0 to week 12 for ITT in the SBWL group (9.7 ± 8.1) and the CI group (5.8 ± 7.0). These findings support the hypothesis that the CI group would achieve similar decreases in dietary intake compared to the SBWL group.

Previous research has shown that reduced dietary intake, in combination with adopting healthy eating behaviors, are important components to assist individuals in losing weight⁸. The reductions in dietary intake (kcal/day) observed in this investigation are consistent with previous SBWL programs at 12-weeks. Jakicic et al.¹⁰ have shown that a SBWL is capable of reducing dietary intake by 601 kcals/day (95% CI, -675 to -526) over the course of 12-weeks. In contrast, reductions in dietary intake in the CI group were slightly lower than previous e-mail based programs^{31,91} at 12 weeks. For example, Tate and colleagues³¹ reduced dietary intake by approximately 500 kcals/days in a 12-week e-mail based program. Interestingly, while both groups improved weight loss eating behaviors, the magnitude of the dietary intake change for the CI group was approximately 200 kcals per day lower. One possible explanation for this difference is that the CI did not reinforce the achievement of specific calorie goals or the quality of foods consumed (e.g., fruits and vegetables). Therefore, it may be possible that greater reductions in dietary intake and improved eating behaviors would have been observed in the CI group if this was addressed within the context of the thematic framework.

5.5 SELF-MONITORING

The number of days that participants logged dietary intake and physical activity were not significantly different between groups for completers and ITT. In addition, there was no significant difference in self-reported calorie intake, self-reported physical activity in minutes per week, and self-weighing days for completers and ITT. Therefore, the hypothesis that the CI would achieve a similar number of days that dietary intake and physical activity would be self-monitored compared to the SBWL was supported.

While there are no statistical differences between the groups in the number of days logged, completers in the SBWL group turned in $96.2 \pm 7.2\%$ of diaries in comparison to $71.8 \pm 35.2\%$ submitted via e-mail by the CI group. With ITT, these numbers decreased to $91.6 \pm 18.0\%$ for the SBWL group and $60.1 \pm 38.5\%$ for the CI group. Previous research has shown that consistent self-monitoring of diet and activity behaviors is a significant predictor of both short-term and long-term weight loss²⁶⁻²⁸. For instance, Boutelle et al.⁸⁸ have shown that self-monitoring food intake consistently, at least 75% of the time, can be a reasonable target for consistency to improve success for weight control during treatment. However, self-monitoring adherence gradually declines over time in behavioral weight loss interventions²⁵. Although direct comparisons cannot be made between the SBWL and CI due to the differences in procedures, this evidence may suggest that the greater magnitude of weight loss in the SBWL may be attributed to more consistent self-monitoring.

5.6 WEIGHT LOSS SELF-EFFICACY AND MOTIVATION

In the current investigation, a significant increase in self-efficacy for weight loss was observed in for completers (SBWL: 28.3 ± 35.7 ; CI: 16.3 ± 35.8) and ITT (SBWL: 26.1 ± 35.0 ; CI: 12.5 ± 31.8) week 0 to week 12. There were no significant differences between the groups. These findings are consistent with previous behavioral weight loss programs in which improvements in self-efficacy were associated with greater weight losses^{122,123}. Therefore, the hypothesis that the CI group would achieve similar changes for weight loss self-efficacy compared to a SBWL was supported.

There was no significant difference between groups in autonomous motivation (SBWL: 6.3 ± 0.9 ; CI: 5.3 ± 1.5) or controlled motivation (SBWL: 2.9 ± 1.1 ; CI: 2.9 ± 1.0) at week 12. These findings support our hypothesis. However, although there was no statistically significant difference between the groups, it appears that the SBWL was trending towards higher levels of autonomy. These findings are similar to Williams et al.⁹⁸ who have shown that perceived autonomy predicts autonomous reasons to continue to participate in treatment and resulted in higher attendance and improved weight loss efforts. One possible explanation is that the SBWL created an autonomy supportive environment in which participants received a variety of options for behavior change from interventionists and other group members.

Participants in the CI group also had the opportunity to win incentives during this investigation. Within the context of a behavioral weight loss program, incentives have been used as strategies to encourage participants to initiate and continue healthy behaviors. However, these strategies could potentially be observed as controlling by the participant, thereby undermining their autonomous motivation for participating in the weight loss program. The results of this investigation suggest the chance of winning incentives did not lead to increases in controlled

motivation and did not undermine autonomous motivation in the CI group at week 12. These findings are consistent to those of Crane and colleagues⁴³ who showed that small financial incentives (\$5.00 per percentage of initial weight loss) used within a 12-month weight loss program did not lead to increases in controlled motivation or influence autonomous motivation.

5.7 SUMMARY OF RESEARCH HYPOTHESES AND CONCLUSIONS

Hypothesis:

The CI would achieve a similar weight loss when compared to the SBWL.

Conclusion:

Both groups achieved significant weight loss from week 0 to week 12 (SBWL group: -5.6 ± 2.9 kg; CI group -3.1 ± 3.4 kg) ($p<0.001$). There were no significant differences between groups ($p=0.603$) or a group X time interaction ($p=0.052$) from baseline. Therefore, this hypothesis was accepted.

Hypothesis:

The CI would achieve a similar increase in moderate to vigorous intensity physical activity when compared to the SBWL.

Conclusion:

Self-reported physical activity with stairs (983.3 ± 567.6 kcal/week), without stairs (938.1 ± 564.4 kcal/week), and minutes per week (141.7 ± 88.3 mins/week) ($p<0.001$) significantly increased from week 0 to week 12 in the SBWL group (Table 13). Similarly, the CI group significantly increased self-reported physical activity with stairs (776.3 ± 1194.8 kcal/week),

self-reported physical activity without stairs (733.2 ± 1182.9 kcal/week), and physical activity minutes per week (146.8 ± 224.9 mins/week) ($p<0.001$) (Table 13) from week 0 to week 12. There were no significant differences between groups in self-reported physical activity with stairs, without stairs, and minutes per week ($p=0.687$, $p=0.494$, and $p=0.882$, respectively) from baseline. There was also no group X time interaction in self-reported physical activity with stairs, without stairs, and minutes per week ($p=0.578$, $p=0.578$, and $p=0.940$, respectively) (Table 13) from baseline. Therefore, this hypothesis was accepted.

Hypothesis:

The CI would achieve a similar reduction in dietary intake when compared to the SBWL.

Conclusion:

Both groups achieved significant reductions in dietary intake (kcal/day) from week 0 to week 12 (SBWL: 474.8 ± 509.0 kcal/day; CI: 242.5 ± 709.3 kcal/day) ($p=0.007$). There were no significant differences between groups ($p=0.347$) or a group X time interaction ($p=0.507$) from baseline. Therefore, this hypothesis was accepted.

Hypothesis:

The CI would achieve a similar number of days that dietary intake and physical activity would be self-monitored compared to the SBWL.

Conclusion:

There was no significant difference in the number of days dietary intake was recorded by the SBWL group on the paper diary (5.8 ± 2.0 days/week) or submitted via e-mail by the CI group (4.0 ± 2.5 days/week) ($p=0.057$) (Table 17). Therefore, this hypothesis was accepted.

Exploratory Hypothesis:

The CI group would achieve similar changes for weight loss self-efficacy compared to a SBWL.

Conclusion:

Both groups significantly increased self-efficacy for weight loss from week 0 to week 12 (SBWL: 9.7 ± 8.1 ; CI: 5.8 ± 7.0) ($p=0.007$). There were no significant differences between groups ($p=0.226$) or a group X time interaction ($p=0.313$) from baseline. Therefore, this hypothesis was accepted.

Exploratory Hypothesis:

There would be no significant difference in autonomous and controlled motivation between the SBWL group and the CI group at week 12.

Conclusion:

There was no significant difference between groups in autonomous motivation (SBWL: 6.3 ± 0.9 ; CI: 5.3 ± 1.5 , $p=0.107$) or controlled motivation (SBWL: 2.9 ± 1.1 ; CI: 2.9 ± 1.0 , $p=0.993$) at week 12 (Table 17). Therefore, this hypothesis was accepted.

5.8 LIMITATIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

This investigation was the first to examine the feasibility of a stand-alone campaign intervention (CI) as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention (SBWL). There are several limitations to this investigation which may have contributed to the interpretation of the observed outcomes. Therefore, these findings must

be considered within the context of these limitations and future investigations should address the following:

1. It was originally proposed that 48 subjects be recruited and complete the intervention, with 24 subjects in each treatment condition. This would have provided a sufficient sample to detect a 2.5 kg difference between groups with a type I error rate of 0.05 at 88% power. With an attrition rate of 20%, 20 subjects per treatment condition (40 total participants) were needed to complete the intervention to detect a 2.5 kg difference between groups with a type 1 error rate of 0.05 at 80% power. However, only 26 subjects completed baseline assessments and were eligible to be randomized to one of the two treatment groups (SBWL, CI). Post hoc analysis determined this sample size had 55% power (45% chance of making a Type 2 error). Therefore, this sample size may have not have been sufficient enough to detect significant differences in outcome measures between the treatment groups. Therefore, future investigations should be conducted with larger sample sizes.
2. This investigation did not include a diverse racial/ethnic population (2 African-American women were randomized into each condition). Therefore, racial/ethnic differences between and within intervention conditions could not be examined. Future investigations should account for larger and more diverse sample sizes that would allow for comparisons of racial/ethnic differences.
3. This investigation did not include a diverse gender population (2 men were randomized into each condition). Therefore, gender differences between and within intervention conditions could not be examined. Further research should account for larger sample

sizes that would increase the number of male participants to allow for comparisons of gender differences.

4. The duration of the study was 12 weeks and may have not been long enough to detect significant differences between groups. Future studies should examine the long-term effect of a CI for weight management when compared to a SBWL.
5. It is unclear if the effects of the CI would persist long-term. Studies such as DPP and Look AHEAD trials have incorporated the use of in-person refresher campaigns as part of the lifestyle intervention to assist participants' with weight maintenance efforts^{7,11}. Therefore, the application of CI to assist with weight maintenance efforts and the prevention of weight regain warrants further investigation. In addition, the duration of the CI thematic framework (e.g., 8 weeks, 12 weeks) and other target goals should be considered such as increasing fruit and vegetable consumption to improve other health outcomes.
6. Participants in the CI group earned chances to win incentives at the end of the study by reporting their self-monitoring information (e.g., food intake, physical activity minutes, and body weight) each week via an e-mail. However, it is unclear if chances to win incentives influenced the CI participants' motivation for reporting their self-monitoring information as this was not measured and not administered throughout the intervention. Participants could have also come in for a mid-point assessment to be able to evaluate the change in motivation due to the CI. Furthermore, it cannot be determined if the incentives chosen by the investigators prior to implementing the study were appropriate to influence behavior changes. Therefore, future studies should examine the magnitude of incentives on behavior changes within the context of the CI intervention. In addition,

the frequency of earning chances to win incentives could also be examined in these investigations.

7. The investigators served as the authors for the e-mail content to CI participants and were not blinded to the study hypotheses. Due to the limited budget of this study, training and hiring additional staff was not possible. While there are multiple pathways by which bias may influence results, the primary outcome of this investigation was an objective measure of body weight, thus providing credibility to the results. Other studies could consider utilizing staff members who are blinded to the randomized conditions to develop e-mail content for the CI group.
8. While direct comparisons cannot be made between the number of diaries that were submitted in person by the SBWL group or submitted via e-mail by the CI group, overall it appears that participants in the SBWL group self-monitored more consistently. This may be possible explanation for the greater magnitude of weight loss in the SBWL. Therefore, strategies to enhance the compliance of completing and submitting diaries via e-mail for the CI group warrants further investigation.
9. There may be bias in the Treatment Self-Regulation Questionnaire (TSRQ) measure as those who completed it for continuing participation in a weight loss program were those who were most motivated to lose weight, earn incentives, and complete the week 12 assessment to receive compensation.

5.9 CONCLUSION

In conclusion, the purpose of this study was to examine a stand-alone campaign as an alternative strategy for weight management when compared to a standard behavioral weight loss intervention. The current investigation demonstrated that participants in the CI group achieved modest yet clinically meaningful weight loss at week 12. In addition, significant improvements were observed in BMI, systolic and diastolic blood pressure, resting heart rate, waist and hip circumference, eating behaviors, self-efficacy for weight loss, dietary intake, and moderate to vigorous physical activity. These findings were similar to the differences observed in the SBWL. This is of importance as standard behavioral weight loss interventions can be intensive, costly, and require substantial time commitments from the participants. Therefore, the CI may provide an alternative approach to disseminate an effective behavioral weight loss program to assist a larger proportion of individuals with weight loss and weight maintenance efforts. This may also result in a more positive net impact on the overall health of the population. Future studies should evaluate the effectiveness of the CI long-term to determine whether these findings can be sustained beyond 12-weeks.

APPENDIX A

SUBJECT RECRUITMENT FLIER

Research Subjects Needed for Weight Management Study

Are you 18 – 55 years of age?

Are you overweight but otherwise healthy?

Do you have a computer with Internet access?

The Physical Activity and Weight Management Research Center at the University of Pittsburgh is looking for overweight and obese adults between the ages of 18-55 to participate in a 12-week research study. The purpose of this study is to examine the effect of an alternative research intervention strategy for weight management compared to a standard behavioral weight loss program. The alternative research intervention strategy includes a combination of approaches that consist of group meetings, Internet Education, and a prize-based point system. The weight loss intervention will be held at a University of Pittsburgh facility located on the Southside of Pittsburgh. You can earn a total of \$50 for your participation in this study.

**For more information please call the Physical
Activity and Weight Management Research Center
at the University of Pittsburgh at 412-488-4184.**

APPENDIX B

OBESITY AND NUTRITION RESEARCH CENTER

REGISTRY RECRUITMENT LETTER

Dear Interested Participant:

You recently contacted the Physical Activity and Weight Management Research Center at the University of Pittsburgh inquiring about our current research studies and programs. We are pleased to inform you that we are in the process of beginning our next research program, and based on the information that you provided to us at that time, it appears that you may be eligible to participate.

For this study, we are interested in recruiting a total of 48, overweight and obese adults between the ages of 18-55. The purpose of this study is to examine the effect of an alternative research intervention strategy for weight management compared to a standard behavioral weight loss program. To do this, eligible individuals will participate in a 12-week program that will assist you with changing your dietary habits and increasing your exercise. You will be randomly assigned to receive one of the two weight loss interventions, which means that you cannot select the intervention that you receive, but this will be determined by a method similar to flipping a coin. Both groups will receive a weight loss program that includes changes in your diet and exercise. One of the groups will receive a standard behavioral weight loss program and will attend weekly group meetings across the 12 weeks. The other group will receive an alternative research intervention strategy for weight management including a combination of approaches that consist of group meetings, Internet Education, and a prize-based point system. Should you be eligible to participate, we would ask that you report to the Physical Activity and Weight Management Research Center on the South Side of Pittsburgh for an orientation session in which we will give you full details of this 12-week study. You can earn a total of \$50 for your participation in this study.

Based upon information that you previously provided us, it appears that you may be eligible to participate in this study. If you would like to hear more information about the study or to find out if you would be eligible to participate, please call the Physical Activity and Weight Management Research Center at 412-488-4184. If you think this is something that you are interesting in participating in, we encourage you to call.

Thank you very much! We look forward to hearing from you!

Sincerely,

David Garcia, MS
Principle Investigator

APPENDIX C

TELEPHONE SCREENING SCRIPT

TELEPHONE SCREENING FORM SCRIPT

1. Thank you for your interest in this study. My name is _____ and I would like to tell you more information about this research study to see if you are interested in participating.
2. **Procedures for Describing the Study and Obtaining Verbal Consent to Conduct the Phone Screen:** A description of the study will be read to participants, and this description includes important components of the informed consent process (see attached script). Individuals who express an interest in participating in this study will be told the following to obtain verbal consent:
 - Investigators Component of Informed Consent: This study is being conducted by Mr. David O. Garcia and Dr. Amy D. Rickman at the University of Pittsburgh.
 - Source of Support Component of Informed Consent: Funding for this study is provided by the University of Pittsburgh Physical Activity and Weight Management Research Center and the Department of Health and Physical Activity.
 - Description Component of the Informed Consent: We are interested in recruiting 48 men and women to participate in this study. The purpose of this study is to examine the effect of an alternative research intervention strategy for weight management compared to a standard behavioral weight loss program. To do this, eligible individuals will participate in a 12-week program that will assist you with changing your dietary habits and increasing your exercise. You will be randomly assigned to receive one of two weight loss interventions, which means that you cannot select the intervention that you receive, but this will be determined by a method similar to flipping a coin. Both groups will receive a weight loss program that includes changes in your diet and exercise. One of the groups will receive a standard behavioral weight loss program and will attend weekly group meetings across the 12 weeks. The other group will receive an alternative research intervention strategy for weight management including a combination of approaches that consist of group meetings, Internet Education, and a prize-based point system. Please understand that the weight loss program will be held at a University of Pittsburgh facility located on the South Side of Pittsburgh, and meetings will start between 5:15 and 6:15 in the evening, and these will be held on (Day of the Week to be determined). Individuals who are eligible to participate in this study will undergo assessments of resting blood pressure, body weight, body composition, and complete questionnaires related to diet and physical activity behaviors. These assessments will be completed before you start the study and at 12-weeks. You can earn \$50 for your participation in this research study.
 - If you are interested in participating in this study, I will need to ask you a few questions about your demographic background, physical health and medical history to determine if you appear to be eligible for this study. It will take approximately 5 minutes to ask you all of these questions. If we complete the interview and you appear to be eligible, I will take down some contact information (complete name, phone number, mailing address) and also schedule you for a

visit so we can explain the study in greater detail for you. Are you interested in participating in this study? If "YES", May I have your permission to ask you some questions about your health and medical history to determine if you are eligible to participate? *If "YES" indicate the participant's agreement with the statement on the top of the next page, and sign and date and continue with the Phone Screen. If "NO", thank the individual for calling and do not complete the phone screen.*

APPENDIX D

PHONE SCREEN INTERVIEW SCRIPT

Page 1

Phone Screen Interview Script

The caller gives verbal permission to conduct the Phone Screen:

_____ YES _____ NO

Verbal Assent was given to:

Staff Member Signature

Date Verbal Assent was given:

Staff: Eligibility requirements are noted in for each question. If an answer to a particular question tells you that the individual is clearly ineligible for this study, stop the phone screen and state, "I am sorry, but you are not eligible to participate in this study".

Eligible based on telephone screening: Yes No

If "No", list reason for ineligibility: _____

1. Gender: Male Female

2.a. Age: (MUST BE BETWEEN THE AGES OF 18-55)

2.b. Date of Birth: / /

3. Which of the following best describes your racial heritage? (you may choose more than one category):

- American Indian or Alaska Native
- Asian
- Black or African-American
- Hispanic, Latino, or Cape Verdean
- Native Hawaiian or Other Pacific Islander
- White
- Other (Specify: _____)

4. Current Weight: pounds

5. Current Height: feet inches *Office Use: BMI = _____*
(MUST BE BETWEEN 25-45.0 kg/m²)

COMPUTER QUESTIONS (#6-8 MUST ANSWER "YES" TO BE ELIGIBLE)

6. Do you have a computer that you are able to use for this study? YES No
7. Does the computer that you are able to use for this study have access to the internet? YES No
8. Do you have an e-mail address that can be used for this study? YES No

QUESTION #9 (MUST ANSWER "YES" TO BE ELIGIBLE)

9. Are you able to walk for exercise? YES No
If "no", specify reason: _____

QUESTION #10 (MUST NOT PARTICIPATE IN REGULAR EXERCISE AT LEAST 20 MINUTES PER DAY ON AT LEAST 3 DAYS PER WEEK DURING THE PREVIOUS SIX MONTHS TO BE ELIGIBLE)

10. Do you currently exercise regularly at least once per week at a moderate intensity for at least 20 minutes? Yes No
If "yes", How many days per week? _____
If "yes", How long have you been exercising this way? _____

QUESTION #11 (MUST ANSWER "NO" TO BE ELIGIBLE)

11. Have you ever been told by a doctor or other medical person that you have any of the following conditions?
If "yes", Specify:

a. Heart Disease	<input type="checkbox"/> Yes	<input type="checkbox"/> NO	_____
b. Angina	<input type="checkbox"/> Yes	<input type="checkbox"/> NO	_____
c. Heart Attack	<input type="checkbox"/> Yes	<input type="checkbox"/> NO	_____
d. Stroke	<input type="checkbox"/> Yes	<input type="checkbox"/> NO	_____
e. Diabetes (sugar)	<input type="checkbox"/> Yes	<input type="checkbox"/> NO	_____
f. Cancer	<input type="checkbox"/> Yes	<input type="checkbox"/> NO	_____

QUESTION #12 (IF "YES", MUST BE CONTROLLED WITH ANTIHYPERTENSIVE MEDICATIONS)

12. Have you ever been told by a doctor or other medical person that you have hypertension or high blood pressure? Yes No

If "yes", are you on antihypertensive medications to control your blood pressure? Yes No
If "yes", specify the medications and dosage: _____

QUESTIONS #13-14 (MUST ANSWER "NO" TO BE ELIGIBLE; IF ANSWER IS "YES", HE/SHE SHOULD NOT HAVE ANY OF THE CONDITIONS LISTED BELOW)

- *History of orthopedic or physical complications that would prevent participation in exercise.*
- *Currently taking any prescription medication that may affect metabolism and/or body weight (e.g., synthroid).*
- *Currently being treated for any psychological issues or problems, taking any psychotropic medications, or receiving treatment with psychotropic medications within the previous 6 months.*

13. Are you presently being treated by a doctor or other medical person for any other physical or psychological problems? Yes No
If "yes", specify: _____

14. Do you take any prescription medications (includes psychotropics)? Yes No

If "yes", specify the following:

Medication Name	Used to Treat:

QUESTIONS #15-16 (MUST ANSWER "NO" TO BE ELIGIBLE)

15. Are you taking any medications for the purpose of weight loss? Yes No
If "yes", specify: _____

16. Are you currently a member of another organized exercise or are you participating in an organized weight reduction program? Yes No
If "yes", specify: _____

QUESTION #17 (INELIGIBLE IF WEIGHT LOSS IS $\geq 5\%$ OF CURRENT BODY WEIGHT)

17. Have you lost weight within the past 6 months? Yes No
If "yes", specify number of pounds: _____ Method used: _____

QUESTIONS #18-19 (MUST ANSWER "NO" TO BE ELIGIBLE)

18. Have you undergone bariatric surgery (e.g., gastric bypass, lap-band, etc.)? Yes No

19. Are you currently being treated for an eating disorder? Yes No

QUESTION #20 (MUST NOT BE PARTICIPATING IN RESEARCH PROJECT IN WHICH THEY ARE RECEIVING AN INTERVENTION WHICH MAY INFLUENCE WEIGHT LOSS AND PHYSICAL ACTIVITY BEHAVIORS)

20. Are you currently participating in other research studies? Yes No
If "yes", specify: _____

QUESTION #21 (MUST NOT HAVE BEEN A PARTICIPANT IN A PREVIOUS PHYSICAL ACTIVITY OR WEIGHT MANAGEMENT RESEARCH PROJECT IN THE PREVIOUS 6 MONTHS)

21. Have you been a participant in a previous exercise or weight control study? Yes No
If "yes", specify: _____

QUESTIONS #22-24 (MUST ANSWER "NO" TO BE ELIGIBLE)

22. Do you plan to spend any time out of town on vacation or business in the next 3 months that may affect your ability to participate in this study? Yes No

23. Do you plan on relocating outside of the Greater Pittsburgh Area within the next 3 months? Yes No

WOMEN ONLY COMPLETE THE FOLLOWING QUESTIONS

24. a. Are you currently pregnant? Yes No
b. Have you been pregnant in the last 6 months? Yes No
c. Have you been breast feeding in the past 3 months? Yes No
d. Are you currently lactating? Yes No
e. Do you plan on becoming pregnant in the next 3 months? Yes No

Contact Tracking Form

** THIS PAGE IS COMPLETED ONLY IF THE RESPONDANT APPEARS TO QUALIFY FOR PARTICIPATION IN THIS STUDY AND IS SCHEDULED FOR THE ORIENTATION VISIT. **

Date: ____ / ____ / ____ Staff Member Completing Form: _____

Name: _____

Street Address: _____

City: _____ State: ____ Zip Code: _____

Home Phone: _____ Cell Phone: _____

Work Phone: _____

E-mail Address: _____

APPENDIX E

WRITTEN INFORMED CONSENT



University of Pittsburgh

*School of Education
Physical Activity and Weight Management Research Center*

Suite 600 Birmingham Towers
2100 Wharton Street
Pittsburgh, PA 15203
412-488-4184
Fax: 412-488-4174

TITLE: Feasibility of a Campaign Intervention Compared to a Standard Behavioral Weight Loss Intervention in Overweight and Obese Adults

PRINCIPLE INVESTIGATOR: David O. Garcia, M.S.
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Email: arickman@pitt.edu

SOURCE OF SUPPORT: Funding for this study is provided by the University of Pittsburgh Physical Activity and Weight Management Research Center and the Department of Health and Physical Activity.

DESCRIPTION:

The number of overweight and obese adults in the United States continues to increase. Excess body weight is associated with a number of negative health consequences including an increased risk for heart disease, diabetes, and certain forms of cancer. Developing improved interventions to treat obesity are needed to improve health outcomes and increase success within weight loss programs. This study will examine the feasibility of a campaign intervention for weight management compared to a standard behavioral weight loss intervention in overweight and obese adults. These interventions include the following:

1. A Standard Behavioral Weight Loss intervention that involves changing your eating behaviors, increasing your physical activity, and attending regular group weight loss meetings.

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University Of Pittsburgh
Institutional Review Board

Approval Date: 4/10/2013
Renewal Date: 12/18/2013

IRB #: PRO12110211

2. A Campaign intervention that involves changing your eating behaviors and increasing your physical activity, however you will not attend regular meetings. Instead you will attend two weekly meetings at weeks 0 and 12. During the weeks you are not scheduled to attend in-person weekly meetings (weeks 1-11), you will receive education materials via e-mail. You will have the opportunity to earn points towards prizes by reporting your diet and physical activity behaviors, and body weight via e-mail to a secured study e-mail address.

These interventions are described in greater detail below. This study will also investigate the effect of these interventions on body composition, cardiovascular disease risk factors, and other behavioral factors related to weight control.

You are being invited to take part in this research study because you are within the body weight range for this study, and do not have any medical conditions that would prohibit you from reducing your calorie intake to 1200 to 1800 calories per day or participating in moderate to vigorous intensity activity. Moderate intensity activity is defined as activity similar to brisk walking where you can also have a conversation, with vigorous intensity activity defined as walking at a faster pace and you cannot have a conversation because you are breathing deeper and faster. People invited into this study have to be men or women between 18-55 years of age. This study is being performed on a total of 48 individuals.

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

Screening Procedures:

Procedures to determine if you are eligible to take part in a research study are called "screening procedures". For this research study the screening procedures will be completed at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. These screening procedures will include:

You will complete a physical activity readiness questionnaire (PAR-Q), and this will take approximately 5 minutes to complete. You will also complete a detailed medical history, and this will take approximately 20 minutes to complete. These questionnaires will allow the investigators to determine if you have any significant medical condition that would indicate that exercise is unsafe for you. You will also be required to provide medical clearance from your personal physician before starting this study. Participants cannot be pregnant, and you will be required to accurately report whether you are pregnant to the investigators prior to beginning this study and during the study if your status should change.

Experimental Procedures:

If you qualify to take part in this research study, you will undergo the following experimental procedures:

You will be asked to complete a series of questionnaires at home and return them to the investigators the day of your assessment. It is estimated that you will be able to complete these questionnaires in approximately 45-60 minutes. These questionnaires will provide information about your health, exercise, and diet habits. Assessments will take place at the Physical



Activity and Weight Management Research Center at the University of Pittsburgh, and these assessments will be completed in approximately 30 minutes. Your body weight, blood pressure, body composition, and level of physical activity will be measured. A brief description of these assessments follows.

- A. Body Weight and Height (5 minutes): Your body weight will be measured using a calibrated electronic scale. Your height will be measured with a ruler that is attached to a flat wall. These will be measured at week 0 and 12.
- B. Body Composition (10 minutes): Measurements of your hip and waist areas will be taken using a measuring tape. These will be measured at week 0 and 12.
- C. Resting Blood Pressure and Heart Rate (10 minutes): Your blood pressure will be measured using a blood pressure cuff that is connected to a machine that will record the values from the blood pressure cuff. This device will also record your resting heart rate. You will be in a seated position for this measurement. These will be measured at weeks 0 and 12. If it is observed that your resting blood pressure is outside of a normal range you will be referred to your personal physician for further evaluation and follow-up care.
- D. Physical Activity (5 minutes): You will be asked to complete a brief structured interview to provide information about your physical activity patterns. This interview will involve a staff member asking you a series of questions related to your physical activity patterns over the past week. This intervention will take 10 minutes to complete. Completing the structured interview about your activity patterns will occur at week 0 and 12.
- E. Dietary Intake: You will be asked to complete a questionnaire about the types and amounts of food that you ate over the prior 6 months. You will also complete a questionnaire about your eating behaviors. These will be completed at week 0 and 12.

Weight Control and Exercise Procedures

After completing these assessments, if you are still eligible to participate, you will be randomly assigned to one of two interventions to assist you with your weight loss and exercise behaviors. Random assignment is similar to flipping a coin to determine the group that you will be in. These groups are described below:

A. Standard Behavioral Weight Loss Intervention:

1. Meetings and Contacts: You will attend weekly meetings for 12-weeks. Each group meeting will last 45-60 minutes. The intervention meetings will be held on the same night every week and the group will have approximately 15 to 25 members that will be dieting and participating in exercise to lose weight. These meetings will involve discussions with the staff and other members of the group about your diet and physical activity to help you to lose weight.
2. Diet: You will be placed on a diet that encourages you to decrease the amount of total calories and fat that you eat. If you are less than 200 pounds, you will be placed on a



1200 calorie per day diet. If you are 200-250 pounds, you will be placed on a 1500 calorie per day diet. If you are more than 250 pounds, you will be placed on an 1800 calorie per day diet. You will also be taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this information will be provided to the investigators weekly.

3. Exercise: You will be given a walking program for exercise. You will be instructed to exercise 5 days per week, with the duration on each day increasing from 15 to 40 minutes over the 12-week program. When you attend an intervention session at the Physical Activity and Weight Management Research Center you will also participate in an exercise session under the supervision of the investigators, and the remaining sessions will be performed on your own not under the supervision of the investigators. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. You will record your exercise in a diary, and this information will be provided to the investigators weekly.

B. Campaign Intervention:

1. Meetings and Contacts: You will attend two weekly meetings as described above for the Standard Behavioral Weight Loss Group at weeks 0 and 12. During the weeks you are not scheduled to attend in-person weekly meetings (weeks 1-11), you will receive two e-mail messages. The first e-mail message will include the behavioral lesson, goal assignments, and feedback on the group progress. The second e-mail will include individual feedback about your progress.
2. Diet: You will be placed on the same diet as described above for the Standard Behavioral Weight Loss Group; however, you will report the food that you eat each week via e-mail to a secured study e-mail address.
3. Exercise: You will be given an exercise program that is the same as described above for the Standard Behavioral Weight Loss Group; however, you will report your exercise each week via e-mail to a secured study e-mail address.
4. Prize-Based Point System: You will have the opportunity to earn points by reporting your diet and physical activity behaviors, and body weight diet via e-mail to a secured study e-mail address. At the final group meeting at week 12, tickets will be awarded based on your point totals and drawing for prizes will occur.

RISKS and BENEFITS:

The possible risks of this research study may be due to the exercise that you will be performing and the assessments that will be performed.



Risks

- A. Risks of Exercise Participation: There are moderate risks associated with participating in a regular exercise program. During exercise, you may experience a serious cardiac (affecting your heart) event, an arrhythmia (your heart beats at a pace that is not normal), or chest pain. An example of a cardiac event would be a heart attack or another medical condition that causes damage to your heart or cardiovascular system. The possibility of experiencing a serious cardiac event has been estimated to be approximately 6 per 10,000 in exercising adults. In addition, during exercise, you may experience an increase in heart rate, an increase in blood pressure, shortness of breath, general fatigue, and in some cases muscle soreness or injury to your muscle, bone, or joints. In the event that you experience a serious medical condition during your exercise session, the session will be stopped and appropriate emergency medical care will be provided. This may include providing CPR until Paramedics or other appropriate medical personnel arrive. Because some of the exercise sessions that you will be asked to do will not be supervised by the staff, the staff cannot provide medical assistance to you in the event of an emergency during these exercise sessions.
- B. Risk Associated with Completion of Questionnaires: You may experience non-physical risks such as boredom, frustration, stress, and time constraints when completing the questionnaires.
- C. Risks of Reducing Your Calorie and Fat Intake: Consuming a moderately low fat and low calorie diet appears to be safe and effective for weight loss. However, if you reduce your calorie or fat intake below recommended levels, you may experience dry skin and thinning of your hair. You may also experience problems with your gall bladder that may include symptoms such as intense abdominal pain that increases from a few minutes to hours, back pain, nausea or vomiting. Other symptoms may include bloating, gas, and indigestion.
- D. Risks Associated with Participating in the Group Intervention: Attending group sessions has been shown to be effective for weight loss. However, attendance at these sessions may involve you sharing information about yourself and your weight loss efforts to other group members. You can elect not to share this private information about yourself to other group members. Members of the group will be instructed to keep all information shared in the group sessions confidential. However, because the investigators cannot guarantee that all group members will keep this information confidential, there is risk that group members may share information about the group session with individuals not participating in this study.

There are also possible benefits of this research study that may be due to the exercises that you will be performing and the diet that will reduce the amount and types of foods that you will be eating. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study.



Benefits:

- A. Benefits of Exercise: The benefits of participating in an exercise program have been shown to include improvements in physical fitness, weight loss, improvements in blood pressure, and improvements in blood cholesterol levels. However, there is no guarantee that any or all of these changes will occur as a result of your participation in this study.
- B. Benefits of Reducing your Calorie and Fat Intake: Consuming a low fat and low calorie diet appears to be safe and effective for weight loss. Additional benefits of eating this type of diet can be improvements in blood pressure and improvements in blood cholesterol levels. However, there is no guarantee that any or all of these changes will occur as a result of your participation in this study.

If we should find out about a medical condition you were unaware of, with your written permission, this information will be shared with the doctor of your choice.

NEW INFORMATION:

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

COSTS and PAYMENTS:

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study. These costs will be paid by the sponsor of this research study.

You will be paid \$50 for completing the assessment at week 12. Thus, a total of \$50 can be earned for your participation in this study.

COMPENSATION FOR INJURY:

University of Pittsburgh researchers and their associates who provide services at the University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.



CONFIDENTIALITY:

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. In addition, all research databases will have password controlled access, and this will be controlled by the researchers. Only the researchers listed on the first page of this form and their staff will have access to your research records. However, other scientists may request data obtained by this study. We will allow data to be released to qualified researchers only after ensuring that your name and other identifying information is not given to these researchers. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

This research study will not involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g. physician office) records. The information that will be recorded will be limited to information concerning medical clearance from your physician to participate in this research study. This may include information related to coronary heart disease risk factors such as blood pressure, blood cholesterol, or other medical conditions that may increase the risk of heart disease and/or indicate that exercise participation may be unsafe for you. This information will be used to determine whether it is safe for you to participate in this research study.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.
- In unusual cases, your research records may be required to release identifiable information (which may include your identifiable medical record information) related to your participation in this research study in response to an order from a court of law. If the researchers learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.
- The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical record information) related to your participation in this research study for 7 years following the completion of this study, as per University policy, or when such is approved by the sponsor of this study, whichever should occur last.

RIGHT TO PARTICIPATE or WITHDRAW FROM PARTICIPATION:

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research



study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide the notice of this decision to the principal investigator listed on the first page of this form in one of the following ways: 1) provide a written and dated notice of this decision, or 2) send an email of this decision, or 3) contact the investigator by telephone to inform him of this decision. This written letter, email, or record of this telephone notice to withdraw your consent from the study will be retained by the investigator.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

It is possible that you may be removed from the research study by the researchers if, for example, your health status changes and it does not appear that it is safe for you to continue to reduce your food intake, participate in exercise, or lose weight. You will also be removed if you should become pregnant during this study.



VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed a listed investigator. I understand that I may contact the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature

Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any question the individual has about this study has been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Page 9 of 9



University Of Pittsburgh
Institutional Review Board

Approval Date: 4/10/2013
Renewal Date: 12/18/2013

IRB #: PRO12110211

APPENDIX F

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q)

Physical Activity Readiness Questionnaire (PAR-Q)

Subject ID: _____ Date: _____

Please read the questions carefully and answer each one honestly: check YES or NO

1. Has your doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?

Yes No

2. Do you feel pain in your chest when you do physical activity?

Yes No

3. In the past month, have you had chest pain when you were not doing physical activity?

Yes No

4. Do you lose your balance because of dizziness or do you ever lose consciousness?

Yes No

5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?

Yes No

6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

Yes No

7. Do you know of any other reason why you should not do physical activity?

Yes No

Reference: American Medical Association: Guides to the Evaluation of Permanent Impairment. AMA, Chicago, 1990.

APPENDIX G

GENERAL HEALTH AND HEALTH BEHAVIOR HISTORY

GENERAL HEALTH AND HEALTH BEHAVIOR HISTORY

Subject ID: _____ DATE: ____ / ____ / ____

1. Do you have or have you ever had any of the following medical conditions?

		Approximate Date of Diagnosis	Describe the Problem
a.	Heart Attack	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
b.	Angina (chest pain on exertion)	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
c.	Irregular Heart Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
d.	Other Heart Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
e.	Stroke	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
f.	Fainting Spells	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
g.	High Blood Pressure	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
h.	High Cholesterol	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
i.	Thyroid Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
j.	Cancer	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
k.	Kidney Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
l.	Liver Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
m.	Gout	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
n.	Diabetes	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
o.	Emotional/Psychiatric Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
p.	Drug/Alcohol Problems	<input type="checkbox"/> yes <input type="checkbox"/> no	_____

2. Do you have any medical problems that would prevent you from participating in a regular walking program? yes no

If yes, please describe the problem: _____

3. Have you participated in a regular exercise program over the past 6 months which consists of at least 20 minutes of activity, 3 days per week? yes no

Please describe: _____

4. Do you have to sleep with extra pillows or have to sit up in the middle of the night because of shortness of breath? yes no

5. Please list all medications that you are currently taking on a regular basis (make sure to indicate if you are taking medication for high blood pressure or cholesterol):

MEDICATION	REASON FOR TAKING
------------	-------------------

_____	_____
_____	_____
_____	_____

6. Over the last 6 months, on how many weekdays (Monday through Friday) do you usually drink wine, beer, or liquor on average?

- | | |
|---|--|
| (0) <input type="checkbox"/> Never | (4) <input type="checkbox"/> 2 days/week |
| (1) <input type="checkbox"/> Less than once/month | (5) <input type="checkbox"/> 3 days/week |
| (2) <input type="checkbox"/> 1-2 times/month | (6) <input type="checkbox"/> 4 days/week |
| (3) <input type="checkbox"/> 1 day/week | (7) <input type="checkbox"/> 5 days/week |

7. On those weekdays that you drink wine, beer, or liquor how many drinks do you have? _____

8. Over the last 6 months, on how many weekend days (Saturday and Sunday) do you usually drink wine, beer, or liquor?

- | | |
|---|--|
| (0) <input type="checkbox"/> Never | (4) <input type="checkbox"/> 1 weekend day/week |
| (1) <input type="checkbox"/> Less than once/month | (5) <input type="checkbox"/> 2 weekend days/week |
| (2) <input type="checkbox"/> 1-2 times/month | |

9. On those weekend days that you drink wine, beer, or liquor how many drinks do you have? _____

10. In the past year, have you regularly smoked cigarettes, pipes, cigars, or used chewing tobacco?

Please describe daily habit

Cigarettes	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
------------	--	-------

Pipe	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
------	--	-------

Cigars	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
--------	--	-------

Chewing Tobacco	<input type="checkbox"/> yes <input type="checkbox"/> no	_____
-----------------	--	-------

11. Do you plan to spend frequent time out of town on business or vacation during the next 3 months? yes no Please describe: _____

12. Is it possible that you will relocate in the next 3 months? yes no
If "yes", please describe: _____

WOMEN ONLY ANSWER THE FOLLOWING QUESTIONS

13. Are you currently pregnant? yes no

14. Were you pregnant within the past 6 months? yes no

15. Do you plan to become pregnant in the next 3 months? yes no

16. Have you gone through menopause or the change of life? yes no

17. Have you had a hysterectomy? yes no

18. When was your last menstrual period? DATE: _____ / _____ / _____

19. Do you take :

Birth Control Pills? yes no

Estrogens (ie. Premarin)? yes no

Progesterone (ie. Provera)? yes no

APPENDIX H

PHYSICIAN CONSENT

PHYSICIAN CONSENT TO PARTICIPATE IN A DIET AND EXERCISE PROGRAM AT THE UNIVERSITY OF PITTSBURGH

TO:	RETURN TO: (envelope provided)		
Physician's Name			David O. Garcia, MS
Address			University of Pittsburgh
City State Zip			Department of Health and Physical Activity
			Physical Activity and Weight Management
			Research Center
			2100 Wharton Street, Suite 600
			Pittsburgh, PA 15203
			Telephone: (412) 488-4184
			FAX: (412) 488-4174
Telephone Number			

Your patient _____ has asked to participate in a diet and exercise program at the University of Pittsburgh. This is a 12-week research study designed to help patients to change their eating and exercise habits and to examine the impact that this will have on weight loss. This will involve the following:

1. A walking program that will be primarily home-based. The exercise will gradually be progressed from 15 minutes per day to as much as 40 minutes per day, 5 days per week. Exercise intensity will be set at 60-70% of the patient's maximal heart rate.
 2. A diet program that will reduce energy intake to 1200-1800 calories per day, with dietary fat reduced to 20-30% of total energy intake.
 3. Behavioral modification techniques for changing eating and exercise behaviors.
 4. A list of additional factors that are exclusionary criteria for this study that you should consider are listed on the attached sheet.
-

Please indicate below if this program seems appropriate for your patient or if you see any contraindications for this patient's participation (please check the appropriate box below).

- I know of no contraindications to this patient participating in any of the above components of the program.
 I feel that this program would not be appropriate for this patient for the following reason(s):
-

Signature of Physician

Date

Please consider the following Inclusion and Exclusion Criteria as you evaluate whether your patient is capable of safely participating in the weight loss and exercise research study at the University of Pittsburgh.

Inclusion Criteria:	Exclusion Criteria:
<ul style="list-style-type: none">• Male or Female• 18 to 55 years of age• Body Mass Index (BMI) between $\geq 25.0 \text{ kg/m}^2$ to 45.0 kg/m^2• Ability to provide informed consent	<ul style="list-style-type: none">• Regular exercise participation of at least 20 minutes per day on at least 3 days per week during the previous six months.• Participation in a previous physical activity or weight management research project in the previous 6 months.• Weight loss of $\geq 5\%$ of current body weight in the previous 6 months.• For women, those currently pregnant, pregnant during the previous 6 months, or plan on becoming pregnant in the next 3 months.• History of myocardial infarction, coronary bypass surgery, angioplasty, or other heart-related surgeries.• History of orthopedic or physical complications that would prevent participation in exercise.• Currently taking any prescription medication that may affect metabolism and/or body weight (e.g., synthroid).• Currently being treated for any condition that could affect body weight, such as coronary heart disease, diabetes mellitus, uncontrolled hypertension, cancer, depression, and anxiety.• Currently being treated for any psychological issues or problems, taking any psychotropic medications, or receiving treatment with psychotropic medications within the previous 6 months.• Resting systolic blood pressure $\geq 150\text{mmHg}$ or diastolic blood pressure $\geq 100\text{mmHg}$. Subjects with controlled hypertension will be allowed to participate if they obtain a medical doctor's written consent to ensure that it is safe to participate in a weight loss intervention.• Currently do not have access to a computer and the Internet.

APPENDIX I

UNIVERSITY OF PITTSBURGH INSTITUTIONAL REVIEW BOARD APPROVAL LETTER



University of Pittsburgh Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: David Garcia, MS
From: Margaret Hsieh, MD, Vice Chair
Date: 1/14/2013
IRB#: [PRO12110211](#)
Subject: Feasibility of a Campaign Intervention Compared to a Standard Behavioral Weight Loss Intervention in Overweight and Obese Adults

At its full board meeting on 12/19/2012, the University of Pittsburgh Institutional Review Board, Committee H, reviewed the above referenced research study and approved it pending minor modifications. Your responses to these comments have been reviewed and the research submission, in its currently modified form, adequately addresses the concerns of the IRB and is therefore approved.

Please note the following information:

The IRB has approved the waiver for the requirement to obtain a written informed consent for the telephone screening process only.

The IRB has approved the advertisement that was submitted for review as written. As a reminder, any changes to the approved advertisement would require IRB approval prior to distribution.

The risk level designation is Minimal Risk.

Approval Date: 1/14/2013
Expiration Date: 12/18/2013

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

APPENDIX J

FOOD FREQUENCY QUESTIONNAIRE (FFQ)

FOOD QUESTIONNAIRE

TODAY'S DATE			
	DAY	YEAR	
○ Jan			
○ Feb			
○ Mar	①	2005	○
○ Apr	②	2006	○
○ May	③	2007	○
○ Jun	④	2008	○
○ Jul	⑤	2009	○
○ Aug	⑥	2010	○
○ Sep	⑦	2011	○
○ Oct	⑧	2012	○
○ Nov	⑨	2013	○
○ Dec	⑩	2014	○



ABOUT THIS SURVEY

This form is about the foods you usually eat.
It will take about 30 - 40 minutes to complete.
Please answer each question as best you can.
Estimate if you aren't sure.

- USE ONLY A NO. 2 PENCIL.
 - Fill in the circles completely, and erase completely if you make any changes.

Please write your name in this box.

ABOUT YOU

SEX

If female, are you pregnant or breast feeding?

No
 Yes
 Not female

AGE	WEIGHT pounds	HEIGHT ft. in.
(9) (0)	(4) (0) (0)	(0)
(1) (1)	(1) (1) (1)	(1)
(2) (2)	(2) (2) (2)	(2)
(3) (3)	(3) (3) (3)	(3)
(4) (4)	(4) (4) (4)	(4)
(5) (5)	(5) (5) (5)	(5)
(6) (6)	(6) (6) (6)	(6)
(7) (7)	(7) (7) (7)	(7)
(8) (8)	(8) (8) (8)	(8)
(9) (9)	(9) (9) (9)	(9)

INSTRUCTIONS

There are usually two kinds of questions to answer for each food:

- 1. HOW OFTEN**, on average, did you eat the food during the past year?
*Please DO NOT SKIP any foods. Mark "Never" if you didn't eat any of the food in the question.

2. HOW MUCH did you usually eat of the food?
*Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., ON THE DAYS YOU EAT IT.
*Sometimes we ask "how much" as A, B, C or D. **LOOK AT THE ENCLOSED PICTURES.**
For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat. (If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D= 2 cups.)

3. EXAMPLE: This person drank apple juice twice a week, and had one glass each time.
Once a week he ate a "C"-sized serving of rice (about 1 cup).

HOW OFTEN IN THE PAST YEAR								HOW MUCH ON THOSE DAYS					
	A FEW TIMES per YEAR	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY		SEE PORTION SIZE PICTURES FOR A-B-C-D				
Apple juice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶	How many glasses each time	<input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
Rice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶	How much each time	<input checked="" type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D

PLEASE DO NOT WRITE IN THIS AREA

A horizontal row of 20 small circles, used for stamping or marking. The 10th circle from the left is filled black, while all other circles are white.

35122

This section is about your usual eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. We will ask you about different TYPES (low-fat, low-carb) at the end of the survey. Include all types (like low-fat, sugar-free). Later you can tell us which type you usually eat.

	NEVER	A FEW TIMES PER YEAR	ONCE PER MONTH	2-3 TIMES PER MONTH	ONCE PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	EVERY DAY
Breakfast sandwiches with eggs, like Egg McMuffins	<input type="radio"/>								
Other eggs like scrambled, boiled or omelets (not egg substitutes)	<input type="radio"/>								
Breakfast sausage, including in sausage biscuits, or in breakfast sandwiches	<input type="radio"/>								
Bacon	<input type="radio"/>								
Pancakes, waffles, French toast or Pop Tarts	<input type="radio"/>								
Cooked cereals like oatmeal, grits or cream of wheat	<input type="radio"/>								
Cold cereals, ANY KIND, like corn flakes, fiber cereals, or sweetened cereals	<input type="radio"/>								
Milk or milk substitutes on cereal	<input type="radio"/>								
Yogurt or frozen yogurt	<input type="radio"/>								
Cheese, sliced cheese or cheese spread, including on sandwiches	<input type="radio"/>								

HOW MUCH ON THOSE DAYS

SEE PORTION SIZE PICTURES FOR A-B-C-D

How many sandwiches in a day	<input type="radio"/>	<input type="radio"/>	1	2
How many eggs a day	<input type="radio"/>	<input type="radio"/>	1	2
How many pieces	<input type="radio"/>	<input type="radio"/>	1	2
How many pieces	<input type="radio"/>	<input type="radio"/>	1	2
Which bowl	<input type="radio"/>	<input type="radio"/>	B	C
Which bowl	<input type="radio"/>	<input type="radio"/>	B	C
Which bowl	<input type="radio"/>	<input type="radio"/>	B	C
How many slices	<input type="radio"/>	<input type="radio"/>	1	2

How often do you eat the following foods all year round? Estimate your average for the whole year.

Bananas	<input type="radio"/>								
Apples or pears	<input type="radio"/>								
Oranges or tangerines	<input type="radio"/>								
Grapefruit	<input type="radio"/>								
Peaches or nectarines, fresh	<input type="radio"/>								
Other fresh fruits like grapes, plums, honeydew, mango	<input type="radio"/>								
Canned fruit like applesauce, fruit cocktail, canned peaches or canned pineapple	<input type="radio"/>								

How many each time	<input type="radio"/>	<input type="radio"/>	1/2	1
How many each time	<input type="radio"/>	<input type="radio"/>	1/2	1
How many each time	<input type="radio"/>	<input type="radio"/>	1/2	1
How much	<input type="radio"/>	<input type="radio"/>	A little	1/2
How many	<input type="radio"/>	<input type="radio"/>	1/2	1
How much	<input type="radio"/>	<input type="radio"/>	A	B
How much	<input type="radio"/>	<input type="radio"/>	A	B

How often do you eat each of the following 3 fruits, just during the summer months when they are in season?

Cantaloupe, in season	<input type="radio"/>								
Strawberries or other berries, in season	<input type="radio"/>								
Watermelon, in season	<input type="radio"/>								

How much	<input type="radio"/>	<input type="radio"/>	1/8	1/4	1/2
How much	<input type="radio"/>	<input type="radio"/>	A	B	
How much	<input type="radio"/>	<input type="radio"/>	A	B	
How much	<input type="radio"/>	<input type="radio"/>	A	B	

How often do you eat each of the following vegetables all year round, including fresh, frozen, canned or in stir-fry, at home or in a restaurant?

Broccoli	<input type="radio"/>								
Carrots, or mixed vegetables with carrots	<input type="radio"/>								
Corn	<input type="radio"/>								

How much	<input type="radio"/>	<input type="radio"/>	A	B
How much	<input type="radio"/>	<input type="radio"/>	A	B
How much	<input type="radio"/>	<input type="radio"/>	A	B

	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2-3 TIMES per WEEK	4-5 TIMES per WEEK	6-8 TIMES per WEEK	EVERY DAY	
Green beans or green peas	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Spinach (cooked)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Greens like collards, turnip greens, mustard greens	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Sweet potatoes, yams	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
French fries, home fries, hash browns	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Potatoes not fried, including mashed, boiled, baked, or potato salad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Cole slaw, cabbage, Chinese cabbage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Green salad, lettuce salad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Raw tomatoes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Salad dressing, any kind, regular or low-fat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Any other vegetable, like squash, cauliflower, okra, cooked peppers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Refried beans or bean burritos	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Pinto beans, black beans, chili with beans, baked beans	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Vegetable stew (without meat)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Vegetable soup, vegetable-beef soup, or tomato soup	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Split pea, bean or lentil soup	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Any other soup including chicken noodle, cream soups, Cup-A-Soup, ramen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Pizza	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Spaghetti, lasagna or other pasta <u>with</u> tomato sauce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Macaroni and cheese	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Other noodles like egg noodles, pasta salad, sopa seca	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Tofu or tempeh	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Meat substitutes like veggie burgers, veggie chicken, vegetarian hot dogs or vegetarian lunch meats	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Do you ever eat chicken, meat or fish?	<input type="radio"/> Yes	<input type="radio"/> No	IF NO, SKIP TO BREADS ON NEXT PAGE							
Hamburgers, cheeseburgers, at home or in a restaurant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
Hot dogs, or sausage like Polish, Italian or chorizo	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	▶
HOW MUCH ON THOSE DAYS SEE PORTION SIZE PICTURES FOR A-B-C-D										
How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How many <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much of the beans <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C Which bowl <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D Which bowl <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D Which bowl <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D Which bowl <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D How many slices <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 How much <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D How much <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D How much <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C How many patties or dogs <input type="radio"/> 1 <input type="radio"/> 2										

PLEASE DO NOT WRITE IN THIS AREA

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	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2-3 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY
Lunch meat like bologna, sliced ham, turkey bologna, or any other lunch meat	<input type="radio"/>								
Meat loaf, meat balls	<input type="radio"/>								
Steak, roast beef, or beef in frozen dinners or sandwiches	<input type="radio"/>								
Tacos, burritos, enchiladas, tamales, with meat or chicken	<input type="radio"/>								
Ribs, spareribs	<input type="radio"/>								
Pork chops, pork roasts, cooked ham (including for breakfast)	<input type="radio"/>								
Veal, lamb, deer meat	<input type="radio"/>								
Liver, including chicken livers or liverwurst	<input type="radio"/>								
Pigs feet, neck bones, oxtails, tongue	<input type="radio"/>								
Menudo, pozole, caldo de res, sancocho, ajiaco	<input type="radio"/>								
Any other beef or pork dish, like beef stew, beef pot pie, corned beef hash, Hamburger Helper	<input type="radio"/>								
Fried chicken, including chicken nuggets, wings, chicken patty	<input type="radio"/>								
Roasted or broiled chicken or turkey	<input type="radio"/>								
Any other chicken dish, like chicken stew, chicken with noodles, chicken salad, Chinese chicken dishes	<input type="radio"/>								
Oysters	<input type="radio"/>								
Shellfish like shrimp, scallops, crabs	<input type="radio"/>								
Tuna, tuna salad, tuna casserole	<input type="radio"/>								
Fried fish or fish sandwich	<input type="radio"/>								
Other fish, not fried	<input type="radio"/>								

BREADS

Biscuits, muffins, croissants (not counting breakfast sandwiches with eggs)	<input type="radio"/>								
Hamburger buns, hotdog buns, hoagie buns, submarines	<input type="radio"/>								
Bagels, English muffins, dinner rolls	<input type="radio"/>								
Tortillas (not counting those eaten in tacos or burritos)	<input type="radio"/>								
Corn bread, corn muffins, hush puppies	<input type="radio"/>								
Any other bread or toast, including white, dark, whole wheat, and what you have in sandwiches	<input type="radio"/>								
Rice, or dishes made with rice	<input type="radio"/>								

HOW MUCH ON THOSE DAYS SEE PORTION SIZE PICTURES FOR A-B-C-D

How many slices	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Which bowl	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many medium pieces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many pieces in a day	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many slices in a day	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How many in a day	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	NEVER	A FEW TMR YEAR	ONCE MTH	2-3 MTH	ONCE WEEK	2 TMR PER WEEK	3-4 TMR PER WEEK	5-6 TMR PER WEEK	EVERY DAY
Margarine (not butter) on bread or on vegetables	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Butter (not margarine) on bread or on vegetables	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Energy bars, like Power Bars, Clif bars, Balance, Luna, Atkins bars	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Breakfast bars, cereal bars, granola bars (not energy bars)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Peanuts, sunflower seeds, other nuts or seeds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Peanut butter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Snack chips like potato chips, tortilla chips, Fritos, Doritos, popcorn (not pretzels)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Crackers, like Saltines, Cheez-Its, or any other snack cracker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Jelly, jam	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Mayonnaise, sandwich spreads	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Catsup, salsa or chile peppers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Mustard, barbecue sauce, soy sauce, gravy, other sauces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Donuts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Cake, or snack cakes like cupcakes, Ho-Hos, Entenmann's, or any other pastry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Cookies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Ice cream, ice cream bars	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Chocolate syrup or sauce (like in milk or on ice cream)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Pumpkin pie, sweet potato pie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Any other pie including fast food pies or snack pies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Chocolate candy like candy bars, M&Ms, Reeses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Any other candy, not chocolate, like hard candy, Lifesavers, Skittles, Starburst	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					

HOW MUCH ON THOSE DAYS
SEE PORTION SIZE PICTURES FOR A-B-C-D

How many pats (tsp)	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
How many pats (tsp)	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
How many	<input type="radio"/> 1	<input type="radio"/> 2		
How many	<input type="radio"/> 1	<input type="radio"/> 2		
How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	
How many tablespoons	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D
How much	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	
How many tablespoons	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	
How many tablespoons	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
How many tablespoons	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
How many	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	
How many pieces	<input type="radio"/> 1 sm	<input type="radio"/> 1 med	<input type="radio"/> 2	<input type="radio"/> 3
How many	<input type="radio"/> 1-2	<input type="radio"/> 3-4	<input type="radio"/> 5-6	<input type="radio"/> 7+
How much	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D	
How many pieces	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	
How many pieces	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2	
How much	<input type="radio"/> 1 min	<input type="radio"/> 1 med	<input type="radio"/> 1 larg	<input type="radio"/> 1 king
How much	<input type="radio"/> 1-2 pcs	<input type="radio"/> 1/2 pkg	<input type="radio"/> 1 pkg	

	NEVER	A FEW TMR YEAR	ONCE MTH	2-3 MTH	ONCE WEEK	2 TMR PER WEEK	3-4 TMR PER WEEK	5-6 TMR PER WEEK	EVERY DAY
Glasses of milk (any kind, including soy), not counting on cereal or coffee	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Drinks like Slim Fast, Sego, Slender, Ensure or Atkins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Tomato juice or V-8 juice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Real 100% orange juice or grapefruit juice. Don't count orange soda or Sunny Delight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Apple juice, grape juice, pineapple juice or fruit smoothies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					

HOW MUCH
on the days you drink it?

How many GLASSES	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
How many CANS OR GLASSES	<input type="radio"/> 1	<input type="radio"/> 2	
How many GLASSES	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2
How many GLASSES	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2
How many GLASSES	<input type="radio"/> 1/2	<input type="radio"/> 1	<input type="radio"/> 2

	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY
Hi-C, Cranberry Juice Cocktail, Hawaiian Punch, Tang	<input type="radio"/>								
Drinks with some juice, like Sunny Delight, Knudsen	<input type="radio"/>								
Iced tea, homemade, instant, or bottled like Nestea, Lipton, Snapple, Tazo	<input type="radio"/>								
Kool-Aid, lemonade, sports drinks like Gatorade, or fruit flavored drinks (not including iced teas)	<input type="radio"/>								
Any kind of soft drink, like cola, Sprite, orange soda, regular or diet	<input type="radio"/>								
Beer or non-alcoholic beer	<input type="radio"/>								
Wine or wine coolers	<input type="radio"/>								
Liquor or mixed drinks	<input type="radio"/>								
Glasses of water, tap or bottled	<input type="radio"/>								
Coffee, regular or decaf	<input type="radio"/>								
Hot tea (not including herbal teas)	<input type="radio"/>								

HOW MUCH on the days you drink it?	
How many GLASSES	<input type="radio"/> 1/2 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3
How many GLASSES	<input type="radio"/> 1/2 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3
How many GLASSES OR BOTTLES	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
How much IN A DAY	<input type="radio"/> 1 glass <input type="radio"/> 1 20-ounce bottle <input type="radio"/> 2 glasses <input type="radio"/> 2 20-ounce bottles
How much IN A DAY	<input type="radio"/> 1 can <input type="radio"/> 1 20-ounce bottle <input type="radio"/> 2 cans <input type="radio"/> Big Gulp or 3 cans
How much IN A DAY	<input type="radio"/> 1 can <input type="radio"/> 2 cans <input type="radio"/> 3-4 cans or small pitcher <input type="radio"/> 6+ cans or large pitcher
How many GLASSES in a day	<input type="radio"/> 1/2 glass <input type="radio"/> 1 glass <input type="radio"/> 2 glasses or half bottle <input type="radio"/> 3 glasses
How many DRINKS	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4
How many GLASSES	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3-4 <input type="radio"/> 5+
How many CUPS	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4+
How many CUPS	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4+

What do you <u>usually</u> add to coffee? MARK ONLY ONE:
<input type="radio"/> Cream or half & half <input type="radio"/> Nondairy creamer <input type="radio"/> Milk <input type="radio"/> None of these <input type="radio"/> Don't drink it
What do you <u>usually</u> add to tea? MARK ONLY ONE:
<input type="radio"/> Cream or half & half <input type="radio"/> Nondairy creamer <input type="radio"/> Milk <input type="radio"/> None of these <input type="radio"/> Don't drink it
Do you usually add sugar (or honey) to coffee? <input type="radio"/> No <input type="radio"/> Yes IF YES, how many teaspoons each cup?
Do you usually add sugar (or honey) to tea? <input type="radio"/> No <input type="radio"/> Yes IF YES, how many teaspoons each cup?

	RARELY	1-2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	1 1/2 PER DAY	2 PER DAY	3 PER DAY	4+ PER DAY
About how many servings of vegetables do you eat, per day or per week, not counting salad or potatoes?	<input type="radio"/>								
About how many servings of fruit do you eat, not counting juices?	<input type="radio"/>								
How often do you use fat or oil in cooking?	<input type="radio"/>								

PLEASE DO NOT WRITE IN THIS AREA



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If you eat the following foods, what type do you usually eat? MARK ONLY ONE ANSWER FOR EACH QUESTION					
Milk	<input type="radio"/> Whole milk <input type="radio"/> Reduced-fat 2% milk	<input type="radio"/> Low-fat 1% milk <input type="radio"/> Non-fat milk	<input type="radio"/> Soy milk <input type="radio"/> Rice milk	<input type="radio"/> Don't drink	
Slim Fast, Sego, Slender or Ensure		<input type="radio"/> Low-Carb like Atkins	<input type="radio"/> Regular	<input type="radio"/> Don't drink	
Orange juice	<input type="radio"/> Calcium-fortified	<input type="radio"/> Not calcium-fortified	<input type="radio"/> I don't know	<input type="radio"/> Don't drink	
Soda or pop	<input type="radio"/> Diet soda, low-calorie	<input type="radio"/> Regular	<input type="radio"/> Don't drink		
Iced tea	<input type="radio"/> Homemade, no sugar <input type="radio"/> Homemade, w/sugar	<input type="radio"/> Bottled, no sugar	<input type="radio"/> Bottled, regular	<input type="radio"/> Don't drink	
Beer	<input type="radio"/> Regular beer <input type="radio"/> Light beer	<input type="radio"/> Low-Carb beer	<input type="radio"/> Non-alcoholic beer	<input type="radio"/> Don't drink	
Hamburgers or cheeseburgers		<input type="radio"/> Hamburgers	<input type="radio"/> Cheeseburgers	<input type="radio"/> Don't eat	
Hot dogs	<input type="radio"/> Low fat or turkey dogs	<input type="radio"/> Regular hot dogs	<input type="radio"/> Don't eat		
Lunch meats	<input type="radio"/> Low-fat or turkey lunch meats	<input type="radio"/> Regular lunch meats	<input type="radio"/> Don't eat		
Spaghetti or lasagna	<input type="radio"/> Meatless	<input type="radio"/> With meat sauce or meatballs		<input type="radio"/> Don't eat	
Cheese	<input type="radio"/> Low Fat	<input type="radio"/> Not Low Fat	<input type="radio"/> Don't eat		
Salad dressing	<input type="radio"/> Low-Carb	<input type="radio"/> Low-fat	<input type="radio"/> Regular	<input type="radio"/> Don't use	
Energy bars like Power Bar, Clif, Atkins	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Low-fat	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Breakfast bars, cereal bars, or granola bars	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Low-fat	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Bread	<input type="radio"/> 100% whole wheat	<input type="radio"/> Low-Carb	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Tortillas	<input type="radio"/> Corn	<input type="radio"/> Flour	<input type="radio"/> Don't know or don't eat		
Chocolate candy or chocolate candy bars	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Low-fat	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Cookies	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Low-fat	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Cake, snack cakes, and other pastries	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Low-fat	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Ice cream	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Low-fat or ice milk	<input type="radio"/> Regular	<input type="radio"/> Don't eat	
Jelly or jam	<input type="radio"/> Low-Carb, low sugar	<input type="radio"/> Regular	<input type="radio"/> Don't use		
Beef or pork	<input type="radio"/> Avoid eating the fat	<input type="radio"/> Sometimes eat the fat	<input type="radio"/> Often eat the fat	<input type="radio"/> Don't eat	
Chicken or Turkey	<input type="radio"/> Avoid eating the skin	<input type="radio"/> Sometimes eat the skin	<input type="radio"/> Often eat the skin	<input type="radio"/> Don't eat	
What kinds of fat or oil do you usually use in cooking? MARK ONLY ONE OR TWO					
<input type="radio"/> Don't know, or Pam	<input type="radio"/> Stick margarine	<input type="radio"/> Corn oil, vegetable oil	<input type="radio"/> Lard, fatback, bacon fat		
<input type="radio"/> Butter	<input type="radio"/> Soft tub margarine	<input type="radio"/> Olive oil or canola oil	<input type="radio"/> Crisco		
<input type="radio"/> Butter/margarine blend	<input type="radio"/> Low-fat margarine				
If you eat cold cereals, what do you eat? Choose one or two that you eat most often. (If you usually just eat one kind, just choose one.)					
<input type="radio"/> Low-carb cereals like Atkins, Low-Carb Special K	<input type="radio"/> Total <input type="radio"/> Fiber One	<input type="radio"/> Other fiber cereals like Raisin Bran, Fruit-n-Fiber			
<input type="radio"/> Cheerios, Grape Nuts, Shredded Wheat, Wheaties, Wheat Chex	<input type="radio"/> Product 19, Complete <input type="radio"/> All Bran, Bran Buds	<input type="radio"/> Sweetened cereals like Frosted Flakes, Froot Loops	<input type="radio"/> Other cold cereals, like Corn Flakes, Rice Krispies, Special K		

What vitamin supplements do you take fairly regularly?

Multiple Vitamins. Did you take...

Prenatal vitamins

Regular Once-A-Day, Centrum, Theragran, "senior" vitamins or house brands of multiple vitamins

Stress-tabs or B-Complex type

DIDN'T TAKE A FEW DAYS per MONTH	HOW OFTEN				FOR HOW MANY YEARS?					
	1-3 DAYS per WEEK	4-6 DAYS per WEEK	EVERY DAY		LESS THAN 1 YEAR	1 YEAR	2 YEARS	3-4 YEARS	5-9 YEARS	10+ YEARS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Single Vitamins, not part of multiple vitamins

Vitamin A (not beta-carotene)

Beta-carotene

Vitamin C

Vitamin E

Folic Acid, Folate

Calcium or Tums

Vitamin D, alone or combined with calcium

Zinc

Iron

Selenium

Omega-3, fish oil, flax seed oil

DIDN'T TAKE A FEW DAYS per MONTH	1-3 DAYS per WEEK	4-6 DAYS per WEEK	EVERY DAY		LESS THAN 1 YEAR	1 YEAR	2 YEARS	3-4 YEARS	5-9 YEARS	10+ YEARS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you took Once-a-day, Centrum or Thera-type multiple vitamins, did you usually take types that

contain minerals, iron, zinc, etc. do not contain minerals Don't know

If you took vitamin C, how many milligrams of vitamin C did you usually take, on the days you took it?

100 250 500 750 1000 1500 2000 3000+ Don't know

If you took vitamin E, how many IU's of vitamin E did you usually take, on the days you took it?

100 200 300 400 600 800 1000 2000+ Don't know

Did you take any of these supplements at least once a week?

Ginkgo St. John's Wort Echinacea DHEA Didn't take these
 Ginseng Kava Kava Melatonin Glucosamine/Chondroitin

SOME LAST QUESTIONS ABOUT YOU

Would you say your health is Excellent Very good Good Fair Poor

Are you currently trying to lose weight? Yes No

Was there ever a time in your life when you often drank more beer, wine or liquor than you do now? Yes No

Do you smoke cigarettes now? Yes No

IF YES, On average about how many cigarettes a day do you smoke now? 1-5 6-14 15-24 25-34 35+

Are you Hispanic or Latino Not Hispanic or Latino

What race do you consider yourself to be? (MARK ALL THAT APPLY)

White Asian Native Hawaiian or Other Pacific Islander
 Black or African American American Indian or Alaska Native Do not wish to provide this information

Thank you very much for filling out this questionnaire.
Please take a minute to go back and fill in anything you may have skipped.

PLEASE DO NOT WRITE IN THIS AREA



35122

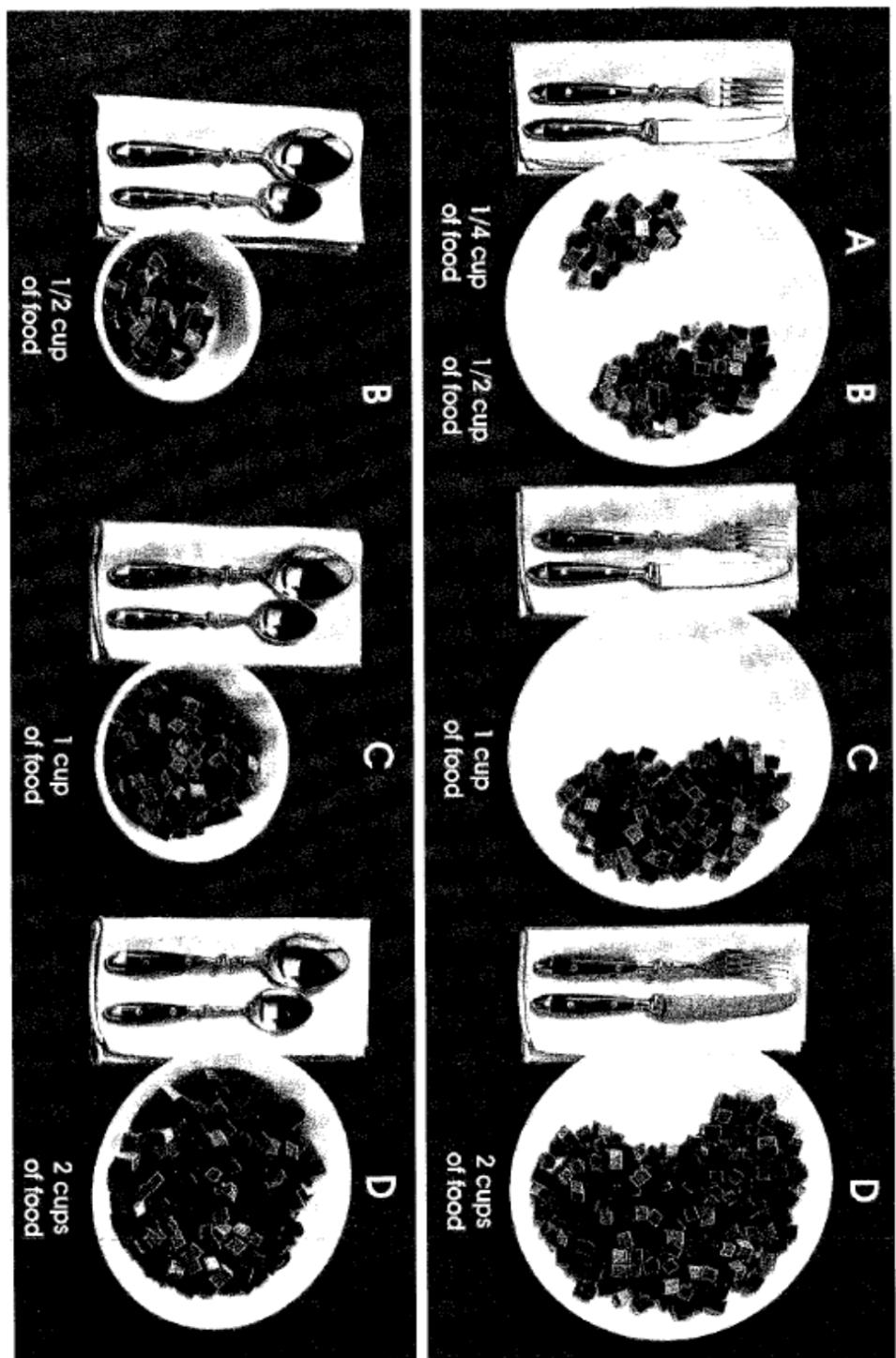
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FOOD QUESTIONNAIRE **Serving Size Choices**

Keep this in front of you while you are filling out The Food Questionnaire. You may use either the plates or the bowls to help you choose your serving size.

Choose A, B, C or D: **A** = 1/4 Cup of Food **B** = 1/2 Cup of Food **C** = 1 Cup of Food **D** = 2 Cups of Food



APPENDIX K

EATING BEHAVIOR INVENTORY (EBI)

Office Use Only	
Subject ID#:	
Assessment #:	

Eating Behavior Inventory

Directions: Check the number that best describes your behavior during the last 6 months.

	Never or Hardly ever	Some of the time	About half of the time	Much of the time	Always or almost always
A. I carefully watch the quantity of food that I eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
B. I eat foods that I believe will aid me in losing weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
C. I keep 1 or 2 raw vegetables available for snacks.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
D. I record the type and quantity of food which I eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
E. I weigh myself daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
F. I refuse food offered to me by others.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
G. I eat quickly compared to most other people.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
H. I consciously try to slow down my eating rate.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I. I eat at only one place in my home.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
J. I use the same placemat and other utensils for each meal.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
K. I eat and just can't seem to stop.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
L. I eat in the middle of the night.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
M. I snack after supper.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
N. My emotions cause me to eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
O. I buy ready-to-eat snack foods for myself.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
P. I shop when I'm hungry.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Q. I shop from a list.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
R. I leave food on my plate.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
S. I serve food family style (serve from bowls on table).	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
T. I watch TV, read, work, or do other things while I eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
U. If I'm served too much, I leave food on my plate.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
V. Generally, while I'm at home, I leave the table as soon as I finish eating.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
W. I keep a graph of my weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
X. I eat when I'm not really hungry.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Y. I store food in containers where it is not readily visible or in a closed cupboard.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Z. I decide ahead of time what I will eat for meals and snacks.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

APPENDIX L

PAFFENBARGER PHYSICAL ACTIVITY QUESTIONNAIRE (EXERCISE HABITS)

Office Use Only
Subject ID#:
Assessment #:

EXERCISE HABITS

1. Was there anything about the past week that made exercising especially different for you in terms of extended illness, injury, or vacation?

Yes No

*If "NO", please complete this questionnaire about this past week.

*If "YES", please complete this questionnaire about the previous week.

2. First, we are interested in the number of flights of stairs you climbed on average **EACH DAY** in this past week. We only want to know the number of flights you climb going UP - not down.

One Flight = 10 steps if you know the number of steps.

Flights per day

3. Next, we want to know how many city blocks or their equivalent you walked on average **EACH DAY** in this past week. We are only interested in walking done out of doors and walking done indoors for the sole purpose of exercise. We do not want walking done around the house or at work.

Consider that 12 city blocks = 1 mile.

Blocks per day

4. Were there any sports, fitness, or recreational activities in which you participated during the past week? We are interested only in time that you were physically active.

(Note: all walking should only be included in Question 3)

Sport, Fitness, or Recreation	Times per Week	Average Time per Episode	Office Use Only
a.	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Minutes	<input type="checkbox"/>
b.	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Minutes	<input type="checkbox"/>
c.	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Minutes	<input type="checkbox"/>
d.	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Minutes	<input type="checkbox"/>

5. Would you say that during the past week (the week used for questions 2-4) you were:

- less active than usual
- more active than usual
- about as active as usual

6. At least once per week, do you engage in regular activity akin to brisk walking, jogging, bicycling, etc. long enough to work up a sweat, get your heart thumping, or get out of breath?

Yes times per week; Activity: _____

No

7. On a usual weekday and a weekend day, how much time (to the nearest 1 hour) do you spend on the following activities? *The total for each day should add to 24 hours*

Sport, Fitness, or Recreation	Usual Weekday Hours per Day	Usual Weekend Day Hours per Day
a) Vigorous Activity (digging in the garden, strenuous sports, jogging, aerobic dancing, sustained swimming, brisk walking, heavy carpentry, bicycling on hills, etc.)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
b) Moderate Activity (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
c) Light Activity (office work, driving car, strolling, personal care, standing with little motion, etc.)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
d) Sitting Activity (eating, reading, desk work, watching TV, computer work, listening to the radio, etc.)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
e) Sleeping or reclining	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

APPENDIX M

WEIGHT EFFICACY LIFESTYLE QUESTIONNAIRE (WEL)

Office Use Only	
Subject ID#:	
Assessment #:	

Directions: Read each situation listed below and decide how confident (or certain) you are that you will able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to eat.

I AM CONFIDENT THAT:	Not Confident at all										Very Confident
1. I can resist eating when I am anxious (or nervous).	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
2. I can control my eating on the weekends.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
3. I can resist eating even when I have to say "no" to others.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
4. I can resist eating when I feel physically run down.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
5. I can resist eating when I am watching TV.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
6. I can resist eating when I am depressed (or down).	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
7. I can resist eating when there are many different kinds of foods available.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
8. I can resist eating even when I feel it's impolite to refuse a second helping.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
9. I can resist eating even when I have a headache.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
10. I can resist eating when I am reading.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
11. I can resist eating when I am angry (or irritable).	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
12. I can resist eating even when I am at a party.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
13. I can resist eating even when others are pressuring me to eat.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
14. I can resist eating when I am in pain.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
15. I can resist eating just before going to bed.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
16. I can resist eating when I have experienced failure.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
17. I can resist eating even when high calorie foods are available.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
18. I can resist eating even when I think others will be upset if I don't eat.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
19. I can resist eating when I feel uncomfortable.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	
20. I can resist eating when I am happy.	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	

APPENDIX N

TREATMENT SELF-REGULATION QUESTIONNAIRE (TSRQ)

CONCERNING ENTERING A WEIGHT LOSS PROGRAM

Directions: There are a variety of reasons why patients decide to enter a weight-loss program such as this and follow its procedures. The items on this questionnaire are broken into four groups. Please read the statement at the beginning of each group and then consider the reasons that follow it in terms of how true that reason is for you.

	Not at all True	Somewhat True		Very True
A. I decided to enter this weight-loss program because:				
1. I won't like myself very much until I lose weight.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
2. People will like me better when I'm thin.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
3. It feels important to me personally to be thinner.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
4. I really want to make some changes in my life.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
B. If I remain in treatment it will probably be because:				
5. I'll feel like a failure if I don't.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
6. People will think I'm a weak person if I don't.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
7. I'll feel very bad about myself if I don't.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
8. Others will be angry at me if I don't.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
9. I feel like it's the best way to help myself.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
C. I plan to lose weight because:				
10. I'll be ashamed of myself if I don't.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
11. I'll hate myself if I can't get my weight under control.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
12. My friends/family don't like the way I look.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
13. Being overweight makes it hard to do many things.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
D. I have agreed to follow the procedures of the program because:				
14. I am worried that I will get in trouble with the staff if I don't follow guidelines.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
15. I'll feel guilty if I don't comply with all the procedures.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
16. I want others to see that I am really trying to lose weight.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
17. I believe that they will help me to solve my problem.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			
18. It's important for me that my efforts succeed.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7			

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Subject ID#:	
Assessment #:	

Treatment Questionnaire Concerning Entering the Weight Loss Program

APPENDIX O

TREATMENT SELF-REGULATION QUESTIONNAIRE (TSRQ)

CONCERNING CONTINUED PROGRAM PARTICIPATION

Treatment Questionnaire Concerning Continued Program Participation

Directions: The following questions relate to your reasons for continuing to participate in the weight-loss program. Different people have different reasons for continuing in such a program, and we want to know how true each of these reasons is for you. There are two groups of questions. The questions in each group pertain to the sentence that begins that group. Please indicate how true each reason is for you, using the following scale:

	Not at all True		Somewhat True		Very True
A. I have remained in treatment because:	<input type="checkbox"/>				
1. I would have felt bad about myself if I didn't.	<input type="checkbox"/>				
2. Others would have been angry at me if I didn't.	<input type="checkbox"/>				
3. I would have felt like a failure if I didn't.	<input type="checkbox"/>				
4. I feel like it's the best way to help myself.	<input type="checkbox"/>				
5. People would think I'm a weak person if I didn't.	<input type="checkbox"/>				
6. I have chosen not to leave this program.	<input type="checkbox"/>				
7. It is a challenge to accomplish my goal.	<input type="checkbox"/>				
8. I have invested so much money in this program.	<input type="checkbox"/>				
B. I have been following the procedures of the program because:	<input type="checkbox"/>				
9. I believe they help me solve my problem.	<input type="checkbox"/>				
10. I have been worried that I would get in trouble with the staff if I didn't follow all the guidelines.	<input type="checkbox"/>				
11. I want others to see that I am really trying to lose weight.	<input type="checkbox"/>				
12. It is important to me that my efforts succeed.	<input type="checkbox"/>				
13. I feel guilty if I don't comply with all the procedures.	<input type="checkbox"/>				

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Assessment #:

APPENDIX P

TREATMENT SATISFACTION SURVEY

Satisfaction Survey

Instructions

Please tell us how satisfied you are overall with the weight management program. We want to know your honest opinions, whether they are positive or negative. Please rate only your satisfaction with the program itself, not the research measures we also had you complete (e.g., lab visits, surveys, etc).

1a. How satisfied are you overall with the weight management program?								
1 Very dissatisfied	2 Somewhat dissatisfied	3 Somewhat satisfied	4 Very satisfied					
<i>1b. If you were "Very dissatisfied" or "Somewhat dissatisfied" with the program please tell us why:</i>								
2a. Would you recommend the weight management program you received to others?								
1 Definitely not	2 Probably not	3 Probably would	4 Definitely would					
<i>2b. If you would "Definitely not" or "Probably not" recommend the program to others, please tell us why:</i>								
3. Given the effort you put into following the weight management program, how satisfied are you with your overall progress over the past 12 weeks? (please circle one)								
-4 Very dissatisfied	-3	-2	-1	0 Neither satisfied nor dissatisfied	1	2	3	4 Very satisfied
4. Given the effort you put into following the weight management program over the past 12-weeks, how satisfied are you overall with your progress on...								
4a. Changing your weight:								
-4 Very dissatisfied	-3	-2	-1	0 Neither satisfied nor dissatisfied	1	2	3	4 Very satisfied
4b. Changing your dietary habits:								
-4 Very dissatisfied	-3	-2	-1	0 Neither satisfied nor dissatisfied	1	2	3	4 Very satisfied
4c. Changing your physical activity habits:								
-4 Very dissatisfied	-3	-2	-1	0 Neither satisfied nor dissatisfied	1	2	3	4 Very satisfied

APPENDIX Q

PARTICIPANT REASONS FOR PROGRAM DISSATISFACTION

Question	SBWL Comments	CI Comments
1. How satisfied are you overall with the weight management program?	<ul style="list-style-type: none">Recording meal calories is not feasible with homemade, ethnic dishes.	<ul style="list-style-type: none">The booklets are way too small to write everything in for complex meals. It was hard to find calories/fat count for things.I feel it would have been more effective in the group treatment.I didn't put in any effort into it, so I didn't get anything out of it.
2. Would you recommend the weight management program you received to others?	<ul style="list-style-type: none">Not recommended for busy persons.	<ul style="list-style-type: none">There isn't enough support.

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