WEIGHT LOSS: EXPLORING SELF- REGULATION THROUGH MINDFULNESS MEDITATION

by

Kathleen C. Spadaro

B.S.N., Marymount University, 1981

M.Ed., University of Virginia, 1987

Submitted to the Graduate Faculty of School of Nursing in partial fulfillment of the requirements for the degree of Doctor of Philosophy

University of Pittsburgh

UNIVERSITY OF PITTSBURGH

SCHOOL OF NURSING

This dissertation was presented

by

Kathleen C. Spadaro

It was defended on

July 24, 2008

and approved by

John M. Jakicic, PhD, Dept of Health & Physical Activity

Susan M. Sereika, PhD

Rebekah Hamilton, PhD, RN

Dissertation Advisor: Susan M. Cohen DSN, APRN, FAAN

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Increasing rates of overweight/obese adults, with corresponding increases in health risks, obesity-related illnesses, and health costs have not been significantly impacted despite research and commercial attempts to provide recommended weight loss strategies. Mindfulness Meditation (MM) teaches individuals to increase their awareness in the present moment which may offer an additional strategy to weight loss interventions. This study explored the effects of MM combined with standard behavioral weight loss intervention (SBWP) on short-term weight loss, physical activity, eating behaviors, food intake and mindfulness in overweight/obese adults. Additionally, adherence, feasibility and acceptability of MM were explored through retention, attendance, diary return rate, MM practice and qualitative interviewing.

This exploratory mixed methods study was a 24 week randomized controlled trial that compared SBWP and Standard Behavioral Weight Loss Program plus Mindfulness Meditation (SBWP+MM) followed by a qualitative interview that explored the experiences of 12 SBWP+MM participants. The sample which was randomized between treatment groups included 46 overweight/obese, 87% female, mean age 45.2 years (SD=8.2), mean weight 91.9 kg. (SD=12.8), 21.7% African American, and 78% college-educated adults living in the Pittsburgh area. Outcome measures of weight, physical activity, eating behavior, food intake and mindfulness were explored at three time points. Data analysis was based on intention-to-treat with linear mixed effects modeling and general linear modeling.

Thirty-five subjects (76%) completed the study. Mean total weight loss was 5.48 kg (SD=2.01) with a significant decrease in food intake (p<.00) and significant increase in physical activity and healthy eating behaviors (p<.000). There was a mean greater weight loss in the SBWP+MM group (6.89kg compared to 4.07kg). Only eating behaviors significantly improved in the SBWP+MM group based on the results of linear mixed effects modeling (p=.034). The SBWP+MM group had higher rates of retention (86.4%) and attendance (75%) and a difference in diary return (15 weeks versus 12 weeks). The overarching SBWP+MM qualitative theme of expanding mindfulness in personal life flowed from taking time intentionally for self to lifestyle changes.

The exploratory results, eating behavior significance and other outcome differences in the SBWP+MM group suggest that a larger sample size over a longer period of time may find further statistical and clinical significance. In light of the current obesity epidemic, hypothesis testing of MM could lead to enhanced weight loss interventions for this overweight/obese population.

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PREFACE

The loving support of my husband, Dallas, my children, Ben, Katie and Stacy, my parents and extended family made this challenge and opportunity obtainable and successful.

With gratitude to Dr. Susan Cohen, my mentor, who kept me focused and "breathing" over the past three years, to Dr. John Jakicic, who believed in my ideas and gave me the opportunity to investigate them, to Dr. Susan Sereika, who assisted in "making statistical sense" of the data, and to Dr. Rebekah Hamilton, who walked me through the qualitative component.

To my doctoral student colleagues who shared the three years of the coursework and dissertation process, I wish each of you educational, professional and personal success.

1.0 PROPOSAL INTRODUCTION

Increasing rates of overweight/obese adults, with corresponding increases in health risks, obesity-related illnesses, and health costs have not been significantly impacted despite research and commercial attempts to provide recommended weight control strategies. This exploratory sequential mixed method study proposes to add mindfulness meditation (MM) to a standard behavioral weight loss intervention to examine if MM will enhance short-term weight loss in overweight and obese adults. A 24 week randomized control trial will consist of the two following intervention approaches: 1) Standard Behavioral Weight Loss Program (SBWP) and 2) Standard Behavioral Weight Loss Program plus Mindfulness Meditation (SBWP+MM). A qualitative interview will used to explore the SBWP+MM participants' experience.

The specific aims are: 1) to explore the effects of a mindfulness meditation intervention added to the standard behavioral weight loss program on weight loss (primary), dietary intake, eating behaviors and physical activity (secondary) compared to a standard behavioral weight loss intervention; 2) to explore the feasibility and acceptability of the SBWP+MM; and 3) to understand the participants' experience of being in the SBWP+MM group.

Approximately 60 overweight/obese adults will be recruited and randomized into the two groups. Assessments of: weight loss, dietary intake, eating behavior, physical activity, mindfulness, and feasibility and acceptability (attendance, diary completion, retention rate, and

for the SBWP+MM group, MM practice in minutes/week) will occur at baseline, 12 weeks and 24 weeks. Qualitative interviews will be completed on 15-18 consented SBWP+MM participants at week 24.

Quantitative analyses will be performed with the type 1 error rate at 0.05. Mixed effects models will be fitted to explore the differences in weight loss and the other outcome measures, feasibility and acceptability measures, between intervention groups. Qualitative data will be analyzed using the interpretative description method.

1.1 SPECIFIC AIMS

The prevalence of obesity has consistently increased over the past three decades. Current estimates indicate that in excess of 65% of adults in the United States are overweight (body mass index (BMI)>25.0 kg/m²) with at least 30% of those adults classified as obese (BMI >30 kg/m²). Overweight and obesity have been linked to numerous chronic diseases including cardiovascular disease, diabetes, many forms of cancer, and numerous musculoskeletal problems (Vaidya, 2006). This has resulted in obesity-related conditions accounting for approximately 7% of total health care costs in the United States, and it is estimated that the cost of obesity is in excess of \$100 billion annually (Colditz, 1999; Finkelstein, Fiebelkorn, & Wang, 2003; Weiss, Galuska, Khan, & Serdula, 2006).

While numerous studies have examined various weight loss interventions, the standard behavioral weight loss intervention, combining dietary reduction of calories and fat grams and increasing physical activity, consistently reports successful short-term results. Standard behavioral weight loss interventions typically result in weight loss of ~9-10 kg (7-10% of initial

body weight) for ~70% of the participants within the initial 3-6 months of treatment which is sufficient to reduce chronic disease risk factors and positively impact health (Gallagher, Jakicic, Napolitano, & Marcus, 2006; Jakicic, Marcus, Gallagher, Napolitano, & Lang, 2003; Pi-Sunyer, 1996; Shaw, O'Rourke, Del Mar, & Kenardy, 2005; Thomas, Jakicic, & Gallagher, 2004). To add to the weight control complexity, for the 30% who do not lose the weight necessary for health improvement and for the 70% who do lose sufficient weight, the incidence of weight regain is common (Jeffrey et al., 2000). Thus, it is important to continue to develop effective intervention strategies to address the obesity epidemic and to increase the percentage of individuals who respond favorably to short-term behavioral weight loss interventions.

Successful weight loss individuals may have better self-regulation skills. When they apply the standard weight loss practices of reduced dietary intake, increased physical activity, and self-monitoring, their internal systems that regulate weight, such as feedback loops for appetite and satiety may self-correct and override "bad" habits. Individuals who have a less than optimal response to standard behavioral weight loss interventions may not experience the physiological cues (hunger pains or a sense of fullness after eating due to disordered feedback loops for hunger and satiety cues) or other self-regulatory weight control processes. These individuals experience a lack of feedback signal to start or stop eating. In the absence of diminished physiological cues, emotional or external cues may lead to patterns of overeating and frequent eating (Kristeller & Rodin, 1989). They may be distracted by external cues that increase caloric consumption through fast food, convenience foods, increased plate and portion size (Blair & Leermakers, 2002). This disregulation could then negatively affect the response to a behavioral weight loss intervention, and may explain why some individuals are non-responsive to this type of intervention.

Feedback loops support self-regulation, an internal process that affects the health of an individual (Schwartz, 1975). Self-regulation supports the internal systems to maintain stable functioning and to adapt to change as needed (Shapiro & Schwartz, 2000). When there is a disorder of a specific self-regulation domain, the health of the individual may be at risk (Bandura, 2005). Disregulation may occur when inner signals are ignored or suppressed (e.g. binge eating, overeating, or not eating for long periods of time). To re-establish connection to improve health, there needs to be communication between the components of the feedback loops in the self-regulation system. It is necessary for the individual to intentionally focus attention to the body, mind, thoughts, emotions, and behaviors (Schwartz, 1984).

Mindfulness meditation has been used in multiple studies to improve self-regulation (Brown & Ryan, 2003). Mindfulness is the ability to have conscious intentional self-regulation (Kabat-Zinn, 1982). Goleman and Schwartz (1977) have described mindfulness meditation as the intentional self-regulation of attention from moment to moment. Mindfulness can be learned, leading to improved self-regulation through increased awareness of hunger and satiety cues and decreased reactivity to emotional, cognitive and external triggers. This pilot study proposes to add mindfulness meditation to a standard behavioral weight loss intervention to examine if this will enhance short-term weight loss in overweight and obese adults. To our knowledge, there has been no published research examining mindfulness meditation within the context of a weight loss intervention.

The proposed study is a quantitative and qualitative mixed method design with the primary focus on the quantitative method. The specific quantitative aims are:

1. To explore the effect of a mindfulness meditation intervention added to the standard behavioral weight loss program on weight loss (primary outcome) and dietary intake,

 To explore the adherence, acceptability, and feasibility of the addition of mindfulness meditation to a standard weight loss intervention through attendance, retention, diary completion rates and mindfulness meditation practice.

The specific qualitative aim is:

3. To understand the participants' perceptions of their experience in the mindfulness meditation with standard weight loss intervention group (SBWP+MM).

While this pilot, feasibility study has not been designed to conduct formal hypothesis testing, several hypotheses will be explored. It is hypothesized that an increase in mindfulness (secondary outcome) through MM will result in greater weight loss, improvements in eating behaviors, reductions in dietary intake and greater physical activity when compared to a standard behavioral weight loss program. It is hypothesized that the addition of mindfulness meditation will be as or more acceptable and feasible to participants when compared to a standard behavioral weight loss program.

The qualitative component will provide specific information from the SBWP+MM group to either support a quantitative finding of effect on weight loss with participant data identifying components of the mindfulness meditation intervention that impacted their weight loss efforts or if an insignificant effect is found, what in the intervention may not be effective or could be modified for further exploration.

1.2 BACKGROUND AND SIGNIFICANCE

1.2.1 Study Framework

The conceptual framework comes from the mindfulness model, Intentional Attention and Attitude (IAA), evolving from self-regulation theory and systems theory, with the addition of intention (Shapiro & Schwartz, 2000). Self-regulation theory supports the numerous internal human systems through regulation of feedback loops to achieve specific goals such as weight control. When change is introduced to the system, the system adapts to change with focused attention on the feedback process to bring about self-regulation (Shapiro & Schwartz, 2000). Feedback loops give the individual the information needed to either maintain an internal, healthy balance or to make changes needed to adapt to a new situation to create a new homeostasis. An example of a change in the self-regulation system of weight control might be weight loss from an extended illness that diminished the appetite cue, thus reduced dietary intake. As the individual recovers from the temporary illness, the appetite cue increases, the individual eats more, and weight is regained, returning to a stable weight.

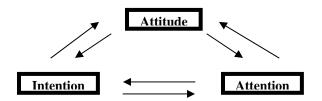


Figure 1: IAA Mindfulness Model that depicts the on-going interaction between the components of mindfulness: intention, attention, and attitude.

Shapiro and Schwartz (2000) describe their model as having a foundation of intention, with the systems theory of interconnectedness of all the parts (hence the arrows in both directions in Figure 1. the Mindfulness Model (IAA), and the need for all living things to maintain inner balance and order through their ability to self-regulate. The three components defined in the IAA mindfulness model include intention defined as "on purpose", attention as "paying attention" and attitude as "in a particular way" (Shapiro, Carlson, Astin, & Freedman, 2006).

The IAA Mindfulness Model provides a comprehensive and integrative approach to selfregulation and health, and replaces the simplistic stress reduction and symptom reduction approach towards improving health (Shapiro et al., 2006). Through mindfulness, the individual consciously (intention) brings awareness (attention) to the present moment with acceptance and openness (attitude). Using weight loss as an example in applying the mindfulness model, individuals have an "intention" to lose weight or maintain a healthy weight, with an increased awareness or "attention" to their dietary intake, eating behaviors, physical activity, moods and thoughts that may affect these behaviors, and their environment. Their "attitude" can support their intention and attention by being open, non-judgmental, accepting, and compassionate towards the self, allowing for the potential to change unhealthy dietary intake, eating behaviors, and sedentary habits.

Described in Shapiro and Schwartz's earlier work (2000), intention and attention enhance the feedback loops of self-regulation to create or improve health:

intention \rightarrow attention \rightarrow connection \rightarrow regulation \rightarrow order \rightarrow health. Through further concept exploration, a third axiom of mindfulness, attitude, was added (Shapiro et al., 2006). (See Figure 2).

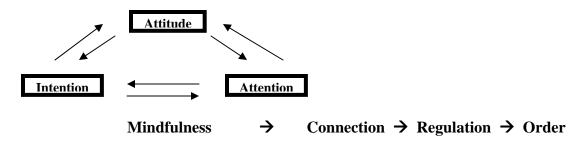


Figure 2: IAA Mindfulness Model applied to the self-regulation of health

Using Shapiro et al.'s work on mindfulness and self-regulation (2006), Figure 2 outlines the potential impact of mindfulness in the self-regulation mechanism of healthy weight. The three components of mindfulness start the process and each of the three components can affect each other. The intention is to achieve or maintain a healthy weight. Attention is focused the physiological (hunger and satiety cues), cognitive (negative, neutral, or positive thoughts about food or physical activity), emotional (depressed, anxious, excited), environmental (visual food choices), and interpersonal (self-esteem, body image, peer pressure) domains in the present moment. Attitude (accepting, non-judging, compassion, and openness) affects both intention and attention in the present moment as well as can be affected by intention and attention.

Connection is made between the thoughts, feelings, body cues and sensations, environmental influences, and interpersonal experiences to distinguish between the habitual reaction and a conscious, chosen response. Regulation occurs when hunger/satiety cues are responded to by healthy choices to eat or stop eating and when emotional, cognitive, other physiological, environmental, and interpersonal cues are not "fed" by reactive behaviors, but rather by alternative healthy responses. The natural order of the body systems and functions occur when the habitual reactions are replaced with on-going, lifestyle changes in dietary intake, healthy eating behaviors, and increased physical activity. Health improves with a reduction and maintenance of weight loss, sense of inner control, mood improvement, and increased coping through healthy choices that replace unhealthy habits.

1.2.2 Review of Related Literature

The literature review focuses on the variables to be studied: weight loss with dietary reduction, eating behavior changes, and physical activity increases; mindfulness; and feasibility and acceptability of weight loss interventions.

1.2.2.1 Weight Loss with dietary intake, eating behaviors, and physical activity. Body weight regulation involves a balance between dietary intake and energy expenditure (resting, thermal, and physical activity) to maintain a steady state. In order for an overweight or obese adult to lose weight, dietary intake needs to be reduced and energy expenditure needs to increase. The biological mechanisms for body weight regulation are complex with numerous research studies exploring body weight with the various physiological components (Chua & Leibel, 2002). These components include but are not limited to the hypothalamus for regulating satiety and eating and skeletal muscle mass with altered body composition and brown adipose tissue (BAT) stimulated by the sympathetic nervous system to assist in the maintenance of a constant White adipose tissue (WAT) affects the regulation of metabolic rate and leptin weight. deficiency from WAT increases intake, decreases thermal energy expenditure, and increases preferential fat deposition. The central nervous system also plays a role in the self-regulatory process of weight control with dopamine increases reducing intake, impaired serotonin pathways that produce weight gain through hyperphagia, and gut factors that impact satiety signals. Impaired feedback loops and self-regulatory pathways that affect dietary intake, energy

expenditure, hyperphagia, low metabolic rate, low rate of fat oxidation, and impaired sympathetic nervous system can contribute to overweight or obesity (Chua & Leibel, 2002).

Obesity poses a significant health crisis in the United States with approximately 50% of the overweight/obese population attempting to lose weight. Yet only 20% of those trying to lose weight actually classify themselves as successfully losing weight and there are high rates of weight regain within the first year (Jeffery et al., 2000; Wing & Phelan, 2005). The National Center for Health Statistics using NHANES 2002 data shows a 65.2% rate of overweight and obese adults in the United States with 30% of those adults being obese (Ogden, Carroll, Curtin, McDowell, & Tabak, 2006). These rates are despite the ~\$50 billion a year spent on weight-loss products and services in this country (Weiss et al., 2006).

The negative physiological health consequences of obesity are well documented and include type II diabetes, cardiovascular disease, breast and colon cancer, gall bladder disease and high blood pressure (Finkelstein et al., 2003). The total health care cost related to overweight and obesity was as high as \$92.6 billion in 2002 (Finkelstein et al., 2003). Other national costs of obesity include more than \$218 million on lost productivity of workdays, physician office visits, restricted activity days, and bed-related days. There is an increased prevalence (40-60%) of psychiatric morbidity, usually depression, among obese individuals seeking treatment, possibly from physical complications and limitations, social stigma and bias (Vaidya, 2006). Women, who are restrictive in dietary habits, may be at higher risk for stress-induced eating, obesity and dysphoria from constant weight control pressure (Wadden, Berkowitz, Womble, Sarwer, Phelan, Caton, et al., 2005). Emotional overeating has been found to be positively associated with binge eating, depression and eating disorders (Masheb & Grilo, 2006).

Many studies support the behavioral interventions of low fat diet, increased regular exercise and self-monitoring for successful weight loss demonstrated over the last 20 years (Jakicic et al., 2003; Jeffery, Wing, Sherwood, & Tate, 2003; Knowler, Barrett-Connor, & Fowler, 2002; Shaw et al., 2005; Slentz et al., 2004; Weiss, et al., 2006). Standard behavioral interventions have maximal weight loss occurring around 6 months (~10%) with some weight regain within the first year (Wing, 2002). Physical activity studies have shown that increasing minutes of physical activity from 100 minutes/week to 200-300 min/week also impacts weight loss with levels of physical activity >200 minutes/week resulting in 13.1kg weight loss, 150-200 minutes/week in 8.5 kg. weight loss or < 150 minutes/week in 3.5 kg. weight loss (Jakicic, Winters, Lang, & Wing, 1999). Successful weight maintainers from the National Weight Control Registry exercise an average of 60 minutes/day (McGuire, Wing, Klem, Seagle, & Hill, 1998).

Numerous weight loss studies have shown that 5-10% weight loss can reduce risk factors for chronic disease (Knowler et al., 2002; Pi-Sunyer, 1996). One study resulting in a 5.8% weight loss was associated with 16% reduction in total cholesterol, 18% increase in HDL cholesterol and 12% decrease in LDL cholesterol (Ditschuneit, Frier, & Flechtner-Mors, 2002). Weight loss goals of 7-10% have been adopted for large NIH-funded multi-center trials such as the Diabetes Prevention Program (Wing et al., 2004) and Look AHEAD (Ryan et al., 2003).

With university-based research weight loss programs often providing the gold standard intervention with weight losses of ~7-10%, commercial weight loss programs attempt to provide alternative opportunities for the overweight and obese adult population. A review of 10 studies of community weight loss programs for effectiveness identified Weight Watchers as the only commercial weight loss program that had a loss of 5%, was inexpensive, and easily accessible

(Tsai & Wadden, 2005). Medically supervised programs were more costly, produced a more rapid, 15-25% initial weight loss over 3-6 months, but participants were more likely to regain their weight and self-help groups reported minimal weight loss.

1.2.2.2 Mindfulness. Studies of biofeedback and self-regulation have demonstrated that individuals learn to control physiological processes that originally were thought to be involuntary (Schwartz, 1975). These studies used relaxation, meditation, breathing techniques and yoga to teach individuals to control their heart rate, skin temperature, blood pressure, skin conductance and brainwaves (Schwartz, 1975; Schwartz & Androsik, 2003). Benson's Relaxation Response research showed that focused attention meditation affects stress on the human body and shows decreases in heart rate, respiratory rate, blood pressure, oxygen consumption and muscle tension (Benson, Beary, & Carol, 1974). Studies also reported a reduction in stress, hypertension and headaches (Benson, 1975). Research studies involving lifestyle interventions that include meditation and yoga had positive results in cardiac and diabetes risk factors (Edelman et al., 2006; Ornish et al., 1998)

Mindfulness meditation (MM) originated in Buddhism, based on the concept of experiencing increased awareness and total acceptance of the present moment which affects the spiritual, emotional and physical aspects of self (Johnson, 1986). Since 1979, when Kabat-Zinn first introduced MM as an intervention, studies have supported its use in healthy and disordered populations (Grossman, Niemann, Schmidt, & Walach, 2004). The National Center for Complementary and Alternative Medicine describes the use of meditation, a mind-body practice, for health purposes as being used to increase physical relaxation, mental calmness and psychological balance and to cope with one or more diseases and conditions and for overall

wellness (NCCAM, 2006). MM, which enhances attention, increases awareness in the present moment, and heightens self-knowledge, assists in the facilitation of self-regulation.

Kabat-Zinn (1982) defined MM as emphasizing a detached, non-judgmental, or interpretative observation in the present moment of continually changing objects, thoughts, emotions, body sensations, and perceptions. Mindfulness is a technique and a way of life that may enhance the effectiveness of weight loss interventions (Kabat-Zinn, 2005). Formal MM practice consists of the body scan, focused breathing, sitting meditation, mindful eating meditation, hatha yoga or movement meditation and walking meditation (Kabat-Zinn, 1991).

The practice of informal mindfulness is staying intentionally focused in the present that is not influenced by past experiences or imaged future expectations, paying attention to the body and its sensations, to the emotions, to the thoughts, to the perceptions and to the experience in the present moment as it unfolds and changes and accepting this moment as it is without criticizing it, judging it, or trying to change it.

Kristeller, Hallett, and Brendan (1999) explored the role of mindfulness in the treatment of binge-eating disorders across multiple domains of functioning: physical, emotional, behavioral, cognitive, relation to self and others, and spiritual. Kristeller's model suggests that meditation increases self-awareness, promotes general self-regulation, decreases emotional reactivity and integrates the perceptual, cognitive and behavioral aspects of human functioning, using eating as the specific example (2003). In binge-eating disordered subjects, MM demonstrated an effect on the dysfunctional eating patterns with the following results: the number of binges decreased significantly over the course of treatment (from 4.02/week to 1.57/week, p<.001) with significant improvement noted in mindfulness (t=8.31, p<.001), perceived control of eating (t=9.51, p<.001) and awareness of hunger (t=5.48, p<.001) and

satiety (t=7.21, p<.001) cues (Kristeller et al., 1999). The study also found that levels of anxiety and depression fell to normal ranges on average after the study (t=4.48, p<.001, t=3.10, p<.01, respectively), providing emotional regulation as well.

Hatha yoga, a formal MM practice, accesses mindfulness through the breath and movement. A recently published study supports regular yoga practice as a means of losing or maintaining weight with findings of a 3.1lb. lower weight gain for normal weight participants and an 18.5 lb. lower weight gain among overweight participants (p<.001) (Kristal, Littman, Benitez, & White, 2005). Jayasinghe (2004) reviewed 13 research studies of yoga on cardiac health with statistically significant findings (p<.05) in changes of blood pressure, BMI, lipid profile, body weight, physiological markers of exercise tolerance, breath volume, and oxygen consumption. La Forge (1997) reported research-supported benefits of mindfulness exercise through hatha yoga compared to vigorous aerobic exercise that included: cardiorespiratory, musculoskeletal, psychophysiological and other outcomes that would have an impact on the health concerns of the overweight and obese population.

Other studies support the use of MM in self-regulation of: mood, anxiety and depression, pain management, cancer support, hypertension, coronary artery disease, substance abuse, transplant symptoms, self-regulation of binge eating, stress management, hot flashes, and psoriasis treatment (Alterman, Koppenhaver, Mulholland, Ladden, & Baime, 2004; Bowen et al., 2006; Carlson, Ursuliak, Goodey, Angen, & Speca, 2001; Chang et al., 2004; Davidson et al., 2003; Gross et al., 2004; Kabat-Zinn, 1982; Kabat-Zinn et al., 1992; Kristeller, Hallett, & Brendan, 1999; Majumdar, Grossman, Dietz-Waschkowski, Kersig, & Walach, 2002; Miller, Fletcher, & Kabat-Zinn, 1995; Morone, Weiner, & Greco, 2006; Tacon, McComb, Caldera, & Randoph, 2003; Williams, Kolar, Reger, & Pearson, 2001). The concept of self-regulation through MM has been supported in the development, testing and use of the Mindfulness Awareness Assessment Scale (MAAS). In the MAAS, mindfulness is associated with selfregulation, can predict well-being outcomes, and can be cultivated by practice (Brown & Ryan, 2003).

Brown and Ryan (2003) conducted three separate studies exploring self-regulation impacted by mindfulness meditation. In their first study, Brown and Ryan (2003) explored psychological well-being, finding a negative correlation of mindfulness with personality traits which included depression (-.53), self-consciousness (-.45), anger and hostility (-.41) and impulsivity (-.29), state traits of depression (-.41) and anxiety (-.40) and a positive correlation with positive affect (.30,.39), life satisfaction (.26,.37), self-esteem (.43), autonomy (.34,.37), competence (.39,.68), and relatedness (.31,.28) at p<.0001. In their second study, Brown and Ryan (2003) examined mindfulness and self-regulation of emotion with individuals with higher scores of mindfulness demonstrating increased awareness, being more attuned to their internal emotional states and their responding expression of emotion (p<.05). Their last study focused on mindfulness in a sample of cancer patients showing a higher level of mindfulness was inversely related to mood disturbance (-.43), stress levels (-.46), and fatigue (-.44) with p<.01 (Brown & Ryan, 2003). Many of these areas impacted by mindfulness are areas that could be related to weight loss struggles of overweight and obese individuals: self-consciousness of body during physical activity, impulsivity related to food choices or not sticking with weight loss regime, stress-related eating and mood-related eating.

Bonadonna (2003) described the use of meditation with chronic disorders as bringing awareness to habitual patterns of thought, feeling and behavior, increasing conscious choices to support health and well-being, and supporting the view of the whole self rather than fragmenting the self through various symptoms. Hypertension has been reduced in response to meditation intervention using transcendental and MM interventions (mean adjusted systolic blood pressure changes (-3.4, p=.04) (Barclay & Lie, 2006). Just as hypertension is a lifelong disease process, so is overweight/obesity. Obesity, viewed as a chronic illness, is often accompanied with habits of overeating or restricted eating followed by binges, guilt and negative feelings about the self, preoccupation with weight, food and body image and an inability to make healthy choices in the emotional, cognitive or physical realms (Adolfsson, Carlson, Unden, & Rossner, 2002).

Studies of mindfulness meditation with follow-up of three month to 4 years reported ongoing maintenance of health improvement and continued mindfulness meditation practice (Kabat-Zinn, Lipworth, Burney, & Sellers, 1987; Miller et al., 1995; Morone et al., 2006). Moderate to large effect sizes found with mindfulness interventions include improving wellbeing, depression and anxiety, physical symptoms of specific medical conditions, sleep, pain, and quality of life (Carlson & Garland, 2005; Chang et al., 2004; Cohen-Katz, Wiley, Capuano, Baker, & Shapiro, 2005a; Grossman et al., 2004; Kabat-Zinn, 1982; Kabat-Zinn et al., 1987; Kabat-Zinn et al., 1992; Kristeller, Hallett, & Brendan, 1999; Miller et al., 1995; Riebel, Greeson, Brainard, & Rosenzweig, 2001; Shapiro, Schwartz, & Bonner, 1998; Tacon, McComb, Caldera, & Randoph, 2003; Teasdale et al., 2000; Williams, Kolar, Reger, & Pearson, 2001). In a meta-analysis of mindfulness meditation by Grossman et al. (2004), the mean effect size was 0.54 for all mental health variable studies and 0.53 for all physical health variable studies.

1.2.2.3 Adherence, Acceptability and Feasibility: The varying needs of the overweight population are a challenge to the healthcare system. What may be acceptable and feasible for one individual, may not be for another. A phenomenological study of women across three different weight loss programs found that the women's struggle to be spontaneous and flexible

with emerging priorities to nurture and maintain family relationships was perceived as a conflict with the required structure and control of the structured weight loss programs which resulted in minimal weight loss (Lopez, 1997).

There is a continuing challenge to engage overweight and obese adults into treatment, to stay in treatment, and successful complete treatment. Recent research has explored the use of diet choices (vegetarian or non-vegetarian) and self-monitoring tools, ranging from paper to electronic diaries, with a standard behavioral weight loss program (Burke, Sereika, et al., 2006; Burke, Music, et al., 2006; Fletcher et al., 2005). In exploring the interpersonal needs of those who are overweight or obese, research has demonstrated that increasing social support with friends and group support increases the likelihood that there would be greater weight loss and weight maintenance six months out (Berry, 2004; Thomas, Jakicic, & Gallagher, 2004; Wing & Jeffery, 1999).

Despite the various interventions available for weight loss, the overweight/obese population's needs do not appear to be served, given the present obesity statistics. For the overweight/obese individual, the self-regulation of weight is not only affected by eating and activity behaviors and lack of or diminished hunger and satiety cues but often also influenced by moods, negative cognitions, and environment. There are two major challenges in overweight/obesity treatment of a diverse needs population. First, only a small percentage of this population lose 7% -10% of their weight to reduce health risks and second, once the initial weight loss occurs, the loss often cannot be maintained beyond 1-2 years (Anderson, Konz, Frederick, & Wood, 2001; Jeffery et al., 2000; Wing & Phelan, 2005). What appears to be lacking is a way to make behavioral changes in an individual's life for initial weight loss with

corresponding integration of healthy eating and lifestyle behaviors for long-term weight maintenance.

1.2.3 Concepts for Investigation

The above review discusses the roles of self-regulation, systems theory and intention in weight loss/management. The proposed study will examine the influence of mindfulness meditation on weight loss with subjects following a reduced caloric, low-fat diet (dietary intake), changing eating behaviors, and increasing physical activity behaviors associated with weight loss in overweight and obese adults.

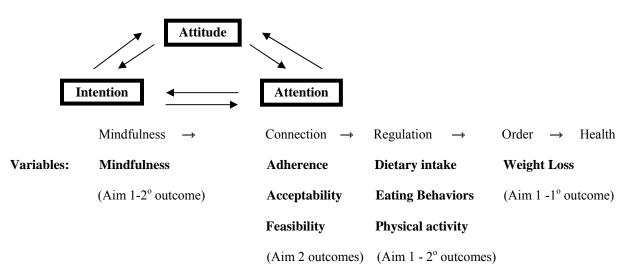


Figure 3: Study variables used to explore IAA Mindfulness Model in enhancing feedback loops of selfregulation in weight loss to improve health

1.2.4 Significance

A striking gap in the literature appears to be between the standard recommendations for treatment and the different needs and intention levels of individuals struggling with weight control. MM can address this gap as a unique component; both as an intervention and a lifestyle and has the potential to support the overweight and obese population in their struggle to control weight over their lifetime. MM taught through a structured format (Kabat-Zinn,1991; Kabat-Zinn, 2003, Kristeller et al., 1999) may increase the success of weight loss and weight maintenance for individuals who also participate in a standard behavioral obesity treatment program by impacting the self-regulation processes involved in eating and activity. MM starts within and expands outward just as weight issues are both internally and externally driven. Through mindfulness, the overweight/obese individual can apply the behavioral strategies to meet their individual life demands, ethnic and gender differences, and competing interpersonal roles and adapt them to support their internal and external environments.

1.2.5 Innovation

This study would be the one of the first known to use MM added to a standard behavioral program to explore the acceptability, feasibility and effectiveness of the intervention with overweight/obese adults to successfully lose and maintain their weight. Due to the uniqueness of the application of mindfulness to this population, a qualitative component will follow the randomized controlled trial (RCT) to explore individual perceptions and experiences of MM. A mixed methods approach has been used to explore mindfulness meditation in two other

populations, nurses with stress and burnout (Cohen-Katz, Wiley, Capuano, Baker, & Shapiro, 2005b) and depressed and anxious patients (Finucane & Mercer, 2006).

1.3 PRELIMINARY STUDIES

In preparation for this dissertation work, I have had several years of diverse research experience at the University of Pittsburgh, School of Nursing and at University of Pittsburgh Medical Center Western Psychiatric Institute & Clinic. In two studies, a randomized control trial and a telephone screening and intervention pilot, my roles included experience in all aspects of the study, from development, screening, interventionist, data management and manuscript writing. To supplement my research knowledge and experience, I have also played smaller roles on several other studies in both organizations. As a prerequisite, I have successfully passed the University of Pittsburgh Education and Certification Program Modules related to research integrity, human subject research, and the HIPAA physicians and researchers privacy awareness training (Appendix U). This experience described below, combined with the support of my dissertation committee and doctoral coursework, has provided a solid foundation to initiate this proposal.

1.3.1 Study 1

Menopause and Meditation for Breast Cancer Survivors (Cohen, S., P.I.) is an on-going three year NCI funded R21 (1R21CA106336-01A1), a randomized controlled trial exploring mindfulness meditation as an intervention for menopausal symptoms, including hot flashes, in

women with naturally occurring and breast cancer treatment-induced menopause. I have been involved with this grant since February 2005, starting with mindfulness meditation group training and leading mindfulness meditation intervention groups in the fall of 2005. I collaborated with Dr. Cohen and Dr. Greco on the development of the mindfulness intervention manual for the subjects and recorded 5 different meditation CD's for participant home practice. I also participated in peer supervision on mindfulness group facilitation with Dr. Greco during the intervention phase.

As part of the study start-up, I researched and explored the BodyMedia armband for hot flash assessment, assisted in the development of protocol for its use including uploading and downloading data. My role extended to recruitment: contacting various women's groups and agencies, delivering recruitment materials, and presenting information at local breast cancer survivor groups. I was trained in telephone screening, data collection, form scanning, initial interviews with informed consent, and final interviews. I am also involved in manuscript preparation to report results from this study.

1.3.2 Study 2

Telephone Screening and Care Management for Postpartum Depression (Hudson-Scholle, S., P.I.) was a pilot project for the Mental Health Intervention Research Center at Western Psychiatric Clinic & Institute. As a Senior Nurse Researcher, I ran a pilot testing a telephone screening and care management program for women 4-6 weeks postpartum for six months. I was responsible for the revising of a telephone care management manual, coordinating efforts with a local behavioral health managed care company, revising forms, recruiting and screening ~ 300 women with repeat screening over a six month period, and telephone care management for

17 identified postpartum depressed women. I contributed to a manuscript that is currently under review regarding the use of 3 different postpartum depression screening tools. The study was funded as an R01 by the National Institutes of Health in 2005 shortly after I began the menopause and meditation study with Dr. Cohen.

1.3.3 Additional Experiences

I have had other varying research experience that has increased my knowledge and assisted in the preparation of my dissertation study. I assisted in staff training for recruitment and presented on postpartum depression for staff at Magee Women's Hospital for recruitment purposed for Dr. Wisner's multiple women and depression studies. I assisted in the development of and had full responsibility for the management of a monthly women's behavioral health researcher's meeting which presented and reviewed current studies related to women's mental health issues. I have been a member of the data monitoring and safety committee for Dr. Engberg's R01 grant studying acupuncture and incontinence in women for the past 2 years. I have been a doctoral student member of Dr. Burke's R01 quarterly research meetings studying obesity treatment and technology strategies for the past 2 years, participating in quarterly meetings reviewing recruitment, form development and assessment tool review, and study procedures progress.

1.4 RESEARCH DESIGN AND METHODS

The proposed sequential mixed method study is part of a larger, four-arm randomized control trial, Alternative Behavioral and Physical Activity Approaches to Weight Loss, (Jakicic, J., P.I.)

through the University of Pittsburgh Physical Activity and Weight Management Research Center. Funding for the study is provided by the University of Pittsburgh, Department of Physical Activity through the Physical Activity and Weight Management Research Center.

Parent Study Design

The Alternative Behavioral and Physical Activity Approaches to Weight Loss research study will explore three interventions compared to a standard behavioral weight loss program (see Appendix A). The four arms of the study will include: 1) standard behavioral weight loss (SBWP), 2) standard behavioral weight loss plus resistance exercise (SBWP+RE), 3) standard behavioral weight loss plus mindfulness meditation (SBWP+MM), and 4) technology-based weight loss intervention (TECH). Following the baseline assessments, eligible participants will be randomly assigned to one of four groups in the larger study. Pre-randomization stratification will be based on gender and race. Randomization will be based on a list of computer-generated random assignment with equal allocation, with each subject assigned to one of the four group numbers (1=SBWP, 2=SBWP+RE, 3=SBWP+MM, 4=TECH) that corresponds to the group assignment.

The plan is to recruit 120 sedentary, overweight and obese adults to participate in the four-arm randomized control trial. Both men and women will be included, with a minimum of 50% of this sample being women, and genders equally divided among the intervention groups. In addition, this sample will include a minimum of 20% minority representation, based on recruitment rates in the Greater Pittsburgh Metropolitan area and Providence, R.I. for recent weight control intervention studies coordinated through the University of Pittsburgh Physical Activity and Weight Management Research Center (Jakicic et al., 2003). The study will be using physiological measures of outcome including: anthropometric measures, cardio-respiratory

fitness, muscular strength, physical function as well as other psychosocial correlates of weight loss and behavior change (lifestyle, depression, barriers and expected outcomes, motivational readiness, body image) not included in this dissertation. Since the proposed dissertation study only involves 2 of the 4 groups, only the comparison group, SBWP (1) and the SBWP+MM (3) will be described and discussed.

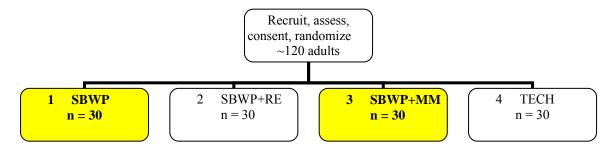


Figure 4: Parent 4-arm study with SBWP and SBWP+MM highlighted

1.4.1 Design

Approximately 60 overweight/obese adults will be randomized into one of the two following intervention approaches: 1) Standard Behavioral Weight Loss Program (SBWP) and 2) Standard Behavioral Weight Loss Program plus Mindfulness Meditation (SBWP+MM). Outcomes will be measured at 0, 12, and 24 weeks. Following the completion of the 24 week intervention, a qualitative interview will explore the SBWP+MM group participants' experience. Once consented, a diverse sample of 12-15 SBWP+MM participants will be chosen to explore experiences using race, age, gender, mindfulness practice and weight loss differences. The researcher will analyze the qualitative data, comparing both individual and group experiences of

the mindfulness meditation intervention's effect on weight control. The resulting knowledge can then be applied to further research in this area and potentially be used in clinical applications for weight control.

Weight Control: Exploring Self-Regulation Through Mindfulness Meditation											
	24 week weight loss intervention										
		\uparrow			\uparrow			\uparrow			
Recruit a	nd Basel	ine			Week 12			Week 2	.4		
Assessments					Assessments			Assessments			
								Qualitative			
								Interviews			
								(SBWP+MM)			
Training of Staff.									Data Cleaning,		
Develop Intervention									Data Analysis, Manuscripts		
Materials											
Month	Month	Month	Month	Month	Month	Month	Month	Month	Month	Month	Month
1	2	3	4	5	6	7	8	9	10	11	12

Table 1: Study timeline for this study using the SBWP and SBWP+MM groups

1.4.2 Sample Size Justification

This study is exploratory by design and there have been no reported mindfulness meditation and weight loss studies in the literature for power analysis. For this study, recruitment of 60 participants with a retention rate of 85% over a 24 week intervention period would yield a sample of 51 participants. Using two groups with three assessment time points, the between-subject standard deviation is 0.58 and the within-subject standard deviation is 1.00. This design achieves 100% power when an F test is used to test the Groups factor at a 5% significance level and the actual standard deviation among the means is 0.50 (an effect size of 0.87), achieves 100% power when an F test is used to test the Times factor at a 5% significance level and the

actual standard deviation among the means is 0.82 (an effect size of 0.82) and achieves 5% power when an F test is used to test the Group Times interaction at a 5 % significance level and the actual standard deviation among the means is 0.00 (an effect size of 0.00). For a preliminary qualitative study, a sample size of 12-15 is considered adequate with purposeful sampling (Sandelowski, 1995). Following the completion and analysis of this study, the intent is to use the results of this study in the design and planning of a larger study for hypothesis testing.

1.4.3 Variables

Weight Loss is the amount of body weight lost from baseline to the midpoint and to the endpoint of the study. Body weight will be measured at baseline, week 12, and week 24. Weight loss will be in absolute kilograms and percent change from baseline to week 12 and week 12 to week 24, as well as the overall baseline to week 24.

Dietary intake is expressed as kcal/day and macronutrient composition with percentages of fat, protein, and carbohydrates measured by the Block Food Frequency Questionnaire at baseline, week 12 and week 24. A reduction in total caloric intake and percentage reduction of carbohydrates, dietary fat, and protein increases the likelihood of weight loss.

Eating behaviors are the behaviors that influence the choices and amount of food eaten, as measured by the total score on the Eating Behavior Inventory at baseline, week 12 and week 24.

Physical activity is the amount and frequency of physical activity, with higher levels of physical activity increasing the likelihood of weight loss measured by the Paffenbarger Questionnaire at baseline, week 12 and week 24.

Mindfulness is the ability to be aware or mindful in the present moment will be measured at baseline, week 12, and week 24 using the Mindfulness Attention Awareness Scale (MAAS) and the Five Factor Mindfulness Questionnaire. Higher scores reflect mindfulness.

Adherence, Acceptability and Feasibility: Participants' adherence and acceptance of the intervention and how practical or feasible the intervention was in fitting into the participants' life will be measured by weekly attendance, diary record completion, retention rate, and for the SBWP+MM group, mindfulness meditation practice in minutes per week recorded by participants on the weekly mindfulness log. Qualitative interview data may potentially provide interpretative descriptive data on acceptability and feasibility.

1.4.4 Setting

The study will be conducted through the University of Pittsburgh Physical Activity and Weight Management Research Center. Data will be collected and stored at the Center in the Southside of Pittsburgh. Interviews, assessments, and interventions for all study participants will take place at the Center. The Center has several group rooms, exercise rooms and assessment rooms appropriate for this study.

1.4.5 Sample

A convenience sample will be recruited from the greater Pittsburgh community based population of adults who are overweight or obese. Both men and women will be invited to participate in the study intervention of weight management. All interested adults will complete initial screening procedures prior to baseline assessments. Initial screening will include: a general medical history (Appendix F), a lifestyle questionnaire (Appendix G), and a physical activity readiness questionnaire (PAR-Q) (Appendix H) which will altogether take approximately 25 minutes to complete. Subjects will also need to provide medical clearance from the personal physician to participate. Subjects will be given a Physician Consent Form (Appendix E) and instructed to bring the form to their physician to complete and sign prior to starting the study.

Inclusion criteria include:

- 18-55 years of age because behavioral interventions for weight loss may be different for individuals who are younger or older than this proposed age range.
- body mass index (BMI) between 25.0-39.9 kg/m² since individuals with a BMI less that 25 kg/m² are not currently classified as overweight, and individuals with a BMI >39.9 kg/m² may require more aggressive weight loss interventions than what is proposed in this study (e.g., surgery, medication, etc.),

Exclusion criteria include:

- report losing >5% of current body weight in the previous 6 months. Individuals who
 have recently lost significant body weight may be at high risk for weight regain, which
 could result in this study examining prevention of weight regain rather than weight loss;
- report regular exercise participation of at least 20 minutes per day on at least 3 days per week during the previous 6 months, as regular exercise may impact results of this study;
- report participating in a research project involving weight loss or physical activity in the previous 6 months, as these proximal experiences may impact the results of this study
- report being pregnant during the previous 6 months, lactating, or planned pregnancy in the following 6 months;

- report current treatment for any medical condition that could impact body weight (i.e., diabetes mellitus, cancer, etc.);
- history of myocardial infarction or heart surgery such as bypass or angioplasty, since this may require additional medical monitoring and adjustments to the exercise prescription throughout the course of this study;
- non-medicated resting systolic blood pressure ≥ 160mmHg or non-medicated resting diastolic blood pressure ≥100mmHg, or currently taking medication that would affect heart rate or blood pressure responses to exercise (e.g., beta blockers). Again, this may require additional medical monitoring during the duration of this study and could impact exercise prescription and participation;
- report taking medication that could affect metabolism or change body weight (e.g., synthroid);
- currently treated for psychological issues, or taking psychotropic medications within the previous 6 months;
- history of orthopedic complications that would prevent optimal participation in the exercise component (e.g., heel spurs, severe arthritis).
- No exclusion criteria shall be based on race, age, or gender.

1.4.6 Recruitment

Subjects will be recruited using a variety of media including newspaper advertisements, newsletters, television/radio advertisements and mass mailing that will be approved by the Institutional Review Board at the University of Pittsburgh prior to initiation (Appendix C).

Potential subjects will be instructed to contact the investigators via a telephone number that is provided in these advertisements.

1.4.7 Retention Procedures

Obesity treatment studies generally are able to successfully maintain approximately 85-90% of subjects that are at 6 months in duration (Jakicic et al., 2003). The University of Pittsburgh Department of Health and Physical Activity's Center for Weight Management has demonstrated retention rates as high as 90%, been based on the following strategies that will also be implemented for this proposed intervention. Subjects will provide contact information including address, home telephone number, work telephone number, and email address. As commonly used in clinical trials, subjects will complete a "Participant Contact" form that will include the name, address, telephone number, and email address of at least two family members or close friends who will know the location of the participant throughout the 6 month intervention. Subjects will be provided free parking. Subjects will be paid \$25 for participating in the 12 week assessment and also in the 24 week assessment for this study.

Subjects who cannot make the weekly group will be assigned another time that week to be weighed at the Center and given the weekly group materials. Subjects who do not call to cancel will be contacted by the assigned Physical Activity and Weight Management Research Center staff when they do not attend the weekly group. If the subject is not able to be contacted, staff will mail the weekly materials to the subjects that do not come in that week.

1.4.8 Gender and Minority Inclusion

The proposed study demographic data is based on recruitment from the general Pittsburgh area and past weight loss studies by the University of Pittsburgh Physical Activity and Weight Management Research Center, and will include > 50% adult females. Women respond to and engage in research studies with greater frequency than men so specific recruitment efforts will actively target overweight/obese men to increase male enrollment.

Based on 1999-2004 NHANES data, black and Mexican American women are significantly more likely to be obese than white women (Ogden et al., 2006). The Physical Activity and Weight Management Research Center's prior studies have had a representation of 25- 29% minorities. Acknowledging the current minority data, recruitment activities will make every effort to maintain this proportion.

Inclusion of children: According to the inclusion criteria of the proposed pilot study, children under the age of 18 years are not eligible to participate, and thus will not be included in the proposed study. Children under 18 years of age are not included in the study because of the belief that behavioral interventions for weight loss may be different for individuals who are younger and would require the involvement of parents. The exploration of this intervention is purposefully chosen with the adult population since adults have the ability to make choices on their own. If the intervention demonstrates promise, larger scale studies would be sought with the intention of conducting a program of research to pursue interventions that include family involvement.

1.4.9 Subject enrollment

Individuals who inquire about this study will be asked to complete a brief telephone interview (Appendix D) to assess initial eligibility. The University of Pittsburgh's Internal Review Board granted permission for verbal consent for the brief telephone interview based on the concept that the brief interview would only address questions that would routinely be asked by medical office personnel scheduling an outpatient appointment for weight concerns. If the subject does not meet inclusion criteria, all the collected information during the telephone screening process will be destroyed. The name of the potential participant is not recorded on the forms where personal information is recorded from the telephone screen. All personal information will be destroyed (shredded) at the conclusion of the telephone contact.

Eligible participants will be invited to attend a group orientation for 60-90 minutes. At this orientation session a detailed description of the study will be provided by the Principal Investigator of the larger four-arm study, John Jakicic, Ph.D., and includes: background and significance of the study, the intervention groups and procedures, all assessment procedures, and the risks/benefits of participating in this study. Subjects will be encouraged to ask questions regarding their participation in this study during this orientation. Informed consent and other logistical procedures will then be explained prior to individuals signing the consent document. The personal information will be collected again and retained after written informed consent is obtained from the participants.

Subjects will complete the Physical Activity Readiness Questionnaire (PAR-Q), a detailed medical history, and a lifestyle questionnaire prior to participating in baseline assessments (Appendices F-H). To minimize potential risks to the subjects, all subjects will provide written consent from their personal physician prior to further participation in this study.

Subjects will complete baseline assessments that include: weight, height, physical activity, eating behaviors, and mindfulness questionnaires.

1.4.10 Intervention

To facilitate attendance at these sessions and enhance retention over the period of 24 weeks, free parking is provided and the intervention site is easily accessible and affordable using the local mass transit system. To minimize contamination, each intervention group (consisting of ~ 30 subjects) will be closed group meetings that are limited to participants randomly assigned to either the SBWP group or the SBWP+MM group. SBWP group sessions typically last ~ 30 minutes, which permits time to distribute intervention materials, interact with each participant, identify participants that need additional support, and conduct the group intervention.

1.4.10.1 Standard Behavioral Weight Control Program (SBWP): Intervention

Contact: During the 24 weeks of treatment, the intervention group will meet weekly for a total of 24 group sessions. Subjects in this intervention group will receive the Physical Activity and Weight Management Research Center's standard behavioral weight control program that is delivered in a group format. The group intervention will be followed by a 30 minute supervised exercise of: walking on the treadmill, walking on the local trail, or using an exercise bike.

Behavioral Lesson Content: Each group visit will focus on a specific behavioral topic related to weight loss, eating behaviors, or exercise behaviors. Discussion related to this topic will be facilitated by a trained and supervised Physical Activity and Weight Management Research Center staff interventionist and interactive group participation will be encouraged. An example list of the topics that are typically included in in-person group sessions is provided in

Appendix Q, and participants are provided written materials to supplement the group discussion. Individuals who miss a group session can come by the Center during the week for an individual session or are mailed the intervention materials for review prior to the next group meeting.

Self-Monitoring: Self-monitoring is an important component of behavioral weight loss interventions. Participants will monitor body weight, eating behaviors, and exercise behaviors. Body weight will be measured at each in-person group meeting and participants will also be encouraged to measure their body weight on their own at least one other time between intervention visits.

Participants will be encouraged to self-monitor their eating and exercise behaviors throughout the intervention period. Participants will be provided with a weekly diary to record eating and exercise patterns (Appendix O). Participants will return the completed diary to the intervention staff at each in-person visit for review, and the intervention staff will provide written feedback on the diary prior to it being returned to the participant the following week. The diaries will also be used to generate discussion with the participant during the weigh-in period and within the in-person group session. Participants will also be provided with self-addressed stamped envelopes to facilitate the return of these diaries in the event that they need to miss an in-person visit. Participants identified as engaging in eating and exercise behaviors that are deemed to be unsafe will be contacted and receive appropriate counseling from the investigators.

The behavioral strategies that will be integrated into the SBWP will include, but will not be limited to, self-monitoring, goal setting, problem solving, mastery skills to influence selfefficacy, social support, and relapse prevention strategies. The behavioral strategies will be

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equivalent across the intervention groups, a traditional, empirically-supported Standard Behavioral Weight Loss Program intervention.

Dietary Recommendations: All subjects will be prescribed an energy restricted dietary intervention that we have shown to effectively reduce body weight by 8-10% within the initial 6 months of treatment. This will include reducing dietary intake to 1200 to 1800 kcal/d based on initial body weight (<200 pounds = 1200 kcal/d; 200 to 250 pounds = 1500 kcal/d; >250 pounds = 1800 kcal/d). Data from research studies and the National Weight Control Registry indicated that macronutrient composition in the most successful participants consists of 20-30% dietary fat intake, 50-55% carbohydrate intake, and 20-25% protein intake (Wing, 1998). Therefore, a similar dietary composition will be recommended in this study (Appendix N). However, low carbohydrate/high protein diets are currently popular, have demonstrated some initial efficacy, and some participants may gravitate towards this macronutrient composition, and this will be acceptable provided that total dietary intake is within the prescribed range. To facilitate the adoption of the dietary recommendations, individuals will be provided with meal plans that will allow them to plan for modifications in their daily and weekly meal plans, and a calorie counter book.

Physical Activity Recommendations: Participants will be prescribed exercise that is consistent with data that have shown that higher levels of exercise may be important for preventing weight regain (Jakicic et al., 2003). Specifically, subjects will be instructed to engage in moderate intensity exercise 5 days per week. The total duration per day will begin at 20 minutes per day and will gradually progress to at least 60 minutes per day, as this level of exercise has been shown to be associated with improved long-term weight loss (Gallagher, Jakicic, Napolitano, & Marcus, 2006) and is recommended by leading organizations (ACSM,

2006; ACSM, 2001). Exercise will be progressed in a gradual manner (5-10 min/d in 4 week intervals) in an attempt to maximize adherence and minimize the onset of musculoskeletal injury. Previous studies have demonstrated that permitting overweight participants to accumulate their exercise in multiple 10-minute exercise sessions per day enhances the initial adoption of exercise (Gallagher et al., 2006), and this will be recommended as an option for participants in this study. Exercise intensity will be set at 55-70% of maximal heart rate. As a component of the weekly group sessions, all subjects will be required to do 30 minutes of supervised exercise either prior to or after the group session. Participants will be offered treadmills, exercise bikes, or a supervised outdoor trail walk.

1.4.10.2 Standard Behavioral Weight Control Program + Mindfulness Meditation (**SBWP+MM**): *Intervention Contact*: Subjects in this intervention group will receive same 24 week intervention contact, by the same trained and supervised Physical Activity and Weight Management Research Center staff interventionist, and all of the components as described above for SBWP. In addition, this intervention will be enhanced with the addition of mindfulness meditation. A subset of this group will also participate in qualitative interviews following the 6 month intervention.

Behavioral Lesson Content: Each group visit will focus on mindfulness meditation as related to weight loss, eating behaviors, or exercise behaviors based on the work of Kabat-Zinn (1991;2005) and Kristeller (2005). Experiential learning of mindfulness meditations in group will be led by the Principal Investigator. Discussion related to the session topic (Appendix R), homework practice, and examples of incorporating mindfulness meditation in daily life will be facilitated and interactive group participation will be encouraged. Participants are provided CDs or DVDs of mindfulness meditations and written materials to supplement the discussion and

home practice. Individuals who miss an in-person session will be contacted and scheduled for a phone session, mailed all intervention materials and will be encouraged to continue mindfulness meditation practice prior to the next group meeting.

Self-Monitoring: Subjects in this intervention group will instructed to self-monitor body weight, eating behaviors, and exercise behaviors as described above for SBWP with additional documentation of mindfulness meditation, formal and informal, practice in minutes per day. Notation of mindfulness practice will be made on the back of the weekly diaries and on a weekly mindfulness recall form (Appendix P) distributed at the weekly weigh-in component.

Dietary Recommendations: Subjects in this intervention group will receive dietary recommendations as described for the SBWP group.

Physical Activity Recommendations: Subjects in this intervention group will receive exercise recommendations as described for the SBWP group. In addition, mindfulness movement, hatha yoga, and walking meditations will be introduced. The hatha yoga component will focus in awareness of breath, body sensations, personal limitations and the attitude brought to the practice (Kabat-Zinn, 2005). Gentle, slow, beginner yoga postures will be practiced in group, visualized on handouts, and described on CD or DVD. Yoga is introduced to encourage the participants to inhabit their body, to rehabilitate the body through increased balance and flexibility (LaForge, 1997). Walking meditation is practiced in group and supported by a CD for home practice. Walking meditation starts with a slow mindful step with awareness of each body part's movement and role in walking. It supports the individual's heightened awareness in the present moment, being with every step and not getting ahead of oneself (J. Kabat-Zinn, 2005). The walking meditation can be used to meet physical activity requirements by increasing the speed of the walk mindfully.

1.4.11 Data Collection

The participants will record their dietary intake in calories and fat grams, minutes of physical activity, and for the SBWP+MM, minutes of mindfulness meditation practice daily in a weekly diary that will be turned in each week at their weigh-in prior to the weekly intervention. New dated, blank diaries and old diaries from the previous week with written comments from staff will be given each week to the participants. If a participant misses a session, the diaries will be mailed to them or given to them if they come to the Center for the weekly materials.

Both groups will receive the same number of contacts for the quantitative component: a baseline assessment, a 12 week assessment, a 24 week assessment, and 24 weekly intervention sessions. A subset of the SBWP+MM group will have additional qualitative interview contacts during the 24 week assessment period.

1.4.12 Assessments

Assessments of weight (loss), mindfulness, acceptability and feasibility measures, and measures of dietary intake, eating behaviors, and physical activity will occur at baseline, week 12, and week 24. The qualitative interviews will only be completed on SBWP+MM participants who consent to this component of the research study and will occur around the 24 week assessment period. Weekly weights of the participants, in exercise clothes without shoes, will be recorded each session to provide subject feedback and will be used in the event that a subject drops from the study prior to the next scheduled assessment.

1.4.12.1 Weight Loss: Body weight will be measured using a calibrated medical balancebeam scale (Health-O-Meter Inc., Bridgeview, IL) with the subjects clothed in a lightweight hospital gown. Weight loss will be calculated at week 12 by subtracting the week 12 weight from baseline weight and at week 24 by subtracting week 24 weight from the week 12 weight.

1.4.12.2 Dietary Intake will be assessed using the Block Food Frequency Questionnaire (Block et al., 1986) which measures the daily total dietary intake with energy percentages of fat, carbohydrates, and protein, with lower total dietary intake and lower fat intake increasing the potential for weight loss. This is an 8 page paper and pencil questionnaire that inquires about the type, frequency (9 response choices from never to every day), and serving size (four choices based on type of food and using a picture of choice sizes) of a variety of foods. This questionnaire has been used in previous studies and has shown that it is sensitive to change in dietary intake resulting from a behavioral intervention.

1.4.12.3 Eating behaviors will be assessed using the Eating Behavior Inventory (O'Neil et al., 1979). This 26-item questionnaire has been shown to be sensitive to change in dietary intake and eating behaviors resulting from a behavioral intervention and corresponding weight loss (O'Neil & Reider, 2005). Scores range from 26 to 130 with higher scores indicating weight loss behaviors.

1.4.12.4 Physical Activity will be assessed using the Paffenbarger Physical Activity Questionnaire (Paffenbarger, Hyde, Wing, & Hsieh, 1986). The physical activity score is measured in kilocalories per week and is based on the sum of calories expended through several forms of physical activity. This questionnaire is typically used in weight loss intervention

studies to assess physical activity and have been shown to be sensitive to change (Jakicic, Marcus, et al., 2003; Jeffery, Wing, Sherwood, & Tate, 2003).

1.4.12.5 Mindfulness: - Mindfulness Attention Awareness Scale (MAAS) is a 15-item questionnaire that uses a 6-point Likert scale from 1 (almost always) to 6 (almost never) to assess present moment, attention and awareness by Brown and Ryan (2003). The MAAS (Appendix L) has been tested in college student, general adult and early stage breast and prostate cancer patient samples with an internal consistency (alpha) of .82 , .87 and .83, respectively. Test-retest reliability over four weeks was reported to be .81 (p<.0001) (Brown & Ryan, 2003).

Five Factor Mindfulness Questionnaire is a 39-item questionnaire (Appendix M) that uses a 5-point Likert scale from 1 (never or very rarely true) to 5 (very often or always true) used to measure five facets of mindfulness identified by Baer: observe, describe, act with awareness, non-judging and non-reactivity (Baer, Smith, & Allen, 2004; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). It was developed by Baer et al. following a factor analysis and comparison of five mindfulness questionnaires. It will be used as an additional mindfulness rating tool based on Baer's work with mindfulness and binge-eating (Baer, Fischer, & Huss, 2005).

1.4.12.6 Adherence, Acceptability and Feasibility: Adherence, acceptability and feasibility of the addition of the mindfulness component to the Standard Behavioral Weight Control Plan will be assessed using the following measures of adherence at 12 week and 24 week assessment periods of this study. These assessments will include the following: 1) attendance rate – based on attendance recorded weekly by the group interventionist, 2) completion rate of self-monitoring diaries – based on the number of diaries turned in by participants and recorded by assigned group research staff, 3) retention rate of subjects per group based on participant

drop-outs, and 4) meditation practice assessed in the SBWP+MM groups as the number of minutes per week self-reported in the weekly diary and the weekly practice log. A qualitative interview of a sample of SBWP+MM participants may further inform the quantitative results.

1.4.12.7 Other Measures for Eligibility: <u>Height</u> will be measured using a calibrated, wall mounted stadiometer (Perspective Enterprises, Inc., Kalamazoo, MI). Subjects will be instructed to remove their shoes and to stand upright with their back and heels of their feet against the wall for this measurement. <u>Body Mass Index (BMI)</u> will be computed as kg/m² using weight and height measurements as described above.

1.4.13 Qualitative Interview Component

The methodological method to be used with the qualitative component is interpretative description, a method that came out of the researcher's needs for a method that embraces the clinical questions and applications related to human health needs (Thorne, Kirkham, & MacDonald-Emes, 1997). Thorne et al. (1997) introduced interpretative description as an approach to qualitative research that was not founded in any specific qualitative theories (i.e. grounded theory, phenomenology, ethnography) to "develop knowledge about human health and illness experience" (p169). Interpretative description begins with what is known through a critical review of current knowledge (in this study-standard behavioral weight loss interventions), proceeding with utilizing inductive reasoning to test and challenge initial interpretations of the inquiry (what is the experience of overweight/obese adults in a weight loss intervention with mindfulness added?), and to develop knowledge that can be conceptualized as a coherent final product, such as could be applied to general and individual client weight loss

strategies (Thorne, 2000). Key components of this method are: 1) individuals hold multiple constructed realities that are complex, contextual, and subjective and these realities need to be holistically studied and 2) the investigator and the interviewee are both influenced by their reactions (Lincoln & Guba, 1985; Thorne et al., 1997).

A qualitative interview of participants in the SBWP+MM group following the intervention will be used to interpret their response to the mindfulness meditation intervention and to determine if there are specific components of this intervention that are or not appealing, feasible, and/or effective (Fonteyn & Bauer-Wu, 2005). The individuals will be purposefully selected and consented (Appendix S) from the SBWP+MM intervention group at the 24 week assessment period based on differences in age, race, gender, mindfulness practice, and weight loss. Purposeful sampling will be used based on what is known from the literature and the researcher's questions. Participants will be given a choice of: internet, telephone, or in-person interviews. The informed consent will delineate the telephone interview up to 2 separate contacts. The participants will sign an informed consent for audio-taping of the interview if they choose telephone or in-person interviews.

The qualitative interviews may start during the analysis of the quantitative data to allow for prompt feedback. The interviews are based on brief list of broad, open-ended questions to have the participants in the SBWP+MM group describe their experience (Appendix T). The questions are used as a guide and are not meant to be rigid or restrictive but will become more focused and reiterative as the interview progresses. The interpretative description method calls for the researcher to move back and forth between the process of data collection (interviews) and data analysis. By analyzing data concurrently, the investigator can change or expand on the original inquiry based on data collected and investigator interpretation of that data. Developing concepts will be challenged and tested through more specific questioning of past and current interviewees. In-depth analysis of individual interviews will result in common themes that may be relevant to the larger group of weight loss participants. These themes could potentially increase nursing knowledge in the treatment of overweight/obese populations, and more directly the overweight/obese individual requiring nursing care (Thorne et al.,1997). To allow for relevant themes to be identified, the investigator will begin by reading each interview completely and write a brief summary of the interview prior to coding. Unlike grounded theory that codes word by word, line by line, interpretative description uses thematic coding. Concept designation and links between participant experiences will be made later in the analysis process after several interviews have been analyzed, As the interview process continues, more specific questioning will explore both similarities and differences between individuals.

1.5 DATA ANALYSIS

The specific aims of this study are: 1) to explore the effect of a mindfulness meditation intervention added to a standard behavioral weight loss program on weight loss (primary outcome) and dietary intake, eating behaviors, physical activity and mindfulness meditation (secondary outcomes) compared to a standard behavioral weight loss intervention; 2) to explore the feasibility and acceptability of the addition of mindfulness meditation to a standard weight loss intervention, and 3) to understand the participants' experience of being in the mindfulness meditation with standard weight loss intervention group through qualitative interviews. Although the following hypotheses will be explored, they will not be tested in this study. It is hypothesized that an increase in the scores of mindfulness and practicing mindfulness meditation

will result in greater improvements in weight loss, reductions in dietary intake and greater physical activity when compared to a standard behavioral weight loss program. Since this is an exploratory study these hypotheses will be explored and not be formally tested in this study.

1.5.1 Quantitative Data Analysis

All analyses will be performed using SPSS v15.0 for Windows (SPSS Inc., Chicago, IL, 2006) or SAS 9.1.3 (SAS Institute Inc., Cary, NC). Descriptive statistics for continuous data will be computed and presented as means +/- standard deviations, medians and ranges for the total sample and for each group separately (SBWP and SBWP+MM). Categorical data will be presented as frequency counts and percentages for the total sample and by group. Initial analyses will include assessments: 1) to determine the distributions of the continuous data with appropriate transformations to be conducted for data that are not normally distributed, 2) for imbalances in randomization assignment (identifying any differences between groups) and 3) of missing data.

If data are not normally distributed, appropriate data transformations will be attempted before resorting to using nonparametric statistical analysis methods. Differences in baseline characteristics between intervention groups will be adjusted in the mixed effects models and other analysis models as covariates. Participants with missing data will be compared to those with complete data to test for differences in baseline characteristics as well as observed outcome responses. The mixed effects model can handle data that are missing at random (MAR as defined by Little and Rubin, 1987) (i.e., chance of being missing does not depend on unobserved outcome values but can depend on covariates and observed outcomes). Assuming that the missing data mechanism involved in the current study satisfies the MAR assumption, participants with missing outcomes will be kept in the analyses rather than deleted.

Analyses of the specific quantitative aims will be assessed using repeated measures of analysis with assessment period (time) considered a fixed within-subject factor and randomized group assignment considered as a fixed between-subject factor and fixed interactions between group and assessment period. Mixed effects models will be fitted to explore and examine the differences in weight loss and the other outcome measures between intervention groups.

1.5.2 Data Analysis for Specific Aim 1 primary outcome (weight loss)

Analysis will be performed to first test the effectiveness of randomization assignment using a ttest to detect body weight differences between the two groups. With inequality, a significant difference in mean weight at baseline would be used as a covariate in the mixed effects modeling. Weight loss, as the primary outcome will be analyzed using body weights measured at baseline, week 12, and week 24; subtracting the week 12 body weight from baseline for weight loss at week 12 assessment and subtracting week 24 body weight from week 12 for weight loss at week 24. Analysis will include: 1) using linear mixed effects modeling with two time points, weeks 12 and 24, will be fitted to compare the SBWP+MM group with the SBWP group followed by linear contrast at those 2 time points, 2) computing estimates of the effects of the model with confidence intervals, the between effect (group assignment) and within effect (time), and the interaction of group and time to explore both the fixed effects and the random effects of the model, 3) obtain the restricted maximum likelihood estimation (REML), 4) use repeated measures find the best covariance structure and explore possible to covariance/correlational structures using the repeating assessments to determine which

covariance structure fits the data best by Akaike Information Criteria (AIC), 5) estimate the regression parameter for each effect including the confidence interval, and 6) analyze the residuals after fitting the model for outliers and influential points. All randomized participants will be included in the analysis regardless of follow-up status.

1.5.3 Data Analysis for secondary outcomes of Aim 1

The analysis will be the same for secondary outcomes of dietary intake, eating behaviors, physical activity and mindfulness meditation as described for Aim 1 primary outcome, weight loss, will be used.

1.5.4 Data Analysis for Aim 2 – Adherence, feasibility and acceptability

Adherence with the study protocol will be compared between groups, SBWP and SBWP+MM, for attendance rates, diary completion rates, and group retention using categorical data, contingency table analysis using chi square or Fisher's exact test based on distribution of the data. In the SBWP+MM, mindfulness meditation practice in minutes per week will be totaled with a mean per subject. Descriptive analysis of mindfulness meditation practice by the SBWP+MM group subjects will include frequencies and percentages.

1.5.5 Data Analysis for Aim 3 - Qualitative Interview Data Analysis

The analysis is based on the interpretative description method; a method that combines the interaction of the investigator with the data. This will include: exploring and understanding the

data, drawing meaning from the data, describing relationships or linkages in data, and producing a narrative description as a final product (Morse, 1994). Each interview will be transcribed verbatim or if using the internet, will be cut and pasted into Microsoft Word. The Word document will be double-spaced, numbered lines in left margin, and a 3 inch margin on the right side of the page to allow for written analysis to be added.

Each interview will be read in totality with the intent of generating a preliminary set of broad, creative codes by the investigator to allow for further intellectual inquiry of a range of possibilities based on the data collected. The investigator will: 1) write a brief summary of the interview, 2) explore how the participant answered each of the questions, 3) identify major questions that the interview raises, 4) identify any gaps that need to be questioned further, and 5) identify the next best questions to consider. This range of possibilities will generate further questions for the next participant interview and possibly to participants already interviewed.

The interview process and analysis process will be continuous and iterative, allowing for new possibilities of the inquiry to evolve (Thorne, 2000). The interpretation will be guided by the investigator, using constant comparative analysis to allow for themes present in the literature to emerge. For example, one theme from the literature may be the awareness of the internal struggle to meet the standard behavioral weight loss program expectations of dietary intake and physical activity and the external demands of daily life, as described by Lopez (1997). The coding will then move to the differences, exceptions, and disagreements with weight loss literature (Thorne, 2000). New emerging themes may lead the investigator to ask additional questions to previously interviewed subjects, to explore and challenge earlier assumptions. The investigator will keep written memos of thoughts and decisions to pursue or eliminate a line of questioning during the analysis process. Dr. Hamilton will review the transcripts and memos prior to engaging in constant comparative analysis with the investigator. This step will support the reflexivity, the interaction of the data and the investigator, required of the data analysis and prevent premature closure of the analysis or maintaining earlier assumptions by the researcher (Thorne, 2000). The data analysis will be descriptive and interpretative, providing meaning to mindfulness meditation in context of the weight loss intervention. The final product will be based on specific analytic decisions clearly supported by the data, conceptualized within the larger picture of weight loss using the addition of mindfulness meditation, and with a "tentative truth claim" about the experience of SBWP+MM for weight loss (Sandelowski, 2000; Thorne, 2000). The interpretative description of the results may serve to support or identify further questions in the quantitative analysis of the study and be used in future research applications (Thorne, Paterson, Russell, & Schultz, 2002).

1.5.6 Protection of Research Participants

Prior to the initiation of this proposed study, the researcher will seek approval for the research through the University of Pittsburgh IRB. The IRB will approve all aspects of the study including but not limited to: all the components of the study, the recruiting advertisements, the telephone screening script, the participant's informed consents, and the participants and data safety monitoring plan. Potential risks to the research participants are reviewed by the IRB and included in the informed consent. A waiver of signed informed consent will be sought through the IRB, to approve telephone screening that will be limited to information that a potential

participant would routinely give to schedule an outpatient appointment for this condition (weight control). Signed informed consent will occur after the potential research participants attend a group orientation session and have questions answered by the primary investigator and prior to assessments (Appendix B). Potential risks are reduced by appropriately trained staff, identifying personal information kept in a separate filing cabinet than the subject research data, subject data being assigned a number, subject data being kept in a locked filing cabinet, and participants and research staff being reminded of confidentiality, both in group and individually.

The recruited participants will be adults ages 18-55, with at least 50% of the participants being women and approximately a 20-25% minority representation of the Pittsburgh regional area. Specific recruiting plans will target minority populations through newsletters and radio advertisements on minority stations. There will be no children under the age of 18 included in this research study as that population has different needs than individuals' ages18 to 55. There will no older adults beyond 55 years old due to increased medical needs, monitoring, and limitations that can occur with the older age group, which would require additional intervention needs.

1.6 PUBLICATIONS

- Hanusa, B.H.; Hudson Scholle, S.; Haskett, R.F.; Spadaro, K.; & Wisner, K.L. (in press).
 - Comparison of Three Instruments to Screen for Postpartum Depression: The EPDS, PHQ-9, and PDSS, Journal of Women's Health.
- Contributing author of "Standards of Care for Intensive Outpatient Programs", published by the Association of Behavioral Healthcare, 1998.

1.7 RESEARCH PARTICIPANT RISK AND PROTECTION

1.7.1 Human Subjects Research

Procedures will be reviewed to ensure that data are being collected in a manner to protect the confidentiality of subjects. All subject information will be coded with a study identification number to maintain confidentiality so that there is no linkage to the individual enrolled in the study. At the beginning of the group intervention and frequently throughout the 24 week intervention, participants will be reminded of group confidentiality. In addition, all study data, including audiotapes and paper documents will be locked in a secured area (e.g., locked file cabinet). Audiotapes will be destroyed following verbatim transcription into Word documents. Computer database materials will be securely password protected. Research records will be maintained for a minimum of 5 years or as long as it may take to complete the research study. Participants will be identified by study identification numbers or code, not name or other identifying information, in any publications of research results. Every effort will be made to ensure confidentiality and anonymity of each participant.

1.7.2 Protection of Human Subjects

The proposed pilot study will be approved by the Institutional Review Board of the University of Pittsburgh and written informed consent will be obtained for all participants. Sample population characteristics: a convenience sample of 50-60 adults 18-55 years of age, body mass index (BMI) between 25.0-39.9 kg/m², and a minority sample reflective of the Pittsburgh area. The sample is restricted to this range of body mass index because individuals with a BMI less that 25

kg/m² are not classified as overweight, and individuals with a BMI \geq 39.9 kg/m² may require more aggressive weight loss interventions than what is proposed in this study (e.g., surgery, medication, etc). Subjects will be between 18 and 55 years of age and otherwise considered to be healthy. The sample has been restricted to this age range because behavioral interventions for weight loss may be different for individuals who are younger or older than this proposed age range. If adults, older or with a higher BMI, apply for the study, there will be referral list to other appropriate weight loss programs, clinics, or to their primary care physician.

Exclusion criteria includes: report losing >5% of current body weight in the previous 6 months, participating in a research project involving weight loss or physical activity in the previous 6 months, women not being pregnant during the previous 6 months, lactating, or planned pregnancy in the following 6 months, current treatment for any medical condition that could impact body weight (e.g., diabetes mellitus, cancer, etc.), history of myocardial infarction or heart surgery such as bypass or angioplasty, non-medicated resting systolic blood pressure \geq 160mmHg or non-medicated resting diastolic blood pressure \geq 100mmHg, or currently taking medication that would affect heart rate or blood pressure responses to exercise (e.g., beta blockers), taking medication that could affect metabolism or change body weight (e.g., synthroid), currently treated for psychological issues, or taking psychotropic medications within the previous 6 months . No exclusion criteria shall be based on race, ethnicity, gender or HIV status.

All subjects will complete a physical activity readiness questionnaire (PAR-Q) and a detailed medical history, and will provide written informed consent prior to participating in this study. In addition, all subjects will provide written consent from their personal physician indicating that participation in the proposed intervention is not contraindicated.

1.7.3 Sources of Materials

The proposed study will utilize demographic data including age, race, gender, weight, body mass index, prior weight loss history, prior physical activity experience and prior eating patterns. In addition, body weight and height will be measured pre- and post- intervention and weekly weights during the 6 months intervention. Five paper and pencil tools will be administered at 0, 12 and 24 weeks. The burden to the participant has been taken into account; the measures are easy to complete and most are brief in length. Completion time is estimated at 30 to 45 minutes. Qualitative data will be collected from a subsample of the SBWP+MM group.

1.7.4 Potential Risks

The possible risks of this research study may include the following:

Risk Associated with Completion of Questionnaires: There are no apparent risks associated with completion of the questionnaires proposed for this study. Fatigue could be a factor that would be addressed by having the participant take a break between questionnaires.

Risks Associated with Assessment of Body Weight, Height, BMI: Assessment of body physical measurements will be performed using a wall calibrated medical balance-beam scale and stadiometer. BMI is calculated based on weight and height measurements. There are no apparent risks associated with assessment of body physical measurements Therefore, the risk of an adverse event is rare (occurs in less than 1% of people or less than 1 out of 100 people).

Risks Associated with the Group Interventions: Participants in the group intervention may be asked to discuss personal factors related to their weight loss, physical activity, and dietary patterns. Participants are not required to share this information and can elect not to share

sensitive and confidential information with the interventionist or other members of the group. The investigators can not guarantee that members of the group will not share this information with individuals not in this study outside of the group setting. It is likely that subjects will experience this during the group intervention sessions (occurs in more than 25% of people or more than 25 out of 100 people).

Risks Associated with Mindfulness Meditation: Mindfulness meditation has minimal risk associated with it. A qualitative study by Cohen-Katz identified few challenges from the participants, restlessness, dealing with difficult emotions and for those already dealing with chronic pain, increased awareness of physical pain (Cohen-Katz et al., 2005b). The hatha yoga postures that are included in the mindfulness movement components are beginner's postures and participants will be encouraged through the session to be mindful of their physical limitations and to stop prior to pain or injury. If injury does occur, the participant will be escorted to the local emergency room five blocks away. The applicant has been facilitating mindfulness meditation groups including hatha yoga for the past year and has had no adverse events.

1.7.5 Recruitment and Informed Consent

Recruitment advertisements, mailings and posters will include a telephone number for prospective participants to call for information. The applicant will monitor telephone messages and return calls based on the potential participant's request. Initial screening will occur over the telephone to verify inclusion/exclusion criteria following HIPPA guidelines. Prior to initiation of the study, IRB approved, written informed consent will be obtained from the participants.

1.7.6 Protection Against Risks

All physical measurements- weight, height and BMI- will be obtained in a private room in the Physical Activity and Weight Management Research Center to maintain confidentiality. Confidentially will be protected through coding procedures which are HIPPA compliant for all participants' forms. All data will be compliant with the guidelines of the Complete Health Insurance Portability and Accountability Act (HIPPA) of 1996, and no data will be able to be linked to the individual participant. Data forms will be stored in a locked file in the Physical Activity and Weight Management Research Center in the University of Pittsburgh. In the event that distress results, an initial assessment will be done by Kathleen Spadaro, a clinical nurse specialist or Dr. Jakicic. If further intervention is needed, the participant will be escorted or sent by ambulance to the local emergency room (five blocks from the research center). A data and safety monitoring plan will be in place and described in the Data and Safety Monitoring Plan section.

1.7.7 Potential Benefits of the Proposed Research to the Subjects and Others

Subjects that participate in this study may experience the following benefits associated with weight loss, dietary change, and exercise:

- 1. The proposed intervention may result in weight loss.
- 2. The proposed intervention may result in improvements in their eating behaviors and choices and physical activity behaviors.

- 3. The proposed intervention may result in improvements in psychosocial factors such as self-efficacy, mood, quality of life, and other related factors.
- 4. The proposed intervention may result in improvements in the participants' self-care, ability to relax, awareness both to internal and external stimuli, and decreased reactivity.

1.7.8 Importance of Knowledge Gained from the Proposed Study

The knowledge gained through this investigation involving minimal risk to the participants is of great significance to the public health and clinical health providers in the treatment of overweight and obese adults. With the steadily increasing rates of overweight and obesity in the United States, an innovative, cost-effective, and individualized tool for enhancing the success of weight loss, and potentially weight control could provide renewed hope for the health of this population and support the efforts of their healthcare providers.

1.7.9 Inclusion of Women and Minorities

The proposed study demographic data is based on recruitment from the general Pittsburgh area and past weight loss studies by Dr. Jakicic, and will include > 50% adult females. Women respond to and engage in research studies with greater frequency than men so specific recruitment efforts will actively target overweight/obese men to increase male enrollment.

Based on 1999-2004 NHANES data, black and Mexican American women are significantly more likely to be obese than white women (Ogden et al., 2006). The Physical Activity and Weight Management Research Center's prior studies have had a representation of

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25- 29% minorities. Acknowledging the current minority data, recruitment activities will make every effort to maintain this proportion.

1.7.10 Inclusion of children

According to the inclusion criteria of the proposed pilot study, children under the age of 18 are not eligible to participate, and thus will not be included in the proposed study. Children under 18 years of age are not included in the study because of the belief that behavioral interventions for weight loss may be different for individuals who are younger and would require the involvement of parents. The exploration of this intervention is purposefully chosen with the adult population since adults have the ability to make choices on their own. If the intervention demonstrates promise, larger scale studies would be sought with the intention of conducting a program of research to pursue interventions that include family involvement.

1.7.11 Data Safety Monitoring Plan

This proposal will be submitted and approved by the University of Pittsburgh IRB prior to conducting this pilot study. The parent study P.I., Dr. Jakicic will be responsible for implementing the Data Safety Monitoring Plan which will include meetings with the study coordinator, study program staff and this investigator to review recruitment accrual, confidentiality issues and any adverse events. This investigator will participate in the weekly intervention groups and in weekly staff meetings with the research team at the Center for Physical Activity and Weight Management. At these meetings, weekly weight loss, diaries with nutritional, exercise, and meditation data and any adverse events will be reviewed. In addition,

this investigator will review all data and procedures, data following the baseline, 12 week and 24 week assessment periods, participant recruitment procedures and the recruitment timeline. Data that will be monitored to assess completion of the proposed protocols, documentation indicating that an adverse event occurred during the exercise session, review of medical history and PAR-Q, and review of study data to insure that outcome data are within acceptable criteria. Data will also be reviewed to assess whether there is any change in the risk-to-benefit ratio of this study. If potential safety concerns are identified that change the benefit-to-risk ratio, the study will be stopped until modifications can be made and approved by the IRB to address these safety concerns.

1.7.12 Vertebrae Animals – None.

2.0 STUDY SUMMARY

This section summarized the researcher's experience, knowledge gained, and potential future directions that came from this dissertation study. Since two manuscripts follow the summary with details specific to the quantitative and qualitative components of the study for publication, this summary does not repeat the areas reported, except to illustrate learning from experience. This section identified and discussed areas that were not included in the manuscripts.

This study involved two arms of a proposed four-arm parent study that had been approved by the University of Pittsburgh's Internal Review Board (IRB). Although the original intent of the parent study was to recruit and randomize 60 overweight/obese adults to two intervention groups studied in this dissertation, ultimately 49 subjects were consented and participated in baseline assessments.

In general, the convenience sample was not representative of the overweight/obese community population in gender or age. Despite the attempt to recruit males, only 6 (13%) males were randomized in this study. There was a very representative sample of race from the Pittsburgh community with 21.7% representation of African Americans (n=10). However, there were no other minorities included. The youngest subject was 21.4 years of age with the mean age 45.2 years (SD=8.2). A challenge for further study would be to increase the recruitment of males, younger adults, and possibly other races.

Due to holidays and group schedules, the SBWP received 22 group sessions and the SBWP+MM received 24 group sessions. Although both groups received the same materials for

the SBWP component, missing 2 group contacts could have had an effect on the SBWP group retention rate over a relatively short period of time if the assumption is that group contact makes a difference. However, the lesser contact could also be viewed as less burdensome to the SBWP subjects. If contact is considered, there was an unequal time factor between groups, with the SBWP group lasting ~30 minutes and the SBWP+MM group lasting ~ 30 minutes (SBWP) and an additional ~30 minutes (MM) content. In future studies, a planned intervention would include a 12 to 18 month follow-up, with an equal number of sessions per group offered despite holidays and a blended SBWP+MM content ~ 45 minutes in length.

The qualitative interview was not a component of the initial parent study proposal that was approved by the IRB. IRB approval for the qualitative interviews was not obtained until late December, 2 months following the 24 week intervention (Appendix W). The IRB required inclusion of all interested participants in the interview process that conflicted with the initial proposal of purposeful sampling. The P.I. and the interventionist met to discuss the implementation plan of the qualitative component to meet IRB requirements.

Subjects in the SBWP+MM group were contacted in late December by telephone to discuss their interest in participating in a qualitative interview. Seventeen of the 22 group subjects were reached and expressed willingness to participate in the interview process. One subject refused due to time constraints. Those subjects were mailed a packet containing a letter describing the process (Appendix X), two copies of the consent form (Appendix Y) for their signatures, and a stamped addressed envelope to mail the signed consents. When mailed consents were received at the Center, the P.I. signed the consents and the SBWP+MM interventionist recorded the documents, filed one copy of the subjects chart, and mailed the

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second copy back to the subject for their record keeping. Signed consents were received from 15 subjects.

Interviews started ~ 3 months following the completion of the quantitative study. Each subject was given the choice of an internet or telephone interview. An Excel sheet was used to track the procedure for each subject from initial phone contact, mailing of consent forms, receiving consent forms, and date of each contact with subject. Qualitative interviews had a three month lag time between the 24 week assessment and the interview process due to a delay in IRB approval. This delay may have had an effect on the participants who agreed but did not follow through with consent or response to internet interview questions.

Assigned staff members and interventionists were required to enter study data. Data were entered with date and staff initials and then checked, dated and initialed by another staff member. The Block Food Questionnaire was mailed to another location for encoding. The Physical Activity and Weight Management Research Center data manager gave access to the checked data for the SBWP and SBWP+MM groups. The P.I. of the parent study reviewed the participant lists and data in both groups using intention-to-treat philosophy for final total participant number for analysis.

Once the analysis process began, several issues arose. The weekly attendance had not been documented the same way for each group. The decision was made to analyze attendance rates based on the presence of a documented weekly weight, measured at the weekly group intervention session or at a scheduled make-up appointment with staff later in the week. This measure compared the commitment of subjects in each group to attend weekly. Future study would include a documented group session attendance protocol to be used with both groups, possibly using a subject sign-in sheet with first name and last initial. Mindfulness meditation practice was recorded on mindfulness recall forms completed weekly by subjects in the SBWP+MM group who chose from a range of minutes for daily practice each group. Weekly practice minutes were calculated from the mindfulness recall forms, using the mean for each time range (<15 minutes = 7 minutes, 15 – 30 minutes = 22.5 minutes). Mean weekly minutes of MM practice was 22.45 minutes per week for the 12 week time point for 21 subjects (one subject did not practice and dropped out at week 2) and 34.92 for 24 week time point for 18 subjects based on the above averaging. There was a mean 5.29 MM practices per week. There were several subjects who did little practice of MM and several subjects practicing for 30+minutes at a time. The majority of subjects appeared to use MM for brief checking in with themselves throughout their week.

There were no differences in physical activity and dietary intake between groups, possibly due to the short length of the study.. There was also no difference on the mindfulness measures between groups. These findings may be due to the increased "paying attention" of these areas inherent in a short-term standard behavioral weight loss program. Although MM practice in the SBWP+MM group did increase over time, 24 weeks may not be sufficient to note changes when the subjects are trying to add exercise time and mindfulness meditation practice to their busy lives.

There were several limitations to this study. First, the sample size was small, not very diverse and the length of the study was focused on short-term weight loss. The intervention being explored, MM, conflicts with the lifestyle of most adults. MM teaches individuals to take time to focus in the present moment. To make changes that are quantitatively significant, the intervention may need to be tested on a larger sample size and extended over a 12-18 month time frame.

There were also limitations in several of the measures in the study. The measure for collecting data on MM practice was not "in the present moment". Although subjects in the SBWP+MM group were to check on the back of their diary if they practiced each day during that week, they did not document the amount of practice daily. Although this type of self-reporting decreases subject burden, it did not allow for specific data analysis. The mindfulness recall form captured the amount of practice for the week past, allowing for error in recall. The time interval choices did not capture actual practice in minutes, but rather an estimate, again increasing the error. The Block Food Questionnaire is lengthy to complete so the data were not captured when time was an issue for subjects which increased the error rate due to missing values.

There were limitations to the SBWP+MM intervention. Although there were many resources for mindfulness exercises and materials related to eating and food, there were not as many resources available for mindfulness related to movement and exercise. The walking meditation, in its conception, was a focused, slow movement activity that was not appealing to adults attempting to lose weight. Since eating behaviors were significantly improved following the SBWP+MM intervention, a concentrated effort to explore more mindfulness meditation exercises related to physical activity is needed.

The final limitation was that the study was a component of a larger, parent study. Most of decisions, recruitment, number of subjects, and the format of the study were made by the P.I. of the parent study. However, for the learning and development of a young researcher, this limitation was also an opportunity to work within a structured research program of study.

This study can lead to a program of research study exploring and testing mindfulness meditation in weight loss interventions and in other areas of chronic health concerns. The mixed methods design allowed the participants to share their experience with the SBWP+MM

intervention which supported and provided more robust findings. The qualitative data also provided information that could assist in the further development and refinement of the SBWP+MM intervention.

There are several directions to take for future study. One study could focus on the development and testing of mindfulness meditation and exercise activities to refine the SBWP+MM intervention. Another study could focus on male recruitment issues with mindfulness meditation interventions. The next major study would be a larger sample size randomized controlled trial over a longer period of time, 12 to 18 months, to test hypotheses. With each of the studies, other ideas would emerge that could lead to further exploration and new directions of study.

3.0 MANUSCRIPT 1: MINDFULNESS MEDITATION: AN INNOVATIVE, ADDITIONAL STRATEGY FOR WEIGHT LOSS

3.1 LETTER TO EDITOR OF JOURNAL OF BEHAVIORAL MEDICINE

Christopher France, Ph.D. Editor, Journal of Behavioral Medicine Ohio University Department of Psychology 245 Porter Hall Athens, OH 45701-2979

August 15, 2008

Dear Dr. France:

I would like to submit the attached manuscript, "Mindfulness Meditation: An Innovative, Additional Strategy for Weight Loss," for consideration for possible publication in the Journal of Behavioral Medicine. This manuscript explores the findings of a 24 week randomized controlled trial with overweight/obese adults with a standard behavioral weight loss program and a standard behavioral weight loss program plus mindfulness meditation. The mindfulness meditation intervention was based on Jon Kabat-Zinn's Mindfulness-Based Stress Reduction that has been tested with many health conditions and disorders with positive results.

This paper has not been published or accepted for publication. A poster of the 12 week findings has been accepted at the Annual Scientific Meeting of the Obesity Society, 2008. I look forward to your feedback and can be reached at <u>spadarok@pitt.edu</u>.

Sincerely,

Kathleen C. Spadaro M.Ed., B.S.N 104 Berrybush Drive Harrison City, PA 15636

3.2 ABSTRACT

Background: Obesity has become a national health concern. Standard Behavioral Weight Loss (SBWP) interventions have proven successful in research settings for overweight/obese adults. However the majority of overweight/obese community-dwelling adults continue to struggle with weight loss. A modified version of Mindfulness-Based Stress Reduction added to SBWP (SBWP+MM), may enhance the weight loss intervention through activating self-regulation processes within the individual.

Methods: A randomized, controlled trial was conducted among 46 overweight/obese adults from the Pittsburgh community. Subjects were recruited through a local University Physical Activity and Weight Management Research Center. Following initial screening and medical clearance, subjects attended weekly group sessions in either the SBWP intervention or the SBWP+MM intervention for 24 weeks. Outcomes included: body weight, dietary intake measured by Block Food Questionnaire, eating behaviors measured by the Eating Behavior Inventory, physical activity measured by the Paffenbarger Questionnaire and mindfulness measured by the Mindfulness Attention and Awareness Scale (MAAS) and the Five Factor Mindfulness Questionnaire at baseline, week 12 and week 24. Adherence, feasibility and acceptability were measured through retention, attendance and self-monitoring (diary) rates.

Results: Thirty-five subjects (76%) completed the study. Using an intention-to-treat model, mean total weight loss was 5.48 kg (SD=2.01) with a significant decrease in food intake (p<.00) and significant increase in physical activity and healthy eating behaviors (p<.00). There was a nonsignificant mean greater weight loss in the SBWP+MM group (6.89kg compared to 4.07kg). Only eating behaviors significantly improved in the SBWP+MM group with mixed effects

modeling (p=.015). The SBWP+MM group had higher rates of retention (86.4%) and attendance (75%) and a higher number of diaries returned than the SBWP group.

Conclusions: Mindfulness Meditation added to SBWP could potentially enhance the weight loss success of overweight/obese adults with changes in eating behaviors, increased adherence and self-monitoring. A larger, long-term study is needed for hypothesis testing.

KEY WORDS: obesity, behavioral weight loss, mindfulness-based stress reduction, meditation

3.3 INTRODUCTION

Obesity poses a significant health crisis in the United States. The National Center for Health Statistics using NHANES 2002 data shows a 65.2% rate of overweight and obese adults in the United States with 30% of those adults obese (Ogden, Carroll, Curtin, McDowell, & Tabak, 2006). Nearly 50% of the overweight/obese population attempt to lose weight and spend ~\$50 billion a year on weight-loss products and services in this country (Weiss, Galuska, Khan, & Serdula, 2006). Only 20% of those adults are successful in losing weight and there are high rates of weight regain within the first year (Jeffery et al., 2000; Wing & Phelan, 2005). There is a crucial need to identify additional effective strategies that combined with research-proven weight loss interventions would improve success with this population.

Over the past 20 years, many studies support the behavioral interventions of low fat diet, increased regular exercise and self-monitoring for successful weight loss (Jakicic, Marcus, Gallagher, Napolitano, & Lang, 2003; Jeffery, Wing, Sherwood, & Tate, 2003; Knowler, Barrett-Connor, & Fowler, 2002; Shaw, O'Rourke, Del Mar, & Kenardy, 2005; Slentz et al., 2004;

Weiss, Galuska, Khan, & Serdula, 2006). These successful weight loss individuals may have better self-regulation skills. Studies of biofeedback and self-regulation have demonstrated that individuals learn to control physiological processes that originally were thought to be involuntary (Schwartz, 1975). These studies used relaxation, meditation, breathing techniques and yoga to teach individuals to control their heart rate, skin temperature, blood pressure, skin conductance and brainwaves (Schwartz, 1975; Schwartz & Androsik, 2003).

One self-regulation program, Mindfulness-Based Stress Reduction (MBSR), was introduced to healthcare by Kabat-Zinn in 1979 (2005). MBSR is based on the concept of experiencing increased awareness and total acceptance of the present moment which affects the spiritual, emotional and physical aspects of self with origins in Buddhism (Johnson, 1986). MBSR, which enhances attention, increases awareness in the present moment, heightens selfknowledge and assists in the facilitation of self-regulation. Kabat-Zinn (1982) defined MBSR as emphasizing a detached, non-judgmental, or interpretative observation in the present moment of continually changing objects, thoughts, emotions, body sensations, and perceptions. Mindfulness is a technique and a way of life (Kabat-Zinn, 2005) that may enhance the effectiveness of standard behavioral weight loss interventions.

Kristeller, Hallett, and Brendan (1999) explored the role of mindfulness in the treatment of binge-eating disorders across multiple domains of functioning: physical, emotional, behavioral, cognitive, relation to self and others, and spiritual. Kristeller's model suggests that meditation increases self-awareness, promotes general self-regulation, decreases emotional reactivity and integrates the perceptual, cognitive and behavioral aspects of human functioning, using eating as the specific example (Kristeller, 2003).

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There is a continuing challenge to engage overweight and obese adults with varying needs into treatment, to stay in treatment, and successfully lose weight. What appears to be lacking is a way to make behavioral changes in an individual's life for initial weight loss with corresponding integration of healthy eating and lifestyle behaviors. Many of the domains that mindfulness impacts (Kristeller, 2003) could be related to the weight loss struggles of overweight and obese individuals: self-consciousness of body during physical activity, impulsivity related to food choices or not sticking with weight loss regime, stress related to eating and mood-related eating.

The primary objective of this study was to explore the effect of a modified MBSR program, Mindfulness Meditation (MM) combined with a Standard Behavioral Weight Loss Program (SBWP), on weight loss in an overweight/obese adult population. The specific aims of this study included: to explore the effect of a mindfulness meditation intervention added to the standard behavioral weight loss program on weight loss, dietary intake, eating behaviors and physical activity compared to a standard behavioral weight loss intervention. Secondarily, adherence, feasibility and acceptability of the addition of mindfulness meditation to a standard weight loss intervention through attendance, retention, and diary return rates were investigated.

3.4 METHODS

This randomized, controlled trial of SBWP and SBWP+MM was conducted at the University of Pittsburgh Physical Activity and Weight Management Research Center. The study was part of a larger, four-arm parent study, Alternative Behavioral and Physical Activity Approaches to Weight Loss, Dr. Jakicic, Principal Investigator. The University of Pittsburgh Internal Review Board approved all study protocols and procedures. Subjects provided written informed consent prior to starting the study.

3.4.1 Subjects

Admission criteria required adults ≥ 18 years with a body mass index (BMI) between 25.0-39.9 kg/m². BMI <25 kg/m² is not classified as overweight and BMI>39.9 kg/m² may require more aggressive treatment than this intervention offers subjects. Interested adults were excluded for recent weight loss >5%, reported routine exercise ≥ 20 minutes day for three or more days per week, participation in a weight loss or physical activity research project, all within the previous six months due to the potential influence on study results. Other exclusions included pregnancy or planned pregnancy in the next six months, medical conditions that could affect body weight or affect metabolism, history of myocardial infarction or heart surgery, non-medicated hypertension or taking medication that would affect heart rate or blood pressure response to exercise, taking psychotropic medications within the previous six months or in current treatment for psychological issues, or history of orthopedic complications that would prevent optimal exercise participation.

3.4.2 Intervention

After signed informed consent and baseline data were collected, subjects were randomized into the SBWP group or the SBWP+MM group that met weekly over a 24 week time period. To provide consistency with the Standard Behavioral Weight Loss component (SBWP), the Project Coordinator was the interventionist with both groups. The behavioral strategies were equivalent across the intervention groups, a traditional, empirically-supported standard behavioral weight loss intervention. To minimize contamination, each group was a closed group meeting that was limited to the participants randomly assigned to either the SBWP or SBWP+MM group and was held on different evenings of the week. Subjects were provided free parking to facilitate attendance at the group sessions.

In both groups, the SBWP component lasted ~ 30 minutes and the same handouts were given to the participants weekly, which included group materials presented that week and a recipe to try. Subjects from both groups participated in 30 minutes of supervised exercise the evening of their intervention walking on a treadmill, walking on a local trail, or using an exercise bike.

3.4.3 Standard Behavioral Weight Control Program (SBWP)

Intervention Contact: Subjects in this intervention group received the Physical Activity and Weight Management Research Center's standard behavioral weight control program delivered in a group format.

Behavioral Lesson Content: Each group visit focused on a specific behavioral topic related to weight loss, eating behaviors, or exercise behaviors with interactive group discussion. The behavioral strategies that were integrated into the lessons included self-monitoring, goal setting, problem solving, mastery skills to influence self-efficacy, social support, and relapse prevention strategies. Written materials were provided to supplement the group discussion. Individuals who missed an in-person session were scheduled later in the week at the Center or were mailed the intervention materials if they could not attend.

Self-Monitoring: Participants monitored body weight, eating behaviors, and exercise behaviors. Body weight was measured at each in-person group meeting and participants were encouraged to measure their body weight on their own at least one other time between intervention visits.

Participants recorded their dietary intake in calories and fat grams, minutes of physical activity, and for the SBWP+MM, minutes of mindfulness meditation practice daily in a weekly diary that was turned weekly at their weigh-in prior to the weekly intervention. New dated, blank diaries and old diaries with written comments from staff were distributed at the same time. When weekly sessions were missed, participants were provided with self-addressed stamped envelopes to facilitate the return and review of these diaries.

Dietary Recommendations: All subjects were prescribed an energy restricted dietary intervention that we have shown to effectively reduce body weight by 8-10% within the initial 6 months of treatment. This included reducing dietary intake to 1200 to 1800 kcal/d based on initial body weight (<200 pounds = 1200 kcal/d; 200 to 250 pounds = 1500 kcal/d; >250 pounds = 1800 kcal/d). Dietary composition was similar to the macronutrient composition of diets consisting of 20-30% dietary fat intake, 50-55% carbohydrate intake, and 20-25% protein intake in the most successful participants indicated by data from research studies and the National Weight Control Registry (McGuire, Wing, Klem, Seagle, & Hill, 1998). Along with the dietary recommendations, subjects were provided with meal plans that allowed for modifications in their daily and weekly meal plans, and a calorie counter book.

Physical Activity Recommendations: Participants were prescribed exercise that is consistent with data that have shown that higher levels of exercise may be important for preventing weight regain (Jakicic et al., 2003). Specifically, subjects were instructed to engage

in moderate intensity exercise 5 days per week. The total duration per day began at 20 minutes per day and gradually progressed to at least 60 minutes per day, as this level of exercise has been shown to be associated with improved long-term weight loss (Jakicic, Winters, Lang, & Wing, 1999) and is recommended by leading organizations (ACSM, 2006; Jakicic et al., 2001). Exercise was progressed in a gradual manner (5-10 min/d in 4 week intervals) in an attempt to maximize adherence and minimize the onset of musculoskeletal injury. Exercise intensity was set at 55-70% of maximal heart rate.

3.4.4 Standard Behavioral Weight Control Program + Mindfulness Meditation

(SBWP+MM)

Intervention Contact: Subjects in this intervention group received the Physical Activity and Weight Management Research Center's standard behavioral weight control program delivered in a group format over 24 weeks by the same trained and supervised Physical Activity and Weight Management Research Center staff interventionist, and all of the components as described above for SBWP. In addition, this intervention was enhanced with the addition of mindfulness meditation.

Mindfulness Meditation Lesson Content: Each group visit focused on mindfulness meditation as related to weight loss, eating behaviors, or exercise behaviors based on MBSR (Kabat-Zinn, 1991, 2005) and MB-EAT (Kristeller, 2005; Kristeller, Baer, & Quillian-Wolever, 2006). Experiential learning of mindfulness meditations in group was led by this investigator. Discussion related to the session topics, homework practice, and examples of incorporating mindfulness meditation in daily life were facilitated by the interventionist with interactive group participation. Participants were provided with five CDs and three DVDs of mindfulness

meditations and written materials to supplement the discussion and home practice. Individuals who missed a weekly session were contacted and mailed intervention materials. The interventionist reviewed missing material with the subject during their 30 minute supervised exercise the following week.

Self-Monitoring: Subjects in this intervention group did self-monitoring of body weight, eating behaviors, and exercise behaviors as described above for SBWP with additional documentation of mindfulness meditation practice in minutes per day.

Dietary Recommendations: Subjects in this intervention group received dietary recommendations as described above for SBWP based on baseline weight.

Physical Activity Recommendations: Subjects in this intervention group received exercise recommendations as described above for SBWP. In addition, mindfulness movement, hatha yoga, and walking meditations were introduced. The hatha yoga component focused in awareness of breath, body sensations, personal limitations and the attitude brought to the practice (Kabat-Zinn, 2005). Walking meditation was practiced in group and supported by a CD for home practice. It supports the individual's heightened awareness in the present moment, being with every step and not getting ahead of oneself (Kabat-Zinn, 2005). Walking meditation could be incorporated into any intensity or any speed including running, to meet physical activity requirements.

3.4.5 Primary Aim Outcome Measures

Weight loss was the primary outcome. Body weight was measured using a calibrated medical balance-beam scale (Health-O-Meter Inc., Bridgeview, IL) with the subjects clothed in a lightweight hospital gown at baseline, week 12 and week 24.

Dietary Intake was assessed using the Block Food Frequency Questionnaire (Block, 1986) which measures the daily total dietary intake with energy percentages of fat, carbohydrates, and protein, with lower total dietary intake and lower fat intake increasing the potential for weight loss. This is an 8 page paper and pencil questionnaire that inquires about the type, frequency (9 response choices from never to every day), and serving size (four choices based on type of food and using a picture of choice sizes) of a variety of foods. This questionnaire has been used in previous studies and has shown that it is sensitive to change in dietary intake resulting from a behavioral intervention.

Eating behaviors were assessed using the Eating Behavior Inventory (O'Neil et al., 1979). This 26-item questionnaire has been shown to be sensitive to change in dietary intake and eating behaviors resulting from a behavioral intervention and corresponding weight loss (O'Neil & Rieder, 2005). Test scores range from 26 to 130 with higher scores indicating weight loss behaviors.

Physical Activity was assessed using the Paffenbarger Physical Activity Questionnaire (Paffenbarger, Hyde, Wing, & Hsieh, 1986). The physical activity score is measured in kilocalories per week and is based on the sum of calories expended through several forms of physical activity. This questionnaire is typically used in weight loss intervention studies to assess physical activity and have been shown to be sensitive to change (Jakicic et al., 2003; Jeffery et al., 2003).

Mindfulness was measured using two different scales. The Mindfulness Attention Awareness Scale (MAAS) is a 15-item questionnaire that uses a 6-point Likert scale from 1 (almost always) to 6 (almost never) to assess present moment attention and awareness by Brown and Ryan (2003). The MAAS has been tested in college student, general adult and early stage

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breast and prostate cancer patient samples with an internal consistency (alpha) of .82, .87 and .83, respectively. Test-retest reliability was reported to be .81 (p<.0001) over a four week period (Brown & Ryan, 2003).

The Five Factor Mindfulness Questionnaire (5FMQ) is a 39-item questionnaire that uses a 5 point Likert scale from 1 (never or very rarely true) to 5 (very often or always true) used to measure five facets of mindfulness identified by Baer: observe, describe, act with awareness, non-judging and non-reactivity (Baer, Smith, & Allen, 2004; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). It was developed by Baer et al. following an exploratory factor analysis and comparison of five mindfulness questionnaires. It will be used as an additional mindfulness rating tool based on Baer's work with mindfulness and binge-eating (Kristeller.., 2006).

3.4.6 Secondary Aim Outcome Measures

Adherence, Acceptability and Feasibility were assessed using the following measures at 12 week and 24 week assessment periods of this study. These measures included: attendance rate, selfmonitoring based on diaries turned in by participants and recorded by assigned group research staff, retention rate of subjects per group based on subject assessment completion at week 12 and week 24, and meditation practice assessed in the SBWP+MM groups as the number of minutes per week.

A documented weekly weight was used in place of weekly attendance to compare the commitment of subjects in each group to attending the weekly intervention sessions or a makeup appointment with staff later in the week. Since there was a difference in the number of weeks each group intervention was held, SBWP=22 weeks and SBWP+MM=24 weeks, percent attendance (to the Center) was used. Mindfulness meditation practice was recorded on mindfulness recall forms completed weekly by subjects in the SBWP+MM group. Weekly practice minutes were calculated from the mindfulness recall forms, using the mean for each time range (<15 minutes = 7 minutes, 15 - 30 minutes = 22.5 minutes).

3.4.7 Analysis

All analyses were performed using SPSS v15.0 for Windows (SPSS Inc., Chicago, IL, 2006). Intention-to-treat principles were used for all comparisons between treatment groups. To assess the impact of drop-outs in the findings, missing values were replaced with baseline data carried forward for all subjects who did not participate in week 12 or week 24 assessments. Three subjects, one at 12 weeks and two at 24 weeks, had incomplete assessment data. These subjects were missing only the MAAS, Five Factor Mindfulness, and Block Food Frequency Questionnaires due to participant time constraints. These missing values were replaced with last assessment value carried forward since the other assessment data were measured and demonstrated no or some positive change since the last assessment time point. There was only one baseline value outlier (z score=3.34) the carbohydrate value of the Block Food Frequency Questionnaire. Linear mixed effects modeling was explored including the outlier, with a changed value (the next highest baseline data point plus one), and with the outlier not included in the analysis. The outlier was found to not be influential so the value was kept in the analysis.

For primary analysis, linear mixed-effects model analysis compared first-order autoregressive, compound symmetry, toeplitz, and unstructured covariance structures for best fit model using treatment, time, and treatment-time interaction as fixed effects. Secondary outcomes

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were analyzed using the same linear effects model process. General linear modeling (GLM) repeated measures were performed on the outcomes using only the "completers" of the study.

3.5 **RESULTS**

3.5.1 Subject Enrollment and Demographics

Flowchart for enrollment and randomization is shown in Figure 1. Seventy-six overweight/obese adults from the local Pittsburgh community participated in orientation groups and baseline assessments over several weeks for the larger, parent study. Follow-up with medical clearances resulted in 49 subjects being randomized into the two arms of the study. The SBWP had 25 subjects and the SBWP+MM had 24 subjects. Three subjects were removed from the study and analysis, one from SBWP for medical concerns by the primary care physician and two from the SBWP+MM due to relocation out-of-state that did not allow the participants to receive the intervention or participate in the week 12 or week 24 assessments.

Subject retention at week12 was similar in both groups, 22 (91.7%) in SBWP and 20 (90.9%) in SBWP+MM. The differences came at week 24, with retention of 16 (66.7%) in SBWP and 19 (86.4%) in SBWP+MM. Lack of interest and time commitment were the primary reasons for non-completers, however one subject in the SBWP+MM dropped out after the initial session that revealed randomized group assignment.

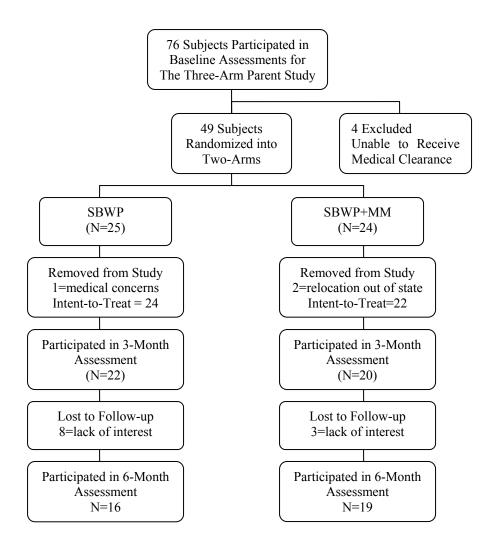


Figure 5: Flow chart of subject randomization and follow-up

Baseline subject characteristics are summarized in Table 2. The total sample included 76 overweight/obese adults, mean age 45.2 years (8.2), mean weight 91.9 kg. (12.8), 87% female (40), and 21.7% African American (10) recruited from the Pittsburgh community area. Seventy-eight percent (36) of the sample had some college or college degree education and 22% (10) had high school or vocational training. Using an intention-to-treat, SBWP had 24 subjects and the SBWP+MM had 22 subjects. The baseline weight was higher (2.5 kg.) and there were more

African-Americans (+4) in SBWP group. There were no significant differences between groups at baseline.

Baseline Characteristic	Total	SBWP	SBWP+MM	Test statistic	df	t-test p-value/ *fisher's exact	
Number of Subjects	46 (100%)	24 (52%)	22 (48%)			1.00*	
Age (yrs)	45.2 (8.2)	44.8 (9.1)	45.8 (7.2)	t=-0.368	44	.714	
Height (cm)	168.06 (6.2)	167.948 (6.5)	168.2 (5.9)	t=-0.136	44	.893	
Weight (kg)	91.9 (12.8)	93.2 (11.9)	90.7 (13.9)	t=0.669	44	.507	
Gender (%) Female Male	87.0% (40) 13.0% (6)	83.3% (20) 16.7% (4)	90.9% (20) 9.1% (2)			.667*	
Race (%) Black/AA Caucasian	21.7% (10) 78.3% (36)	29.2% (7) 70.8% (17)	13.6% (3) 86.4% (19)			.289*	
Education (%) HS/vocational Some college College +	21.7% (10) 32.6% (15) 45.7% (21)	25% (6) 29.2% (7) 45.8% (11)	18.2% (4) 36.4% (8) 45.4% (10)			.928*	
Body Mass Index	32.5 (3.7)	33.0 (3.5)	32.1 (3.8)	t=0.958	44	.343	

Table 2:	Baseline characteristics of subjects	randomly assigned to SB	WP and SBWP+MM	with Intention-to-
Treat				

Categorical data are presented as %. *Comparison of percentages between groups use Fisher's Exact (2-sided) statistics.

3.5.2 Aim 1. Primary Outcome

Weight Loss: There were no significant differences in weight loss over time between SBWP and SBWP+MM groups. To analyze the effects of drop-outs on the analysis, the baseline weight was carried forward for any missing weight time points. Both groups lost weight over the 24 weeks with mean weight loss 4.07 kg (SD=5.65) in the SBWP group and 6.89 kg (SD=4.74) in the SBWP+MM group. Best fit linear mixed-effects model for weight loss variable was first-order regressive with Akaike's Information Criterion (AIC) 855.019 with no significant treatment interaction. There was a time effect (with all the outcome variables except four of the 5FMQ components) and there was a time-treatment interaction effect, F statistic = 3.679, p=.029. For "completers" analysis, GLM repeated measures resulted in a test statistic F= 1.75 with p=.195 between-subject effects and within-subject effects time-treatment interaction effect, F=.568, p=.563.

3.5.3 Aim 1. Secondary Outcomes

Dietary intake using the Block Food Questionnaire had no significance between groups. Best fit linear mixed-effects model for kcal was unstructured covariance with AIC=2103.057. Best fit linear mixed-effects model for protein was unstructured covariance with AIC=1278.364. Best fit linear mixed-effects model for carbohydrates was unstructured covariance with AIC=1495.388. Best fit linear mixed-effects model for fat was unstructured covariance with AIC=1348.961.

For completers, GLM repeated measures were not significant for between-subject effects for the Block Food Questionnaire. Results were: for kilocalories, F=.183, P=.672, for protein, F=..019, p=.891; for carbohydrates, F=.005, p=943; and for fat, F=.697, p=.410 for between-

subject effects. Time-treatment interaction, within-subject effects, was significant for carbohydrates, F=4.26, p=.023. The other three components of the Block Food Questionnaire were not significant in within-subject effects time by treatment interaction, for kilocalories, F=2.878, p=.071, for protein, F=1.177, p=.321, for carbohydrates, or for fat, F=1.507, p=.237.

Eating Behaviors using the Eating Behavior Inventory at 3 time points, had significant difference between groups. Using linear mixed-effects model analysis, compound symmetry covariance was the best fit model with AIC of 987.437 and fixed effects treatment, F=6.368, p=.015 and time- treatment interaction, F=4.441, p=.015. For completers, GLM repeated measures were significant for both between-subject effects, F=4.112, p=.051 and within-subjects effects time-treatment interaction F=3.998, p=.023.

Physical Activity using the Paffenbarger scores at the three time points resulted in no significant difference. Best fit linear mixed-effects model for the physical activity variable was unstructured covariance with AIC at 2197.324 with no significant treatment or treatment-time interaction. Both groups had an increase (doubling their score) at month 3 time point but had a decrease (\sim 7.5%) from 3 months to 6 months (time effect, F=19.654, p<.00).

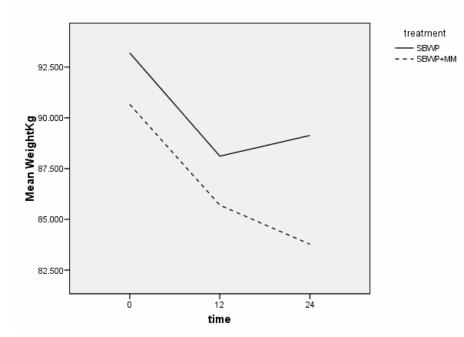
Using GLM repeated measures with completers, the F statistic = 1.223, p=.277 for between-subject effects and an F statistic=.977, p=.382 for within-subject effects for time-treatment interaction. Both groups had an increase (doubling their score) at month 3 time point but had a decrease (~7.5%) from 3 months to 6 months.

Mindfulness using the MAAS and the 5FMQ at three time points had no significant difference between groups. Best fit linear mixed-effects model for mindfulness using MAAS was compound symmetry covariance structure with AIC=974.878. Best fit linear mixed-effects model was identified for each of the five factors in the 5FMQ: for observe, compound symmetry

covariance structure with AIC=785.082; for describe, toeplitz covariance structure with AIC=755.232; for act with awareness, compound symmetry covariance structure with AIC=738.453; for nonjudge, toeplitz covariance structure with AIC=765.934; for nonreact, toeplitz covariance structure with AIC=700.790.

For completers, there was no significance with GLM repeated measures for betweensubject effects and within-subject effects for MAAS or the 5FMQ. For between-subjects effects, for MAAS, F=.124, p=.727 and the five components of the 5FMQ had: observe, F=.440, p=.512; describe, F=1.916, p=.176, act with awareness, F=.028, p=.868; nonjudge, F=.374, p=.545, and nonreact, F=.2.355, p=.134. For within-subjects time-treatment effects, MAAS had F=.464, p=.631, for 5FMQ, observe, F=.876, p=.421, describe, F=.627, p=538, act with awareness, F=.335, p=.717, nonjudge, F=.170, p=.844, and nonreact, F=1.088, p=.343. Withinsubject time effects reached significance, with MAAS, F=3.236, p=.046, and 5FMQ, nonjudge, F=10.560, p<.000.







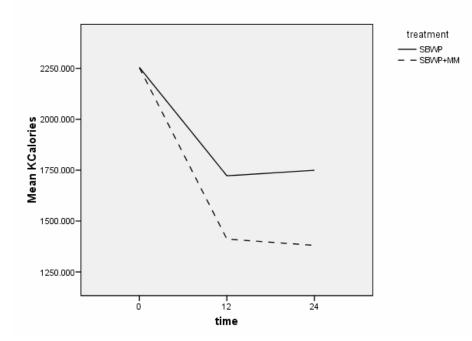
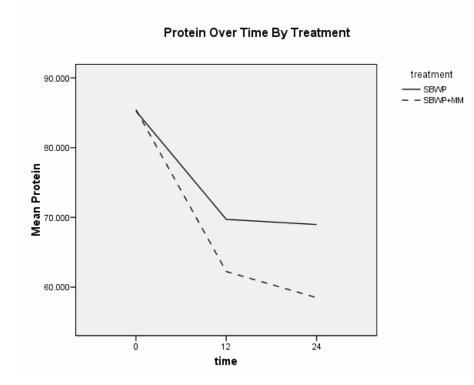


Figure 6: (continued)





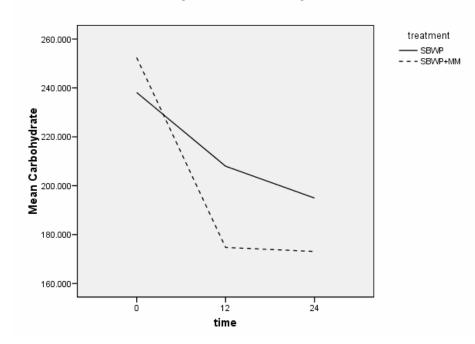


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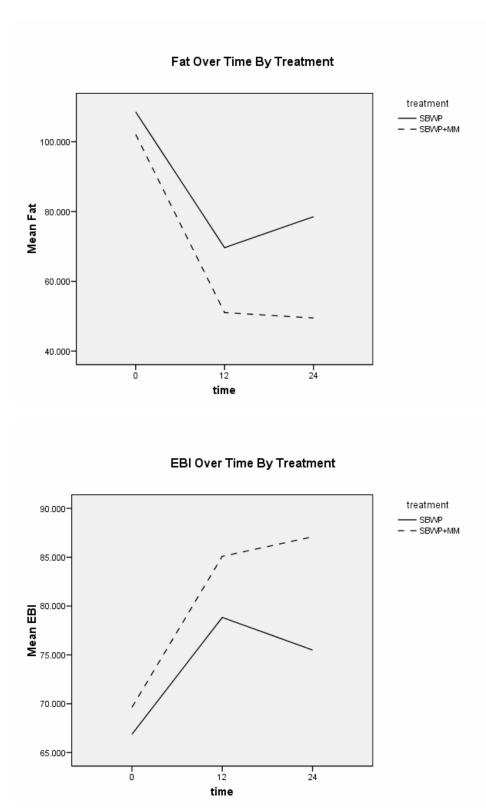


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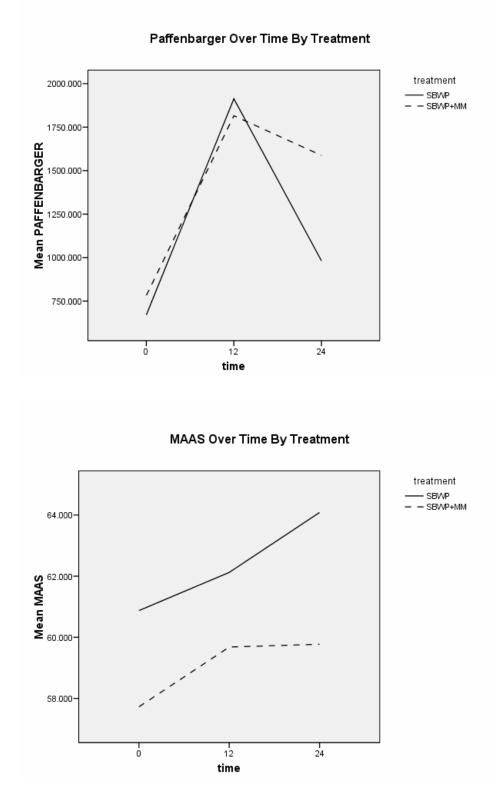
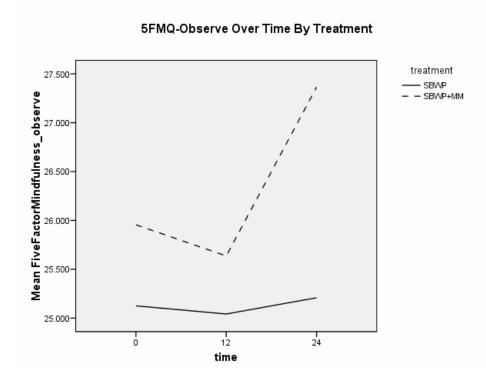


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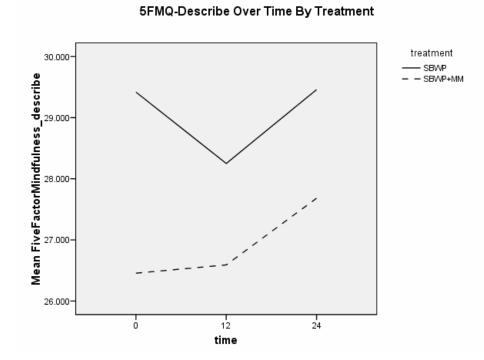


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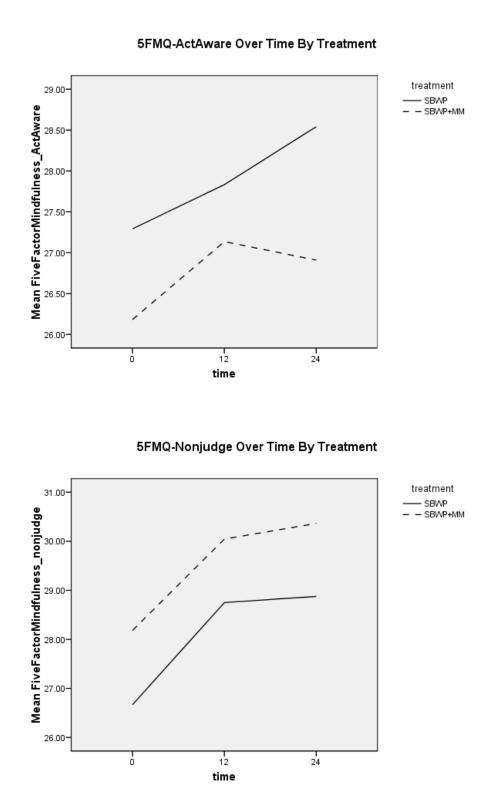


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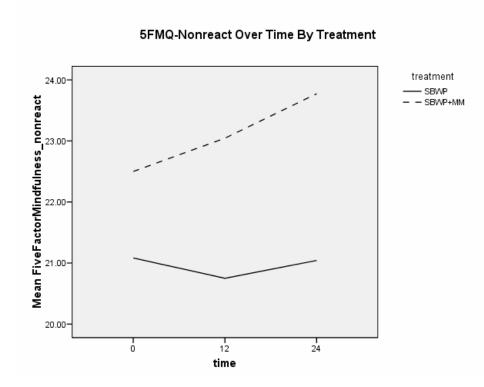


Figure 6: Changes in outcomes, SBWP versus SBWP+MM

Thirty-five subjects (76.1%) completed the 6 month intervention, 16 in the SBWP group and 19 in the SBWP+MM group. There was no significant difference between the completers and non-completers at baseline (see Table 3). Non-completers were generally older (+2.6 years), higher in body weight (+6.6 kg), and were less educated (36.4% high school/vocational training).

Mean percent attendance for the SBWP group was 62.4% and for the SBWP+MM group 75.2% (t=-1.689, p=.098). Self-monitoring was analyzed by the number and percent of diaries turned in for review by staff. These data were based on the 24 week period for both groups. Based on participants turning in weekly diaries, the mean diary return was 12.38 (SD=7.17) in the SBWP group and 15.09 (SD=6.09) in the SBWP+MM group, t= -1.377, p=.175.

Mean weekly minutes of MM practice was 22.45 minutes per week for the 12 week time point for 21 subjects and 34.92 for 24 week time point for 18 subjects based on the above averaging. Average number of times MM practiced per week was 5.29 (SD=2.9).

3.6 DISCUSSION

Significant eating behavior changes found in this exploratory study could have a larger impact on weight loss over time. Mindfulness, paying attention in the present moment to physiological, emotional and environmental cues that influence eating, may lead overweight/obese adults to healthier eating choices and behaviors to lose weight. Although weight loss was not statistically significant between groups, the 6.2 lbs. (2.8kg) weight loss difference may have clinical meaning for healthcare concerns. Also, the SBWP+MM group continued a downward trend in weight loss beyond the SBWP group from week 12 to week 24 assessments, suggesting that MM may contribute to extending subjects' commitment to behavior changes.

Table 3: Bas	eline demographics	of completers and	non-completers
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Baseline Variable	Total N=46	test statistic N=46	df	t-test p- value/ *fisher's exact	SBWP N=24	SBWP+MM N=22	test statistic	df	ANOVA p-value *fisher's exact
Number of Subjects Completers Non-completers	35 (76.1%) 11 (23.9%)			.171*	16 (66.7%) 8 (33.3%)	19 (86.4%) 3 (13.6%)			
Age (yrs) Completers Non-completers	44.6 (8.7) 47.2 (6.2)	t=889	44	.379	43.4 (9.8) 47.6 (7.1)	45.7 (7.8) 45.9 (3.5)	f=501	3	.683
Height (cm) Completers Non-completers	167.9 (5.8) 168.7 (7.4)	t=397	44	.694	168.5 (6.5) 166.9 (6.9)	167.3 (5.3) 173.6 (7.6)	f=1.007	3	.399
Weight (kg) Completers Non-completers	90.4 (12.3) 97.0 (13.7)	t=-1.516	44	.137	92.9 (11.0) 93.7 (14.2)	88.3 (13.1) 105.8 (8.1)	f=1.885	3	.147
Gender (%) Completers Female Male Non-completers	88.6% (31) 11.4% (4)			.619*	81.3% (13) 18.8% (3)	94.7% (18) 5.3% (1)	Chi- square= 3.154		.296*
Female Male	81.1% (9) 18.2% (2)				87.5% (7) 12.5% (1)	66.7% (2) 33.3% (1)			
Race (%) Completers Black/AA Caucasian Non-completers	20% (7) 80% (28)			.682*	31.2% (5) 68.8% (11)	10.5% (2) 89.5% (17)	Chi- square= 3.081		.387*
Black/AA Caucasian	27.3% (3) 72.7% (8)				25.0% (2) 75.0% (6)	33.3% (1) 66.7% (2)			
Education (%) Completers HS/vocational Some college College +	17% (6) 29% (10) 54% (19)			.084*	18.8% (3) 18.8% (3) 62.5%(10)	15.8% (3) 36.8% (7) 47.4% (9)	Chi- square= 7.006		.280*
Non-completers HS/vocational Some college College +	36.4% (4) 45.5% (5) 18.2% (2)				37.5% (3) 50.0% (4) 12.5% (1)	33.3% (1) 33.3% (1) 33.3% (1)			
Body Mass Index Completers Non-completers	32.1 (3.8) 34.0 (3.2)	t=-1.505	44	.139	32.8 (3.5) 33.5 (3.6)	31.5 (4.0) 35.1 (0.8)	f=1.225	3	.312

Continuous data are presented as mean with (standard deviation) based on t-test. Categorical data are presented as

%. *Comparison of percentages between groups uses Fisher's Exact (2-sided) statistics.

There were other findings that support MM as an additional weight loss strategy. Differences in retention at 24 weeks and percentage of participants attending the Center weekly suggest that mindfulness may support the individual in continuing the process of weight loss, an issue the

literature has identified for this population. There were significant differences in attendance between groups, another critical factor in successful weight loss, and a nonsignificant difference in dairy completion (self-monitoring) both which support MM in weight loss interventions.

There were no differences in physical activity and dietary intake between groups, possibly due to the short length of the study over time. There was also no difference on the mindfulness measures between groups. These findings may be due to the increased "paying attention" of these areas inherent in a standard behavioral weight loss program that were not show differences over a short period of time. Although MM practice in the SBWP+MM group did increase over time, 24 weeks may not be sufficient to note changes when the subjects are trying to add exercise time and mindfulness meditation practice to their busy lives.

Limitations to this study included a small sample size and a focus on short-term weight loss intervention. Due to difference in attendance measures between groups, commitment to treatment was measured in place of attendance. The measure for collecting data on MM practice was a weekly form, emphasizing recall instead of "present moment" recording. The time interval choices on the mindfulness recall form did not allow for documentation of actual practice in minutes, which reduced subject burden but decreased statistical accuracy of data gathered.

This study was exploratory by design to observe any effects Mindfulness Meditation may have combined with a Standard Behavioral Weight Loss Program for weight loss with overweight/obese adults. The findings suggest that MM may be an additional strategy to assist adults in weight loss interventions for improved success. Taking the time intentionally for the self lays a foundation for behavior change through diet and exercise. Paying attention, listening to the self, and making conscious choices in dietary decisions, eating behaviors and exercise can support the adult in weight loss. The increasing tolerance and self-responsibility that are reenforced by positive outcomes (weight loss) and lifestyle changes could assist the overweight/obese adult in staying with a weight loss program and maintaining a healthier weight over time.

The findings of this study support a larger study over a longer time period to test the hypotheses of SBWP+MM. A weight loss study over a longer period of time may allow for significant differences to emerge, beyond eating behavior changes, as the individual internalizes and incorporates MM as a weight loss strategy and a lifestyle change.

4.0 MANUSCRIPT 2: TAKING TIME INTENTIONALLY FOR THE SELF: MINDFUL WEIGHT LOSS

4.1 LETTER TO EDITOR OF BEHAVIORAL MEDICINE JOURNAL

Editor, Journal of Behavioral Medicine

Ohio University

Department of Psychology

245 Porter Hall

Athens, OH 45701-2979

August 15, 2008

Dear Dr. France:

I would like to submit the attached manuscript, "Taking Time Intentionally for the Self: Mindful Weight Loss," for consideration for possible publication in the Journal of Behavioral Medicine.

This qualitative manuscript explores the experiences of overweight/obese adults following a 24 week randomized controlled trial in a standard behavioral weight loss program plus mindfulness

meditation. This document speaks to the effects of mindfulness meditation on participants' eating behaviors, choices with food and exercise, and lifestyle changes that occurred over the length of the intervention and up to five months post-intervention.

This paper has not been published or accepted for publication. I look forward to your feedback and can be reached at spadarok@pitt.edu.

Sincerely,

Kathleen C. Spadaro M.Ed., B.S.N 104 Berrybush Drive Harrison City, PA 15636

4.2 ABSTRACT

Objective: To explore the experiences of adults following participation in a 24 week Standard Behavioral Weight Loss Program plus Mindfulness Meditation (SBWP+MM).

Design: Qualitative research methods (telephone or email interviews) were used to understand and interpret individual and the larger group experiences with mindfulness meditation as an addition to dietary restrictions, increased exercise prescription, self-monitoring and other standard behavioral weight loss strategies.

Subjects: Twelve subjects from the SBWP+MM intervention arm (n=22) were recruited into the qualitative arm of the study. Purposeful sampling included: 1 male, 1 African American, the youngest in age and three of the older participants (age range = 21.40 - 55.60), and seven participants who represent the range of the weight loss, attendance and diary completion range.

Results: The over-arching theme from the interview analysis was expanding mindfulness in personal life. Specific sub-themes described the theme of expanding mindfulness in personal life and were related to the MM component. These themes appeared to assist subjects in their weight loss. The themes were: taking time for self, paying attention, listening to self, conscious choice (these four with intentionality), openness/tolerance, self-responsibility, positive outcomes and lifestyle changes.

Conclusion: This study suggests that MM combined with a SBWP may enhance the success of overweight/obese adults. Factors identified in this study need to be examined further using prospective designs, a longer study time frame, a larger sample size, and greater variability in the sample.

KEYWOODS: obesity; mindfulness meditation; weight loss

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4.3 INTRODUCTION

There is an underlying assumption that improving self-regulation skills in overweight/obese adults will lead to successful weight loss. Standard behavioral weight loss programs (SBWP) attempt to help individuals monitor their food intake, implement a plan to increase their physical activity, and follow weight loss tips and guidelines. However, there appears to be something missing in the process for many of those individuals. Using diet recommendations, increasing exercise and self-monitoring does not always lead to weight loss success. Mindfulness meditation, based on Mindfulness-Based Stress Reduction (MBSR) (Kabat-Zinn,1991), is a self-regulation strategy that has been explored in other healthcare issues, including eating disorders. Mindfulness meditation strategies may improve self-regulation with eating, exercising, and self-monitoring behaviors in overweight/obese adults who are trying to lose weight.

To examine the effects of MM on weight loss efforts, a qualitative component was added to a 24 week randomized, controlled trial that explored MM with standard behavioral weight loss strategies. The individual and group SBWP+MM intervention experience was of particular interest, beyond the quantitative findings, for several reasons. First, this intervention was an innovative weight loss approach which may best be investigated by getting the participants' perceptions of their experiences. Although MBSR has been explored in adults with eatingdisorders, (binge-eating and anorexia), in multiple exploratory studies with promising results (Baer, Fischer, & Huss, 2005), there is no current documentation in the literature of its use with a community population of overweight/obese adults.

Second, MBSR has had promising results with other chronic health concerns such as selfregulation of: mood, anxiety and depression, pain management, cancer support, hypertension, coronary artery disease, substance abuse, transplant symptoms, stress management, hot flashes, and psoriasis treatment (Alterman, Koppenhaver, Mulholland, Ladden, & Baime 2004; Bowen et al., 2006; Carlson, Ursuliak, Goodey, Angen, & Speca, 2001; Chang et al., 2004; Davidson et al., 2003; Gross et al., 2004; Kabat-Zinn, 1982; J. Kabat-Zinn et al., 1992; Majumdar, Grossman, Dietz-Waschkowski, Kersig, & Walach, 2002; Miller, Fletcher, & Kabat-Zinn, 1995; Morone, Weiner, & Greco, 2006; Speroff, Glass, & Kase, 2001; Tacon, McComb, Caldera, & Randoph, 2003). Yet as suggested through some exploratory studies (Kristeller, Hallet, & Brendan,1999; Marlatt & Donovan, 2005; Segal, Williams, & Teasdale, 2002), MBSR strategies may be more effective if the techniques are fine-tuned for the targeted population and health concern. Kristeller et al. developed mindfulness based-eating awareness training (MB-EAT) for disordered eating; Segal et al. created mindfulness-based cognitive therapy (MBCT) for mood disorders and disordered eating and Marlatt and Donovan created Mindfulness-Based Relapse Prevention (MBRP) for addictions. Exploration of the SBWP+MM participants' experience for effectiveness and potential refinement of the intervention was important for qualitative exploration (Fonteyn & Bauer-Wu, 2005).

Lastly, the qualitative data can be used to support the quantitative findings of the study. Although weight loss was the primary outcome of the study, changing behaviors of dietary intake, eating, and physical activity are essential components to weight loss success, both immediate and long-term. Exploring participants' experiences through qualitative interviews and interpreting their language to describe their experience may tease out further information regarding the intervention on both an individual and larger group level.

4.4 BACKGROUND

Although SBWP's that include restricted dietary intake, prescribed physical activity and selfmonitoring have proven successful in weight loss research (Gallagher,

Jakicic, Napolitano, & Marcus, 2006; Jakicic, Marcus, Gallagher, Napolitano, & Lang, 2003; Pi-Sunyer, 1996; Shaw, O'Rourke, Del Mar, & Kenardy, 2005; Thomas, Jakicic, & Gallagher, 2004), the national obesity statistics have reached an epidemic level (Statistics, 2004). Multiple qualitative studies in the literature explored issues with weight loss. Factors that increase weight loss success and barriers that interfere with weight loss were noted.

Tod and Lacey (2004) reported that factors that motivate adults to take action regarding their weight were the ability to act for themselves (willpower), health problems or fears, looking and feeling good about themselves, and special events such as critical birthdays, weddings, and holidays. Timko, Perone and Crossfield (2006) studied behaviors college students engaged in trying to lose or maintain weight. They targeted their focus on healthy eating, exercise, and reduced caloric intake. Yet findings showed that fewer women than men used healthy eating behaviors and exercise.

Berry (2004) described adults who successfully achieved and maintained weight loss as having recognized the problem of weight with readiness to act and deciding to change. These adults took control by actively engaging in new behaviors, thus improving self-efficacy. They incorporated these behaviors of increased awareness of food, portion control, exercise and selfmonitoring into their lives which led to life-style changes. The study also described the women prior to weight loss as having "low self-awareness" with not being in tune with the self, not being aware of events contributing to weight gain, and not being aware of nor practicing health behaviors in their lives. These findings identify factors in weight loss efforts that lead to success. Other studies explored the barriers to weight loss and maintenance. Byrne, Cooper, and Fairburn (2003) identified lack of vigilance (self-monitoring), dichotomous or black-and-white thinking style, a tendency to use eating to regulate mood, and a tendency to evaluate self-worth by weight and shape, and dissatisfaction with weight loss achieved. Adolfsson, Carlson, Unden, and Rossner (2002) identified eating habits as being behaviors hard to replace. Adults struggled to think differently about eating and increase healthy food choices. They could not change expectations that eating would decrease stress, promote calmness and relaxation, and soothe uncomfortable feelings like pain, anger or worry. Despite support from the weight loss program, these adults struggled to apply the knowledge and behavioral change for daily use away from the program. Bidgood and Buckroyd (2005) added that dieting had limited success and was seen as boring, unsociable, too difficult a commitment counting calories, and once interrupted it was hard to return to dietary plan. Multiple factors have been identified in the literature to why weight loss is difficult to achieve and maintain.

Mindfulness Meditation was added to a weight loss program to address the weight loss issues described in the literature. Kabat-Zinn (1991) described MBSR as having specific qualities and Shapiro and Schwartz (2000) who developed the mindfulness model, Intentional Attention & Attitude (IAA), which evolved from self-regulation theory and systems theory, re-iterated these qualities. The seven qualities of mindfulness are: nonjudging, nonstriving, acceptance, patience, trust, openness and letting go. These qualities could support the individual in successful weight loss.

In applying these qualities to weight loss, MM could help adults develop the ability to observe the present moment without evaluation and remain unattached to outcome (not forcing or expecting quick results). They could learn to be open to the present moment, allowing for time in the process of change, and trusting self through body, intuition, emotions as well as trusting in life itself. Seeing each situation or event as it is in the present moment as new with possibility and not holding on to thoughts, feelings or experiences beyond the present moment may allow adults struggling with weight loss attempts to experience success.

MBSR has been explored in other areas as well. For example, in an article exploring MBSR with nurses on stress reduction and burn-out, results included increased self-awareness of body, thoughts and emotions, focus on self-care, increased patience, calmness or relaxation, improved self-confidence, and more conscious eating habits. Even though the main focus was on stress and not weight, one nurse reported successful weight loss over the course of the intervention (Cohen-Katz, Wiley, Capuano, Baker, & Shapiro, 2005). In a study exploring MBSR with mental health in-patients, results reported changes in thoughts and attitudes by increased awareness of thoughts and tolerance for exposure to problem thoughts and beliefs. These patients learned to observe their thoughts with nonjudgement of difficult feelings, without trying to avoid or change them and found a heightened state of awareness and increased self-management by taking responsibility for oneself (York, 2007).

Dobkin (2008) supported Shapiro et al.'s theory that MBSR subjects "reperceive" their daily life experiences over time through understanding and accepting that "the way things are" are not always how one wants or expects them to be thus learning to accept life in the present moment. In taking care of the self, subjects took responsibility for what they could change and let go of what they could not change, and experienced a spirit of openness and connectedness to the self and others. Proulx (2003) found that the women who attended a MM eating disorders group described themselves as more self-aware, self-accepting, assertive, less impulsive, and experienced less out-of-control behaviors than prior to the intervention.

Majumdar, Grossman, Dietz-Waschkowski, Kersig and Walach (2002) explored the effects of mindfulness on a healthy adult German sample and found that they had an ability to live daily life with awareness, calmness, and less burdened sense of self. With mindfulness used as a coping tool, suffering (emotional and physical) was reduced either through symptoms reduction with enhanced coping skills or an enhanced sense of self-responsibility. The findings from these qualitative mindfulness studies lead us to support Kabat-Zinn's theory that "mindfulness integrated into daily life positively affects one's capacity of self-regulation and of health-promoting adaptive behavior" (Kabat-Zinn, 2005).

4.5 METHODS

This qualitative study was part of a mixed methods design exploring Mindfulness Meditation in a randomized, controlled study with overweight/obese adults. The quantitative component, using intention-to-treat principles, had 22 subjects randomized to the SBWP+MM intervention. An addendum to the initial proposal was approved by the University of Pittsburgh Internal Review Board 2 months following the intervention. Subjects signed an additional informed consent to participate in the qualitative component of the study.

The qualitative method used was interpretative description, a method that came from the nursing researcher's needs for a method that embraces the clinical questions and applications related to human health needs (Thorne, Kirkham, & MacDonald-Emes,1997). Thorne et al. introduced interpretative description as an approach to qualitative research that was not founded in any specific qualitative theories (i.e. grounded theory, phenomenology, ethnography) to "develop knowledge about human health and illness experience" (p169). Interpretative

description begins with what is known through a critical review of current knowledge (in this study-standard behavioral weight loss interventions), proceeding with utilizing inductive reasoning to test and challenge initial interpretations of the inquiry (what is the experience of overweight/obese adults in a weight loss intervention with mindfulness added?), and to develop knowledge that can be conceptualized as a coherent final product (such as could be applied to general and individual client weight loss strategies (Thorne, 2000). Key components of this method are: 1) individuals hold multiple constructed realities that are complex, contextual, and subjective and these realities need to be holistically studied and 2) the investigator and the interviewee are both influenced by their reactions (Lincoln & Guba,1985; Thorne et al.,1997).

4.5.1 Participants

Keeping with Thorne's purposeful interviewing technique while responding to the IRB's request to include all subjects in the interview process, more effort was made to obtain interviews from specific participants to increase the diversity of the sample. This required re-contacting them by telephone when three email promptings did not receive a response. The three consented subjects who did not respond to email interview questions were not contacted by telephone since similar demographics and experiential differences were already provided through the other interviewees.

Purposeful sampling was based on age differences, race and gender. The SBWP+MM group had three African American (AA) subjects, two males, and a wide age range (21.40 – 55.60). Nineteen of 22 participants completed the 24 week intervention. An attempt was made to have both completers and non-completers in the sample. Other purposeful sampling included differences in weight loss, attendance, and diary completion.

Table 4: Interview Questions

	Il me what it means to you to be mindful when you are trying to lose weight? . Probe: What does it mean for you to be mindful with eating? . Probe: What does it mean for you to be mindful with physical activity/exercise?
3.a. 3.b.	 I me what it has been like for you to be in a weekly weight control intervention for six months. Probe: Were there any mindfulness meditation exercises that you wished you had more in the program? Probe: Were there any mindfulness meditation exercises that you didn't like or would not like included in the intervention? e there any additional comments you would like to make?

4.5.2 Design

Each participant was given the choice of a telephone interview or an email interview. The qualitative interview guide is in Table 1. The telephone interview would go through all the questions in the same phone contact. The email interview broke the questions over three different contacts so as to not overwhelm the subject and to allow for further feedback over time. Both choices, telephone and email contact, allowed the investigator to re-contact the subject for further questioning.

4.5.3 Procedure

Subjects in the SBWP+MM group were contacted two months following the 24 week intervention by telephone to discuss their interest in participating in a qualitative interview. Seventeen of the 22 group subjects were reached and expressed willingness to participate in the

interview process. One subject was not approached since he had withdrawn by written notice after week 1 of the quantitative component. Another non-completer refused stating time constraints due to moving. Three subjects did not respond to telephone enquiry. The remaining 17 subjects were mailed a packet containing a letter describing the interview, two copies of the consent form for their signatures, and a stamped addressed envelope to mail the signed consents. When mailed consents were received at the Center, the Principal Investigator signed the consents and the documents were recorded, one copy filed and a copy mailed back to the subject for their record keeping. Signed consents were received from 15 subjects.

Subjects were assigned identification (ID) numbers following the receipt of signed informed consents. A de-identified interview excel sheet was used to track the procedure for each subject from initial phone contact, mailing of consent forms, receiving consent forms, and date of each contact with subject. With the choice of telephone contact, subjects were notified that the call would be recorded for transcription purposes, both verbally and in writing in the informed consent. Telephone contacts were transcribed verbatim into Word Documents. Email contacts were cut and pasted into Word Documents and email documents were deleted. Word Documents were identified by subject ID and date.

Initially two subjects chose telephone due to no or limited email access. Telephone contact was scheduled with the subject prior to the interview with subject awareness that the process would be \sim 20-30 minutes long. Participants who chose email were sent an email containing interview questions as soon as the signed consent form was received and signed.

Interviews were conducted with a total of 12 subjects from the SBWP+MM group. Three of the 15 consented subjects did not respond to email contacts despite their request for email contact. After two reminders, the interventionist did not continue to pursue these subjects.

Although initially only two subjects requested telephone interviews, the interventionist contacted two other subjects, the youngest and the remaining male, by telephone when the email contact was not made. Both of those subjects agreed to the telephone interview and kept the scheduled interview times. See Table 2 for the summary of contacts. Although the initial implementation plan was to question the subject via the email three different times, five subjects did not respond to further prompting email so they did not respond to all the interview questions. Because of the redundancy in the collected data, efforts to keep contacting these participants were not pursued.

4.5.4 Data Analysis

Qualitative analysis of the 12 interviews was continuous and iterative over a two month period. Transcripts were reviewed in their entirety following the interview and a summary of the transcript was made. This investigator then reviewed transcripts with two other qualitative researchers who are not familiar with mindfulness meditation on multiple occasions over the course of the interview process to address bias concerns and to expand the perspectives of the analysis. Notes of those meetings and continued review of transcription moved into broad coding of themes. Themes were made into lists and cross-referenced with transcriptions for support of themes, variation of themes, and consolidation of themes. Finally, flow charts depicting the themes were made and refined into a qualitative matrix with further review of transcripts.

4.6 **RESULTS**

4.6.1 Sample

Twelve subjects from the SBWP+MM group consented and participated in qualitative interviews. Mean age of the participants was 48.5 years (range 21.4-53.1), 91.6% (11) female, 8.3% (1) African American, 16.6% (2) high school/vocational training, 50% (6) some college, and 33.3% (4) college + prepared. Of the 12, 33.3% (4) were interviewed by telephone and 66.6% (8) were interviewed through email. See Table 6 for subjects' demographics and contact information.

Subject ID	Age (yrs)	Gender	Race	Ed. Level	6 Month Wt Loss	Type of Contact	Total Contact	Total Response	Questions Answered
01	53.1	Female	Cauc	2	9.16	Phone	3	1	100%
02	47.2	Female	Cauc	3	8.07	Email	5	3	100%
03	45.7	Female	Caud	3	11.70	Email	4	3	100%
04	44.2	Female	Cauc	2	10.25	Email	4	1	33.3%
06	45.3	Female	Cauc	2	7.89	Email	5	2	66.6%
07	51.3	Female	Cauc	2	7.05	Email	4	3	100%
08	49.5	Female	AA	2	5.44	Phone	2	1	100%
09	49.7	Female	Cauc	3	11.79	Email	5	2	66.6%
11	21.4	Female	Cauc	2	15.33	Phone	4	1	100%
12	52.0	Male	Cauc	3	9.34	Phone	4	1	100%
13	43.7	Female	Cauc	1	6.62	Email	4	1	33.3%
15	39.6	Female	Cauc	1	2.35	Email	5	1	33.3%

Table 5: Subjects demographics and contact information

Cauc=Caucasian, AA=African American; Education: 1=high school/vocational training, 2=some college, 3=college+; 6 Month Wt Loss =kg. There was a three month lag time between the 24 week assessment and the interview process due to a delay in IRB approval. This delay may have had an effect on the participants who agreed but did not follow through with consent or response to email interview questions.

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4.6.2 Themes

Over the length of the analytic process, many concepts were explored and resulted in an overarching theme of expanding mindfulness in personal life which was further described by four major overlapping themes (initial process) and four themes that expand from the initial process. The data analysis was detailed, leading to the conception of a qualitative matrix which could be better conceptualized if it was a 3- dimensional matrix (see Figure 7).

Analysis began with a foundation of four themes: taking time for self, paying attention, listening to self and conscious choice. These four themes were all connected by intentionality. Intentionality is the "aboutness *or* directedness of mind (or states of mind) to things, objects, states of affairs, events" (Siewert, 2002) or as defined by French philosopher <u>Jean-Paul Sartre</u> (1943) intentionality is indistinguishable from consciousness. Overlapping of the 4 themes depicted the building upon and supporting one theme with another and the on-going interaction between the 4 themes. Taking time for self, paying attention and listening to self allowed the subject to make conscious choices. Conscious choice, especially in relation to food, exercise,

and giving permission to take care of the self re-enforced the other 3 themes, taking time for self, paying attention and listening to self. Each theme interacted with each other and was an integral part of the sum of the four themes.

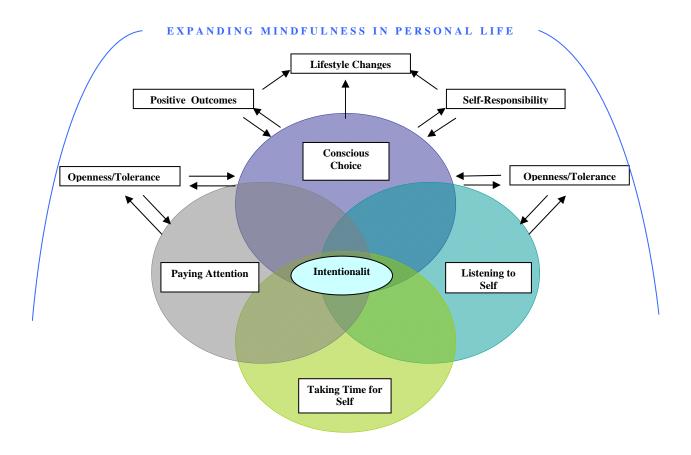


Figure 7: Themes from Mindfulness Meditation participants' qualitative interviews

The next four themes developed from the foundational four major themes. The theme openness/tolerance came from both paying attention and listening to self which supported

conscious choice. An openness/tolerance for ambiguity in thoughts and emotions or difficult thoughts or emotions allowed for more options with conscious choice. Conscious choice led to positive outcomes, increased self-responsibility, and lifestyle changes. Positive outcomes, such as weight loss, eating healthier, exercising more, feeling stronger and taking care of the self reenforced self-responsibility and conscious choice. Over the time in the study and the several months following, subjects began to see taking time for self and conscious choice in eating, exercise, as taking care of the self and as lifestyle changes.

Subjects expanded the concept of mindfulness, not only in eating and exercising, but work, family and other aspects of their personal life. Although the last four themes developed from the first four themes, these themes were not just outcomes. These themes also became reenforcers of the initial process of taking time for self, paying attention, listening to self and making conscious choices with intentionality, and served to keep the process on-going. The intention to use mindfulness with weight loss expanded to mindfulness in the participant's life as a whole. Each theme will be further explained with quotes from the interviews.

4.6.2.1 Taking Time Intentionally for Self. The beginning step for participants and consistent theme in the analysis was taking time intentionally for the self. This theme set a foundation of mindfulness with the subjects. Eight of the subjects described and used the language of "taking time" in the interview process. This "time" was intentionally focused on eating, exercising, exploring thoughts, decision-making through exploring alternatives, living in the moment, and food choices. If participants took time to think about foods prior to eating, healthier choices and smaller portion sizes occurred. Allowing time to eat to enjoy the process and not rush through a meal was important. Waiting a few minutes to check in with the body on hunger reduced overeating and the unpleasant feelings that accompanied it. Taking time to walk, do aerobics,

and other exercise changed the daily routine. As expressed by one subject, "Taking time was helpful to lose weight and live in the moment."

This concept appeared to be new and positive to the participants as they shared their experiences. As subject phrased it, "speedy results were no longer important if I was hurting my health or happiness". Taking time impacted decision-making and choice, "I take a step back and think about alternatives." Taking time also appeared to be re-enforcing, "I find the time to exercise because I like it and I like myself doing it".

4.6.2.2 Paying Attention. Eleven of the 12 subjects described an intentional "paying attention" to their body, senses, thoughts and emotions. Paying attention brought new insight into their previous mindless eating behavior. These subjects recognized that they had been unaware of their bodies and physiological cues and were more impulsive with food choices and eating prior to the SBWP+MM group experience. When they paid attention, eating was pleasurable, tastes were heightened, all their senses were engaged in the eating process and smaller portions of food choices were still enjoyable. They were able to assess their hunger and satiety levels. Subjects not only tasted but also enjoyed the flavors, textures and smells of food, and separated hunger from habit, emotional or self-soothing eating behaviors.

The language the subjects used to describe this theme emphasized the activation of their senses in the process of paying attention, especially to the eating process. With eating, subjects described "savoring the flavor, the textures, and the smells of food" and the added ability to explore desires in food choices between "salty or sweet" taste. Consequences of their eating behaviors and food choices were also noticed. A subject described "feeling pants tighter and thinking about the consequences" with regaining 6 lbs. since the intervention ended. Another individual described "feeling comfortable after eating, not overly full" now.

Several participants were using mindfulness meditation exercises to pay attention and described "checking in" with themselves using body awareness and emotional awareness" prior to eating and making food choices. One such example was the "raisin exercise" which consisted of mindfully eating a raisin using all of the senses (Kabat-Zinn, 1991). "I have used the raisin exercise to gauge my hunger level, to control my eating, to increase my awareness of taste, texture and smell". Only one subject described paying attention in relation to exercise. "I check in with my body about how exercise makes me feel and being aware of low energy days so I can make changes to exercise plans". Paying attention appeared to lead to behavior changes.

4.6.2.3 Listening to Self. Along with paying attention was listening to the self. If one pays attention but doesn't listen to oneself, the information or message, received from paying attention is ignored. As the earlier subject mentioned her pants becoming tighter, she listened to the discomfort that came from that sensation and she didn't like it. Listening to the self encompassed the body, the mind, and the emotions.

Five subjects gave descriptions of this process as it related to their experience. With exercise, one subject described, "I am feeling better but am also listening to my aches and pains". Describing weight loss another participant stated, "I got a wake-up call (from my experience in the group), and I felt back on track when I followed the SBWP + MM strategies". Listening to self was seen as "beneficial while not staying on task equaled weight gain".

Through listening to herself, one participant had a powerful realization. "I was not always hungry when I felt hunger or that I wanted more to eat but wasn't always hungry for all of the food I took". Listening to the self, one subject described how she has changed how she tries to cope with stress. "When I feel stressed, I now take deep breaths to reduce muscle tension and stress." One participant summed listening to the self this way, "being in tune of your body yet the mind controlling and the body (behavior) following, making it easier to control what you eat and do". Listening to self appeared to be a beneficial step for these participants prior to making a choice or acting impulsively.

4.6.2.4 Conscious Choice. Combining the actions of taking time for self, paying attention and listening to self with intentionality, allowed the participant to make conscious choices rather than act impulsively, out of habit or mindlessly. These processes provided internal and external feedback from which to base a conscious choice. Increasing conscious choice regarding both eating and exercise issues was described in detail by eight of the interviewed subjects.

Again the language was significant as subjects used very specific words, planning, preparing, determined, choose, choices and conscious effort in their interviews. There were many examples from the transcripts. "I would determine what I was hungry for, what it would take to satisfy a craving, eating only when hungry". "I chose healthy alternatives that were good and satisfying". I make the right choices before putting food in my mouth". "I make a conscious effort to make time in the day to exercise, planning the night before". "I planned breakfast and lunch every day for a week at a time." Clearly, conscious choice affected previous habitual behaviors or impulsive reactions.

4.6.2.5 Openness/Tolerance. Listening to self and paying attention led subjects to the next connecting theme of openness/tolerance. In the literature, qualitative studies pointed to dichotomous thinking, viewing body size and shape as a basis for self-esteem, and struggles with difficult thoughts or emotions as barriers to weight loss. SBWP+MM subjects experienced more open-minded thinking which led to a range of options and choices that were helpful in their weight loss. They found that they could tolerate both positive and negative thoughts and feelings

together which allowed them to cope differently than through emotional eating. Self-judgment, especially with the body, was being actively worked on to change.

This newfound openness/tolerance also supported conscious choice with a decrease of impulsiveness and taking self needs into consideration. Subjects described their openness/tolerance in their own words. "I chose to stay healthy with food choices and I also allow for a glass of wine or a snack by fitting it in the meal plan". "To change impulsive behaviors, I stop to evaluate first, and then choose."

Examples of changing dichotomous thought were found in the transcripts. "I am changing my 'all or nothing' thinking now when it comes to eating". "This experience opened my mind to different (exercise) options". "I am not avoiding certain foods like on previous diets but I am limiting amounts of them". "You should see me, I am exercising whenever possible, not just when I have an hour, (but when I am) cooking in the kitchen, brushing my teeth".

Tolerating contrasts were also described through the interviews. "I found the weekly sessions were mixed, seen with excitement and as a weekly chore". "I am able to recognize the competing forces in my brain, making peace between them". "I find exercise hard but relaxing and it increases my energy. I didn't feel like doing it but did it".

"It is hard when you love food but I need to portion sizes, not give it up entirely". "It is good to know your strengths and weaknesses, good at times, difficult at times".

Attempting to change self-judgment was actively explored by several subjects. "I started to consciously not judge myself with imperfect days". "I am not beating myself up when my day wasn't perfect". "It is okay now for me to open up more". These subjects were able to describe openness/tolerance in their thoughts, with their emotions, in their choices, and in their view of themselves.

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4.6.2.6 Self-Responsibility. Five of the respondents identified an increase in self-responsibility towards their health and their weight. Adults struggle with weight loss interventions because they want the intervention to extend over a longer period of time and want more support outside of program hours. With an increase in self-responsibility, dependency on a structured program can be reduced over time and the problem, weight, is owned by the individual, not the person or program treating them.

Given that these interviews occurred three to four months following the intervention, the subjects have taken self-responsibility as heard through these transcripts. "I am trying to lose the 6 lbs. I gained back, I planning to quit drinking (wine) for Lent." "I viewed the 24 weeks almost as an obligation to myself to lose 2 lbs a week". "I try to remember the hard work done to not overeat and to continue to exercise". "I make myself a priority, make the effort to exercise almost every day with the purpose of maintaining health and weight, not just for fun or convenience". "I have renewed my commitment to journal again to avoid mindless eating". These participants appear to have internalized the need to be responsible for their weight, weight loss choices and behaviors.

4.6.2.7 Positive Outcomes. The experience of the SBWP+MM was surprisingly pleasant for many subjects, for others it was a welcome and wanted change. They found that positive outcomes from MM were not only related to weight, food and exercise, but to other areas of their life. Seeing and feeling the positive results appeared to re-enforce the MM process and increased their self-esteem and self-efficacy with weight loss.

The following transcript examples described the positive outcomes of many participants. "I felt good about myself, I had more energy, and I knew it was healthy for me". "I liked myself as an exerciser, I learned a lot about myself". "This experience aided in my overall well-being". "I enjoyed myself, I was pleasantly surprised". "MM is relaxing and calming". "I wanted to focus on being good to myself instead of not caring about damaging self for the sake of thinness". "I am finding more enjoyment in eating, more satisfied with food". "I put myself higher on my mental radar or to-do list". "MM motivated me, changed my bad mood, and kept me from being depressed".

Also there was an increase in awareness of other reasons to eat (or not eat). "I know I don't want to eat because of boredom and emotions". "With stress, instead of eating chocolate I try breathing". "I am checking in with myself to see how I am feeling and why I am eating". "I am not being emotional about eating". Although this theme was a result of the preceding themes, the positive outcomes described above re-enforced and supported the on-going repetition of openness/tolerance and the four foundational themes.

4.6.2.8 Lifestyle changes. One of the common barriers to weight loss is breaking old habits and replacing them with new healthy lifestyle changes involving dietary intake, eating behavior, exercise and self-monitoring in a nonjudgmental manner. Breaking habits involve all of the previous themes: taking time for self, paying attention, listening to self and making conscious choices with intentionality. Openness/tolerance to both internal and external difficulties, self-responsibility and positive outcomes come from the founding four themes and with the on-going, repetitious cycle replace old habits with new behaviors.

Ten of the subjects described the theme of lifestyle changes in their interview. Subjects' transcripts described the process of losing weight as integrative and encompassing their lives. "I was more thoughtful about what I was doing during the week, the weight loss program became a habit, not like my previous hypnosis experience (with weight loss) a one shot thing". "I used to write down food intake, now I do it in my head". "I was a veteran of diets, disciplined for a

while but not lasting, reverting back to bad habits. SBWP+MM helped me get into a routine, eat fewer calories." "To deal with the process of eating, I was looking for something long term. I found checking in with myself, my hunger, my satiety, watching ingredients, is a lifelong habit I have acquired and exercise is a daily routine now". "I found myself teaching others in work what I was learning and doing, while past diets didn't change the bad habits". "I have incorporated mindfulness in my daily life". "I am incorporating changes in daily life." As one subjected summed her experience, "We are on a weight loss journey". There was a collective agreement, 10 out of 12 subjects, that MM supported lifestyle changes in each of their lives.

4.6.2.9 Expanding Mindfulness in Personal Life. From the initial taking time for self through lifestyle change, participants reported that mindfulness meditation did not just affect weight loss, eating and exercise behaviors. Taking time for self with meals and exercise opened to possibilities of taking time for self with other aspects of the self. Paying attention and listening to the self expanded to other areas as well. The mindfulness meditation activates the matrix and all the themes become involved in the process. The over-arching theme of this study was expanding mindfulness in personal life which started with taking time for self. Encompassing all of the themes identified, the process leads to mindfulness in life in general, not limiting it to one aspect of the life, weight loss.

Five subjects spoke directly to this theme. "I am making healthy choices for myself and my family". "I am using MM at work and I am teaching others at work about MM". "I am mindful in many other aspects of life". "This (practicing MM) has helped me to control all aspects of my life". All of the eight preceding themes added and supported a total encompassing theme of expanding mindfulness in personal life. Being mindful was not limited to one aspect of the self, weight loss, but affected many other parts of the individual's life.

Recognizing the MM is a process, this theme appears to be later in the development process. Fewer subjects reflected on this aspect while most of the subjects reported lifestyle changes.

4.7 DISCUSSION

The qualitative component of this mixed methods study supports the quantitative findings that SBWP+MM had a significant effect on eating behaviors. Although the difference in weight loss was not statistically significant between groups, the SBWP+MM lost more weight (by 2.8 kg.) than the SBWP group. That difference in weight loss may be clinically meaningful. Understanding the themes that these subjects described from their experience may have longer term effects from a self-regulatory perspective, both on weight loss and their health in general. The themes identified in the transcripts echo the literature documenting the struggles and successes in the overweight/obese adult population. The themes also coincide with mindfulness qualities and other qualitative findings in the study of mindfulness meditation.

Through transcript analysis, the foundational themes with intentionality were more descriptive and detailed. The subjects' emphasis on these themes may indicate a timeline of mindfulness meditation practice development. Current emphasis on these four themes by participants may suggest that MM was in the earlier stages of developing a lifelong pattern or integration that results in and is re-forced by openness/tolerance, positive outcomes, self-responsibility, and lifestyle changes.

The first four themes, taking time for self, paying attention, listening to self, and conscious choice were re-enforced by experiential exercises in the SBWP+MM that the subjects shared in their interviews. They described carrying over these experiences into their lives even

months after the program had ended. Their ability to be more open, tolerate ambiguity while monitoring body, mind and emotions supported conscious choices with their eating, exercises and other stresses in their lives. These described experiences counter the barriers to weight loss described in the literature, specifically a black-and-white thinking style and the tendency to use eating to regulate mood (Byrne, Cooper, Fairburn, 2003). Even making choices that did not support weight loss did not become viewed as a failure as it would have previously.

Positive outcomes came from the conscious choices, the intentional listening, paying attention and taking time for self. Participants expressed a sense of self-control, self-responsibility. The literature review suggested self-responsibility assisted in weight loss as individuals recognized the problem of weight, decided to change, took control and actively engaged in new behaviors (Berry, 2004).

Obesity literature has identified many challenges facing the overweight/obese population attempting to lose weight. Bonadonna (2003) described the use of meditation with chronic disorders as bringing awareness to habitual patterns of thought, feeling and behavior, increasing conscious choices to support health and well-being, and supporting the view of the whole self rather than fragmenting the self through various symptoms. Results from the analysis of the SBWP+MM participants' interviews suggest that MM can also work in similar ways with overweight/obese adults. The themes from the participants support on-going weight loss and healthy lifestyle focus with intentionality based on the literature findings.

Over time and repetition of the process for the subjects, moving through, up and down and across the themes, lifestyle changes started to occur in these subjects. Literature supports the need for lifestyle changes for successful weight loss (Adolfsson et al., 2002; Berry, 2004; Wing et al., 2005) and to maintain the weight loss over time. Mindfulness Meditation has had promising results in many areas of life, medical health concerns, mental health, stress, health maintenance, and work. Mindfulness is a technique and a way of life (Kabat-Zinn, 2005) that may enhance the effectiveness of weight loss interventions.

All of the participants interviewed supported a positive experience with SBWP+MM. There were no known negative side effects or consequences. The few negative comments regarding specific exercises were actually mixed, both seeing yoga as a benefit and as hard or uncomfortable to do as a mindfulness movement exercise. The lone male subject admitted he stopped doing yoga when his wife and daughter made fun of him, yet he never missed a session and was always doing whatever MM exercise was being taught that evening. Mindfulness walking felt "foolish" to one participant who was a brisk walker on the treadmill prior to injuring her foot during the 24 week intervention.

There was a noticeable difference in the number of references to eating and food compared to exercise in discussing the SBWP+MM. The few negative comments focused on the exercise component of mindfulness movement, the focus on the body in motion using yoga and mindfulness walking meditation. This would be an area to explore and expand on for future SBWP+MM interventions. There were limited resources when the intervention was being developed besides the MBSR model by Kabat-Zinn.

Other limits to this study include the lack of feedback from participants that were in the SBWP group and SBWP+MM participants that did not complete the study. Supposing the worst, three out of 22 overweight/obese adults did not have a favorable response to their assignment to SBWP+MM. Considering there is no intervention that would meet the needs of everyone, 86% participation in the SBWP+MM intervention also supports further testing of SBWP+MM for weight loss.

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Another limit, yet possible strength, was that the interview process did not start until three months following the 24 week intervention and ended two months later. Of those who agreed to the interview but did not send back consent forms or did not respond to internet contact, it leaves an unanswered question. Could the lack of response be due to their experience of the SBWP+MM intervention, due to the length of time between intervention and interview, or due to unrelated personal reasons?

4.8 FUTURE CONSIDERATIONS

Given the detailed description that subjects gave to their experience in the SBWP+MM group, further study both quantitatively and qualitatively are needed using a SBWP+MM intervention with the overweight/obese adult population. Repeating the qualitative study with a pilot to test more specific MM exercise strategies and more MM eating, food choices, and meal planning would be one course of study. This could be followed by a larger mixed methods study over a longer period of time with a more diverse qualitative subsample to replicate or challenge the qualitative findings in this study.

APPENDIX A

IRB FOR PARENT STUDY

Study Title: ALTERNATIVE BEHAVIORAL AND PHYSICAL ACTIVITY APPROACHES TO WEIGHT LOSS

Principal Investigator: John M. Jakicic, Ph.D. Co-Investigator: Amy D. Otto, Ph.D., Laura Fonzi, BS, Kathleen Spadaro, MEd Objective and Specific Aims

This proposal outlines pilot studies that expand on the ongoing research begin conducted in the Physical Activity and Weight Management Research Center. These studies will provide pilot data for potential extramural grant applications and with allow for the completion of thesis and/or dissertation requirements for current graduate students. Therefore, the specific aims are as follows:

The specific aims of this proposal are:

- 1. Compared to a standard behavioral weight loss intervention, this study will examine the effect of the addition of resistance exercise training using resistance bands and exercise balls on weight loss, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, process measures of physical activity and eating behaviors, and related psychosocial factors.
- Compared to a standard behavioral weight loss intervention, this study will examine the effect of the addition of mindfulness meditation on weight loss, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, process measures of physical activity and eating behaviors, and related psychosocial factors.
- Compared to a standard behavioral weight loss intervention, this study will examine the effect of a technology-based intervention on weight loss, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, process measures of physical activity and eating behaviors, and related psychosocial factors.

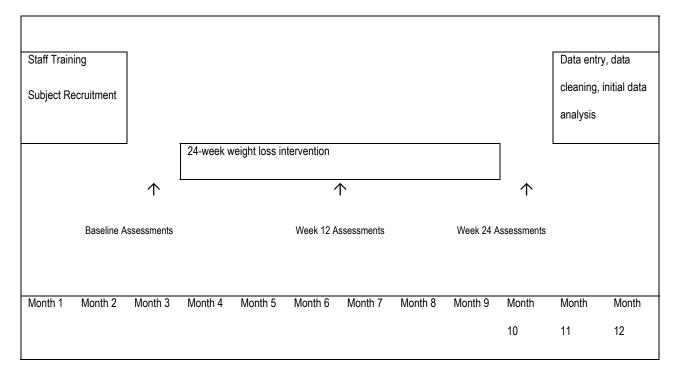
BACKGROUND AND SIGNIFICANCE

In excess of 65 percent of adults in the United States are overweight (body mass index = \geq 25.0 kg/m²), with in excess of 30 percent of adults classified as obese (body mass index \geq 30.0 kg/m²) ³. Overweight and obesity are associated with risk factors and the potential onset of chronic diseases including heart disease, diabetes mellitus, and cancer ⁷. Thus, it is important to develop effective interventions for weight loss.

The most effective behavioral interventions for weight loss combine a reduction in energy intake with an increase in energy expenditure via physical activity ⁷. These interventions have typically been shown to result in

weight loss of approximately 7-10% of initial body weight during a 4 to 6 month period ¹¹. However, these interventions may have limitations that include the following:

- Based on data from our research center, approximately 70% of individuals lose at least 7% of their baseline body weight during the initial 3-6 months of these weight loss interventions. Therefore, approximately 30% of individuals do not achieve a clinically meaningful weight loss of at least 7%, which has been show to improve health-related risk factors. Thus, improvement in standard behavioral interventions may assist in improving weight loss for those who otherwise may not be responsive to these interventions.
- 2. Most weight loss interventions have focused on traditional health-related outcomes. However, physical function and health-related quality of life have been shown to be reduced in overweight and obese individuals. Resistance exercise using exercise bands and exercise stability balls have been shown to improve physical function and strength in elderly individuals; however, this type of intervention has not been systematically examined in overweight and obese individuals.
- 3. Traditional weight loss interventions have typically been provided in group or individual delivered programs. However, attendance at weekly intervention sessions may not be appealing to some individuals or may provide a barrier to participation. Technology may allow for dissemination of weight loss information that can be effective for weight loss. However, to date these interventions have been limited to the internet and/or email rather than use of a broader spectrum of technologies that may enhance weight loss.



RESEARCH DESIGN AND METHODS Timeline

One hundred and twenty (120) sedentary, overweight and obese adult men and women will be recruited to participate in this study. Prior to completing baseline assessments, all subjects will complete initial screening procedures. These initial screening procedures will include completion of a physical activity readiness questionnaire (PAR-Q) (approximately 5 minutes to complete) and a detailed medical history (approximately 20 minutes to complete) (see Appendix A). Subjects will also be required to provide medical clearance from their personal

physician before starting this study. A Physician Consent form (see Appendix B) will be provided to the subject, and the subject will be instructed to have their primary care physician complete and sign the document. The subject will be responsible for returning the completed document to the principal investigator prior to participating in the experimental procedures (assessments and weight loss intervention) for this study.

Subjects will undergo a series of baseline assessments that will include the following measures: weight, height, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, physical activity, eating behaviors, and questionnaires to assess potential psychosocial correlates of weight loss. These procedures are explained in detail below. Following baseline assessments, eligible participants will be randomly assigned to one of four groups: 1) Standard behavioral weight loss group (SBWP) (N=25), 2) SBWP plus resistance exercise (SBWP+RE) (N=25), SBWP plus mindfulness meditation (SBWP+MM) (N=25), or 4) a technology-based weight loss intervention (TECH). Randomization will be based on a list of computer-generated random numbers, with each subject ID number assigned one of four group numbers (1 = SBWP, 2 = SBWP+RE, 3 = SBWP + MM, 4 = TECH) that corresponds to the group assignment. Assessments will be completed at baseline and following 12 and 24 weeks in the weight loss Intervention. The intervention groups and assessments are described in detail below.

Description of Weight Loss Interventions

1. Standard Behavioral Weight Loss Intervention (SBWP)

<u>Treatment Meetings and Contacts:</u> Subjects will attend weekly group meetings for 6 months at the University of Pittsburgh's Physical Activity and Weight Management Research Center. The group intervention will be conducted in a period of 45-60 minutes. During these face-to-face interactions the interventionist will integrate behavioral strategies for adopting and maintaining exercise into the intervention. These behavioral strategies are based primarily on social cognitive theory and include the following: self-monitoring, stimulus control, problem solving, relapse prevention, social assertion, goal-setting and feedback, and cognitive strategies to overcome negative thinking. These strategies will be blended into didactic sessions which are lead by a nutritionist, exercise physiologist, or health psychologist with experience conducting weight loss intervention groups. Subjects who miss group sessions will not be considered as "dropouts" for this study. A subject will only be considered a "dropout" if the subject notifies the principal investigator in writing that he/she no longer wishes to participate in the study.

<u>Diet:</u> Subjects will be instructed to reduce calorie intake to 1200-1800 calories per day and to reduce fat intake to 20-30% of total dietary intake. Subjects will be provided with sample meal plans and menus to assist them with making appropriate food selections, and these will be developed by registered dietitians. Subjects will record their eating behaviors in a weekly food diary that will be reviewed weekly by the intervention staff. Subjects participating in eating behaviors inconsistent with the recommendations for this study will be counseled by the registered dietitian affiliated with this study.

Exercise: Subjects will be instructed to increase their exercise. Subjects will begin at 100 minutes of exercise per week (20 minutes per day, 5 days per week) and will progressively increase by 10 minutes per day at 4-week intervals to 300 minutes per week (60 minutes per day, 5 days per week). The prescribed intensity of the exercise will be moderate (60 to 70% of age-predicted maximal heart rate), which is the equivalent of brisk walking for most individuals. Subjects will record their exercise in a weekly exercise diary that will be reviewed weekly by the intervention staff. Subjects participating in exercise that is inconsistent with the recommendations for this study will be counseled by the study affiliated exercise physiologist.

<u>Access to Technology:</u> All participants will be provided access to the secured study website where they can record their daily energy intake, fat intake, and physical activity if they would prefer this rather than using the paper diary described above. In addition, this will provide the participants access to updated intervention calendars and

other study information that will also be provided to them in the form of paper at the group meetings. (Note: Participants will be required to provide their own computer and internet access at their own expense for this study.) These standard features are enhanced in the TECH group as described below. In addition, as described below, only those participants in the TECH group will be provided with an electronic scale to monitor their body weight.

2. SBWP plus Resistance Exercise (SBWP+RE)

Participants in SBWP+RE will receive the same 24-week weight loss intervention as described above for the SBWP Group that includes treatment meetings and contacts, diet, and exercise. In addition, participants in SBWP+RE will receive components of a resistance exercise program as described below.

<u>Resistance Exercise Program</u> Subjects will be provided with elastic exercise bands, exercise ball (appropriate for height), and illustrations of the recommended exercises that will be performed. Resistance bands will be available in 4 different resistance levels ranging from easy to difficult. Subjects will be provided with bands appropriate for individual strength levels. In order to determine what bands are appropriate, an exercise class including all prescribed exercises will be conducted by a staff member. Subjects will be encouraged to use elastic tubing that forces the specific muscle group being worked to be at a rating of perceived exertion (RPE) between 6 and 8 (OMNI 1-10 scale) upon completing all of the recommended sets and repetitions.

Subjects will perform all resistance exercises during each in-person session and will also be directed to engage in the resistance training exercises on an additional 4 days per week, to total 5 days per week of resistance training exercises. The resistance training exercises will be performed in addition to the aerobic component of the SBWP. Subjects will be instructed to complete 3 sets of 8 to 12 repetitions with the appropriate level of resistance.

Subjects will be instructed to monitor and record their resistance exercise in their exercise diaries. Interventionists will review the diaries and provide feedback to subjects that will focus on achievement of weekly resistance training goals, daily resistance exercise consistency, etc. Subjects will progress to the next highest resistance band when reporting an RPE of less than 6 for the active muscle involved on 2 separate occasions when completing the prescribed repetitions and sets. This progression will minimize the risk of injury that may prevent a subject from participating in exercise as well as ensure that the specific muscle groups are being given the appropriate load for individual strength levels.

3. SBWP plus Mindfulness Meditation (SBWP+MM)

Participants in SBWP+MM will receive the same 24-week weight loss intervention as described above for the SBWP Group that includes treatment meetings and contacts, diet, and exercise. In addition, participants in SBWP+MM will receive components of mindfulness meditation as described below.

<u>Mindfulness Meditation Component</u> Subjects in SBWP+MM will be taught techniques of mindfulness meditation to regulate eating and physical activity behaviors. These techniques include but are not limited to breathing exercises, visualization, and relaxation exercise. These common techniques allow for mindful awareness of both thoughts and the environment as these impact eating and physical activity behaviors. Mindfulness meditation focuses on staying in the present moment, non-judging or criticizing the self, increased self-awareness of current thoughts, physical sensations, emotions and environment and supports self-regulation within the individual to achieve balance and homeostasis after the change of weight loss occurs. Mindfulness continues to support self-regulation within the individual to achieve balance and homeostasis after the change of weight loss occurs. This pilot study would be one of the first to use mindfulness meditation incorporated into a standard behavioral program as an intervention for weight loss to explore the acceptability, feasibility and effectiveness of the intervention with overweight and obese adults.

Subjects will perform the components of mindfulness meditation during each in-person session and will also be directed to engage in these mindfulness meditation exercises on their own during the remaining days of the week. To facilitate engagement in the mindfulness meditation exercises, each participate will also be provided with a CD that they are to listen to on a daily basis that will guide them through the mindfulness meditation exercises. These mindfulness meditation exercises will be identical to the exercises that are practiced during the in-person weekly session. Subjects will be instructed to monitor and record their participation in the mindfulness meditation exercises.

4. Technology-based weight loss intervention (TECH)

Subjects in the TECH intervention will receive a home-based behavioral weight program that is delivered via the internet and email. Rather than attend in-person sessions, the intervention material will be provided to the participant using technology, with the intervention materials posted on a password protected study website each week. These materials will be identical to the materials provided to SBWP. Each week the participant will receive an email message indicating that the materials for the week have been posted and a link will be provided to the study website to facilitate access to these materials. If the materials are not accessed by a participant within 48 hours of being posted, an additional email will be sent prompting the participant to access the materials will be made. If the materials are still not accessed by a participant within the next 24 hours, a telephone call prompting the participant to access the materials will be made.

The diet and exercise components will be identical to what is described above for SBWP. This will include reducing energy intake to 1200-1800 kcal/d, reducing dietary fat intake to <30% of total energy intake, and progressively increasing exercise to 300 min/wk.

Participants will also be instructed to self-monitor their eating behaviors, physical activity behaviors, and body weight. Participants will be provided access to the secured study website where they will record their daily energy intake, fat intake, and physical activity. (Note: Participants will be required to provide their own computer and internet access at their own expense for this study.) This information will be provided to the intervention team and a weekly message will be sent from the intervention team to the participant with feedback from the previous week (note: this is a feature that is available on the secured study website) In addition, participants will be provided with an electronic scale to monitor their body weight. This scale will store body weight and transmit the data to the investigators daily using a standard telephone line (Note: There is no additional telephone cost to the participant beyond their typical local land-line telephone service, but the participant is responsible for providing this telephone service at their own expense. In addition, there is no identifiable information transmitted as the body weight is associated with a scale number, and the investigators will be able to link the scale number to an individual study participant ID number within the secured study database.) If either eating behaviors, physical activity behavior, or body weight are not transmitted to the investigators, an email will be sent and a telephone call will be made to prompt the participant to submit this information.

NOTE: Information that is uploaded to a secured server will be accessible to the investigators and the intervention team. This information will be reviewed and the participant will be contact by telephone if necessary to address potential safety concerns related to unhealthy eating or exercise behaviors based on the data uploaded by the participant to the secured server. To enhance confidentiality, all participants will select an alias and a password. Data transfer to the server will not include identifiable information that can be associated with an individual participant name. The investigators will know the alias so that they can link information that is received to the participant, but this alias will be kept confidential and only available to the investigators.

Assessments:

Assessments will be conducted on weekdays during the hours of 7:00 AM and 11:00 AM at the University of Pittsburgh's Physical Activity and Weight Management Research Center. As described above, assessments will be completed at baseline and following 12 and 24 weeks of the weight loss intervention.

<u>Weight and Body Mass Index</u>: Body weight will be assessed using a calibrated medical balance-beam scale. Body mass index will be computed from measurements of weight and height (kg/m²). Height will be measured using a wall-mounted stadiometer.

Body composition: Measurement of body composition to determine LBM using Bioelectrical impedance analysis (BIA) will be performed on the same morning as REE measurement using a RJL BIA-101A (RJL Systems, Inc., Clinton Twp, MI) four terminal impedance analyzer. This instrument will be calibrated throughout the study using a 500- Ω resistor according to the procedures recommended by the manufacturer. BIA will be assessed with subjects in a supine position. The skin surface will be cleaned using rubbing alcohol prior to applying disposable electrodes on the right side of the body at the following four sites: between the styloid processes of the ulna and the radius (E1), distal end of the second and third metacarpals (E2), between the lateral malleolus and the medial malleolus (E3), and the distal end of the first and second metatarsals (E4). There will be a minimum of 8 cm between electrodes E1 and E2, and electrodes E3 and E4. LBM will be estimated using the equations validated by Segal and colleagues ⁹.

<u>Anthropometric Measures:</u> Circumferences of the waist and hip will be measured in centimeters, using a Gulick tape measure. The waist circumference will be measured at the smallest part of the waistline, between the xyphoid process and umbilicus. The hip measurement will be taken at the largest part of the hips, above the gluteal fold. The waist measurement will be divided by the hip measurement to obtain the waist-to-hip ratio (WHR).

<u>Cardiorespiratory Fitness</u>: Subjects will participate in an assessment of cardiorespiratory fitness to determine functional capacity. An Exercise Specialists certified by the American College of Sports Medicine will conduct these tests. The exercise testing protocol will be done according to the following procedures. Subjects will be placed in a resting position for a period of 5-10 minutes and will be instructed to relax and keep movement to a minimum. Following this rest period, resting blood pressure and heart rate will be assessed.

A treadmill protocol will be used for exercise testing. The speed of the treadmill will be kept constant at 3.0 mph (80.4 m/min) with the initial grade of the treadmill being 0% and increasing at 2.5% increments at 3-minute intervals. During this exercise test, subjects will breathe through a mass flow sensor with expired gas volumes and concentrations being measured continuously using a SensorMedics V-Max Metabolic Measuring Cart. Prior to each test, this metabolic cart sterilized and calibrated according to the procedures recommended by the manufacturer. Heart rate during exercise testing will be obtained at one-minute intervals using a 12-lead ECG (GE Medical) and immediately upon termination of the exercise test. Blood pressure will be assessed during the last minute of each stage and at the point of test termination. Ratings of perceived exertion (RPE) will be assessed during the last 15 seconds of each stage and at the point of termination. The test will be terminated at the point the subject achieves 85% of age-predicted maximal heart rate. In addition, the ACSM criteria for test termination will be followed. Following termination of the test, the subject will undergo a 5 to 10-minute recovery period to insure that heart rate and blood pressure have returned to pretesting levels. A certified physician trained in ECG interpretation will evaluate the results of each test to insure that exercise training is not contraindicated. We are not proposing that a physician be present during each test, but rather that a physician review the test once it has been completed. Our rationale for this is the following:

1. We are proposing to use a submaximal exercise protocol (85% of age-predicted maximal heart rate). In addition we are recruiting individuals that are classified as low-to-moderate risk based on the risk stratification published in the recent edition of the American College of Sports Medicine Guidelines for Exercise Testing and Prescription. Based on these guidelines, it is not necessary to have physician supervision for submaximal exercise testing when the individuals are stratified as low-to-moderate.

- 2. A physician will review the results (ECG) of the submaximal exercise test to identify abnormalities on these tests that would require follow-up evaluation by the participant's personal physician prior to proceeding with participation in this study.
- 3. We are taking many safeguards to exclude individuals that may be at increased risk during exercise. This includes receiving consent from the participant's personal physician prior to participating in any of the physiological assessments and intervention for this study.
- 4. <u>Each test will be supervised by a certified ACSM Exercise Specialist</u>. This individual will be certified in CPR and the use of an AED. An AED is available for use in the event that it is needed prior to emergency personnel arriving.

<u>Muscular Strength</u>: Muscular strength will be estimated for upper and lower body by having the subject perform one weight lifting exercise that uses the chest muscles (seated chest press) and one that uses the leg muscles (leg extension). The subject will warm-up with 5-10 repetitions at 40-60% of their perceived maximum. Following a one minute rest with light stretching, the subject will perform 4-5 repetitions at 60-80% of their perceived maximum. A small amount of weight will be added, and a 1-RM lift will be attempted. If successful, a rest period of 1-2 minutes will be provided prior to additional weight being added and another lift being attempted. These procedures will be repeated until a lift can not be successfully completed.

<u>Physical Function</u>: Physical function will be determined through the use of a Physical Performance Test (PPT) that has been used to compare obese and normal weight adults ⁶. The PPT consists of the following standardized tests: 1) the time to complete a 50 foot walk while carrying 2 shopping bags weighing approximately 10 pounds each, 2) the time required to sit down and get out of a chair 5 consecutive times, 3) the length of time the participant can balance on their left leg for up to 60 seconds, 4) the length of time the participant can balance on their right leg for up to 60 seconds, 5) the length of time it takes to step up and down twice on a step that is approximately 20 inches high. The rating of perceived exertion will also be assessed at the completion of each of these tasks.

<u>Health Related Quality of Life (HRQOL)</u>: Health-related quality of life will be assessed using a modified version of the Impact of Weight on Quality of Life Questionnaire ^{4, 5} and the SF-36 ¹⁰.

Dietary Intake: Dietary intake will be assessed using a food frequency questionnaire ^{1, 2}.

<u>Exercise and Leisure-Time Physical Activity:</u> The Paffenbarger Questionnaire ⁸ will be used to assess physical activity at each assessment period.

<u>Correlates of Weight Loss and Behavior Change</u>: We are also interested in factors that may be correlated with changes in physical activity, eating behavior, and body weight. *These questionnaires will take approximately 60-90 minutes to complete.* We will include measures of the following (These questionnaires are included in Appendix C):

- 1) Lifestyle Questionnaire
- 2) Eating Behavior Inventory
- 3) Eating Habits Checklist
- 4) Three Factor Eating Inventory
- 5) Beck Depression Inventory (BDI)

Note: In the event that a positive score on the BDI is observed, the PI or Project Director will be notified immediately. Either the PI or Project Director will contact Dr. Marsha Marcus, a Clinical Psychologists, to direct the most appropriate course of action. This may require the individual to be referred to their PCP for follow-up screening, or under extreme circumstances be transported and admitted to the hospital.

- 6) Barriers and Expected Outcomes (Exercise Beliefs)
- 7) Stages of Motivational Readiness for Change

8) Body Image

9) Injury and Illness Questionnaire: This questionnaire will allow the investigators to monitor reported injuries and/or illnesses that may be related to the proposed study. This will permit accurate follow-up and reporting to the IRB.

Data Collection and Statistical Considerations

All analyses will be performed using SPSS software for Windows or SAS. Descriptive statistics will be analyzed and presented as means +/- standard deviations. Statistical significance will be defined at p < 0.05 level of confidence. Analyses will be performed to determine if the data are normally distributed and appropriate

transformations will be conducted for data that is not normally distributed.

Analyses of the specific aims will be assessed using repeated measures analysis of variance (ANOVA) with assessment period considered a within-subject factor and randomized group assignment consider as the between-subject factor. Significant main effects and interaction effects will be probed using appropriate post-hoc tests with critical p-values adjusted using the Bonferroni procedure.

<u>Power Analysis:</u> This study will provide pilot data for a larger study to more thoroughly test the specific aims outlined in this proposal. A power analysis determined that 100 subjects (25 per group) would allow for 0.70 statistical power to detect a large effect size (0.80) between SBWP and either SBWP+RE, SBWP+MM, or TECH with alpha set to 0.05. Moreover, this sample size will allow for estimates of appropriate effect sizes to adequately power a larger study should any of these the interventions in this current study demonstrate promising results when compared to SBWP.

Human Subjects

General Characteristics

The 120 subjects that are necessary for this project will be recruited at the University of Pittsburgh. Inclusion and exclusion criteria are listed below.

Inclusion Criteria

- 1. 18-55 years of age.
- 2. Body mass index (BMI) between 25.0-39.9 kg/m2.
- 3. Access to a computer with internet access. This is required should the participant be randomly assigned to the TECH intervention group described above. In addition, the participant will have to demonstrate their ability to access the study website prior to randomization.

Exclusion Criteria

- 1. Reporting regular exercise participation of at least 20 minutes per day on at least 3 days per week during the previous six months. (This study is designed to recruit relatively sedentary adults.)
- 2. Report losing >5% of current body weight in the previous 6 months.
- 3. Report participating in a research project involving weight loss or physical activity in the previous 6 months.
- 4. For women, report being pregnant during the previous 6 months, or planning on becoming pregnant over the following 3 months of the intervention. (Pregnancy during initial screening will be based on self-report and will be included on the detailed medical history that is completed by subjects. In addition, this will also be obtained as part of the signed medical clearance from the individual's personal physician.)
- 5. Currently being treated for any medical condition that could impact body weight (i.e., diabetes mellitus, cancer, etc.).
- 6. History of myocardial infarction, or a history of undergoing heart surgery such as bypass or angioplasty.

- Non-medicated resting systolic blood pressure >160 mmHg or non-medicated resting diastolic blood pressure >100 mmHg, or taking medication that would affect blood pressure or heart rate at rest or in response to exercise (e.g., beta blockers).
- 8. Taking medication that could affect metabolism and/or contribute to a change in body weight (e.g., synthroid).
- 9. Being treated by a therapist for psychological issues or problems, taking pyschotropic medications, or receiving treatment with psychotropic medications within the previous 6 months.
- 10. History of orthopedic complications that would prevent optimal participation in the exercise component (e.g., heel spurs, severe arthritis).
- 11. No exclusion criteria shall be based on race, ethnicity, or gender.

All subjects will complete a physical activity readiness questionnaire (PAR-Q) and a detailed medical history, and will provide written informed consent prior to participating in this study. In addition, all subjects will provide written consent from their personal physician indicating that participation in the proposed intervention is not contraindicated.

Recruitment Procedures

Subjects will be recruited from advertisements in local newspapers, newsletters, and radio/TV advertisements. These advertisements will be submitted and approved by the IRB at the University of Pittsburgh prior to these advertisements being used for recruitment. An example of the advertisement that will be used is shown in the Appendices. (NOTE: This is an example of an advertisement. The actual advertisements that will be used will be submitted to the IRB for approval after they have been developed and prior to use for recruitment for this study. Recruitment will not be initiated until the advertisements developed by University Marketing and Communications that meet University of Pittsburgh standards are approved by the IRB.) Potential subjects will not be directly approach by the Principal Investigator in an attempt to recruit them for participation in this proposed study. In previous studies, Dr. Jakicic has been able to successfully recruit at least 20-25% of study participants from minority populations. Similar strategies will be used in this study and advertisements will be submitted to the IRB for approval prior to use in this study.

Subjects will be screened via the telephone (see attached telephone script). <u>We request a waiver to</u> <u>document written informed consent of the screening process, which will take place over the phone.</u> We believe we meet the following criteria: 1) the respective research procedures present no more than minimal risk of harm to the involved subjects and involve no procedures for which written consent is normally required outside of the research context, 2) the information being obtained during the screening phone call is the same type of information that would be collected on patients setting up an appointment for their condition (weight control). Refer to Appendix D for the screening script and tool that will be utilized. If the subject does not meet inclusion criteria, all the information collected during the screening process will be destroyed. In addition, written informed consent will be obtained at the screening visit prior to any research activities. The investigator or co-investigator will obtain written informed consent.

The name of the potential participant is not recorded on the forms where private information is recorded for this telephone screen. In addition, all private information will be destroyed (shredded) at the conclusion of the telephone call (see attached telephone script), and the individual's name will be kept separate from private information.

Written informed consent will be obtained following the orientation visit (this is just to further explain the details of the study) and prior to the baseline assessment visit. The orientation session typically takes approximately 60 minutes to complete. At this orientation session, Dr. Jakicic will describe the background and significance of the study, the intervention groups and procedures, all of the assessment procedures, and the risks/benefits of participating in this study. Moreover, individuals attending the orientation session will be encouraged to ask for clarification to make sure that they clearly understand all aspects of this study. Individuals will then be explained the

informed consent procedures and other logistical procedures prior to signing the consent document. In addition, written consent will be obtained by the subject's primary care physician prior to participation in any aspect of the clinical assessments and intervention for this study (see attached Physician Consent Form). The Principal Investigator will be available at these orientation visits to thoroughly describe the study procedures and to respond to any questions that may be raised by the subject. The private information that was destroyed following the initial telephone screening will be collected again and retained after written informed consent it obtained from subjects.

Risk/Benefit Ratio

The possible risks of this research study may include the following:

<u>Risks Associated with Assessment of Body Composition</u>: Assessment of body composition will be performed using bio-electrical impedance analysis. Subjects may experience skin irritation or skin redness from electrodes being placed on their skin. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

<u>Risks of the Exercise Testing and Physical Function Sessions</u>: Subjects may experience general fatigue and shortness of breath during their participation in these activities. Therefore, it is likely that subjects will experience this during the submaximal exercise test (occurs in more that 25% of people or more than 25 out of 100 people).

During exercise, heart rate and blood pressure will increase. It is likely that subjects will experience this during the submaximal exercise test (occurs in more that 25% of people or more than 25 out of 100 people). Under extreme conditions, the participant may experience a serious cardiac event (i.e., heart attack). The possibility of experiencing a serious cardiac event has been estimated to be less than 1 per 20,000 in exercising adults, with the risk of death during a maximal exercise test being less than 0.5 per 10,000 tests. Therefore, this will be rare (occurs in less than 1% of people or less than 1 out of 100 people). Numerous precautions will be in place to minimize the risk, and these include the following:

- 1. Subjects will provide medical clearance from their personal physician to participate in all aspects of this study, including the submaximal exercise test, prior to baseline assessments being initiated. (see Appendices)
- 2. A submaximal rather than a maximal exercise test will be used to assess changes in fitness in this study. In addition, the exercise will be prescribed at an intensity that is significantly lower than the termination point of the submaximal exercise test (85% of age-predicted maximal heart rate).
- 3. In the event that a serious cardiac event occurs, CPR will be initiated and an AED will be available for use by certified staff until emergency medical personnel arrive to take over emergency procedures.
- 4. All ECG's from the exercise test along with the medical history will be reviewed by a board certified physician prior to subjects being randomized to participate in this study.
- 5. Subjects may also experience redness, chaffing, and skin irritation from the electrodes that will be used during the submaximal graded exercise tests that are conducted for this study. It is likely that subjects will experience this during the submaximal graded exercise test (occurs in more than 25% of people or more than 25 out of 100 people).

<u>Risk of Electrocardiogram (ECG)</u>: Subjects may experience skin irritation or skin redness from electrodes being placed on their skin. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

<u>Risks of Assessing Oxygen Uptake during Exercise Testing</u>: Oxygen uptake will be assessed using indirect calorimetry. During this assessment, subjects may experience a dry mouth. It is likely that subjects will experience this during the submaximal graded exercise test (occurs in more than 25% of people or more than 25 out of 100 people). To minimize additional risks, the mouthpiece, mass flow sensor, and nose clips will be sterilized prior to each use according to procedures outlined by the manufacturer. These are the minimal procedures that will be

adopted for this study within the Department of HPA at the University of Pittsburgh. Items will first be rinsed and placed in a prewash (water and dishwashing soap) for 10 minutes, followed by 10 minutes in <4% gluteraldehide (according to the manufacturer, the mass flow sensor can be damaged by soaking for >10 minutes), followed by a final rinse.

<u>Risk of Assessing Strength</u>: Subjects may experience muscle fatigue or muscle soreness from this assessment. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people). There is also the risk of muscle sprain/strain, and the risk of this is rare because this occurs in less than 1% of people (less than 1 out of 100 people).

<u>Risk Associated with Completion of Questionnaires</u>: Subjects may experience non-physical risks such as boredom, frustration, stress, and time constraints when completing the questionnaires. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

<u>Risks of Reducing Calorie and Fat Intake</u>: Consuming a moderately low fat and low calorie diet appears to be safe and effective for weight loss. However, reducing calorie or fat intake below recommended levels may cause dry skin and thinning of hair. This is common and occurs in 10% to 25% of people (10 to 25 out of 100 people). This may also cause gall bladder disorders. This is rare and occurs in less than 1% of people (less than 1 out of 100 people).

<u>Risks Associated with the Group Interventions</u>: Participants in the group intervention may be asked to discuss personal factors related to their weight loss, physical activity, and dietary patterns. Participants are not required to share this information and can elect not to share sensitive and confidential information with the interventionist or other members of the group. The investigators can not guarantee that members of the group will not share this information with individuals not in this study outside of the group setting. It is common that subjects will experience this during the group intervention sessions (occurs in 10-25% of people or 10-25 out of 100 people).

To ensure that any injury or illness related to this study will be detected, subjects will be queried on the occurrence of any injury/illness that has limited or continues to limit their physical activity in this study since their last assessment. Moreover, subjects will be instructed to contact the investigators if they experience an injury/illness that is either caused by their participation in physical activity or is limiting their participation in physical activity.

<u>Steps to Ensure Confidentiality of Participants</u>: The following steps will be taken to ensure subject confidentiality in this study.

- 1. Subjects will be assigned an ID number and only the investigators will have access to the list which will link the ID number to a participant. This information will be stored in a locked file cabinet that is only accessible by the investigators.
- 2. All participant questionnaires and assessment forms will code with an ID number rather than the participant name.
- 3. For individuals who are randomly assigned to the TECH intervention group, a confidential user name and password will be assigned that will allow uploading of data to the server. The list linking the user name and password to a participant will be accessible only to the investigators and this will be kept in a locked filing cabinet.
- 4. All databases will be password protected.
- 5. All identifiable medical information will be kept in a locked filing cabinet that will only be accessible to the investigators.
- 6. Information collected about participants after they complete the "Consent to Act as a Subject in a Research Study" form will remain on file for the duration of this study, even if they choose to discontinue your participation in this study. Information about subjects that was collected prior to them signing this form will be destroyed if they do not qualify for participation in this study unless the investigators receive their consent to keep this information.

<u>Benefits</u>: Subjects in this study may experience the following benefits associated with weight loss, dietary change, and exercise; however, these benefits can not be guaranteed.

- 1. The proposed intervention may result in weight loss.
- 2. The proposed intervention may result in improvements in cardiovascular risk factors including blood lipids and blood pressure.
- 3. The proposed intervention may result in improvements in fitness and function.
- 4. The proposed intervention may result in improvements in psychosocial factors such as self-efficacy, mood, quality of life, and other related factors.

<u>Alternative Treatments</u>: The assessments being performed for this study are for research purposes and need to be consistent across all subjects. Therefore, no alternative assessment approaches will be implemented in this study. In the event that an eligible participant elects not to participate in this study, there are alternative exercise and weight control treatments available in the Greater Pittsburgh Area, however no alternative treatments will be available through the investigators on this current study. Rather, individuals will be instructed to seek a referral from their personal physician, to contact the UPMC Health System to inquire about clinical programs that may be available, or to contact local commercial exercise and/or weight loss programs (e.g., Weight Watchers, Jenny Craig, etc.).

Data Safety Monitoring Plan: This is not a multi-center trial and does not include pharmacological treatments.

Who will be responsible for the data and safety monitoring?

The Principal Investigator will be responsible for implementing the Data Safety Monitoring Plan. The Principal Investigator will conduct weekly study meetings at which time weight loss and exercise data will be reviewed. In addition, the Principal Investigator will review the data following each assessment period (0, 12, and 24 weeks).

What will be monitored?

All data and procedures will be reviewed weekly by the Principal Investigator. This will include review of participant recruitment procedures and the recruitment timeline. Data that will be monitored to assess completion of the proposed protocols, documentation indicating that an adverse event occurred during the exercise session, review of medical history and PAR-Q, and review of study data to insure that outcome data are within acceptable criteria. In addition, the Principal Investigator will perform quality control procedures at quarterly intervals to insure that the research assistant is compliant with the research protocol. Data will also be reviewed to assess whether there is any change in the risk-to-benefit ratio of this study. If potential safety concerns are identified that change the benefit-to-risk ratio, the study will be stopped until modifications can be made and approved by the IRB to address these safety concerns. Procedures will be reviewed to ensure that data are being collected in a manner to protect the confidentiality of subjects. All subject information will be coded with a study identification number to maintain confidentiality. In addition, all study data will be locked in a secured area (e.g., locked file cabinet).

- The Principal Investigator will submit the following data to the IRB at the time of renewal. However, this information may be submitted more frequently when necessary to ensure the safety of subject in this study.
- The frequency of monitoring that took place during the renewal interval.
- A summary of the cumulative adverse event data including a respective assessment of experimental intervention causality.
- A summary of the assessment that was performed to evaluate external factors or relevant information that may have an impact on the safety of study participants or ethics of the research study.
- A summary of the outcome of procedural reviews conducted to ensure subject privacy and research data confidentiality,

- Final conclusions regarding changes to the anticipated benefit-to-risk ratio of study participants and final recommendations related to continuing, changing, or terminating the study.
- If potential safety concerns are identified that change the benefit-to-risk ratio, the study will be stopped until
 modifications can be made and approved by the IRB to address these safety concerns. All adverse events
 will be reported to the University of Pittsburgh IRB in compliance with the IRB policy as outlined in the IRB
 Reference Manual.

Costs and Payments

<u>Research Study Costs</u>: There is no cost to subjects for participating in this research study. All costs will be paid by the sponsor of this research study.

<u>Research Study Payments:</u> Subjects in the Weight Loss Intervention Group will be offered a \$25 honorarium for completion of the assessments following 12-weeks of the intervention, and a \$25 honorarium for completion of the assessments following 24-weeks of the intervention.

Appendices

Qualifications of Investigators

John M. Jakicic, Ph.D.: Dr. Jakicic is an Associate Professor in the Department of Health and Physical Activity with a secondary appointment in the Department of Psychiatry at the University of Pittsburgh. Dr. Jakicic is trained as an exercise physiologist with experience in conducting clinical research that focuses on obesity and physical activity. He is certified as both an Exercise Specialist and an Exercise Test Technologist by the American College of Sports Medicine. Dr. Jakicic is the Principal Investigator and Co-Investigator on numerous NIH funded projects focusing on weight loss and physical activity interventions. Dr. Jakicic is responsible for all aspects of this proposed study.

<u>Amy D. Otto, Ph.D., RD</u>: Dr. Otto is a Research Assistant Professor in the Department of Health and Physical Activity at the University of Pittsburgh. Dr. Otto is involved in all aspects of this research study including issues related to study design, data analysis, and manuscript preparation. Dr. Otto's primary function on this project is to oversee matters related to development and implementation of the behavioral intervention.

<u>Ms. Laura Fonzi</u>: Ms. Fonzi is a graduate student in the Department of Health and Physical Activity with expertise in group exercise and fitness. She developed the resistance exercise program that is proposed for this study and will deliver this aspect of the proposed intervention.

<u>Ms. Kathleen Spadaro</u>: Ms. Spadaro is a doctoral student in the School of Nursing at the University of Pittsburgh. She has expertise in mindfulness meditation and will implement this aspect of the proposed intervention.

Additional Appendices (See Attached)

Appendix A: Physical Activity Readiness Questionnaire and General Health History
Appendix B: Physician Consent/Medical Clearance Form
Appendix C: Questionnaires that are used in this study
Appendix D: Recruitment Form and Script
Appendix E: Example of Recruitment Advertisement

List of References

1. Block, G., A. M. Hartman, C. M. Dresser, C. M.D., G. J., and G. L. A data-based approach to diet questionnaire design and testing. Am J Epidemiol. 108:161-175, 1986.

- 2. Block, G., M. Woods, A. Potosky, and C. Clifford. Validation of a self-administered diet history questionnaire using multiple diet records. J Clin Epidemiol. 43:1327-1335, 1990.
- 3. Hedley, A. A., C. L. Ogden, C. L. Johnson, M. D. Carroll, L. R. Curtin, and K. M. Flegal. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. JAMA. 291:2847-2850, 2004.
- 4. Kolotkin, R. L., R. D. Crosby, K. D. Kosloski, and G. R. Williams. Development of a brief measure to assess quality of life in obesity. Obes. Res. 9:102-111, 2001.
- 5. Kolotkin, R. L., S. Head, and A. Brookhart. Construct validity of the impact of weight on quality of life questionnaire. Obes. Res. 5:434-441, 1997.
- 6. Larsson, U. E. and E. Mattsson. Functional limitations linked to high body mass index, age and current pain in obese women. Int. J. Obes. 25:893-899, 2001.
- 7. National Institutes of Health. National Heart, Lung and Blood Institute. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults The Evidence Report. Obes. Res. 6(suppl.2), 1998.
- 8. Paffenbarger, R. S., R. T. Hyde, A. L. Wing, and C. C. Hsieh. Physical activity, all-cause mortality, and longevity of college alumni. N Engl J Med. 314:605-613, 1986.
- 9. Segal, K. R., B. Gutin, E. Presta, J. Wang, and T. B. Van Itallie. Estimation of human body composition by electrical impedance methods: a comparative study. J Appl Physiol. 58:1565-1571, 1985.
- 10. Ware, J. E., K. K. Snow, M. Kosinski, et al. SF-36 Health Survey: manual and interpretation guide. Boston, Mass: New England Medical Center, 1993
- 11. Wing, R. R. Behavioral Weight Control. In: Handbook of Obesity Treatment. T. A. Wadden and A. J. Stunkard (Eds.) New York: The Guilford Press, 2002, pp. 301-316.

APPENDIX B

CONSENT FORM



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

Approval Date: January 9, 2007 Renewal Date: January 8, 2008 University of Pittsburgh Institutional Review Board IRB #0701013

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Alternative Behavioral and Physical Activity Approaches to Weight Loss

PRINCIPAL INVESTIGATOR:

John M. Jakicic, Ph.D. Associate Professor Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184 CO-INVESTIGATORS:

Amy D. Otto, Ph.D. Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184

Laura Fonzi, BSKathleen Spadaro, MEdDepartment of Health and Physical ActivityDepartment of Health and Physical ActivityUniversity of PittsburghUniversity of PittsburghBirmingham Towers, Suite 600Birmingham Towers, Suite 6002100 Wharton Street2100 Wharton StreetPittsburgh, PA 15203Pittsburgh, PA 15203Telephone: 412-488-4184Telephone: 412-488-4184SOURCE OF SUPPORT:Internal Support – Department of Health and Physical Activity

DESCRIPTION:

The number of overweight and obese (having a body weight that is more than a recommended healthy weight) adults in the United States has been increasing at a rapid rate. Improved interventions, programs to help you to lose weight, are needed to increase success within weight loss programs. In addition, these interventions may improve exercise participation, which is an important component of weight loss programs. This study will examine interventions for improving weight loss and exercise participation in overweight adults. These interventions include the following:

- 1. A Behavioral Weight Control intervention that involves changing your eating behaviors, increasing your physical activity, and attending regular weekly group weight loss meetings.
- 2. A Behavioral Weight Control intervention that adds resistance (weight training) exercise. This involves changing your eating behaviors, increasing your physical activity, attending regular weekly group weight loss meetings, and participating in resistance exercise.
- A Behavioral Weight Control Group that adds mindfulness meditation in which you perform relaxation exercises and positive thinking related to your weight loss efforts. Thus, this involves changing your eating behaviors, increasing your physical activity, attending regular weekly group weight loss meetings, and participating in these mindfulness meditation activities.
- 4. A Technology-Based Weight Control intervention that involves you changing you eating behaviors and increasing your physical activity. However, you do not need to attend group meetings, but you will need to have access to your own computer to allow you to use the website developed for this study to access weight loss information and record your eating and physical activity behaviors. In addition, you will be provided a scale to weight yourself, and this information will be sent confidentially over your telephone line to the investigators.

These interventions are described in greater detail below. This study will also investigate the effect of these interventions on fitness, body composition, muscular strength, physical function, and other behavioral factors related to weight control and physical activity behaviors.

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 participating in moderate to vigorous activity. Moderate activity is defined as activity similar to brisk walking where you can also have a conversation, with vigorous activity defined as activity is walking at a faster pace and you can not 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 120 individuals at the University of Pittsburgh.

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 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. Women participants cannot be pregnant, and if you are a woman 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 first be asked to complete a series of questionnaires, and it is estimated that you will be able to complete these questionnaires in approximately 90 minutes. These questionnaires will provide information about your health, exercise and diet habits. Your body weight, body composition, blood pressure, physical fitness, muscular strength, physical function, level of physical activity, and food intake will be measured. These assessments will take place at the Physical Activity and Weight Management Research Center in Birmingham Towers (South Side of Pittsburgh) at the University of Pittsburgh, and these assessments will be completed in approximately 90 minutes. A brief description of these assessments follows.

- A. <u>Body Weight and Height (10 minutes)</u>: Your body weight will be measured using a standard medical scale. Your height will be measured with a ruler that is attached to a flat wall. These will be measured at 0, 3, and 6 months during this study.
- B. <u>Body Composition (10 minutes)</u>: Your body composition is the amount of fat weight and lean weight (muscle and bone) that you have on your body. Your body composition will be measured using a technique known as Bioelectrical Impedance Analysis (BIA). This procedure requires that a small electrode be placed on your hand, wrist, ankle, and foot. A low-level signal that is not harmful to you and that you will not feel is transmitted between the electrodes. Measurements of your waist and hip areas will also be made using a measuring tape. These measures will be made at 0, 3, and 6 months during this study.
- C. <u>Blood Pressure (5 minutes)</u>: Your blood pressure will be measured using a standard blood pressure cuff and will follow standard measurement procedures. Blood pressure will be measured at 0, 3, and 6 months during this study.
- D. <u>Cardiorespiratory Fitness (30 minutes)</u>: Measurement of your cardiorespiratory fitness will provide information about how fit your heart and lungs are to perform exercise. Your fitness will be estimated by having you walk on a treadmill. The speed of the treadmill will be kept at 3.0 mph (a brisk pace), however the grade of the treadmill will increase 2.5% every 3 minutes so that it feels like you are walking up a hill. As you are walking, your heart rate, blood pressure, and perception of physical exertion will be measured. Your heart rate will be measured using an electrocardiogram, which is also known as an ECG. The ECG will require that electrodes be placed on the chest and abdomen areas of your body. You will continue to walk on this treadmill until you reach a heart rate that is 85 percent of your maximal capacity, which is the highest heart rate you can achieve and is estimated by subtracting your age from 220 beats per minute, and then the test will be stopped. During this test you will breathe in and out through a sterilized (cleaned to prevent the spread of germs and disease) mouthpiece and will wear a set of nose clips so that no air flows through your nose. The air that you breathe will be measured by a machine known as a metabolic cart. This will provide information about the amount of

oxygen that you need when you are exercising. Fitness will be measured at 0, 3, and 6 months during this study. A staff member who is certified as an Exercise Specialist by the American College of Sports Medicine and at least one additional staff member will conduct this test. No other study participants will be in the testing room during this assessment. If during this test it is determined that you have a medical condition that makes it unsafe for you to exercise or lose weight you will no longer be permitted to participate in this study, and you will be referred to your primary care physician for medical follow-up.

- E. <u>Muscular Strength (15 minutes)</u>: Muscular strength refers to the maximum amount of weight you can lift and is specific to each muscle group. Your muscular strength will be estimated for upper and lower body by having you perform one weight lifting exercise that uses the chest muscles and one that uses the leg muscles. You will be asked to lift the maximum amount of weight you can lift 1 time when performing a seated chest press (which uses the chest muscles) and single leg extension (which uses the leg muscles) on an exercise machine. Muscular strength will be measured at 0, 3, and 6 months during this study.
- F. <u>Physical Function (20 minutes)</u>: Physical function refers to how well you can perform common tasks. Your physical function will be measured by having you perform a series of tasks that include the following: a 50 foot walk while carrying 2 shopping bags weighing approximately 10 pounds each, sitting down and getting out of a chair 5 times, balancing on your left leg for up to 60 seconds, balancing on your right leg for up to 60 seconds, stepping up and down twice on a step that is approximately 20 inches high. These tasks will be measured at 0, 3, and 6 months during this study.
- G. <u>Exercise, Dietary Patterns, and Factors that Influence Behavior Change (60 minutes)</u>: You will complete questionnaires about the amount of exercise that you do, and the amount and types of foods that you eat. You will also complete questionnaires about factors such as your mood, general health, and other things that may affect your exercise and eating behaviors. Participants who have a positive score on the mood measure that is being used in this study will be referred to their personal physician or other appropriate medical personnel for follow-up care. These questionnaires will be completed at 0, 3, and 6 months during this study.

Weight Control and Exercise Procedures

After completing these assessments you will be randomly assigned to one of four groups 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. The groups are described below.

- A. Standard Behavioral Weight Control Group:
 - 1.) <u>Group Meetings and Contacts:</u> You will attend weekly group meetings for 6 months. Each group meeting will last 45 to 60 minutes. These weekly meetings will be held on the same night every week, and the group will have approximately 25 members that will be dieting and participating in exercise to lose weight.
 - 2.) <u>Diet:</u> 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 pounds or greater, 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.) <u>Exercise:</u> 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 20 to 60 minutes over the 6 month program. One of these sessions will be performed at the Physical Activity and Weight Management Research Center under the supervision of the investigators, and the other four sessions will be performed on your own not under the supervision on 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.
- 4.) <u>Website Access</u>: You will be provided access to a website that will provide you information about your participation in this study. You are not required to use this website, but if you want to use this website you will need to provide your own computer and internet access. This website will provide you a study calendar, information about how to change your eating and exercise behaviors that will also be provided to you in the group meetings, and you can enter your daily eating and exercise information.

B. Standard Behavioral Weight Control plus Resistance Exercise Group:

- 1.) <u>Group Meetings and Contacts:</u> You will attend weekly group meetings for 6 months as described above for the Standard Behavioral Weight Control Group.
- 2.) <u>Diet:</u> You will be placed on the same diet as described above for the Standard Behavioral Weight Control Group.
- 3.) <u>Exercise:</u> You will be given a walking program for exercise that is the same as the exercise described above for the Standard Behavioral Weight Control Group.
- 4.) <u>Website Access:</u> You will be provided access to a website as described above for the Standard Behavioral Weight Control Group.
- 5.) <u>Resistance Exercise:</u> In addition to the exercise described above you will perform resistance exercise. This will involve the use of resistance exercise bands and an inflated exercise ball, with this equipment provided to you by the investigators. At each group session you will be taught resistance exercises that will use this equipment, and you will be asked to perform these exercises on your own for an additional 4 days each week. Written instructions and illustrations will be provided to you to assist you in performing these exercises. As the exercise becomes easier for you additional resistance will be added by changing the exercise band or how you are using the exercise ball. You will report your resistance exercise to the investigators each week.

C. Standard Behavioral Weight Control plus Mindfulness Meditation:

- 1.) <u>Group Meetings and Contacts:</u> You will attend weekly group meetings for 6 months as described above for the Standard Behavioral Weight Control Group.
- 2.) <u>Diet:</u> You will be placed on the same diet as described above for the Standard Behavioral Weight Control Group.
- 3.) <u>Exercise:</u> You will be given a walking program for exercise that is the same as the exercise described above for the Standard Behavioral Weight Control Group.

- 4.) <u>Website Access:</u> You will be provided access to a website as described above for the Standard Behavioral Weight Control Group.
- 5.) <u>Mindfulness Meditation</u>: Mindfulness meditation involves you performing relaxation exercises and positive thinking related to your weight loss efforts. At each group session you will be taught how to perform these relaxation and positive thinking exercises, and you will be asked to perform these exercises on your own for the remaining days of the week. To assist you, an audio CD will be provided to you that will guide you through these exercises. You will report your completion of these mindfulness meditation exercises to the investigators each week.

D. Technology-Based Weight Loss Intervention Group:

- 1.) <u>Contacts:</u> You will not attend in-person meetings during this study. Rather, you will receive a weekly email message from the investigators related to your weight loss efforts. In addition, the investigators will provide you with weight loss information through the use of a secured website that you will access with your own computer. You will be responsible for providing your own computer and access to the internet for this study. You will also need to demonstrate to the investigators that you can use a computer and access the internet.
- 5.) <u>Measuring Body Weight:</u> You will be instructed to weight yourself at least 2 days per week. You will be provided an electronic scale by the investigators. This scale will be plugged into your existing telephone line at your home so that these body weights will automatically be sent to the investigators. You will be responsible for providing and maintaining a usable telephone line, but a cell phone can not be used as the telephone line to transmit these body weights for this study. You will also be required to limit access to this scale to only yourself, and others in your household should not use this scale during this study. This scale will be returned to the investigators at the completion of this study.
- 6.) <u>Diet:</u> You will be placed on the same diet as described above for the Standard Behavioral Weight Control Group.
- 7.) <u>Exercise:</u> You will be given a walking program for exercise that is the same as the exercise described above for the Standard Behavioral Weight Control Group.

RISKS and BENEFITS:

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

<u>Risks</u>

A. <u>Risks of Exercise and test of Physical Function</u>: There are moderate risks associated with participating in an exercise test, a physical function test, and 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 less than 1 per 20,000 in exercising adults, with the risk of death during a maximal exercise test being less than 0.5 per 10,000 tests. Therefore, the risk is of this happening to you is rare, because it occurs in less than 1% of people (less than 1 out of 100 people). 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. The risk of this happening to you is likely because these occur in more that 25% of people (more than 25 out of 100 people). When testing muscular strength you may experience muscle strain, with the risk of this

happening to you infrequent because it occurs in 1-10% of people (1-10 out of 100 people). In the event that you experience a serious medical condition during your exercise testing session or during a supervised 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 ask 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. <u>Risk of having the air that you breath in and out measured by a metabolic cart:</u> When measuring the air that you breath in and out during exercise, you may experience a dry mouth. This risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people).
- C. <u>Risk of Electrocardiogram (ECG)</u>: You may experience skin irritation or skin redness from electrodes being placed on your skin. The risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people).
- D. <u>Risk of Bioelectrical Impedance Analysis (BIA)</u>: You may experience skin irritation or skin redness from electrodes being placed on your skin. The risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people).
- E. <u>Risk Associated with Completion of Questionnaires:</u> You may experience non-physical risks such as boredom, frustration, stress, and time constraints when completing the questionnaires. The risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people).
- F. <u>Risks of Reducing Your Calorie and Fat Intake:</u> 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. This is common and occurs in 10% to 25% of people (10 to 25 out of 100 people). 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. This is rare and occurs in less than 1% of people (less than 1 out of 100 people).
- G. <u>Risk Associated with Participating in the Group Intervention:</u> 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 can not 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. The risk of this happening to you is common because this may occur in 10-25% of people (10-25 out of 100 people).

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. <u>Benefits of Exercise</u>: The benefits of participation 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 you participating in this study.

B. <u>Benefits of Reducing your Calorie and Fat Intake:</u> 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 you participating 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 \$25 for completing the assessments following 3 months, and \$25 for completing the assessments following 6 months.

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. 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 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.

A cardiologist in the University of Pittsburgh School of Medicine and UPMC will review the exercise tests that are completed as part of your participation in this study, and he/she will have access to your identifiable medical information. If you who have a positive score on the mood measure that is being used in this study a clinical psychologist affiliated with the Obesity/Nutrition Research Center at the University of Pittsburgh will review this information, which may require access to identifiable medical information.

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 5 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 affect 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 affect 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 a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no affect 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 affect 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, 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

VERIFICATION OF EXPLANATION

I certify that I explained the nature and purpose of this research to the above-named participants in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

Investigator's Signature

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 have 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

Signature of Person Obtaining Consent

Date

Role in Research Study

...

Date

Date

APPENDIX C

EXAMPLE OF RECRUITMENT FLIER

Research Subjects Needed for Weight Loss and Exercise Study

Are you 18-55 years of age? Are you overweight and interested in losing weight? Do you exercise less than 3 days per week and are you interested in becoming more active?

Women and Men who meet the above criteria and do not currently participate in a weight loss or exercise program may be eligible to participate in an 6-month study to examine methods to improve weight loss and exercise participation. This study is being conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. Eligible subjects will be compensated for their participation in this study.

Women who are pregnant are not eligible to participate in this study.

For more information please call 412-488-4184

APPENDIX D

RECRUITMENT FORM

Thank you for calling to find out more about our research study. My name is ______ and I am part of a team of researchers at the University of Pittsburgh Physical Activity and Weight Management Research Center. The purpose of this research study is to look at ways to improve weight loss. Specifically, we want to determine if adding resistance exercise, also know as weight training, or teaching people how to use meditation can improve weight loss. We will also study whether providing access to a weight loss program using the internet can help people to lose weight.

As part of this study you will be randomly assigned to receive one of four weight loss interventions, which means that you can not select the intervention that you receive, but that this will be determined by a method similar to flipping a coin. All groups will receive a weight loss program that includes changes in your diet and exercise. Three of the groups will attend group meetings weekly for 6 months, with one of the groups receiving this weight loss intervention primarily through the internet. You will also have measurements of your body weight, body composition to determine the amount of fat and lean weight on their body, fitness, strength, and physical function, and you will also complete questionnaires about exercise and other behaviors related to weight loss. These assessments will be completed before you start the study and following 12 and 24 weeks of participation. Everyone will be paid \$25 in the form of a check for completing assessments at 3 months and 6 months of this study, which means that you can earn a total of \$50 for your participation in this study.

Do you think that you might be interested in participating in this study?

- If NO: Thank you very much for calling.
- If YES: Before enrolling people in this study, we need to determine if they are eligible. And so what I would now like to do is to ask you a series of questions about your current and past health and medical conditions. There is a possibility that some of these questions may make you uncomfortable or distressed; if so, please let me know. You do not have to answer those questions if you do not want to. You also need to

understand that all information that I receive from you by phone, including your name and any other identifying information, will be strictly confidential and will be kept under lock and key. The purpose of these questions is only to determine whether you are eligible for study. Remember, your participation is voluntary; you do not have to complete these questions.

Staff Signature Page 1 (PAGE 1 WILL BE RETAINED FOR DEMO	Date
Page 1 (PAGE 1 WILL BE RETAINED FOR DEM	
	OGRAPHIC STATISTICS)
Phone Screen Inte	erview
The caller gives verbal permission to conduct the Phone	e Screen: YES NO
Verbal Assent was given to:	
Staff Member Signature	Date Verbal Assent was given:
1. Gender: θ Male θ Female	
2.a. Age: θθ (18-55) 2.b. Date of Bi	irth: 00/00/00
3. Which of the following best describes your racial he category):	eritage? (you may choose more than one
θ American Indian or Alaska N	Native
θ Asian	
θ Black or African-American	
θ Hispanic, Latino, or Cape Ve	erdean
θ Native Hawaiian or Other Pa	acific Islander
θ White	
θ Other (Specify:	

5. Current Height: θfeet θθinches

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6. Are you able to walk for exercise? θ **YES** θ No If "no", specify reason: Do you currently exercise regularly at least once per week at a moderate intensity for at 7. least 20 minutes? θ Yes θ NO If "yes", How many days per week? If "yes", How long have you been exercising this way? Have you ever been told by a doctor or other medical person that you have any of the 8. following conditions? If "yes", Specify: a. Heart Disease θ Yes θ NO b. Angina θ Yes θ NO c. Hypertension θ Yes θ NO d. Heart Attack θ Yes θ NO e. Stroke θ Yes θ NO f. Diabetes (sugar) θ Yes θ NO θ Yes θ NO g. Cancer 9. Are you presently being treated by a doctor or other medical person for any other physical or psychological problems? θ Yes θ NO If "yes", specify: 10. Do you take any prescription medications (includes psychotropics)? θ Yes θ NO

If "yes", specify the following:	
Medication Name	Used to Treat:

11. Are you taking any medications for the purpose of weight loss? θ Yes θ NO If "yes", specify:

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12.	Do you currently smoke?	θ Yes θ) NO
	If "yes", specify:		
13.	Are you currently a member of another organized exercise or are you	ı participating i	in an
	organized weight reduction program?	θ Yes θ) NO
	If "yes", specify:	-	
14.	Have you lost 10 or more pounds within the past year?	θ Yes θ) NO
	If "yes", specify number of pounds:Method used:		
15.	Are you currently participating in other research studies?	θ Yes θ) NO
	If "yes", specify:	-	
16.	Have you been a participant in a previous exercise or weight control	study?θ Yes θ) NO
	If "yes", specify:		
17.	Do you plan to spend any time out of town on vacation or business	in the next 6 r	nonths
	that may affect your ability to attend weekly group meetings?	θ Yes θ) NO
	If "yes", specify:		
18.	Do you plan on relocating outside of the Greater Pittsburgh Are		next 6
	months?	θ Yes θ) NO
	If "yes", specify:		

WOMEN ONLY COMPLETE THE FOLLOWING QUESTIONS

19.	a.	Are you currently pregnant?	θYes	θΝΟ
	b.	Have you been pregnant in the last 6 months?	θ Yes	θ NO
	c.	Do you plan on becoming pregnant in the next 6 months?	θ Yes	θ NO

THIS PAGE WILL BE RETAINED TO SEND AN INVITATION TO THE SCHEDULED ORIENTATION SESSION FOR THOSE WHO ARE ELIGIBLE AND TO TRACK ELIGIBLE/INELIGIBLE DATA.

Eligible: θ Yes θ No

If "No", list reason for ineligibility:

If eligible schedule the participant for their group orientation session based on the schedule of available dates. A follow-up reminder will be send via the mail.

Invited to Orientation: θ Yes θ No

Date of Orientation: ___/ ___/

CONTACT INFORMATION

** THIS INFORMATION IS ONLY COLLECTED IF THE RESPONDANT APPEARS TO QUALIFY FOR PARTICIPATION IN THIS STUDY BASED ON THE TELEPHONE SCREEN AND IS SCHEDULED FOR THE ORIENTATION VISIT. **

	Participant Information
D:	Date://(MM/DD/YY)
Name:	Staff:
Address:	
hone #: (Home)_() (Work) ()	
(other)_()	
mail:	
Alternative Contact:	
Phone (Home): ()	
(Preferably somebody who	does not live with you)
elation to Participant:	
(Work): _()	
(Work): _() Emergency Contact:	
(Work): _()_ Emergency Contact: Relation to Participant:	
(Work): _() Emergency Contact: Relation to Participant: Phone (Home): _()_	
(Work): _() Emergency Contact: Relation to Participant: Phone (Home): _()_	
(Work): _() Emergency Contact: Relation to Participant: Phone (Home): _() (Work): _()	

APPENDIX E

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

TO:				RETURN TO: (envelope provided)			
	Physician's Name			John M. Jakicic, Ph.D.			
	-			University of Pittsburgh			
				Department of Health and Physical Activity			
	Address			Physical Activity and Weight Management Research Cente 2100 Wharton Street, Suite 600 Pittsburgh, PA 15203			
	City	State	Zip	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 an 6 month research study designed to help patients to change their eating and exercise habits and to examine the impact that this will have on long-term weight loss and increases in physical fitness. This will involve the following:

- 1. A walking program that will be primarily home-based. The exercise will gradually be progressed from 20 minutes per day to as much as 60 minutes per day, 5 days per week. Exercise intensity will be set at 60-70% of the patient's maximal heart rate.
- 2. Participation in resistance exercise that will include resistance exercise bands and exercise balls.
- 3. 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.
- 4. A graded exercise test which involves walking on a motorized treadmill, with the workload gradually increasing every 3 minutes. The test will be terminated when the patient achieves 85% of their age-predicted maximal heart rate, or prior to this level if the individual experiences signs or symptoms that would indicate that exercise is contraindicated. Both blood pressure and heart rate will be monitored continuously. The ACSM Guidelines for Exercise Testing will be followed.
- 5. Assessment of physical function that will involve activities such as walking, getting in and out of a chair, balancing on one leg, and stepping up and down to an elevation of approximately 20 inches.
- 6. Behavioral modification techniques for changing exercise behaviors.

7. 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 her participation (*please check the appropriate box below*).

- θ I know of no contraindications to this patient participating in any of the above components of the program.
- θ 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: Female or Male 18-55 years of age BMI = 25-39.9 kg/m ²	Exclusion Criteria: Reporting regular exercise participation of at least 20 minutes per day on at least 3 days per week during the previous six months. (This study is designed to recruit relatively sedentary adults.)
Ability to provide informed consent. Ability to provide consent from their personal physician to participate in this study.	Weight loss of >5% of body weight within the previous 6 months. Women who are currently pregnant, pregnant within the previous six months, or planning on becoming pregnant within the next 6 months. (Pregnancy during initial screening will be based on self-report and will be included on the detailed medical history that is completed by subjects) Diabetes, hypothyroidism, or other medical conditions which would affect energy metabolism. History of myocardial infarction or valvular disease. Non-medicated resting systolic blood pressure ≥160 mmHg or non-medicated resting diastolic blood pressure ≥100 mmHg, or taking medication that would affect resting heart rate or the heart rate response during exercise (e.g., beta blockade). Arrhythmia on resting or exercise vas contraindicated. Taking medication that could affect metabolism and/or contribute to change in body weight. Being treated by a therapist for psychological issues or problems, taking psychotropic medications, or receiving treatment with psychotropic medications that would prevent optimal participation in the exercise component (e.g., heel spurs, severe arthritis).

APPENDIX F

GENERAL HEALTH HISTORY

Subject ID:_____

DATE: 00/00/00

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

				Approximate Date of	Describe the Problem
				Diagnosis	TIODICITI
a.	Heart Attack	oyes	ono		
b.	Angina (chest pain on exertion)	oyes	ono		
C.	Irregular Heart Problems	oyes	ono		
d.	Other Heart Problems	oyes	ono		
e.	Stroke	oyes	ono		
f.	Fainting Spells	oyes	ono		
g.	High Blood Pressure	oyes	ono		
h.	High Cholesterol	oyes	ono		
i.	Thyroid Problems	oyes	ono		
j.	Cancer	oyes	ono		
k.	Kidney Problems	oyes	ono		
Ι.	Liver Problems	oyes	ono		
m.	Gout	oyes	ono		
n.	Diabetes	oyes	ono		
0.	Emotional/Psychiatric Problems	s oyes	ono		
р.	Drug/Alcohol Problems	oyes	ono		

2.	Do you have any r	medical prot	olems	that would	prevent you	from	participating	in a	a regular
	walking program?	oyes	ono						
	If yes, please desc	ribe the prot	olem:_						

- 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? oyes ono 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? oves ono
- Please list all medications that you are currently taking on a regular basis (make sure to 5. indicate if you are taking medication for high blood pressure or cholesterol): MEDICATION REASON FOR TAKING
- Over the last 6 months, on how many weekdays (Monday through Friday) do you usually 6. drink wine, beer, or liquor on average?
 - (0)o Never (1)o Less than once/month(2) o 1-2 times/month

- (3)o1 day/week

- (4)o 2 days/week (5)o 3 days/week (6)o 4 days/week (7)o 5 days/week
- On those weekdays that you drink wine, beer, or liquor how many drinks do you have? oo 7.
- Over the last 6 months, on how many weekend days (Saturday and Sunday) do you 8. usually drink wine, beer, or liquor?
 - (0)o Never(4)o 1 weekend day/week(1)o Less than once/month(5)o 2 weekend days/week

- (2)o 1-2 times/month

- On those weekend days that you drink wine, beer, or liquor how many drinks do you have? 9. 00
- 10. In the past year, have you regularly smoked cigarettes, pipes, cigars, or used chewing tobacco? Please describe daily habit

oyes	ono	
oyes	ono	
oyes	ono	
oyes	ono	
	oyes oyes	oyes ono oyes ono oyes ono oyes ono

- 11. Do you plan to spend frequent time out of town on business or vacation during the next 6 months? oyes ono Please describe:_____
- 12. Is it possible that you will relocate in the next 6 months? oyes ono Please describe: ______

WOMEN ONLY ANSWER THE FOLLOWING QUESTIONS

13. Are you currently pregnant? oyes ono 14. Were you pregnant within the past 6 months? oyes ono 15. Do you plan to become pregnant in the next 6 months? oyes ono 16. Have you gone through menopause or the change of life? oyes ono 17. Have you had a hysterectomy? oyes ono 18. When was your last menstrual period? DATE: 00/00/00 19. Do you take : **Birth Control Pills?** oyes ono Estrogens (ie. Premarin)? oyes ono Progesterone (ie. Provera)? oyes

ono

APPENDIX G

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q)

Su	bject ID:	Date:
Ple	ase read the questions carefully and an	swer each one honestly: check YES or NO
1.	Has your doctor ever said you have a by a doctor?	heart condition and that you should only do physical activity recommended
	oyes	ono
2.	Do you feel pain in you chest when you	u do physical activity?
	oyes	ono
3.	In the past month, have you had chest oyes	pain when you were not doing physical activity?
4.	Do you lose your balance because of o	dizziness or do you ever lose consciousness?
	oyes	ono
5.	Do you have a bone or joint problem th oyes	nat could be made worse by a change in your physical activity? ono
6.	Is your doctor currently prescribing dru	gs (for example, water pills) for your blood pressure or heart condition?
	oyes	ono
7.	Do you know of any other reason why	you should not do physical activity?
	oyes	ono
Ref	erence: American Medical Association:	Guides to the Evaluation of Permanent Impairment. AMA, Chicago, 1990.

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APPENDIX H

LIFESTYLE QUESTIONNAIRE

Office Use Onl	у		
Subject ID #:		Assessment#:	

- 1. Education: Check years of school completed: (CHECK ONLY ONE ANSWER)
 - θ_1 Grade School (6 years or less)
 - θ_2 Junior High School (7-9 years)
 - θ_3 High School (10-12 years)
 - θ_4 Vocational Training (beyond High School)
 - θ_5 Some College (less than 4 years)
 - θ_6 College/University degree
 - θ₇ Graduate or Professional Education
- 2. Employment Status: Are you currently working for pay full or part-time?
 - θ_1 Yes
 - θ_2 No (GO TO QUESTION #5)
- 3. If yes, what is your job? Check the box that is most appropriate then Go to Question #5:
 - θ₁ Professional, administrator, or executive
 (Examples: Government official, manager, purchasing agent, marketing rep, doctor, nurse, lawyer, teacher)
 - θ₂ Clerical work, administrative support, sales, or technician
 (Examples: Office worker, data processing, sales clerk or supervisor, lab tech, LPN, legal assistant)
 - *Crafts, trade, factory work, service, or labor* (Examples: Carpenter, electrician, machine operator, machinist, foreman, police officer, restaurant worker, barber)
 - θ_4 Other (Please describe)
- 4. If you are not working for pay, which of the following best describes you?
 - $\theta_1 \quad \text{a homemaker} \quad$
 - θ_2 retired or disabled
 - θ_3 a student
 - θ_4 not currently employed
- 5. Which of the following best describes you?
 - θ_1 American Indian or Alaska Native
 - θ_2 Asian

- Black or African-American θ_3
- Hispanic, Latino, Portuguese, or Cape Verdean θ_4
- Native Hawaiian or Other Pacific Islander θ_5
- White θ_6
- Other: (Specify) θ_7
- 6. Marital Status:
 - Married θ_1
 - Separated θ_2
 - θ_3 Divorced
 - Widowed θ_4
 - Never Married θ_5

7.	Number of adults living in household including yourself.	$\theta \theta$

8.	Number of children under age 18 living in household.	$\theta \theta$	
	WEIGHT HISTORY		
9a.	What is the most you have weighed, not counting pregnancies?		000 pounds
9b.	How old were you then?		000 years
10a.	What is the least you have weighed since age 18?		000 pounds
10b.	How old were you then?		000 years
11.	How much would you like to weigh?		000 pounds

		YES	NO
12.	Have you ever dieted to lose weight?	θ_1	θ_2
13.	Have you ever participated in an organized weight loss program (e.g., Weight Watchers, TOPS, etc.)	θ_1	θ_2
14.	Are you currently dieting to lose weight?	θ_1	θ_2
15.	Are you currently dieting to maintain you current weight?	θ_1	θ_2

If NOT Married, go to Question #9

16. Put a check to indicate whether you were: extremely underweight, underweight, normal weight, overweight, or extremely overweight at each of the following ages:

		Extremely Underweight	Underweight	Normal Weight	Overweight	Extremely Overweight	Not Applicable
a.	Pre School	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6
b.	Elem. School	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6
C.	Junior High (12-14 yrs)	θ_1	θ_2	θ_3	θ_4	θ_5	Θ_6
d.	High School (15-18 yrs)	θ_1	θ2	θ_3	θ4	θ_5	Θ_6
e.	19-25 yrs	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6
f.	26-35 yrs	θ_1	θ_2	θ_3	θ_4	Θ_5	θ_6
g.	36-45 yrs	θ_1	θ_2	θ_3	θ_4	Θ_5	θ_6
h.	46-55 yrs	θ_1	θ2	θ3	θ4	Θ_5	Θ_6

	unough del, exercise, a formal weight control p	iogiani, eic	•)			
		NEVER	1-2	3-5	6-10	More than 10
a.	How often have you lost 10-19 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
b.	How often have you lost 20-49 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
C.	How often have you lost 50-79 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
d.	How often have you lost 80-99 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
e.	How often have you lost 100+ pounds?	θ_1	θ_2	θ_3	θ_4	θ_5

17. Check the number of times in your life you have <u>intentionally</u> lost the number of pounds shown below (e.g., through diet, exercise, a formal weight control program, etc.)

18. Check the number of times in your life you have <u>unintentionally</u> lost the number of pounds shown below (e.g., because of illness, injury, etc.)

		NEVER	1-2	3-5	6-10	More than 10
a.	How often have you lost 10-19 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
b.	How often have you lost 20-49 pounds?	θ_1	θ_2	θ3	θ_4	θ_5
C.	How often have you lost 50-79 pounds?	θ_1	θ_2	θ3	θ_4	θ_5
d.	How often have you lost 80-99 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
e.	How often have you lost 100+ pounds?	θ_1	θ_2	θ_3	θ_4	θ_5

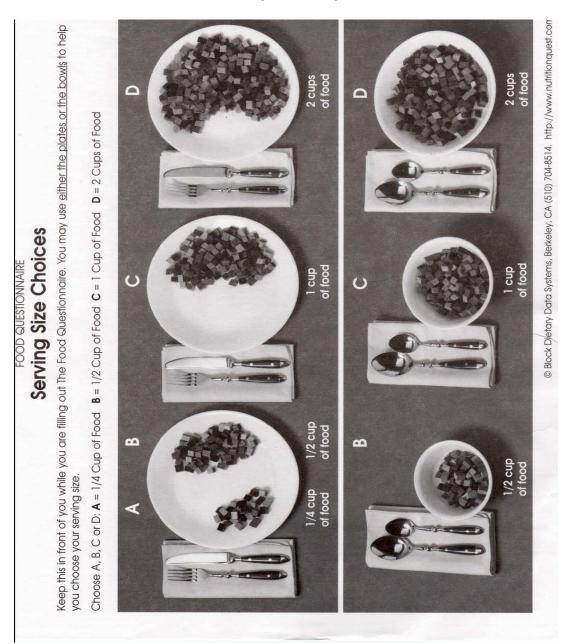
19. If you gained weight, how much would your weight have to increase before you considered this weight gain to be significant?

***Please select one of the following.

а.	< 5 pounds?	θ ₁
b.	5-10 pounds?	θ_2
С.	11-15 pounds?	θ_3
d.	16-20 pounds?	θ_4
е.	> 20 pounds?	θ_5

APPENDIX I

BLOCK FOOD FREQUENCY QUESTIONNAIRE



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Image: Constraint of the constraint	399 000 001 002 003 004 005	Q	U	ES'	TI	ON			RE
	ete.		SEX Ma Fe			AGE	WEIG pour	nds	HEIGHT ft. in.
 Use only a No. 2 pencil. 	I		pregna breast	feeding?					0) 02 3 03 4 09 5 05
 Fill in the circles completely, and erase completely if you make any changes. Please print your name in this box. 		1				66		0	6 0
completely if you make any changes.	-		O Ye	s			6		
completely if you make any changes.	LESS THAN ONCE per WEEK	1-2 per WEEK		s	E IN TH 1 per DAY	6 7 7 8 8 9 9		0 (7) (8)	© @ @ @ @ @ (1) (1) 4+ per
 completely if you make any changes. Please print your name in this box. First, a few general questions about what you eat. bout how many servings of vegetables o you eat, per day or per week, not ounting salad or potatoes? bout how many servings of fruit do you 	THAN ONCE per WEEK	per WEEK	AVER	AGE US 5-6 per WEEK	1 per DAY	6 6 7 7 6 6 6 7 7 7 6 6 6 7 7 7 6 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	TYEAR 2 per DAY	3 per DAY	() () () () () () () () () () () () () (
 completely if you make any changes. Please print your name in this box. First, a few general questions about what you eat. bout how many servings of vegetables o you eat, per day or per week, not pounting salad or potatoes? 	THAN ONCE per WEEK	per WEEK	AVER	AGE US 5-6 per WEEK	1 per DAY	© © ⑦ ⑦ ⑨ ⑨ ⑨ ⑨ ■ E PAST 1 1/2 per DAY	TYEAR 2 per DAY	G G G G G G S	© @ © @ @ @ @ @ @ @ @ @ @ @ @ @

During the past year, have you taken any vitamins or minerals regularly, at least once a month?

TIA	MIN TYPE			HO	W OF	TEN		Т	FO	R HO	W MA		EAD	22
			DIDN'T			per	EVERY		LESS THAN 1 YR.	1 YEAR	2	3-4 YEARS	5-9	10-
Multiple Vitamins. Did y	ou take								1.11.	TEAN	TEARS	TEARS	YEARS	TEA
Regular Once-A-Day, C	Centrum, or The	era tvpe	0	0	0	0	0		0					
Stress-tabs or B-Comp	lex type					0	0		0	0	0	0	0	C
Antioxidant combination	n type		lo	0	0	0	0			0	0	0	00	
Single Vitamins (not part	t of multiple vita	amins)												-
Vitamin A (not beta-car	otene)	,	0	0	0	0	0		0	0	0	0	0	
Beta-carotene			0	0	l o	0	õ		0	0	0	0		
Vitamin C			0	0	l õ	l õ	0		0	0			0	
Vitamin E		`	lo		lõ	Ö	0		0	0	0		0	
Folic acid, folate			lõ		0	0	0		0	0	0	0		
Calcium, alone or com	pined with some	ethina else	0	0	0	0			0				0	
Zinc, alone or combine	d with somethin	na else	0			0	0			0		0	0	
Iron		goloo	0			0						0	0	
Selenium			lõ			l õ			0			0	0	
Did you take any of the	ese suppleme	400 🗆 6 nts at least		80 80 80		⊃ 10	00 c	⊃ 2 (+000	0	Don't	know	1	
 Ginkgo Gincosamine/Cho Glucosamine/Cho The next section is about	eng O St. Jo ndroitin	nts at least hn's Wort O Somet	once a C Ka hing el	a mor ava Ka se	ava (hinac dn't ta	ea ke th	⊖ Me nese		in (IEA	
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Ginkgo Gins Glucosamine/Cho The next section is abor snacks, at home or in a HOW OFTEN, on average	eng O St. Jo Indroitin ut your <u>usual</u> restaurant or e, did you eat th O NOT SKIP ar	eating habit carry-out. he food duri he food s. M	once a C Ka hing el ts in the There ng the	a mor ava Ka se ne pas are tv past y	ava () st yea wo kii	⇒ Ec ⇒ Dia nor s	hinac dn't ta 30. Ti f ques	ea ke th nis i stion	⊖ Me nese		in (IEA	:
Ginkgo Gins Glucosamine/Cho Glucosamine/Cho snacks, at home or in a HOW OFTEN, on average "Please Do HOW MUCH did you usus "Sometimes food, pick th (If you do "Sometimes	eng O St. Jo Indroitin ut your <u>usual</u> restaurant or e, did you eat th O NOT SKIP ar	eating habit carry-out. he food duriny foods. M bood? hany you ea much" as A, is or plates) es: A=1/4 ct D" column	once a C Ka hing el ks in the There ng the ark "Na a, such B, C o that lo p, B=	a mor ava Ka se ne pas are tv past y ever" as 1 o r D. L oks th 1/2 cu	st yea wo kin year? if you egg, 2 _OOK	C Ec Did nr or s nds o didn'i 2 eggs AT T st like	hinac dn't ta so. Ti f ques t eat it s, etc. HE Et the s D=2	ea kett stion , ON VCL0 ervir	Menese nclude ns to a I THE [OSED ng size s.)	elaton es all nswe	meal r for YOU URES	⊃ D⊢ s or each EAT S. For y eat.	food	
Ginkgo Gins Glucosamine/Cho Glucosamine/Cho snacks, at home or in a HOW OFTEN, on average *Please Du HOW MUCH did you usu *Sometimes food, pick th (If you du *Sometimes really ea	eng St. Jo ndroitin ut your <u>usual</u> of restaurant or e, did you eat the O NOT SKIP ar ally eat of the for s we ask how <u>m</u> s we ask how <u>m</u> s we ask how <u>m</u> thave picture (bow) on't have picture s we made the bill t that large a se rank apple juice (about 1 cup).	eating habit carry-out. he food duri ny foods. M ood? hany you ea much" as A, ls or plates) es: A=1/4 ci "D" column erving.	once a C Ka hing el tis in the fhere ng the ark "Ne a, such B, C o that lo ip, B= a darke	a mor ava Ka ise are tw past y past y as 1 (r D. L oks th 1/2 cu	st yea wo kin year? -OOK -OOK ne mo pp, C= pr. Th	 Ec Dia Dia didn'n 2 eggs AT Ti st like 1 cup is is j 	hinac dn't ta so. TI f ques a eat it s, etc. HE EN the s , D=2 ust to	ea ke th stion	Menese nclude ns to a I THE [OSED ng size s.) ind you	DAYS PICT you u	meal meal er for VOU URES usuall sake s	⊃ D⊢ sor each S. Fo y eat. ure y	food IT. r eacl	ı
Ginkgo Gins Glucosamine/Cho Glucosamine/Cho snacks, at home or in a HOW OFTEN, on average *Please Du HOW MUCH did you usus *Sometimes food, pick th (If you du *Sometimes really ea	eng St. Jo ndroitin ut your <u>usual</u> of restaurant or e, did you eat the O NOT SKIP ar ally eat of the for s we ask how <u>m</u> s we ask "how <u>m</u> be picture (bow) on't have pictur s we made the t that large a se rank apple juice	eating habi carry-out. he food duri he food duri he food duri hy foods. M ood? hany you ea much" as A, Is or plates) es: A=1/4 ct "D" column "D" column "D" column arving. e twice a we carry-out. b twice a we	once a Kanning ele Kanning el	a mor ava Ka se ne pas are tw past y ever" as 1 (r D. L oks th 1/2 cu er cold 1 had 34	st yea st yea wo kin year? if you egg, 2 _OOK he mo op, C= _ or. Th one g	 Ec Dia Dia didn'n 2 eggs AT Ti st like 1 cup is is j 	hinac dn't ta so. TI f ques a eat it s, etc. HE EN the s , D=2 ust to	, ON NCLO ervir cup rem	Menese I THE [OSED Ing size S.) Once	DAYS PICT you u to m a wee	meal meal or for SYOU URES usuall make s	⊃ D⊢ s or eeach EAT S. For y eat. uure y ate a HTIM IZZE	IEA food IT. react ou "C" s	ı

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PAGE 2

OB

How much each time

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HOW OFTEN	NEVER	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	HOW M How ma day		lasse	s on	
How often do you drink the following	bever	ages	?							How many				
Tomato juice or V-8 juice	0	0	0	0	0	0	0	0	0	glasses each time	0	0	03	0
Real 100% orange juice or grapefruit uice, including fresh, frozen or bottled	0	0	0	0	0	- 0	0	0	0	How many glasses each time	0	02	03	0
When you drink orange juice, how often you drink a calcium-fortified brand?	do	0	Some	ly calo times y ever	calci	um-fo	rtified	C		on't know on't drink o	range		1	
Other real fruit juices like apple uice, prune juice, lemonade	0	0	0	0	0	0	0	0	0	How many glasses	0	02	03	0
Kool-Aid, Hi-C, or other drinks with added vitamin C	0	0	0	0	0	0	0	0	0	How many glasses	0	0	03	0
Drinks with some juice in them, ike Sunny Delight, Juice Squeeze	0	0	0	0	0	0	0	0	0	How many bottles	0	2	3	4
nstant breakfast milkshakes like Carnation, diet shakes like SlimFast, or liquid supplements like Ensure	0	0	0	0	0	0	0	0	0	How many glasses or cans	0	0 2	0 3	0
Glasses of milk (any kind)	0	0	0	0	0	0	0	0	0	How many glasses	0	0	0	0
 Whole milk Rice milk Roy milk 	5 MIIK		Low-fa	at 1% drink				n-fat r	nilk					
HOW OFTEN	NEVER					24 200	1. 2. 2. 2. 3. 3. 3. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.		EVERY	HOW	MUCH	FAC	нтім	F
HOW OFTEN		FEW/ YEAR	ONCE/ Month	2-3 TIMES/ Month	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	1000	HOW I How many				
HOW OFTEN Regular soft drinks, or bottled	NEVER					24 200	1. 2. 2. 2. 3. 3. 3. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.		EVERY DAY				H TIM 0 34	E 0 5+
		FEW/ YEAR	ONCE/ Month	2-3 TIMES/ Month	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	1000	How many bottles or				
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer	0	FEW/ YEAR		2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEX	5-6 TIMES/ WEEX	0 0	How many bottles or cans How many bottles or	0 1 0	0 2 0 2	034	0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer	0	FEW/ YEAR		2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEX	5-6 TIMES/ WEEX	0 0	How many bottles or cans How many bottles or cans	0 1 0	0 2 0 2	034	0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: O Re	O egular b	FEW/ YEAR		2-3 TIMES/ MONTH	ONCE/ WEEK		3-4 TIMES/ WEEX		O O c beer	How many bottles or cans How many bottles or cans I don't How many glasses How many drinks	0 1 drink l		034	0 5+ 0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (not diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: ORe Wine or wine coolers	egular b	FEW/ YEAR		2-3 TIMES/ MONTH	ONCE/ WEEK		3-4 TIMES/ WEEK	S-6 TIMES/ WEEK	O C beer	How many bottles or cans How many bottles or cans I don't How many glasses How many	0 1 drink 1 1 0		034 034 034	0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (not diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: OR Vine or wine coolers Liquor or mixed drinks	egular b			2-3 TIMES/ MONTH O Light bo	OWCEEX O O O O O O O O O O O O O		Von-ale	s-6 times/ WEEX	C beer	How many bottles or cans How many bottles or cans I don't How many glasses How many drinks How many	01 01 drink I 01 01		034 034 034 0	0 5+ 0 5+ 0 5+ 0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: O Re Vine or wine coolers Liquor or mixed drinks Blasses of water, tap or bottled Coffee, regular or decaf Tea or iced tea (<u>not</u> herb teas)	egular b			Light bo			Von-al	coholic	0 c beer 0 0	How many bottles or cans How many bottles or cans I don't How many glasses How many glasses How many glasses How many	01 drink 1 01 01 01 01		034 034 034 034 0	0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: Ref Wine or wine coolers Liquor or mixed drinks Blasses of water, tap or bottled Coffee, regular or decaf Tea or iced tea (<u>not</u> herb teas) What do you usually add to coffee?	egular b			23 TIMES/ MONTH ight b			Sar THREES	SST THESE COORDOLOGY	0 c beer 0 0	How many bottles or cans How many bottles or cans I don't How many glasses How many glasses How many glasses How many cups	01 drink 01 01 01 01 01 01 01 01		04 34 04 04 04 04 04 04 034	0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (not diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: Vine or wine coolers Liquor or mixed drinks Blasses of water, tap or bottled Coffee, regular or decaf Tea or iced tea (not herb teas) What do you usually add to coffee? MARK ONLY ONE: What do you usually add to tea?			MORTH MONTH I	23 TIMES/ MONTH			34 TIMES	statunes/ week	0 beer 0 0 0	How many bottles or cans How many bottles or cans I don't How many glasses How many glasses How many glasses How many cups	01 01 01 01 01 01 01 01 01	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	034 034 034 034 034 034 034 034	0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+ 0 5+
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: Ref Wine or wine coolers Liquor or mixed drinks Glasses of water, tap or bottled Coffee, regular or decaf Tea or iced tea (<u>not</u> herb teas) What do you usually add to coffee? MARK ONLY ONE: What do you usually add to tea?	Cree	eer am or am or	MONTH MONTH I	23 TIMES/ MONTH			Von-al	set Times/ WEX Coholic		How many bottles or cans How many bottles or cans I don't How many glasses How many glasses How many glasses How many cups	0 1 1 1 1 1 1 1 1 1 1 1 1 1	2 2 2 2 2 2 2 2 2 2 2 2 2 2	0 34 0 34 0 34 0 34 0 34 0 34 0 34 0 34	0 5t 0 5t 0 5t 0 5t 0 5t
HOW OFTEN Regular soft drinks, or bottled drinks like Snapple (<u>not</u> diet drinks) Beer or non-alcoholic beer What kind? MARK ONLY ONE: Ref Wine or wine coolers Liquor or mixed drinks Glasses of water, tap or bottled Coffee, regular or decaf Tea or iced tea (<u>not</u> herb teas) What do you usually add to coffee? MARK ONLY ONE: What do you usually add to tea? MARK ONLY ONE:	egular b egular b o o c c re fee?	eer	MORTH MONTH I I I I I I I I I I I I I I I I I I I	AND CONTRACTORS OF CO			34 TIMES/ ONOn-all	Set Times/ WEX	C beer	How many bottles or cans How many bottles or cans I don't How many glasses How many glasses How many cups How many cups	on the second se	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	034 034 034 034 034 034 034 034 034 034	0 5+ 0 5+ 0 5+ 0 5+ 0 5+

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per Month	2-3 TIME\$ per	per	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MU SEE I PICTUR	ORTIC	ON SIZ	E
How often do you eat each of the f	ollow									n they are in	seas	son?	
Raw peaches, apricots, nectarines, while they are in season	0	0	0	0	0	0	0	0	0	How many each time	0		2
Cantaloupe, <u>in season</u>	0	0	0	0	0	0	0	0	0	How much	0	0	0
Strawberries, in season	0	0	0	0	0	0	0	0	0	How much	Ŷ	OB B	C
Watermelon, in season	0	0	0	0	0	0	0	0	0	How much	•	O B	0
Any other fruit <u>in season</u> , like grapes, honeydew, pineapple, kiwi	0	0	0	0	0	0	0	0	0	How much	0	O B	O c
How often do you eat the following	g foo	ds <u>all</u>	year	roun	d? Es	timat	te you	ur ave	erage	for the whol	e yea	r.	
Bananas	0	0	0	0	0	0	0	0	0	How many each time	0	0	0
Apples or pears	0	0	0	0	0	0	0	0	0	How many each time	0		2
Oranges or tangerines	0	0	0	0	0	0	0	0	0	How many each time	0		02
Grapefruit	0	0	0	0	0	0	0	0	0	How much	0	01	02
Canned fruit like applesauce, fruit cocktail, or dried fruit like raisins	0	0	0	0	0	0	0	0	0	How much	•	OB	ç
HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES WEEK	V 5-6 TIMER WEEK	DAY	HOW M How many	UCH	EACH	1
Eggs, including egg biscuits or Egg McMuffins (Not egg substitutes)	0	0	0	0	0	0	0	0	0	eggs each time	9	2	3
Bacon	0	0	0	0	0	0	0	0	0	How many pieces	P.	2	9
Breakfast sausage, including sausage biscuits	0	0	0	0	0	0	0	0	0	How many pieces	0	02	9 3
Pancakes, waffles, French toast, Pop Tarts	0	0	0	0	0	0	0	0	0	How many pieces	0	2	0,3
Breakfast bars, granola bars, Power bars	0	0	0	0	0	0	0	ò	0	How many	0	02	03
Cooked cereals like oatmeal, cream of wheat or grits	0	0	0	0	0	0	0	0	0	Which bowl		9	00
High-fiber cereals like All Bran, Raisin Bran, Fruit-n-Fiber	0	0	0	0	0	0	0	0	0	Which bowl		OB	0 c
Which high-fiber cereal do you eat r			MAR ng else		ILY O			Bran on't kr		Buds O	Raisin I don't		
Product 19, Just Right or					1	1	1	1	1		1		_
Total cereal	0	0	0	0	0	0	0	0	0	Which bowl		8	00
Any other cold cereal, like Corn Flakes, Cheerios, Special K	0	0	0	0	0	0	0	0	0	Which bowl How many	_	B	000
Milk or milk substitutes on cereal	0	0	0	0	0	0	0	0	0	oz. on cerea			1
Yogurt or frozen yogurt	0	0	0	0	0	0	0	0	0	How much		B	00
Cheese, sliced cheese or cheese spread, including on sandwiches	0	0	0	0	0	0	0	0	0	How many slices	0	0	0,3

HOW OFTEN	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		EE PO	H EA	SIZE	
How often do you eat the following veg in a restaurant?	jetab								or in	stir-fry,	at ho	ome	or	
Broccoli	0	0	0	0	0	0	0	0	0	How much		OB	00	O
Carrots, or mixed vegetables or stews containing carrots	0	0	0	0	0	0	0	0	0	How much	0		00	o
Com	0	0	0	0	0	0	0	0	0	How much			00	°.
Green beans or green peas	0	0	0	0	0	0	0	0	0	How much			0	o
Spinach	0	0	0	0	0	0	0	0	0	How much	0		0 0	0
Mustard greens, turnip greens, collards	0	0	0	0	0	0	0	0	0	How much			ç	P
French fries, fried potatoes or hash browns	0	0	0	0	0	0	0	0	0	How much	Q	O B	00	o
White potatoes not fried, incl. boiled, baked, mashed & potato salad	0	0	0	0	0	0	0	0	0	How	O A	OB	00	0
Sweet potatoes, yams (Not in pie)	0	0	0	0	0	0	0	0	0	How	0	OB	00	0 D
Cole slaw, cabbage	0	0	0	0	0	0	0	0	0	How	Q.		00	0
Green salad	0	0	0	0	0	0	0	0	0	How			с () с	0
Raw tomatoes, including in salad	0	0	0	0	0	0	0	0	0	How	A 0	0	C 0	
Salad dressing	0	0	0	0	0	0	0	0	0	How many	0	1/2		2
Is your salad dressing \bigcirc Usually low-fat	t C	i ⊃ Sor	netim	i nes lor	" w-fat	0	Hardly	/ ever	low-f	∎Tbspi. at ⊂[i 1 Don't i			use
HOW OFTEN	NEVER	FEW/ Year	ONCE/ MONTH	2-3 TIMES/ MONTH	ONCE/ WEEK	TWIČE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW	MUC	HEA	CH TI	ME
Any other vegetable, like okra, squash, cooked green peppers	0	0	0	0	0	0	0	0	0	How much	0	OB	ç	0
Refried beans or bean burritos	0	0	0	0	0	0	0	0	0	How much		OB	0	0
Chili with beans (with or without meat)	0	0	0	0	0	0	0	0	0	How much		0	0	0
Baked beans, black-eye peas, pintos, any other dried beans	0	0	0	0	0	0	0	0	0	How much	0	OB	00	0
Vegetable stew	0	0	0	0	0	0	0	0	0	Which Bowl		OB	0	0
Vegetable soup, vegetable beef, chicken vegetable, or tomato soup	0	0	0	0	0	0	0	0	0	Which Bowl		0	0°	o
Split pea, bean or lentil soup	0	0	0	0	0	0	0	0	0	Which Bowl		O B	00	0
Any other soup, like chicken noodle, chowder, mushroom, instant soups	0	0	0	0	0	0	0	0	0	Which Bowl			00	0
Spaghetti, lasagna or other pasta with tomato sauce	0	0	0	0	0	0	0	0	0	How	0	OB	00	0
Cheese dishes <u>without</u> tomato sauce, like macaroni and cheese	0	0	0	0	0	0	0	0	0	How		B	с 0	0
		0	0	0	0		0	0	0	How		8	C	D

+

Do you ever eat chicken, meat or fis Hamburgers, cheeseburgers, meat loaf, at home or in a restaurant Tacos, burritos, enchiladas, tamales, etc. with meat or chicken Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches How do you like beef cooked?	ih? (Mônth - No		SKI							-	-
loaf, at home or in a restaurant Tacos, burritos, enchiladas, tamales, etc. with meat or chicken Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches		0	0			, oran	TON	EXT I	PAGE					
tamales, etc. with meat or chicken Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches	0			0	0	0	0	0	0	How much meat	0 1/8 lb.	0 1/4 lb.	01/2 lb.	3/41
frozen dinners or sandwiches		0	0	0	0	0	0	0	0	How much	0	O _B	00	C
How do you like beef cooked?	0	0	0	0	0	0	0	0	0	How much	0	OB	00	C
	Rare	C		dium	C) Wel	l done		01	don't eat bee	ef			
Pork chops, pork roasts, or dinner ham	0	0	0	0	0	0	0	0	0	How much	•	OB	00	C
When you eat meat, do you O Avoid	eating	the fa	t (Son	netime	es eat	the fat	C	Ofte	n eat the fat	C	ldo	n't eat	me
Veal, lamb or deer meat	0	0	0	0	0	0	0	0	0	How much	0	OB	0 c	C
Ribs, spareribs	0	0	0	0	0	0	0	0	0	How many ribs	0,4	0	0	94
Liver, including chicken livers or liverwurst	0	0	0	0	0	0	0	0	0	How much	0	0	00	C
Gizzard, pork neckbones, chitlins, pigs feet, etc.	0	0	0	0	0	0	0	0	0	How much	•	0	O _c	C
Mixed dishes with beef or pork, like stew, corned beef hash, stuffed cabbage, meat dish with noodles	0	0	0	0	0	0	0	0	0	How much	•	OB	00	0
Mixed dishes with chicken, like chicken casserole, chicken & noodles, pot pie or in stir-fry	0	0	0	0	0	0	0	0	0	How much	•	OB	00	0
Fried chicken, at home or in a restaurant	0	0	0	0	0	0	0	0	0	# medium pieces	0	02	03	4
Chicken or turkey not fried, such as baked, grilled, or on sandwiches	0	0	0	0	0	0	0	0	0	How much		OB	00	
When you eat chicken, do you	Avoid	eating	the sl				es eat			Often eat	the sk	in		
HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ Month	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW	MUCH	EAC	HTIM	E
Oysters	0	0	0	0	0	0	0	0	0	How much		B	O c	
Other shellfish like shrimp, scallops, crabs	0	0	0	0	0	0	0	0	0	How much	•	O B	00	
Tuna, tuna salad, tuna casserole	0	0	0	0	0	0	0	0	0	How much of the tuna		B	00	
Fried fish or fish sandwich, at home or in a restaurant	0	0	0	0	0	0	0	0	0	How much	•	O B	00	0
Other fish, not fried	0	0	0	0	0	0	0	0	0	How much	0	0	00	0
Hot dogs, or sausage like Polish, Italian or chorizos	0	0	0	0	0	0	0	0	0	How many	9	02	9	9
Are your hot dogs	fat	0	Some	times	low-fat	t 🧃	🗆 Hai	rdly ev	er low	fat O Dor	n't kno	w/don	't eat	then
Boloney, sliced ham, turkey lunch meat, other lunch meat	0	0	0	0	0	0	0	0	0	How many slices	0	0	0	0
Are your lunch meats O Usually low-	fat or	turkey	0	Some	times	low-fa	t d		rdly ev	er low-fat				
				-	P	AGE 6	1							

HOW OFTEN	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		E POR	TION S	SIZE	
Noodles, macaroni, pasta salad	0	0	0	0	0	0	0	0	0	How much	0	OB	00	0
Tofu, bean curd	0	0	0	0	0	0	0	0	0	How much	0	OB	000	
Meat substitutes, such as veggie burgers, Gardenburgers	0	0	0	0	0	0	0	0	0	How many patties	•	B 0 2	C O 3	C
Chinese food, Thai or other Asian food, not counted above	0	0	0	0	0	0	0	0	0	How		2 0 8	3 0 C	
Snacks like potato chips, corn chips, popcorn (not pretzels)	0	0	0	0	0	0	0	0	0	How much	0	OB	0°	0
Are these snacks O Usually low-fat	O Son	netime				dly ev	er low	fat C	D Don	't know/don		-		
HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ Month	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW	MUCH	EAC	H TIM	E
Peanuts, other nuts or seeds	0	0	0	0	0	0	0	0	0	How much	O A	OB	00	0
Crackers	0	0	0	0	0	0	0	0	0	How much	O A	OB	00	
Doughnuts, Danish pastry	0	0	0	0	0	0	0	0	0	How many	0	02	03	9
Cake, sweet rolls, coffee cake	0	0	0	0	0	0	0	0	0	How much	0	OB	00	0
Are they O Usually low-fat	Son	netime	s low-	fat C) Har	dly ev	er low-	fat C	Don'	't know/don'	't eat	1.2		
Cookies	0	0	0	0	0	0	0	0	0	How many	0	03-5	0 6-7	8
Are your cookies O Usually low-fat	O Son	netime	s low-	fat 🧲	Har	dly eve	er low-	fat C	l dor	n't know/dor	n't eat			
Ice cream, ice milk, ice cream bars	0	0	0	0	0	0	0	0	0	How much	0	0	0	C
Is your ice cream O Usually low-fat	 Som 	netime	s low-	fat C	Han	dly eve	er low-	fat C	l dor	n't know/dor	n't eat	8	C	0
Pumpkin pie, sweet potato pie	0	0	0	0	0	0	0	0	0	How many slices	0	0	0	C
Any other pie or cobbler	0	0	0	0	0	0	0	0	0	How many slices	1/2	1	2	3
Chocolate candy, candy bars	0	0	0	0	0	0	0	0	0	How many	1/2	1	2	3
Other candy, not chocolate, like hard candy, caramel, jelly beans	0	0	0	0	0	0	0	0	0	bars How many pieces	small	medium	large	
	-		In sub-HD				6	5		picces	1-2	3-5	6-7	8+
			सन्दर्भः	R		sere Lie		2	A		3			
	N	99.5 J				0	0							
				all has	4	The second								
	Minun		phile of the second s		Y		AC	540						
PL	EASE	DO	NO	T WF	RITE	IN T	HIS	ARE	A	-				
and the second s		PA	GE 7	-				-			-	-		
							-							

HOW OFTEN	NEVER Or 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	2+ TIMES per DAY	HOW MI SEE PICTUR	PORT	ON SIZ	ZE.	E
Biscuits or muffins	0	0	0	0	0	0	0	0	0	How many each time	\bigcirc	o,	0	Q
Rolls, hamburger buns, English muffins, bagels	0	0	0	0	0	0	0	0	0	How many each time	0	0	0	
Dark bread like rye or whole wheat, including in sandwiches	0	0	0	0	0	0	0	0	0	How many slices each	1/2		2	3
White bread or toast, including French, Italian, or in sandwiches	0	0	0	0	0	0	0	0	0	time How many slices each	0		3	
Corn bread, corn muffins	0	0	0	0	0	0	0	0	0	time How many	0		3	
Tortillas	0	0	0	0	0	0	0	0	0	pieces How many each time		0	0	
Rice, or dishes made with rice	0	0	0	0	0	0	0	0	0	How much		2	3	
Margarine (not butter) on bread or on potatoes or vegetables, etc.	0	0	0	0	0			0	0	How many	•	в	0	
Butter (not margarine) on bread or	0	0	0	0	0	0	0	0	0	pats (tsp.) How many	ĭ O	02	3	1
on potatoes or vegetables, etc. Gravy	0	0	0	0	0	0	0	0	0	pats (tsp.) How	1	02	3	
Peanut butter	0	0	0							many Tbsp. How	0	2	3	
				0	0	0	0	0	0	many Tbsp. How		2	3	
Jelly, jam, or syrup	0	0	0	0	0	0	0	0	0	many Tbsp. How		2	3	
Mayonnaise, sandwich spreads	0	0	0	0	0	0	0	0	0	many Tbsp.	0	2	3	
Catsup, salsa or chile peppers	0	0	0	0	0	0	0	0	0	How many Tbsp.	9	02	9	
Mustard, soy sauce, steak sauce, barbecue sauce, other sauces	0	0	0	0	0	0	0	0	0	How many Tbsp.	0	0	9	
Did you use the pictures to choo Would you say your health is How many times have you gone Did you ever drink more beer, w	 Excel on a diet 	llent ? — I	⊂ \ Never	/ery g	jood ⊃ 1-2	0	⊃ Go ⊃ 3-5	od ⊂		Fair Of 90	oor		pictu	63.
How many hours do you watch to None 1-6 hours/wee Do you smoke cigarettes now? IF YES, On the average about 1-5 6-14 15-24	k ⊖1h ⊖No (how man	our/da ⊖ Yes i y cig a	ay (; arette	⊃2h sada	ours/o	day	0:	3 hour	s/day		hours	day		
What language do you usually s		ome o methi					glish (k som	ethin	g else equa	ally			
	RK ONE (⊃ Black or ⊃ Asian			erica	n					an or Alask an or Other			Inder	
Thank you very much for filling out t								ack an	d fill i	n anything y	ou ma	ay hav	e skip	pe
								000	2		24	408	378	
			AGE 8			ark Refi								

APPENDIX J

EATING BEHAVIOR INVENTORY

Subject ID:

Date:

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

	Never	Some	About	Much	Always
	or	of the	half of	of the	or
	Hardly	time	the	time	almost
	ever		time		always
A. I carefully watch the quantity of food that I eat.		\square_2	\square_3	\square_4	\square_5
B. I eat foods that I believe will aid me in losing weight.		\square_2		\square_4	\square_5
C. I keep 1 or 2 raw vegetables available for snacks.				\square_4	\square_5
D. I record the type and quantity of food which I eat.				\square_4	\square_5
E. I weigh myself daily.					
F. I refuse food offered to me by others.	\square_1	\square_2		\square_4	\square_5
G. I eat quickly compared to most other people.		\square_2		\square_4	\square_5
H. I consciously try to slow down my eating rate.		\square_2		\square_4	
I. I eat at only one place in my home.				\square_4	
J. I use the same placemat and other utensils for each meal.				\square_4	
K. I eat and just can't seem to stop.		\square_2		\square_4	
L. I eat in the middle of the night.				\square_4	\square_5
M. I snack after supper.				\square_4	\square_5
N. My emotions cause me to eat.				\square_4	
O. I buy ready-to-eat snack foods for myself.		\square_2		\square_4	\square_5
P. I shop when I'm hungry.				\square_4	
Q. I shop from a list.				\square_4	

R. I leave food on my plate.			\square_4	\square_5
S. I serve food family style (serve from bowls on table).	\square_2	\square_3	\square_4	
T. I watch TV, read, work, or do other things while I eat.	\square_2		\square_4	\square_5
U. If I'm served too much, I leave food on my plate.	\square_2		\square_4	\square_5
V. Generally, while I'm at home, I leave the table as soon as I finish eating.	D ₂	\square_3	 4	\square_5
W. I keep a graph of my weight.	\square_2	\square_3	\square_4	\square_5
X. I eat when I'm not really hungry.	\square_2		\square_4	
Y. I store food in containers where it is not readily visible or in a closed cupboard.		□3	 ₄	
Z. I decide ahead of time what I will eat for meals and snacks.	\square_2		\square_4	

APPENDIX K

PAFFENBARGER PHYSICAL ACTIVITY QUESTIONNAIRE

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?

 \square_1 Yes If "YES", please complete this questionnaire about the previous week.

 $\square_2 No$

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

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 <u>UP</u> - not down.
 *When answering this question, One Flight of Stairs = 10 steps if you know the number of steps.

 $\theta \theta$ 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.

*When answering this question, consider that 12 city blocks = 1 mile. If you do not know the blocks or distance, 20 minutes of walking = 12 city blocks.

 $\theta \theta$ 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. For example, if you lift weights only include the time that you actually are lifting the weights, not the time you spend moving from machine to machine.

*Note: All walking should only be included in Question 3

*Note: Household activities such as cleaning and laundry are not to be included here as they are not considered to be a sport, fitness, or recreational activity.

Sport, Fitness, or Recreation	Times per Week	Average Time per Episode		Office Use Only
a.	θθ	<u>θθθ</u>	Minutes	θ
b.	θθ	000	Minutes	θ
C.	θθ	000	Minutes	θ
d.	θθ	θθθ	Minutes	θ

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

- θ less active than usual
- θ more active than usual
- θ 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?

- θ Yes $\theta\theta$ times per week; Activity:
- θ Νο

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.)	θθ	θθ
b) Moderate Activity (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)	θθ	θθ
c) Light Activity (office work, driving car, strolling, personal care, standing with little motion, etc.)	θθ	θθ

d) Sitting Activity (eating, reading, desk work, watching TV, computer work,	00	θθ
listening to the radio, etc.)		
e) Sleeping or reclining	θθ	θθ

APPENDIX L

MAAS

Subject Number:_____

Date:

Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what *really reflects* your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1 Almost Always	2 Very Frequently	345SomewhatSomewhatVeryFrequentlyInfrequentlyInfrequently						6 Almost Never			
I could be experiencing some emotion and not be conscious of it until some time later.								4	5	6	
I break or spill things because of carelessness, not paying attention, or thinking of something else.								4	5	6	
I find it difficult to stay focused on what's happening in the present.							3	4	5	6	
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.						2	3	4	5	6	
I tend not to notice f my attention.	eelings of physical	tension or discomfo	rt until they really gra	ıb	1	2	3	4	5	6	
l forget a person's n	ame almost as soo	n as l've been told i	t for the first time.		1	2	3	4	5	6	
It seems I am "running on automatic," without much awareness of what I'm doing.						2	3	4	5	6	
I rush through activit	ties without being re	eally attentive to the	em.		1	2	3	4	5	6	

I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6
I drive places on 'automatic pilot' and then wonder why I went there.	1	2	3	4	5	6
I find myself preoccupied with the future or the past.	1	2	3	4	5	6
I find myself doing things without paying attention	1	2	3	4	5	6
I snack without being aware that I'm eating.	1	2	3	4	5	6

APPENDIX M

5-FACTOR MINDFULNESS QUESTIONNAIRE

Subject number_____

Date

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes <u>your own opinion</u> of what is <u>generally true for you</u>.

1	2	3	4	5
never or very	rarely	sometimes	often	very often or
rarely true	true	true	true	always true

- _____1. When I'm walking, I deliberately notice the sensations of my body moving.
- 2. I'm good at finding words to describe my feelings.
- 3. I criticize myself for having irrational or inappropriate emotions.
- 4. I perceive my feelings and emotions without having to react to them.
- 5. When I do things, my mind wanders off and I'm easily distracted.
- 6. When I take a shower or bath, I stay alert to the sensations of water on my body.
- _____7. I can easily put my beliefs, opinions, and expectations into words.
- 8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.
- 9. I watch my feelings without getting lost in them.
- _____10. I tell myself I shouldn't be feeling the way I'm feeling.
- _____11. I notice how foods and drinks affect my thoughts, bodily sensations, and, emotions.
- _____12. It's hard for me to find the words to describe what I'm thinking.
- ____13. I am easily distracted.
- _____14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.
- _____15. I pay attention to sensations, such as the wind in my hair or sun on my face.

1	2	3	4	5
never or very	rarely	sometimes	often	very often or
rarely true	true	true	true	always true

_____16. I have trouble thinking of the right words to express how I feel about things

17. I make judgments about whether my thoughts are good or bad.

- 18. I find it difficult to stay focused on what's happening in the present.
- 19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.
- 20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.
- 21. In difficult situations, I can pause without immediately reacting.
- 22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.
- _____ 23. It seems I am "running on automatic" without much awareness of what I'm doing.
- _____24. When I have distressing thoughts or images, I feel calm soon after.
- 25. I tell myself that I shouldn't be thinking the way I'm thinking.
- _____ 26. I notice the smells and aromas of things.
- 27. Even when I'm feeling terribly upset, I can find a way to put it into words.
- _____ 28. I rush through activities without being really attentive to them.
- 29. When I have distressing thoughts or images I am able just to notice them without reacting.
- _____ 30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.
- 31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.
- 32. My natural tendency is to put my experiences into words.
- _____ 33. When I have distressing thoughts or images, I just notice them and let them go.
- _____ 34. I do jobs or tasks automatically without being aware of what I'm doing.
- _____ 35. When I have distressing thoughts or images, I judge myself as good or bad, depending on what the thought/image is about.
- _____ 36. I pay attention to how my emotions affect my thoughts and behavior.
- _____ 37. I can usually describe how I feel at the moment in considerable detail.
- _____ 38. I find myself doing things without paying attention.
- _____39. I disapprove of myself when I have irrational ideas.

APPENDIX N

MEAL PLANS

1200 Calorie Eating Plan Guidelines

Getting started on a healthy eating plan can take time. To save time and to get you off to a nutritionally balanced start, the following guidelines are provided:

1. A range of calories for each meal is provided below. You may choose to remain at the lower end of the range and have a snack or choose the higher end of the range and not have a snack.

Breakfast:	200-300 calories
Lunch:	300-350 calories
Dinner:	500-550 calories
Snack:	0-200 calories

- 2. During the initial 12 weeks of the program, meals and snacks should be limited to the foods on the lists that are provided for you.
- 3. Average calorie and fat gram information is provided for all the foods you will be eating. If a particular brand differs from this average, use the calorie and fat gram information on the nutritional label or refer to the Fat Book. Transfer the calorie and fat information to your self-monitoring book.

- 4. Your eating plan is designed to provide no more than 20% of your calories from fat. For your 1200 calorie eating plan, this breaks down to 26 grams of fat.
- 5. We recommend that you weigh and measure your food portions, especially your portions of meat. Purchase a food scale if you do not already have one and use it and the labels on the food to help you select appropriate portions.
- To help ensure adequate intake of vitamins and minerals, a daily multi-vitamin is recommended.

1500 Calorie Eating Plan Guidelines

Getting started on a healthy eating plan can take time. To save time and to get you off to a nutritionally balanced start, the following guidelines are provided:

 A range of calories for each meal is provided below. You may choose to remain at the lower end of the range and have a snack or choose the higher end of the range and not have a snack.

Breakfast:	200-350 calories
Lunch:	400-450 calories
Dinner:	600-650 calories
Snack:	0-250 calories

- 2. During the initial 12 weeks of the program, meals and snacks should be limited to the foods on the lists that are provided for you.
- 3. Average calorie and fat gram information is provided for all the foods you will be eating. If a particular brand differs from this average, use the calorie and fat gram information on the nutritional label or refer to the Fat Book. Transfer the calorie and fat information to your self-monitoring book.
- 4. Your eating plan is designed to provide no more than 20% of your calories from fat. For your 1500 calorie eating plan, this breaks down to 33 grams of fat.

- 5. We recommend that you weigh and measure your food portions, especially your portions of meat. Purchase a food scale if you do not already have one and use it and the labels on the food to help you select appropriate portions.
- 6. To help ensure adequate intake of vitamins and minerals, a daily multi-vitamin is recommended.

1800 Calorie Eating Plan Guidelines

Getting started on a healthy eating plan can take time. To save time and to get you off to a nutritionally balanced start, the following guidelines are provided:

 A range of calories for each meal is provided below. You may choose to remain at the lower end of the range and have a snack or choose the higher end of the range and not have a snack.

Breakfast:	250-350 calories
Lunch:	400-500 calories
Snack:	0-250 calories
Dinner:	600-650 calories
Snack:	0-250 calories

- 2. During the initial 12 weeks of the program, meals and snacks should be limited to the foods on the lists that are provided for you.
- 3. Average calorie and fat gram information is provided for all the foods you will be eating. If a particular brand differs from this average, use the calorie and fat gram information on the nutritional label or refer to the Fat Book. Transfer the calorie and fat information to your self-monitoring book.
- 4. Your eating plan is designed to provide no more than 20% of your calories from fat. For your 1800 calorie eating plan, this breaks down to 40 grams of fat.

- 5. We recommend that you weigh and measure your food portions, especially your portions of meat. Purchase a food scale if you do not already have one and use it and the labels on the food to help you select appropriate portions.
- 6. To help ensure adequate intake of vitamins and minerals, a daily multi-vitamin is recommended.

APPENDIX O

WEEKLY DIARY



FOOD AND EXERCISE RECORD

Very light Fairly light Somewhat hard Hard Very hard Very, very hard

Very, very light

WEEK:

RPE Scale

NAME: START DATE:

CALORIE GOALS:	FAT GOALS:
DAILY	DAILY
WEEKLY	WEEKLY
WEEKLY EXE	RCISE GOALS:
MINU	JTES / WEEK
MINI	ITES / DAY
DAYS	S / WEEK
TARC	GET HEART RATE

NAME: ____

___ WEEK: ____

FOOD OR BEVERAGE AMOUNT AND DESCRIPTION	CALORIES	GRAMS OF FAT
BREAKFAST: DID NOT EAT BREAKFAST		
TOTAL	4	
MORNING SNACK: DID NOT EAT MORNING SNACK: MORNING SNAC	×	
TOTAL		
LUNCH DID NOT EAT		
TQTA		
AFTERNOON SNACK. DID NOT EAT AFTERNOON SNA	CK	
TOTA	L:	

	OOD OR BEVERAGE	CALORIES	GRAMS OF FAT
DINNER:	DID NOT EAT		
EVENING	SNACK: DID NOT EAT		
TIME	TOTAL:	OURAT	
DAY		SESSI	ON
ELACK	OT EXERCISE TODAY: OR NOT EXERCISING (SELECT ONE OF TIME FOR EXERCISE DISE WAS INCONVENIENT OF MOTIVATION FOR EXERCISE	OF THE FOL	LOWING

APPENDIX P

MINDFULNESS MEDITATION RECALL

Subject ID #

Did you practice Mindfulness/Meditation this week? Yes D No D If yes, how many minutes did you practice Mindfulness/Meditation this week?

Minutes Per Day	Did not Practice	<15 min.	16-30 min.	31-45 min.	46-60 min.	> 60 min.
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						
Monday						

Did you practice Yoga this week? Yes I No I If yes, how many minutes did you practice Yoga this week?

Minutes Per Day	Did not Practice	<15 min.	16-30 min.	31-45 min.	46-60 min.	> 60 min.
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						
Monday						

APPENDIX Q

SAMPLE OUTLINE of STANDARD BEHAVIORAL WEIGHT LOSS (SBWP) LESSON TOPICS

Week	Торіс
1	The Behavioral Approach to Changing Eating and Exercise Habits
2	Healthy Food Choices
3	Motivation
4	Developing and Implementing Your Exercise Program
5	Barriers to Exercise
6	Role of Thoughts in Weight Management
7	Stimulus Control: Cues in Your Physical Environment for Eating and Exercise
8	Strategies for Becoming a Skillful Supermarket Shopper
9	Using Food Labels
10	The Art of Positive Thinking and Positive Planning: Taking Responsibility for Your Weight Loss Behaviors
11	Build a Better Breakfast
12	Eating Out in Restaurants
13	Evaluating Your Progress: Where Have You Been? Where Are You Going?
14	My Pyramid: Steps to a Healthier You
15	My Time, My Values
16	Wanting to Eat When You are Not Hungry: Learning to Manage the Urge
17	Laughter: It Does More Than Improve Your Mood
18	Smart Snacking
19	Energy Balance Revisited: The Impact on Body Weight
20	Problem Solving
21	3 month feedback for assessment results
22	Looking Forward

23	Holiday-proofing your home, thanksgiving tips, recipes, etc
24	Oprah inspirational video on motivation to lose weight

APPENDIX R

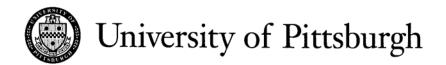
SAMPLE OUTLINE OF STANDARD BEHAVIORAL WEIGHT LOSS + MINDFULNESS MEDITATION (SWBP+MM) LESSON TOPICS

Week	Торіс
1	General Orientation to 6 month program- review of diet plan and exercise plan
2	Raisin eating meditation
3	Sitting meditation-review mindful eating practice
4	Body scan meditation-review sitting practice
5	Hunger meditation-review body scan practice
6	Yoga standing (CD) meditation
7	Eating meditation – hunger and taste and satiety
8	Review meditation progress-recommitment- positives/struggles
9	Yoga Lying meditation (CD)
10	Lake Meditation – eating triggers
11	1 st Yoga DVD- Mindfulness Movement
12	Mindful eating exercise – taste, portion, emotions
13	Handout on negative thinking, being mindful of thoughts
14	2 nd Yoga DVD- Mindfulness Movement
15	Principles of mindful eating, Mindfulness Scales-Body, Mind, Thoughts, Feelings Scales in Relation to Eating
16	Mindfulness and Movement, Exercise
17	3 rd Yoga DVD-Mindfulness Movement

- 18 7 Mindfulness Qualities
- 19 Forgiveness Meditation
- 20 Mindfulness Walking Meditation MBSR
- 21 Mindfulness Walking Meditation- Walking 2 Miles
- 22 Inner Wisdom Meditation/Lovingkindness Meditation
- 23 Mindful Relapse Prevention
- 24 Mindfulness in Everyday Life

APPENDIX S

PROPOSED CONSENT FOR QUALITATIVE INTERVIEW



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

Approval Date: Renewal Date: University of Pittsburgh Institutional Review Board IRB #0701013

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Alternative Behavioral and Physical Activity Approaches to Weight Loss

PRINCIPAL INVESTIGATOR:

John M. Jakicic, Ph.D. Associate Professor Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184

CO-INVESTIGATORS: Amy D. Otto, Ph.D. Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184

Laura Fonzi, BS	Kathleen Spadaro, Med
Department of Health and Physical Activity	Department of Health and Physical Activity
University of Pittsburgh	University of Pittsburgh
Birmingham Towers, Suite 600	Birmingham Towers, Suite 600
2100 Wharton Street	2100 Wharton Street
Pittsburgh, PA 15203	Pittsburgh, PA 15203
Telephone: 412-488-4184	Telephone: 412-488-4184
SOURCE OF SUPPORT: Internal Support -	Department of Health and Physical Activity

Why is this addendum to the study being done?

To learn more about the experience of the participants in the intervention group that had mindfulness meditation added to the weight loss intervention. To understand what parts of the intervention were helpful or not helpful to the participants to make revisions to the intervention prior to future research studies or clinical treatment application.

Who is being asked to take part in this component in the study?

Approximately 15-16 participants from the Standard Behavioral Weight Control plus Mindfulness Meditation group will be invited to participate in this component of the study. Recruitment will take place at the Physical Activity and Weight Management Research Center.

How long will I be in this study?

If you agree to take part in this component of the study, your involvement will last for the time it takes to complete one interview either by in-person, phone or email. In-person and phone interviews last from one to two hours and email interviews generally take a week or two of receiving and responding to emailed questions. You may be asked to participate in a brief follow-up interview with questions based on information that collected from other participants, up to six months following the final 24 week assessment.

What are the procedures of this component of the study?

If you agree to participate, Kathleen Spadaro M.Ed, RN will contact you to arrange either an in-person, phone, or email interview. In this interview you will be asked questions related to your experience in the Standard Behavioral Weight Control plus Mindfulness Meditation Group. For example, one question may be "tell me about your experience in this research group" You may choose not to answer any question at any time and still continue to be in the research study.

With your permission, the in-person and phone interviews will be audiotaped so that nothing you say will be missed. You may also participate if you choose not to be audiotaped. You may stop the interview at any point regardless of whether it is a phone or email interview.

With your permission you may be re-contacted within six months of the initial interview to clarify or elaborate on comments made during the interview. This may be expected to take 15-20 minutes of your time. Please check and initial the following choice as regards the possibility of being re-contacted:

Yes, please re-contact me if necessary _____

No, please do not re-contact me

What are the possible risks of this study?

there may be some risks from being in this study. One possible risk is you may feel uncomfortable about some of the questions that you are asked. Please feel free to answer only the questions you feel comfortable with and remember you can stop the interview at any time for any reason, with no penalties. If you should experience emotional distress, I will assist you in finding appropriate mental health assistance in your geographical area. There is also the possible risk of the breach of confidentiality, however as described in other sections of this consent form, several steps will be taken to maintain confidentiality. However, even though the researcher will be careful to keep your study information confidential, there is a very remote chance this information could accidentally become known to others.

Will I benefit form taking part in this study?

You may not directly benefit from joining this component of the study, although you may find it helpful to be able to express your opinion and/or concerns. We hope to gain a better understanding of your experience of having been a participant in the Standard Behavioral Weight Control plus Mindfulness Meditation group and how it affected your weight control efforts. We believe the information that you and the other study participants provide will lead to improved understanding of how individuals manage their weight, make food choices and incorporate physical activity in their daily lives. This research may help in the development of guidelines for improved weight control programs.

Are there any costs to me if I participate in this study?

There are no material costs to you other than the hour or so it takes to complete the interview.

How much will I be paid if I complete the study?

You will not be paid any extra for completing with component of the research study.

Who is funding this study?

Funding for this study is being obtained from the University of Pittsburgh Department of Health and Physical Activity.

Will anyone know that I am taking part in this study?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, federal government regulatory agencies and the University of Pittsburgh Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

Every effort will be made to maintain the confidentiality of your study records. Only the investigator will have knowledge of the names of the participants. The research team will have access to the transcribed interview, but no identifying information will be in the transcript. Any scientific data or medical information that results from the study may be presented and published so the information can be useful to others, but no data or information will be presented that would make you identifiable.

All contact information, the consent form and the transcript of the interview will be kept in a secured and locked file in the investigator's office at the School of Nursing at the University of Pittsburgh. All information will be coded so that your name does not appear on any interview material. Electronic files of interviews will be password protected and in the sole possession of Kathleen Spadaro. Email interviews will be cut and paste into coded Word document with no personal identifying information attached or within the document itself. The original email will then be deleted. The transcribed interviews, which will be identifiable by code only, will be kept after the research project is completed so that Kathleen Spadaro may access your stories in the future to compare your experiences with research participants in future studies. After the research is completed copies of the consent form and demographics form will be kept by Kathleen Spadaro in a locked file for a minimum of five years.

Will this research study involve the use or disclosure of my identifiable medical record information?

This research study will <u>not</u> involve the use of your identifiable medical information nor will information be placed in your medical record.

Audio Recording

One aspect of this study involves making an audiotape if you choose to do a phone interview. Only Kathleen Spadaro will have access to the audiotapes. The tapes will be kept until the research study is completed and reports are written. Then they will be destroyed.

Audio recording of phone interviews is optional and you will be permitted to participate even if you choose a phone interview but prefer not to have it audiotaped.

- [] Yes I do give you permission to make audio recordings of me during this study.
- [] No I do not give you permission to make audio recordings of me during this study.

Is my participation in this study voluntary?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If I agree to participate in this research study, can I be removed from the study without my consent?

Though unlikely, it is possible that the principle investigator would determine it necessary to remove you from the study in the case of an adverse event. It is also possible that you may be removed in the unlikely event that funding for the study was lost.

How can I get more information about this study?

We encourage you to ask questions. If you have any questions about the interview component of the research study, please contact: Kathleen Spadaro MEd, RN at spadarok@pitt.edu or 412-558-0157.

If you have questions about the rights of research subjects or research related injury, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office, 1-866-212-2668

SUBJECT'S CERTIFICATION

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future care at this institution.
- I agree to participate in this study.
- I will receive a copy of this consent form.

Participant's Name (printed):		_
Email Address:	Preferred Phone:	
Signature of Participant	Date	

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the abovenamed individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of the Person Obtaining Consent

Role in Research Study

Signature of Person who Obtained Consent

Date

APPENDIX T

QUALITATIVE INTERVIEW GUIDE

(For Standard Behavioral Weight Control plus Mindfulness Meditation Group)

1. Please tell me about your experience being a participant in this weight loss (SBWP+MM) group.

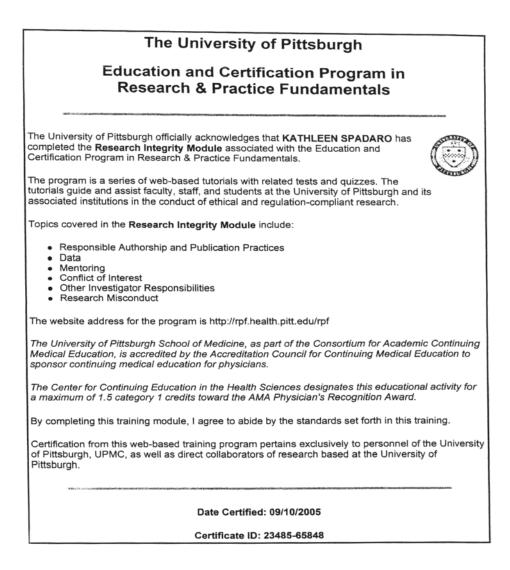
Probe: How was this experience different from past weight loss experiences? Probe: How was it similar?

- 2. Tell me what it means to you to be mindful when you are trying to lose weight? Probe: what does it mean for you to be mindful with eating? Probe: what does it mean for you to be mindful with physical activity/exercise?
- 3. Tell me what it has been like for you to be in a weekly weight control intervention for six months.

Note: These questions will be used as a guide in the interview process and may change as data is collected and analyzed.

APPENDIX U

RESEARCH MODULES



The University of Pittsburgh
Education and Certification Program in Research & Practice Fundamentals
The University of Pittsburgh officially acknowledges that KATHLEEN SPADARO has completed the Human Subject Research in Biomedical Sciences Module associated with the Education and Certification Program in Research & Practice Fundamentals.
The program is a series of web-based tutorials with related tests and quizzes. The tutorials guide and assist faculty, staff, and students at the University of Pittsburgh and its associated institutions in the conduct of ethical and regulation-compliant research.
Topics covered in the Human Subject Research in Biomedical Sciences Module include:
 Developmental Landmarks in Human Subjects Research Current Regulations of Human Subjects Research Institutional Review Boards Informed Consent Principal Investigator Responsibilities Study Documentation
The website address for the program is http://rpf.health.pitt.edu/rpf
The University of Pittsburgh School of Medicine, as part of the Consortium for Academic Continuing Medical Education, is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.
The Center for Continuing Education in the Health Sciences designates this educational activity for a maximum of 2.0 category 1 credits toward the AMA Physician's Recognition Award.
By completing this training module, I agree to abide by the standards set forth in this training.
Certification from this web-based training program pertains exclusively to personnel of the University of Pittsburgh, UPMC, as well as direct collaborators of research based at the University of Pittsburgh.
Date Certified: 09/10/2005
Certificate ID: 23485-65854

The University of Pittsburgh
Education and Certification Program in Research & Practice Fundamentals
The University of Pittsburgh officially acknowledges that KATHLEEN SPADARO has completed the HIPAA Physicians Privacy Awareness Training by UPMC Module associated with the Education and Certification Program in Research & Practice Fundamentals.
The program is a series of web-based tutorials with related tests and quizzes. The tutorials guide and assist faculty, staff, and students at the University of Pittsburgh and its associated institutions in the conduct of ethical and regulation-compliant research.
Topics covered in the HIPAA Physicians Privacy Awareness Training by UPMC Module include:
 Overview of HIPAA University HIPAA Policies Overview Protecting Privacy Computer Users' Security Requirements
The website address for the program is http://rpf.health.pitt.edu/rpf
The University of Pittsburgh School of Medicine, as part of the Consortium for Academic Continuing Medical Education, is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.
The Center for Continuing Education in the Health Sciences designates this educational activity for a maximum of 1.5 category 1 credits toward the AMA Physician's Recognition Award.
By completing this training module, I agree to abide by the standards set forth in this training.
Certification from this web-based training program pertains exclusively to personnel of the University of Pittsburgh, UPMC, as well as direct collaborators of research based at the University of Pittsburgh.
Print Name: Kathlen Spedars SSN: Title: <u>Meditin Mangen</u> Unit Name: Signature: Kath Spadas Date:
Signed certificates should be returned to the person designated by the Dean or Director of each school or unit. To determine where your signed certificate should go, <u>click here</u> or go to the "What Is Required" web page on RPF.
Date Certified: 09/11/2005 Expires: 09/11/2008
Certificate ID: 23485-65874

The University of Pittsburgh
Education and Certification Program in Research & Practice Fundamentals
The University of Pittsburgh officially acknowledges that KATHLEEN SPADARO has completed the HIPAA Researchers Privacy Requirements Module associated with the Education and Certification Program in Research & Practice Fundamentals.
The program is a series of web-based tutorials with related tests and quizzes. The tutorials guide and assist faculty, staff, and students at the University of Pittsburgh and its associated institutions in the conduct of ethical and regulation-compliant research.
Topics covered in the HIPAA Researchers Privacy Requirements Module include:
 Maintaining Privacy Forms of Authorization Revocation of an Authorization Review of PHI Preparatory to Research Other Rights of the Patient PHI of a Decedent Additional Restrictions on Researchers Sanctions for Non-Compliance
The website address for the program is http://rpf.health.pitt.edu/rpf
The University of Pittsburgh School of Medicine, as part of the Consortium for Academic Continuing Medical Education, is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.
The Center for Continuing Education in the Health Sciences designates this educational activity for a maximum of 1.5 category 1 credits toward the AMA Physician's Recognition Award.
By completing this training module, I agree to abide by the standards set forth in this training.
Certification from this web-based training program pertains exclusively to personnel of the University of Pittsburgh, UPMC, as well as direct collaborators of research based at the University of Pittsburgh.
Date Certified: 09/11/2005
Certificate ID: 23485-65871

APPENDIX V

MODIFIED IRB STUDY PROPOSAL

Study Title: ALTERNATIVE BEHAVIORAL AND PHYSICAL ACTIVITY APPROACHES TO WEIGHT LOSS Principal Investigator: John M. Jakicic, Ph.D. Co-Investigator: Amy D. Otto, Ph.D., Laura Fonzi, BS, Kathleen Spadaro, MS, Kelliann Davis, MS

Objective and Specific Aims

This proposal outlines pilot studies that expand on the ongoing research begin conducted in the Physical Activity and Weight Management Research Center. These studies will provide pilot data for potential extramural grant applications and with allow for the completion of thesis and/or dissertation requirements for current graduate students. Therefore, the specific aims are as follows:

The specific aims of this proposal are:

1. Compared to a standard behavioral weight loss intervention, this study will examine the effect of the addition of resistance exercise training using resistance bands and exercise balls on weight loss, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, process measures of physical activity and eating behaviors, and related psychosocial factors.

2. Compared to a standard behavioral weight loss intervention, this study will examine the effect of the addition of mindfulness meditation on weight loss, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, process measures of physical activity and eating behaviors, and related psychosocial factors.

3. Compared to a standard behavioral weight loss intervention, this study will examine the effect of a technologybased intervention on weight loss, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, process measures of physical activity and eating behaviors, and related psychosocial factors.

BACKGROUND AND SIGNIFICANCE

In excess of 65 percent of adults in the United States are overweight (body mass index = $\geq 25.0 \text{ kg/m}^2$), with in excess of 30 percent of adults classified as obese (body mass index $\geq 30.0 \text{ kg/m}^2$)³. Overweight and obesity are associated with risk factors and the potential onset of chronic diseases including heart disease, diabetes mellitus, and cancer⁷. Thus, it is important to develop effective interventions for weight loss.

The most effective behavioral interventions for weight loss combine a reduction in energy intake with an increase in energy expenditure via physical activity ⁷. These interventions have typically been shown to result in weight loss of approximately 7-10% of initial body weight during a 4 to 6 month period ¹¹. However, these interventions may have limitations that include the following:

- Based on data from our research center, approximately 70% of individuals lose at least 7% of their baseline body weight during the initial 3-6 months of these weight loss interventions. Therefore, approximately 30% of individuals do not achieve a clinically meaningful weight loss of at least 7%, which has been show to improve health-related risk factors. Thus, improvement in standard behavioral interventions may assist in improving weight loss for those who otherwise may not be responsive to these interventions.
- 2. Most weight loss interventions have focused on traditional health-related outcomes. However, physical function and health-related quality of life have been shown to be reduced in overweight and obese individuals. Resistance exercise using exercise bands and exercise stability balls have been shown to improve physical function and strength in elderly individuals; however, this type of intervention has not been systematically examined in overweight and obese individuals.
- 3. Traditional weight loss interventions have typically been provided in group or individual delivered programs. However, attendance at weekly intervention sessions may not be appealing to some individuals or may provide a barrier to participation. Technology may allow for dissemination of weight loss information that can be effective for weight loss. However, to date these interventions have been limited to the internet and/or email rather than use of a broader spectrum of technologies that may enhance weight loss.

RESEARCH DESIGN AND METHODS <u>Timeline</u>

Staff Training Subject Recruitment									Data entry, data cleaning, initial data analysis	
24-week weight loss intervention										
	*			+			+			
	Baseline Assessments			Week 12 Assessments			Week 24 Assessments			
Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8 Month 9 Month 1	0 Month 11	Month 12	

One hundred and twenty (120) sedentary, overweight and obese adult men and women will be recruited to participate in this study. Prior to completing baseline assessments, all subjects will complete initial screening procedures. These initial screening procedures will include completion of a physical activity readiness questionnaire (PAR-Q) (approximately 5 minutes to complete) and a detailed medical history (approximately 20 minutes to complete) (see Appendix A). Subjects will also be required to provide medical clearance from their personal physician before starting this study. A Physician Consent form (see Appendix B) will be provided to the subject, and the subject will be instructed to have their primary care physician complete and sign the document. The subject will be responsible for returning the completed document to the principal investigator prior to participating in the experimental procedures (assessments and weight loss intervention) for this study.

Subjects will undergo a series of baseline assessments that will include the following measures: weight, height, body composition, cardiorespiratory fitness, muscular strength, physical function, health-related quality of life, physical activity, eating behaviors, and questionnaires to assess potential psychosocial correlates of weight loss. These procedures are explained in detail below. Following baseline assessments, eligible participants will be randomly assigned to one of four groups: 1) Standard behavioral weight loss group (SBWP) (N=25), 2) SBWP plus resistance exercise (SBWP+RE) (N=25), SBWP plus mindfulness meditation (SBWP+MM) (N=25), or 4) a technology-based weight loss intervention (TECH) (N=25). Randomization will be based on a list of computer-generated random numbers, with each subject ID number assigned one of four group numbers (1 = SBWP, 2 = SBWP+RE, 3 = SBWP + MM, 4 = TECH) that corresponds to the group assignment. Assessments will be completed at baseline and following 12 and 24 weeks in the weight loss Intervention. The intervention groups and assessments are described in detail below.

Description of Weight Loss Interventions

1. Standard Behavioral Weight Loss Intervention (SBWP)

<u>Treatment Meetings and Contacts:</u> Subjects will attend weekly group meetings for 6 months at the University of Pittsburgh's Physical Activity and Weight Management Research Center. The group intervention will be conducted in a period of 45-60 minutes. During these face-to-face interactions the interventionist will integrate behavioral strategies for adopting and maintaining exercise into the intervention. These behavioral strategies are based primarily on social cognitive theory and include the following: self-monitoring, stimulus control, problem solving, relapse prevention, social assertion, goal-setting and feedback, and cognitive strategies to overcome negative thinking. These strategies will be blended into didactic sessions which are lead by a nutritionist, exercise physiologist, or health psychologist with experience conducting weight loss intervention groups. Subjects who miss group sessions will not be considered as "dropouts" for this study. A subject will only be considered a "dropout" if the subject notifies the principal investigator in writing that he/she no longer wishes to participate in the study.

<u>Diet:</u> Subjects will be instructed to reduce calorie intake to 1200-1800 calories per day and to reduce fat intake to 20-30% of total dietary intake. Subjects will be provided with sample meal plans and menus to assist them with making appropriate food selections, and these will be developed by registered dietitians. Subjects will record their eating behaviors in a weekly food diary that will be reviewed weekly by the intervention staff. Subjects participating in eating behaviors inconsistent with the recommendations for this study will be counseled by the registered dietitian affiliated with this study.

Exercise: Subjects will be instructed to increase their exercise. Subjects will begin at 100 minutes of exercise per week (20 minutes per day, 5 days per week) and will progressively increase by 10 minutes per day at 4-week intervals to 300 minutes per week (60 minutes per day, 5 days per week). The prescribed intensity of the exercise will be moderate (60 to 70% of age-predicted maximal heart rate), which is the equivalent of brisk walking for most individuals. Subjects will record their exercise in a weekly exercise diary that will be reviewed weekly by the intervention staff. Subjects participating in exercise that is inconsistent with the recommendations for this study will be counseled by the study affiliated exercise physiologist.

<u>Access to Technology:</u> All participants will be provided access to the secured study website where they can record their daily energy intake, fat intake, and physical activity if they would prefer this rather than using the paper diary described above. In addition, this will provide the participants access to updated intervention calendars and other study information that will also be provided to them in the form of paper at the group meetings. (Note: Participants will be required to provide their own computer and internet access at their own expense for this study.) These standard features are enhanced in the TECH group as described below. In addition, as described below, only those participants in the TECH group will be provided with an electronic scale to monitor their body weight.

2. SBWP plus Resistance Exercise (SBWP+RE)

Participants in SBWP+RE will receive the same 24-week weight loss intervention as described above for the SBWP Group that includes treatment meetings and contacts, diet, and exercise. In addition, participants in SBWP+RE will receive components of a resistance exercise program as described below.

Resistance Exercise Program

Subjects will be provided with elastic exercise bands, exercise ball (appropriate for height), and illustrations of the recommended exercises that will be performed. Resistance bands will be available in 4 different resistance levels ranging from easy to difficult. Subjects will be provided with bands appropriate for individual strength levels. In order to determine what bands are appropriate, an exercise class including all prescribed exercises will be conducted by a staff member. Subjects will be encouraged to use elastic tubing that forces the specific muscle group being worked to be at a rating of perceived exertion (RPE) between 6 and 8 (OMNI 1-10 scale) upon completing all of the recommended sets and repetitions.

Subjects will perform all resistance exercises during each in-person session and will also be directed to engage in the resistance training exercises on an additional 4 days per week, to total 5 days per week of resistance training exercises. The resistance training exercises will be performed in addition to the aerobic component of the SBWP. Subjects will be instructed to complete 3 sets of 8 to 12 repetitions with the appropriate level of resistance.

Subjects will be instructed to monitor and record their resistance exercise in their exercise diaries. Interventionists will review the diaries and provide feedback to subjects that will focus on achievement of weekly resistance training goals, daily resistance exercise consistency, etc. Subjects will progress to the next highest resistance band when reporting an RPE of less than 6 for the active muscle involved on 2 separate occasions when completing the prescribed repetitions and sets. This progression will minimize the risk of injury that may prevent a subject from participating in exercise as well as ensure that the specific muscle groups are being given the appropriate load for individual strength levels.

3. SBWP plus Mindfulness Meditation (SBWP+MM)

Participants in SBWP+MM will receive the same 24-week weight loss intervention as described above for the SBWP Group that includes treatment meetings and contacts, diet, and exercise. In addition, participants in SBWP+MM will receive components of mindfulness meditation as described below.

Mindfulness Meditation Component

Subjects in SBWP+MM will be taught techniques of mindfulness meditation to regulate eating and physical activity behaviors. These techniques include but are not limited to breathing exercises, visualization, and relaxation exercise. These common techniques allow for mindful awareness of both thoughts and the environment as these impact eating and physical activity behaviors. Mindfulness meditation focuses on staying in the present moment, non-judging or criticizing the self, increased self-awareness of current thoughts, physical sensations, emotions and environment and supports self-regulation within the individual to achieve balance and homeostasis after the change of weight loss occurs. Mindfulness continues to support self-regulation within the individual to achieve balance and homeostasis after the change of weight loss occurs. This pilot study would be one of the first to use mindfulness meditation incorporated into a standard behavioral program as an intervention for weight loss to explore the acceptability, feasibility and effectiveness of the intervention with overweight and obese adults.

Subjects will perform the components of mindfulness meditation during each in-person session and will also be directed to engage in these mindfulness meditation exercises on their own during the remaining days of the week. To facilitate engagement in the mindfulness meditation exercises, each participate will also be provided with a CD that they are to listen to on a daily basis that will guide them through the mindfulness meditation exercises. These mindfulness meditation exercises will be identical to the exercises that are practiced during the in-person weekly session. Subjects will be instructed to monitor and record their participation in the mindfulness meditation exercises.

4. Technology-based weight loss intervention (TECH)

Subjects in the TECH intervention will receive a home-based behavioral weight program that is delivered via the internet and email. Rather than attend in-person sessions, the intervention material will be provided to the participant using technology, with the intervention materials posted on a password protected study website each week. These materials will be identical to the materials provided to SBWP. Each week the participant will receive an email message indicating that the materials for the week have been posted and a link will be provided to the study website to facilitate access to these materials. If the materials are not accessed by a participant within 48 hours of being posted, an additional email will be sent prompting the participant to access the materials will be made. If the materials are still not accessed by a participant within the next 24 hours, a telephone call prompting the participant to access the materials will be made.

The diet and exercise components will be identical to what is described above for SBWP. This will include reducing energy intake to 1200-1800 kcal/d, reducing dietary fat intake to <30% of total energy intake, and progressively increasing exercise to 300 min/wk.

Participants will also be instructed to self-monitor their eating behaviors, physical activity behaviors, and body weight. Participants will be provided access to the secured study website where they will record their daily energy intake, fat intake, and physical activity. (Note: Participants will be required to provide their own computer and internet access at their own expense for this study.) This information will be provided to the intervention team and a weekly message will be sent from the intervention team to the participant with feedback from the previous week (note: this is a feature that is available on the secured study website) In addition, participants will be provided with an electronic scale to monitor their body weight. This scale will store body weight and transmit the data to the investigators daily using a standard telephone line (Note: There is no additional telephone cost to the participant

beyond their typical local land-line telephone service, but the participant is responsible for providing this telephone service at their own expense. In addition, there is no identifiable information transmitted as the body weight is associated with a scale number, and the investigators will be able to link the scale number to an individual study participant ID number within the secured study database.) If either eating behaviors, physical activity behavior, or body weight are not transmitted to the investigators, an email will be sent and a telephone call will be made to prompt the participant to submit this information.

NOTE: Information that is uploaded to a secured server will be accessible to the investigators and the intervention team. This information will be reviewed and the participant will be contact by telephone if necessary to address potential safety concerns related to unhealthy eating or exercise behaviors based on the data uploaded by the participant to the secured server. To enhance confidentiality, all participants will select an alias and a password. Data transfer to the server will not include identifiable information that can be associated with an individual participant name. The investigators will know the alias so that they can link information that is received to the participant, but this alias will be kept confidential and only available to the investigators.

Assessments:

Assessments will be conducted on weekdays during the hours of 7:00 AM and 11:00 AM at the University of Pittsburgh's Physical Activity and Weight Management Research Center. As described above, assessments will be completed at baseline and following 12 and 24 weeks of the weight loss intervention.

<u>Weight and Body Mass Index</u>: Body weight will be assessed using a calibrated medical balance-beam scale. Body mass index will be computed from measurements of weight and height (kg/m²). Height will be measured using a wall-mounted stadiometer.

Body composition: Measurement of body composition to determine LBM using Bioelectrical impedance analysis (BIA) will be performed on the same morning as REE measurement using a RJL BIA-101A (RJL Systems, Inc., Clinton Twp, MI) four terminal impedance analyzer. This instrument will be calibrated throughout the study using a 500-Ω resistor according to the procedures recommended by the manufacturer. BIA will be assessed with subjects in a supine position. The skin surface will be cleaned using rubbing alcohol prior to applying disposable electrodes on the right side of the body at the following four sites: between the styloid processes of the ulna and the radius (E1), distal end of the second and third metacarpals (E2), between the lateral malleolus and the medial malleolus (E3), and the distal end of the first and second metatarsals (E4). There will be a minimum of 8 cm between electrodes E1 and

E2, and electrodes E3 and E4. LBM will be estimated using the equations validated by Segal and colleagues ⁹.

<u>Anthropometric Measures</u>: Circumferences of the waist and hip will be measured in centimeters, using a Gulick tape measure. The waist circumference will be measured at the smallest part of the waistline, between the xyphoid process and umbilicus. The hip measurement will be taken at the largest part of the hips, above the gluteal fold. The waist measurement will be divided by the hip measurement to obtain the waist-to-hip ratio (WHR).

<u>Cardiorespiratory Fitness</u>: Subjects will participate in an assessment of cardiorespiratory fitness to determine functional capacity. An Exercise Specialists certified by the American College of Sports Medicine will conduct these tests. The exercise testing protocol will be done according to the following procedures. Sbjects will be placed in a resting position for a period of 5-10 minutes and will be instructed to relax and keep movement to a minimum. Following this rest period, resting blood pressure and heart rate will be assessed.

A treadmill protocol will be used for exercise testing. The speed of the treadmill will be kept constant at 3.0 mph (80.4 m/min) with the initial grade of the treadmill being 0% and increasing at 2.5% increments at 3-minute intervals. During this exercise test, subjects will breathe through a mass flow sensor with expired gas volumes and concentrations being measured continuously using a SensorMedics V-Max Metabolic Measuring Cart. Prior to each test, this metabolic cart sterilized and calibrated according to the procedures recommended by the manufacturer. Heart rate during exercise testing will be obtained at one-minute intervals using a 12-lead ECG (GE Medical) and

immediately upon termination of the exercise test. Blood pressure will be assessed during the last minute of each stage and at the point of test termination. Ratings of perceived exertion (RPE) will be assessed during the last 15 seconds of each stage and at the point of termination. The test will be terminated at the point the subject achieves 85% of age-predicted maximal heart rate. In addition, the ACSM criteria for test termination will be followed. Following termination of the test, the subject will undergo a 5 to 10-minute recovery period to insure that heart rate and blood pressure have returned to pretesting levels. A certified physician trained in ECG interpretation will evaluate the results of each test to insure that exercise training is not contraindicated. We are not proposing that a physician be present during each test, but rather that a physician review the test once it has been completed. Our rationale for this is the following:

- 1. We are proposing to use a submaximal exercise protocol (85% of age-predicted maximal heart rate). In addition we are recruiting individuals that are classified as low-to-moderate risk based on the risk stratification published in the recent edition of the American College of Sports Medicine Guidelines for Exercise Testing and Prescription. Based on these guidelines, it is not necessary to have physician supervision for submaximal exercise testing when the individuals are stratified as low-to-moderate.
- 2. A physician will review the results (ECG) of the submaximal exercise test to identify abnormalities on
- these tests that would require follow-up evaluation by the participant's personal physician prior to proceeding with participation in this study.
 We are taking many safeguards to exclude individuals that may be at increased risk during exercise. This includes receiving consent from the participant's personal physician prior to participating in any of the
- physiological assessments and intervention for this study.
 Each test will be supervised by a certified ACSM Exercise Specialist. This individual will be certified in CPR and the use of an AED. An AED is available for use in the event that it is needed prior to emergency personnel arriving.

<u>Muscular Strength</u>: Muscular strength will be estimated for upper and lower body by having the subject perform one weight lifting exercise that uses the chest muscles (seated chest press) and one that uses the leg muscles (leg extension). The subject will warm-up with 5-10 repetitions at 40-60% of their perceived maximum. Following a one minute rest with light stretching, the subject will perform 4-5 repetitions at 60-80% of their perceived maximum. A small amount of weight will be added, and a 1-RM lift will be attempted. If successful, a rest period of 1-2 minutes will be provided prior to additional weight being added and another lift being attempted. These procedures will be repeated until a lift can not be successfully completed.

Physical Function: Physical function will be determined through the use of a Physical Performance Test (PPT) that

has been used to compare obese and normal weight adults ⁶. The PPT consists of the following standardized tests: 1) the time to complete a 50 foot walk while carrying 2 shopping bags weighing approximately 10 pounds each, 2) the time required to sit down and get out of a chair 5 consecutive times, 3) the length of time the participant can balance on their left leg for up to 60 seconds, 4) the length of time the participant can balance on their right leg for up to 60 seconds, 5) the length of time it takes to step up and down twice on a step that is approximately 20 inches high. The rating of perceived exertion will also be assessed at the completion of each of these tasks.

<u>Health Related Quality of Life (HRQOL</u>): Health-related quality of life will be assessed using a modified version of the Impact of Weight on Quality of Life Questionnaire^{4,5} and the SF-36¹⁰.

<u>Dietary Intake</u>: Dietary intake will be assessed using a food frequency questionnaire ^{1, 2}.

<u>Exercise and Leisure-Time Physical Activity</u>: The Paffenbarger Questionnaire⁸ will be used to assess physical activity at each assessment period.

<u>Correlates of Weight Loss and Behavior Change</u>: We are also interested in factors that may be correlated with changes in physical activity, eating behavior, and body weight. *These questionnaires will take approximately 60-90 minutes to complete.* We will include measures of the following (These questionnaires are included in Appendix C):

- 1) Lifestyle Questionnaire
- 2) Eating Behavior Inventory
- 3) Eating Habits Checklist
- 4) Three Factor Eating Inventory
- 5) Beck Depression Inventory (BDI)

Note: In the event that a positive score on the BDI is observed, the PI or Project Director will be notified immediately. Either the PI or Project Director will contact Dr. Marsha Marcus, a Clinical Psychologists, to direct the most appropriate course of action. This may require the individual to be referred to their PCP for follow-up screening, or under extreme circumstances be transported and admitted to the hospital.

- 6) Barriers and Expected Outcomes (Exercise Beliefs)
- 7) Stages of Motivational Readiness for Change
- 8) Body Image
- 9) Injury and Illness Questionnaire: This questionnaire will allow the investigators to monitor reported injuries and/or illnesses that may be related to the proposed study. This will permit accurate follow-up and reporting to the IRB.

Qualitative Interviews for Participants in SBWP+MM Group: Participants randomly assigned to the SBWP+MM group will also I participate in an interview at the completion of the intervention (following Week 24) that will take approximately 30 minutes to complete. This interview will ask participants a series of questions to allow the investigators to better understand what they may have liked or did not like about the intervention. This interview will be conduct in a face-to-face session or as a telephone call, and this interview will be audio taped so that the investigators can summarize the content of this telephone call. The audiotapes will be under the control of the principal investigator and designated co-investigators of this research project. To protect the confidentiality of the participants, all personal identifiers (i.e., name, social security number, birth date) will be removed (de-identified) and replaced with a specific code number. The information linking these code numbers to the corresponding subjects' identities will be kept in a separate, secure location. The investigators will destroy these audiotapes after the information contained on them has been summarized and interpreted. The audiotapes will not be given to investigators outside of the University of Pittsburgh or UPMC, and they will not be utilized in future studies.

If the participant is unable to participate in a face-to-face interview or a telephone interview, they will be given the option of answering these questions using their computer and electronic mail (email) if they have access to this technology. The email responses will be under the control of the principal investigator and designated co-investigators of this research project. To protect the confidentiality of the participants, the email responses will be printed and the electronic files deleted. In addition, to further protect the confidentiality of the participants, the printed copies of the email responses will have all personal identifiers (i.e., name, social security number, birth date, email address) removed (de-identified) and replaced with a specific code number. The information linking these code numbers to the corresponding subjects' identities will be kept in a separate, secure location (i.e., locked filing cabinet that is located in a locked room). The investigators on this study will destroy the original email responses after the information contained on them has been summarized and interpreted. The email responses will not be given to investigators outside of the University of Pittsburgh or UPMC, and they will not be utilized in future studies.

Data Collection and Statistical Considerations

All analyses will be performed using SPSS software for Windows or SAS. Descriptive statistics will be analyzed and presented as means +/- standard deviations. Statistical significance will be defined at p < 0.05 level of confidence. Analyses will be performed to determine if the data are normally distributed and appropriate transformations will be conducted for data that is not normally distributed.

Analyses of the specific aims will be assessed using repeated measures analysis of variance (ANOVA) with assessment period considered a within-subject factor and randomized group assignment consider as the between-

subject factor. Significant main effects and interaction effects will be probed using appropriate post-hoc tests with critical p-values adjusted using the Bonferroni procedure.

Power Analysis: This study will provide pilot data for a larger study to more thoroughly test the specific aims outlined in this proposal. A power analysis determined that 100 subjects (25 per group) would allow for 0.70 statistical power to detect a large effect size (0.80) between SBWP and either SBWP+RE, SBWP+MM, or TECH with alpha set to 0.05. Moreover, this sample size will allow for estimates of appropriate effect sizes to adequately power a larger study should any of these the interventions in this current study demonstrate promising results when compared to SBWP.

Human Subjects

General Characteristics

The 120 subjects that are necessary for this project will be recruited at the University of Pittsburgh. Inclusion and exclusion criteria are listed below.

Inclusion Criteria

- 1. 18-55 years of age.
- 2. Body mass index (BMI) between 25.0-39.9 kg/m².
- 3. Access to a computer with internet access. This is required should the participant be randomly assigned to the TECH intervention group described above. In addition, the participant will have to demonstrate their ability to access the study website prior to randomization.

Exclusion Criteria

- 1. Reporting regular exercise participation of at least 20 minutes per day on at least 3 days per week during the previous six months. (*This study is designed to recruit relatively sedentary adults.*)
- 2. Report losing >5% of current body weight in the previous 6 months.
- Report participating in a research project involving weight loss or physical activity in the previous 6 months.
- 4. For women, report being pregnant during the previous 6 months, or planning on becoming pregnant over the following 3 months of the intervention. (Pregnancy during initial screening will be based on self-report and will be included on the detailed medical history that is completed by subjects. In addition, this will also be obtained as part of the signed medical clearance from the individual's personal physician.)
- 5. Currently being treated for any medical condition that could impact body weight (i.e., diabetes mellitus, cancer, etc.).
- 6. History of myocardial infarction, or a history of undergoing heart surgery such as bypass or angioplasty.
- Non-medicated resting systolic blood pressure >160 mmHg or non-medicated resting diastolic blood pressure >100 mmHg, or taking medication that would affect blood pressure or heart rate at rest or in response to exercise (e.g., beta blockers).
- 8. Taking medication that could affect metabolism and/or contribute to a change in body weight (e.g., synthroid).
- 9. Being treated by a therapist for psychological issues or problems, taking pyschotropic medications, or receiving treatment with psychotropic medications within the previous 6 months.
- 10. History of orthopedic complications that would prevent optimal participation in the exercise component (e.g., heel spurs, severe arthritis).
- 11. No exclusion criteria shall be based on race, ethnicity, or gender.

All subjects will complete a physical activity readiness questionnaire (PAR-Q) and a detailed medical history, and will provide written informed consent prior to participating in this study. *In addition, all subjects will provide written consent from their personal physician indicating that participation in the proposed intervention is not contraindicated.*

Recruitment Procedures

Subjects will be recruited from advertisements in local newspapers, newsletters, and radio/TV advertisements. These advertisements will be submitted and approved by the IRB at the University of Pittsburgh prior to these advertisements being used for recruitment. An example of the advertisement that will be used is shown in the Appendices. (NOTE: This is an example of an advertisement. The actual advertisements that will be used will be submitted to the IRB for approval after they have been developed and prior to use for recruitment for this study. Recruitment will not be initiated until the advertisements developed by University Marketing and Communications that meet University of Pittsburgh standards are approved by the IRB.) Potential subjects will not be directly approach by the Principal Investigator in an attempt to recruit them for participation in this proposed study. In previous studies, Dr. Jakicic has been able to successfully recruit at least 20-25% of study participants from minority populations. Similar strategies will be used in this study and advertisements will be submitted to the IRB for approval prior to use in this study.

Subjects will be screened via the telephone (see attached telephone script). <u>We request a waiver to</u> <u>document written informed consent of the screening process, which will take place over the phone.</u> We believe we meet the following criteria: 1) the respective research procedures present no more than minimal risk of harm to the involved subjects and involve no procedures for which written consent is normally required outside of the research context, 2) the information being obtained during the screening phone call is the same type of information that would be collected on patients setting up an appointment for their condition (weight control). Refer to Appendix D for the screening script and tool that will be utilized. If the subject does not meet inclusion criteria, all the information collected during the screening process will be destroyed. In addition, written informed consent will be obtained at the screening visit prior to any research activities. The investigator or co-investigator will obtain written informed consent.

The name of the potential participant is not recorded on the forms where private information is recorded for this telephone screen. In addition, all private information will be destroyed (shredded) at the conclusion of the telephone call (see attached telephone script), and the individual's name will be kept separate from private information.

Written informed consent will be obtained following the orientation visit (this is just to further explain the details of the study) and prior to the baseline assessment visit. The orientation session typically takes approximately 60 minutes to complete. At this orientation session, Dr. Jakicic will describe the background and significance of the study, the intervention groups and procedures, all of the assessment procedures, and the risks/benefits of participating in this study. Moreover, individuals attending the orientation session will be encouraged to ask for clarification to make sure that they clearly understand all aspects of this study. Individuals will then be explained the informed consent procedures and other logistical procedures prior to signing the consent document. In addition, written consent will be obtained by the subject's primary care physician prior to participation in any aspect of the clinical assessments and intervention for this study (see attached Physician Consent Form). The Principal Investigator will be available at these orientation visits to thoroughly describe the study procedures and to respond to any questions that may be raised by the subject. The private information that was destroyed following the initial telephone screening will be collected again and retained after written informed consent it obtained from subjects.

Risk/Benefit Ratio

The possible risks of this research study may include the following:

<u>Risks Associated with Assessment of Body Composition</u>: Assessment of body composition will be performed using bio-electrical impedance analysis. Subjects may experience skin irritation or skin redness from electrodes being placed on their skin. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

<u>Risks of the Exercise Testing and Physical Function Sessions</u>: Subjects may experience general fatigue and shortness of breath during their participation in these activities. Therefore, it is likely that subjects will experience this during the submaximal exercise test (occurs in more that 25% of people or more than 25 out of 100 people).

During exercise, heart rate and blood pressure will increase. It is likely that subjects will experience this during the submaximal exercise test (occurs in more that 25% of people or more than 25 out of 100 people). Under extreme conditions, the participant may experience a serious cardiac event (i.e., heart attack). The possibility of experiencing a serious cardiac event has been estimated to be less than 1 per 20,000 in exercising adults, with the

risk of death during a maximal exercise test being less than 0.5 per 10,000 tests. Therefore, this will be rare (occurs in less than 1% of people or less than 1 out of 100 people). Numerous precautions will be in place to minimize the risk, and these include the following:

- 1. Subjects will provide medical clearance from their personal physician to participate in all aspects of this study, including the submaximal exercise test, prior to baseline assessments being initiated. (see Appendices)
- 2. A submaximal rather than a maximal exercise test will be used to assess changes in fitness in this study. In addition, the exercise will be prescribed at an intensity that is significantly lower than the termination point of the submaximal exercise test (85% of age-predicted maximal heart rate).
- 3. In the event that a serious cardiac event occurs, CPR will be initiated and an AED will be available for use by certified staff until emergency medical personnel arrive to take over emergency procedures.
- 4. All ECG's from the exercise test along with the medical history will be reviewed by a board certified physician prior to subjects being randomized to participate in this study.
- 5. Subjects may also experience redness, chaffing, and skin irritation from the electrodes that will be used during the submaximal graded exercise tests that are conducted for this study. It is likely that subjects will experience this during the submaximal graded exercise test (occurs in more than 25% of people or more than 25 out of 100 people).

<u>Risk of Electrocardiogram (ECG)</u>: Subjects may experience skin irritation or skin redness from electrodes being placed on their skin. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

<u>Risks of Assessing Oxygen Uptake during Exercise Testing</u>: Oxygen uptake will be assessed using indirect calorimetry. During this assessment, subjects may experience a dry mouth. It is likely that subjects will experience this during the submaximal graded exercise test (occurs in more than 25% of people or more than 25 out of 100 people). To minimize additional risks, the mouthpiece, mass flow sensor, and nose clips will be sterilized prior to each use according to procedures outlined by the manufacturer. These are the minimal procedures that will be adopted for this study within the Department of HPA at the University of Pittsburgh. Items will first be rinsed and placed in a prewash (water and dishwashing soap) for 10 minutes, followed by 10 minutes in <4% gluteraldehide (according to the manufacturer, the mass flow sensor can be damaged by soaking for >10 minutes), followed by a final rinse.

<u>Risk of Assessing Strength</u>: Subjects may experience muscle fatigue or muscle soreness from this assessment. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people). There is also the risk of muscle sprain/strain, and the risk of this is rare because this occurs in less than 1% of people (less than 1 out of 100 people).

<u>Risk Associated with Completion of Questionnaires</u>: Subjects may experience non-physical risks such as boredom, frustration, stress, and time constraints when completing the questionnaires. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

<u>Risks of Reducing Calorie and Fat Intake</u>: Consuming a moderately low fat and low calorie diet appears to be safe and effective for weight loss. However, reducing calorie or fat intake below recommended levels may cause dry skin and thinning of hair. This is common and occurs in 10% to 25% of people (10 to 25 out of 100 people). This may also cause gall bladder disorders. This is rare and occurs in less than 1% of people (less than 1 out of 100 people).

<u>Risks Associated with the Group Interventions</u>: Participants in the group intervention may be asked to discuss personal factors related to their weight loss, physical activity, and dietary patterns. Participants are not required to share this information and can elect not to share sensitive and confidential information with the interventionist or other members of the group. The investigators can not guarantee that members of the group will not share this information with individuals not in this study outside of the group setting. It is common that subjects will experience this during the group intervention sessions (occurs in 10-25% of people or 10-25 out of 100 people).

To ensure that any injury or illness related to this study will be detected, subjects will be queried on the occurrence of any injury/illness that has limited or continues to limit their physical activity in this study since their last assessment. Moreover, subjects will be instructed to contact the investigators if they experience an injury/illness that is either caused by their participation in physical activity or is limiting their participation in physical activity.

<u>Steps to Ensure Confidentiality of Participants</u>: The following steps will be taken to ensure subject confidentiality in this study.

- Subjects will be assigned an ID number and only the investigators will have access to the list which will link the ID number to a participant. This information will be stored in a locked file cabinet that is only accessible by the investigators.
- 2. All participant questionnaires and assessment forms will code with an ID number rather than the participant name.
- 3. For individuals who are randomly assigned to the TECH intervention group, a confidential user name and password will be assigned that will allow uploading of data to the server. The list linking the user name and password to a participant will be accessible only to the investigators and this will be kept in a locked filing cabinet.
- 4. All databases will be password protected.
- 5. All identifiable medical information will be kept in a locked filing cabinet that will only be accessible to the investigators.
- 6.Information collected about participants after they complete the "Consent to Act as a Subject in a Research Study" form will remain on file for the duration of this study, even if they choose to discontinue your participation in this study. Information about subjects that was collected prior to them signing this form will be destroyed if they do not qualify for participation in this study unless the investigators receive their consent to keep this information.

<u>Benefits</u>: Subjects in this study may experience the following benefits associated with weight loss, dietary change, and exercise; however, these benefits can not be guaranteed.

- 1. The proposed intervention may result in weight loss.
- 2. The proposed intervention may result in improvements in cardiovascular risk factors including blood lipids and blood pressure.
- 3. The proposed intervention may result in improvements in fitness and function.
- 4. The proposed intervention may result in improvements in psychosocial factors such as self-efficacy, mood, quality of life, and other related factors.

<u>Alternative Treatments</u>: The assessments being performed for this study are for research purposes and need to be consistent across all subjects. Therefore, no alternative assessment approaches will be implemented in this study. In the event that an eligible participant elects not to participate in this study, there are alternative exercise and weight control treatments available in the Greater Pittsburgh Area, however no alternative treatments will be available through the investigators on this current study. Rather, individuals

will be instructed to seek a referral from their personal physician, to contact the UPMC Health System to inquire about clinical programs that may be available, or to contact local commercial exercise and/or weight loss programs (e.g., Weight Watchers, Jenny Craig, etc.).

Data Safety Monitoring Plan: This is not a multi-center trial and does not include pharmacological treatments.

Who will be responsible for the data and safety monitoring?

The Principal Investigator will be responsible for implementing the Data Safety Monitoring Plan. The Principal Investigator will conduct weekly study meetings at which time weight loss and exercise data will be reviewed. In addition, the Principal Investigator will review the data following each assessment period (0, 12, and 24 weeks).

What will be monitored?

All data and procedures will be reviewed weekly by the Principal Investigator. This will include review of participant recruitment procedures and the recruitment timeline. Data that will be monitored to assess completion of the proposed protocols, documentation indicating that an adverse event occurred during the exercise session, review of medical history and PAR-Q, and review of study data to insure that outcome data are within acceptable criteria. In addition, the Principal Investigator will perform quality control procedures at quarterly intervals to insure that the research assistant is compliant with the research protocol. Data will also be reviewed to assess whether there is any

change in the risk-to-benefit ratio of this study. If potential safety concerns are identified that change the benefit-torisk ratio, the study will be stopped until modifications can be made and approved by the IRB to address these safety concerns. Procedures will be reviewed to ensure that data are being collected in a manner to protect the confidentiality of subjects. All subject information will be coded with a study identification number to maintain confidentiality. In addition, all study data will be locked in a secured area (e.g., locked file cabinet).

The Principal Investigator will submit the following data to the IRB at the time of renewal. However, this information may be submitted more frequently when necessary to ensure the safety of subject in this study.

- The frequency of monitoring that took place during the renewal interval.
- A summary of the cumulative adverse event data including a respective assessment of experimental intervention causality.
- A summary of the assessment that was performed to evaluate external factors or relevant information that may have an impact on the safety of study participants or ethics of the research study.
- A summary of the outcome of procedural reviews conducted to ensure subject privacy and research data confidentiality,
- Final conclusions regarding changes to the anticipated benefit-to-risk ratio of study participants and final recommendations related to continuing, changing, or terminating the study.
- If potential safety concerns are identified that change the benefit-to-risk ratio, the study will be stopped until modifications can be made and approved by the IRB to address these safety concerns. All adverse events will be reported to the University of Pittsburgh IRB in compliance with the IRB policy as outlined in the IRB Reference Manual.

Costs and Payments

<u>Research Study Costs</u>: There is no cost to subjects for participating in this research study. All costs will be paid by the sponsor of this research study.

<u>Research Study Payments</u>: Subjects in the Weight Loss Intervention Group will be offered a \$25 honorarium for completion of the assessments following 12-weeks of the intervention, and a \$25 honorarium for completion of the assessments following 24-weeks of the intervention.

Appendices

Qualifications of Investigators

John M. Jakicic, Ph.D.: Dr. Jakicic is an Associate Professor in the Department of Health and Physical Activity with a secondary appointment in the Department of Psychiatry at the University of Pittsburgh. Dr. Jakicic is trained as an exercise physiologist with experience in conducting clinical research that focuses on obesity and physical activity. He is certified as both an Exercise Specialist and an Exercise Test Technologist by the American College of Sports Medicine. Dr. Jakicic is the Principal Investigator and Co-Investigator on numerous NIH funded projects focusing on weight loss and physical activity interventions. Dr. Jakicic is responsible for all aspects of this proposed study.

<u>Amy D. Otto, Ph.D., RD</u>: Dr. Otto is a Research Assistant Professor in the Department of Health and Physical Activity at the University of Pittsburgh. Dr. Otto is involved in all aspects of this research study including issues related to study design, data analysis, and manuscript preparation. Dr. Otto's primary function on this project is to oversee matters related to development and implementation of the behavioral intervention.

<u>Ms. Laura Fonzi</u>: Ms. Fonzi is a graduate student in the Department of Health and Physical Activity with expertise in group exercise and fitness. She developed the resistance exercise program that is proposed for this study and will deliver this aspect of the proposed intervention.

<u>Ms. Kathleen Spadaro</u>: Ms. Spadaro is a graduate student at the University of Pittsburgh. She has expertise in mindfulness meditation and will implement this aspect of the proposed intervention.

<u>Ms. Kelliann Davis</u>: Ms. Davis is a Graduate Research Assistant at the University of Pittsburgh. She will assist with the recruitment, assessment, and intervention aspects of this study.

Additional Appendices (See Attached)

Appendix A: Physical Activity Readiness Questionnaire and General Health History Appendix B: Physician Consent/Medical Clearance Form Appendix C: Questionnaires that are used in this study Appendix D: Recruitment Form and Script Appendix E: Example of Recruitment Advertisement

List of References

- 1. Block, G., A. M. Hartman, C. M. Dresser, C. M.D., G. J., and G. L. A data-based approach to diet questionnaire design and testing. *Am J Epidemiol.* 108:161-175, 1986.
- Block, G., M. Woods, A. Potosky, and C. Clifford. Validation of a self-administered diet history questionnaire using multiple diet records. *J Clin Epidemiol.* 43:1327-1335, 1990.
- 3. Hedley, A. A., C. L. Ogden, C. L. Johnson, M. D. Carroll, L. R. Curtin, and K. M. Flegal. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *JAMA*. 291:2847-2850, 2004.
- Kolotkin, R. L., R. D. Crosby, K. D. Kosloski, and G. R. Williams. Development of a brief measure to assess quality of life in obesity. *Obes. Res.* 9:102-111, 2001.
- 5. Kolotkin, R. L., S. Head, and A. Brookhart. Construct validity of the impact of weight on quality of life questionnaire. *Obes. Res.* 5:434-441, 1997.
- 6. Larsson, U. E. and E. Mattsson. Functional limitations linked to high body mass index, age and current pain in obese women. *Int. J. Obes.* 25:893-899, 2001.
- National Institutes of Health. National Heart, Lung and Blood Institute. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults - The Evidence Report. *Obes. Res.* 6(suppl.2), 1998.
- Paffenbarger, R. S., R. T. Hyde, A. L. Wing, and C. C. Hsieh. Physical activity, all-cause mortality, and longevity of college alumni. N Engl J Med. 314:605-613, 1986.
- 9. Segal, K. R., B. Gutin, E. Presta, J. Wang, and T. B. Van Itallie. Estimation of human body composition by electrical impedance methods: a comparative study. *J Appl Physiol*. 58:1565-1571, 1985.
- 10. Ware, J. E., K. K. Snow, M. Kosinski, et al. *SF-36 Health Survey: manual and interpretation guide.* Boston, Mass: New England Medical Center, 1993
- 11. Wing, R. R. Behavioral Weight Control. In: *Handbook of Obesity Treatment*. T. A. Wadden and A. J. Stunkard (Eds.) New York: The Guilford Press, 2002, pp. 301-316.

APPENDIX W

LETTER TO PARTICIPANTS



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

December 27, 2007

Dear

Thank you for agreeing to participate in the second part of the Get Firm weight loss research program. As a researcher, I am interested in finding out from you about your experience in the mindfulness meditation weight loss group. In order to get started as quickly as possible, please do the following:

- 1. Read the enclosed consent form.
- 2. Initial each page of both copies.
- 3. Sign the last page of <u>both</u> copies.
- 4. Send both copies back in the self-addressed, stamped envelope provided.

If you have any questions regarding the consent, please do not hesitate to contact me at 412-558-0157 (cell phone) or the research center at 412-488-4184. Once we receive your signed consent forms, Dr. Jakicic and I will also sign them. One copy will be mailed back to you and one copy will be kept at the research center.

I will be emailing you a few questions regarding your experience after I receive both copies of your signed consent form, unless you change your preference to in-person or by telephone interviews.

Happy New Year!

Best Wishes,

Kathleen Spadaro, M.Ed., C.N.S.

APPENDIX X

QUALITATIVE CONSENT FORM



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

Approval Date: Renewal Date: University of Pittsburgh Institutional Review Board IRB #0701013

ADDENDUM CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Alternative Behavioral and Physical Activity Approaches to Weight Loss

PRINCIPAL INVESTIGATOR:

John M. Jakicic, Ph.D. Associate Professor Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184 CO-INVESTIGATORS:Kelliann IAmy D. Otto, Ph.D.Kelliann IDepartment of Health and Physical ActivityDepartmentUniversity of PittsburghUniversityBirmingham Towers, Suite 600Birmingha2100 Wharton Street2100 WhatPittsburgh, PA 15203PittsburghTelephone: 412-488-4184TelephonLaura Fonzi, BSKathleenDepartment of Health and Physical ActivityDepartmentUniversity of PittsburghUniversityBirmingham Towers, Suite 600Birmingha2100 Wharton Street2100 WhatPittsburgh, PA 15203PittsburghPittsburgh, PA 15203PittsburghTelephone: 412-488-4184Telephon

Kelliann Davis, MS Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184 Kathleen Spadaro, MS Department of Health and Physical Activity University of Pittsburgh Birmingham Towers, Suite 600 2100 Wharton Street Pittsburgh, PA 15203 Telephone: 412-488-4184

Participant's Initials:

Approval Date: Renewal Date: University of Pittsburgh Institutional Review Board IRB #0701013

SOURCE OF SUPPORT: Internal Support – Department of Health and Physical Activity

DESCRIPTION:

You are currently a participant in a study to evaluate the effect of a behavioral weight control program plus mindfulness meditation on fitness, body composition, muscular strength, physical function, and other behavioral factors related to weight control and physical activity behaviors. You are being asked to complete an additional assessment involving an interview as part of this research study. If you agree to complete this additional assessment you will undergo the following procedures.

You will participate in an interview at the completion of the intervention that will take approximately 30 minutes to complete. This interview will ask you a series of questions to allow the investigators to better understand what you may have liked or did not like about the intervention. This interview will be conduct in a face-to-face session or as a telephone call, and this interview will be audio taped so that the investigators can summarize the content of this telephone call. Your audiotapes will be under the control of the principal investigator and designated co-investigators of this research project. To protect your confidentiality, all personal identifiers (i.e., name, social security number, birth date) will be removed (de-identified) and replaced with a specific code number. The information linking these code numbers to the corresponding subjects' identities will be kept in a separate, secure location. The investigators on this study will destroy these audiotapes after the information contained on them has been summarized and interpreted. Your audiotapes will not be given to investigators outside of the University of Pittsburgh or UPMC, and they will not be utilized in future studies.

If you are unable to participate in a face-to-face interview or a telephone interview, you will be given the option of answering these questions using your computer and electronic mail (email) if you have access to this technology. Your email responses will be under the control of the principal investigator and designated co-investigators of this research project. To protect your confidentiality, your email responses will be printed and the electronic files deleted. In addition, to further protect your confidentiality, the printed copies of your email responses will have all personal identifiers (i.e., name, social security number, birth date, email address) removed (de-identified) and replaced with a specific code number. The information linking these code numbers to the corresponding subjects' identities will be kept in a separate, secure location. The investigators on this study will destroy the original email responses after the information contained on them has been summarized and interpreted. Your email responses will not be given to investigators outside of the University of Pittsburgh or UPMC, and they will not be utilized in future studies.

Participants Initials:

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Approval Date: Renewal Date: University of Pittsburgh Institutional Review Board IRB #0701013

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

VERIFICATION OF EXPLANATION

I certify that I explained the nature and purpose of this research to the above-named participants in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

Investigator's Signature

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the abovenamed individual, and I have discussed the potential benefits and possible risks of study participation. Any question the individual has about this study have 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

Signature of Person Obtaining Consent

Role in Research Study

Date

Participants Initials:

Date

Date

BIBLIOGRAPHY

- ACSM. (2006). Strategies to Promote the Adoption and Maintenance of Weight Loss Related Behaviors: American College of Sports Medicine.
- Adolfsson, B., Carlson, A., Unden, A., Rossner, S. (2002). Treating obesity: A qualitative evaluation of a lifestyle intervention for weight reduction. Health Education Journal, 61(3), 244-258.
- Alterman, A. I., Koppenhaver, J.M., Mulholland, E., Ladden, L.J., & Baime, M.J. (2004). Pilot trial of effectiveness of mindfulness meditation for substance abuse patients. Journal of Substance Use, 9(6), 259-268.
- American College of Sports Medicine (2006) *Strategies to Promote the Adoption and Maintenance of Weight Loss Related Behaviors.*
- American College of Sports Medicine (2001) Position Stand: Appropriate Intervention Strategies for Weight Loss and Prevention of Weight Regain for Adults.
- Anderson, J. W., Konz, E. C., Frederich, R. C., & Wood, C. L. (2001). Long-term weight-loss maintenance: A meta-analysis of US studies. American Journal of Clinical Nutrition, 74(5), 579-584.
- Baer, R., Fischer S, & Huss DB. (2005). Mindfulness and acceptance in the treatment of disordered eating. Journal of Rational-Emotive & Cognitive-Behavior Therapy, 23(4), 281-300.
- Baer, R.A., Fischer, S. & Huss, D.B. (2005). Mindfulness-based cognitive therapy applied to eating: A case study. Cognitive and Behavioral Practice, 12, 352-355.
- Baer, R., Smith, GT, & Allen, KB. (2004). Assessment of Mindfulness by Self-Report. Assessment, 11(3), 191-206.
- Baer, R., Smith, G.T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. Assessment, 13(1), 27-45.

- Bandura, A. (2005). The primacy of self-regulation in health promotion. Applied Psychology: An International Review, 54(2), 245-254.
- Barclay, L., & Lie, D. (2006). Transcendental meditation may improve blood pressure and insulin resistance. Archives of Internal Medicine, 166, 1218-1224.
- Benson, H. (1975). The Relaxation Response. New York: Avon Books.
- Benson, H., Beary, J. F., & Carol, M. P. (1974). The Relaxation Response. Psychiatry, 37, 37-46.
- Berry, D. (2004). An emerging model of behavior change in women maintaining weight loss. Nursing Science Quarterly, 17(3), 242-252.
- Bidgood, J., & Buckroyd, J. (2005). An exploration of obese adults' experience of attempting to lose weight and to maintain a reduced weight. Counselling and Psychotherapy Research, 5(3), 221-229.
- Blair, S.N., & Leermakers, E.A. (2002). Exercise and Weight Management. In T.A. Wadden & A.J. Stunkard (Ed.) Handbook of Obesity Treatment, (pp. 283-285), New York: Guilford Press.
- Block, G., Hartman, A.M., Dresser, C.M., Carol, M.D., Gannon, J., & Gardner, L. (1986). A data-based approach to diet questionnaire design and testing. Am J Epidemiol., 108, 161-175.
- Bonadonna, R. (2003). Meditation's impact on chronic illness. Holistic Nursing Practice, 17(6), 309-319.
- Bowen, S., Witkiewitz, K., Dillworth, T.M., Chawla, N., Simpson, T.L., Ostafin, B.D., et al. (2006). Mindfulness Meditation and Substance Use in an Incarcerated Population. Psychology of Addictive Behaviors, 20(3), 343-347.
- Brown, K. W., & Ryan, R.M. (2003). The benefits of being present: mindfulness and its role in psychological well-being. Journal of Personality and Social Psychology, 84(4), 822-848.
- Burke, L. E., Sereika, S., Choo, J., Warziski, M., Music, E., Styn, M., et al. (2006). Ancillary study to the PREFER trial: a descriptive study of participants' patterns of self-monitoringrationale, design and preliminary experiences. Contemporary Clinical Trials, 27(1), 23-33.
- Burke LE., C. J., Music E., Warziski M., Styn MA., Kim Y., & Sevick MA. (2006). PREFER study: a randomized clinical trial testing treatment preference and two dietary options in behavioral weight management--rationale, design and baseline characteristics. Contemporary Clinical Trials, 27(1), 34-48.

- Byrne, S., Cooper, Z, & Fairburn, C. (2003). Weight Maintenance and relapse in obesity: a qualitative study. International Journal of Obesity, 27, 955-962.
- Carlson, L. E., & Garland, S.N. (2005). Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. International Journal of Behavioral Medicine, 12(4), 278-285.
- Carlson, L. E., Ursuliak, Z., Goodey, E., Angen, M., & Speca, M. (2001). The effects of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients: 6 month follow-up. Support Care Cancer, 9, 112-123.
- Chang, V. Y., Palesh, O., Caldwell, R., Glasgow, N., Abramson, A., Luskin, F., et al. (2004). The effects of a mindfulness stress reduction program on stress, mindfulness selfefficacy, and positive states of mind. Stress and Health, 20, 141-147.
- Chua, S.C., & Leibel, R.L. (2002). Body weight regulation: Neural, endocrine, and autocrine mechanisms. In T.A. Wadden & A.J. Stunkard (Ed.) Handbook of Obesity Treatment, (pp. 301-316), New York, NY: Guilford Press.
- Cohen-Katz, J., Wiley, S.D., Capuano, T., Baker, D.B., & Shapiro, S. (2005a). The effects of mindfulness-based stress reduction on nurse stress and burnout, part II. Holistic Nursing Practice, 19(1), 26-35.
- Cohen-Katz, J., Wiley, S.D., Capuano, T., Baker, D.B., & Shapiro, S. (2005b). The effects of mindfulness-based stress reduction on nurse stress and burnout: a qualitative and quantitative study, part III. Holistic Nursing Practice, 19(2), 78-86.
- Colditz, G. A. (1999). Economic costs of obesity and inactivity. Medicine & Science in Sports & Exercise, S663-S667.
- Davidson, R., Kabat-Zinn, J., Schumacher, J., Rosenkranz, M., Muller, D., Santorelli, S.F., et al. (2003). Alterations in brain and immune function produced by mindfulness meditation. Psychosomatic Medicine, 65(4), 564-570.
- Ditschuneit, H.H., Frier, H.I., & Flechtner-Mors, M. (2002). Lipoprotein responses to weight lossand weight maintenance in high-risk obese subjects. European Journal of Clinical Nutrition, 56, 264-270
- Dobkin, P. L. (2008). Mindfulness-based stress reduction: What processes are at work? Complementary Therapies in Clinical Practice, 14, 8-16.
- Ed. Baer, R. (2006). Mindfulness-based treatment approaches: clinician's guide to evidence base and applications.
- Edelman, D., Oddone, E.Z., Liebowitz, R.S., Yancy, W.S., Olsen, M.K., Jeffreys, A.S., et al. (2006). A multidimensional integrative medicine intervention to improve cardiovascular risk. Journal of General Internal Medicine, 21(7), 728-734.

- Finkelstein, E. A., Fiebelkorn, I.C., & Wang, G. (2003). National medical spending attributable to overweight and obesity: how much, and who's paying? Health Affairs, W3, 219-226.
- Finucane, A., & Mercer, S.W. (2006). An exploratory mixed methods study of the acceptability and effectiveness of mindfulness-based cognitive therapy for patients with active depression and anxiety in primary care. BMC Psychiatry, 6, 1-14.
- Fletcher, B., Berra, K., Ades, P., Braun, L.T., Burke, L., Durstine, J.L., et al. (2005). Managing Abnormal Blood Lipids: A Collaborative Approach: Cosponsored by the Councils on Cardiovascular Nursing; Arteriosclerosis, Thrombosis, and Vascular Biology; Basic Cardiovascular Sciences; Cardiovascular Disease in the Young; Clinical Cardiology; Epidemiology and Prevention; Nutrition, Physical Activity, and Metabolism; and Stroke; and the Preventive Cardiovascular Nurses Association. Circulation, 112(20), 3184-3209.
- Fonteyn, M., & Bauer-Wu, S. (2005). Using qualitative evaluation in a feasibility study to improve and refine a complementary therapy intervention prior to subsequent research. Complementary Therapies in Clinical Practice, 11(4), 247-252.
- Gallagher, K., Jakicic, J.M., Napolitano, M.A, & Marcus, B.H. (2006). Psychosocial factors related to physical activity and weight loss in overweight women. Medicine & Science in Sports & Exercise, 38(5), 971-980.
- Goleman, D. J., & Schwartz, G. E. (1977). Meditation as an invention in stress reactivity. Journal of Consulting Clinical Psychology, 44, 456-466.
- Gross, C. R., Kreitzer, M.J., Russas, V., Treesak, C., Frazier, P.A., & Hertz, M.I. (2004). Mindfulness meditation to reduce symptoms after organ transplant: a pilot study. Alternative Therapies in Health and Medicine 10(3), 58-66.
- Grossman, P., Niemann, L., Schmidt, S. & Walach, H. (2004). Mindfulness-based stress reduction and health benefits: a meta-analysis. Journal of Psychosomatic Research, 57, 35-43.
- Jakicic, J. M., Clark, K., Coleman, E., Donnelly, J.E., Foreyt, J., Melcuson, E., et al. (2001). Position Stand: Appropriate Intervention Strategies for Weight Loss and Prevention of Weight Regain for Adults. Medicine & Science in Sports & Exercise, 33(12), 2145-2156.
- Jakicic, J. M., Marcus, B. H., Gallagher, K. I., Napolitano, M., & Lang, W. (2003). Effect of exercise duration and intensity on weight loss in overweight, sedentary women. A randomized trial. JAMA, 290, 1323-1330.
- Jakicic, J. M., Wing, R.R., & Winters-Hart, C. (2003). Relationship of physical activity to eating behaviors and weight loss in women. Medicine & Science in Sports & Exercise, 1653-1659.
- Jakicic, J. M., Winters, C., Lang, W., & Wing, R.R. (1999). Effects of intermittent exercise and use of home exercise equipment on adherence, weight loss, and fitness in overweight women: A randomized trial. JAMA, 282, 1554-1560.

- Jayasinghe, S. R. (2004). Yoga in cardiac health (a review). European Journal of Cardiovascular Prevention and Rehabilitation, 11, 369-375.
- Jeffery, R. W., Drewnowski, A., Epstein, L.H., Stunkard, A.J., Wilson, G.T., Wing, R.R., et al. (2000). Long-term maintenance of weight loss: current status. Health Psychology, 19(supp 1), 5-16.
- Jeffery, R. W., Wing, R.R., Sherwood, N.E., & Tate, D.F. (2003). Physical activity and weight loss: Does prescribing higher physical activity goals improve outcome? Am J Clin Nutr, 78(4), 684-689.
- Johnson, W. (1986). Riding The Ox Home: A History of Meditation from Shamanism to Science. Boston: Beacon Press.
- Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. General Hospital Psychiatry, 4, 33-47.
- Kabat-Zinn, J. (1991). Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness. New York: Dell Publishing.
- Kabat-Zinn, J. (2003). Mindfulness-based interventions in context: past, present, and future. Clinical Psychology: Science and Practice, 10(2), 144-156.
- Kabat-Zinn, J. (2005). Coming to Our Senses: Healing Ourselves and the World Through Mindfulness. New York: Hyperion.
- Kabat-Zinn, J., Lipworth, L, Burney, R, & Sellers, W. (1987). Four-year follow-up of a meditation-based program for the self-regulation of chronic pain: treatment outcomes and compliance. Clinical Journal of Pain, 2, 159-173.
- Kabat-Zinn, J., Massion, M.D., Kristeller, J., Peterson, L.G., Fletcher, K.E., Pert, L., & et al. (1992). Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. American Journal of Psychiatry, 149, 936-943.
- Knowler, W. C., Barrett-Connor, E., & Fowler, S.E. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine, 344, 1343-1350.
- Kristal, A. R., Littman, A.J., Benitez, D., & White, E. (2005). Yoga practice is associated with attenuated weight gain in healthy, middle-aged men and women. Alternative Therapies, 11(4), 28-33.
- Kristeller, J. (2005). Know your hunger. Spirituality & Health, 29-35.

- Kristeller, J. (2003). Mindfulness, wisdom and eating: applying a multi-domain model of meditation effects. Journal of Constructivism in the Human Sciences, 8(2), 107-118.
- Kristeller, J., Hallett, CB, & Brendan, C. (1999). An exploratory study of a meditation-based intervention for binge eating disorder. Journal of Health Psychology, 4(3), 357-363.
- Kristeller, J. L., Baer, R.A., & Quillian-Wolever, R. (2006). Mindfulness-Based Approaches to Eating Disorders. In R. A. Baer (Ed.), Mindfulness-based treatment approaches: clinicians' guide to evidence base and applications (pp. 75-92). Burlington: Academic Press.
- Kristeller, J. L., & Rodin, J. (1989). Identifying eating patterns in male and female undergraduates using cluster analysis. Addictive Behaviors, 14(6), 631-642.
- LaForge, R. (1997). Mind-body fitness: encouraging prospects for primary and secondary prevention. Journal of Cardiovascular Nursing, 11(3), 53-65.
- Lincoln, Y. S., & Guba, E.G. (1985). Naturalistic inquiry. Beverly Hills, CA: Sage.
- Little, R. & Rubin, D.B. (1987). Statistical Analysis With Missing Data. New Jersey: John Wiley & Sons, Inc.
- Lopez, K. (1997). Value conflict: the lived experiences of women in treatment for weight loss. Health Care for Women International, 18(6), 603-611.
- Majumdar, M., Grossman, P, Dietz-Waschkowski, B, Kersig, S, & Walach, H. (2002). Does mindfulness meditation contribute to health? Outcome evaluation of a German sample. Journal of Alternative and Complementary Medicine, 8(6), 719-730.
- Marlatt, G. A., & Donovan, D.M. (Eds.). (2005). Relapse Prevention: Maintenance strategies in the treatment of addictive behaviors (2nd ed.). New York: Guilford Press.
- Marlatt, G. A., & Gordon, J. R. (1985). Relapse Prevention. New York: Guilford Press.
- Masheb, R. M., & Grilo, C.M. (2006). Emotional overeating and its associations with eating disorder psychopathology among overweight patients with binge eating disorder. International Journal of Eating Disorders, 39, 141-146.
- McGuire, M.T., Wing, R.R., Klem, M.L., Seagle, H.M., & Hill, J.O. (1998). Long-term maintenance of weight loss: Do people who lose weight through various weight loss methods use different behaviors to maintain their weight? International Journal of Obesity, 22 (6), 572-577.
- Miller, J., Fletcher, K., & Kabat-Zinn, J. (1995). Three-year follow-up and clinical implications of a mindfulness meditation-based stress reduction intervention in the treatment of anxiety disorders. General Hospital Psychiatry, 17, 192-200.

- Morone, N. E., Weiner, D., & Greco, C. (2006). Randomized trial of mindfulness meditation in older adults for the treatment of chronic low back pain: 3-month follow-up. Journal of General Internal Medicine, 21(Suppl. 4), 120.
- Morse, J. M. (1994). Emerging from the data: Cognitive processes of analysis in qualitative inquiry. In J. M. Morse (Ed.), Critical issues in qualitative research methods (pp. 23-43). Thousand Oaks, CA: Sage.
- National Center for Complementary and Alternative Medicine. (2006). Meditation for health purposes. (NCCAM), 1-7.
- National Center for Health Statistics, (2004). Health, United State, 2004 with chartbook on trends in the health of Americans. Retrieved February 25, 2006, from http://www.cdc.gov/nchs.
- O'Neil, P. M., Currey, H. S., Hirsch, A. A., Malcolm, R. J., Sexauer, J. D., Riddle, F. E., et al. (1979). Development and validation of the eating behavior inventory. Journal of Behavioral Assessment., 1(2), 123-132.
- O'Neil, P.M., & Rieder, S.(2005). Utility and validity of the eating behavior inventory in clinical obesity research: a review of the literature. The International Association for the Study of Obesity: obesity reviews, 6, 209-216.
- Ogden, C. L., Carroll, M.D., Curtin, L.R., McDowell, M.A., & Tabak, C.J. (2006). Prevalence of overweight and obesity in the United States, 1999-2004. JAMA, 295, 1549-1555.
- Ornish, D., Scherwitz, L.W., Billings, J.H., Gould, K.L., Merritt, T.A., Sparler, S., et al. (1998). Intensive lifestyle changes for reversal of coronary heart disease. JAMA, 280(23), 2001-2007.
- Paffenbarger, R. S., Hyde, R. T., Wing, A. L., & Hsieh, C. C. (1986). Physical activity, all-cause mortality, and longevity of college alumni. N Engl J Med., 314, 605-613.
- Pi-Sunyer, F. X. (1996). A review of the long-term studies evaluating the efficacy of weight loss in ameliorating disorders associated with obesity. Clinical Therapeutics, 18, 1006-1035.
- Proulx, K. (2003). Integrating mindfulness-based stress reduction. Holistic Nursing Practice, 17(4), 201-208.
- Riebel, D., Greeson, JM, Brainard, GC, & Rosenzweig, S. (2001). Mindfulness-based stress reduction and health-related quality of life in a heterogeneous patient population. General Hospital Psychiatry, 23, 183-192.
- Ryan, D. H., Espeland, M.A., Foster, G.D., Haffner, S.M., Hubbard, V.S., Johnson, K.C., et al. (2003). Look AHEAD Research Group. Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. Controlled Clinical Trials, 24(5), 610-628.

- Sandelowski, M. (1995). Sample size in qualitative research. Research in Nursing & Health, 18(2), 179 183.
- Sandelowski, M. (2000). Focus on research methods: whatever happened to qualitative description? Research in Nursing & Health, 23, 334-340.
- Sartre, J.-P. (1943). Being and Nothingness A Phenomenological Essay On Ontology. Wikipedia Retrieved June 26, 2008
- Schwartz, G. E. (1975). Biofeedback, self-regulation, and the patterning of physiological processes. American Scientist,, 63(3), 314-324.
- Schwartz, G.E. (1984). Psychology of health: A new synthesis. In B.L. Hammonds & J. Scheirer (Eds), Psychology and health: Master lecture series (Vol. 3, pp. 149-193. Washington, DC: American Psychological Association.
- Schwartz, M. S., & Androsik, F. (2003). Biofeedback: A Practitioner's Guide (Third Edition). New York: Guilford Press.
- Segal, Z. V., Williams, J.M.G., & Teasdale, J.D. (2002). Mindfulness-based cognitive therapy for depressive: A new approach to preventing relapse. New York: Guilford.
- Shapiro, S., Carlson, LE, Astin, JA, & Freedman, B. (2006). Mechanisms of Mindfulness. Journal of Clinical Psychology, 62(3), 373-386.
- Shapiro, S., Schwartz, G.E., & Bonner, G. (1998). Effects of mindfulness-based stress reduction on medical and premedical students. Journal of Behavioral Medicine, 21(6), 581-599.
- Shapiro, S. L., & Schwartz, G.E. (2000). The role of intention in self-regulation: toward intentional systemic mindfulness. In M. Boekaerts, Pintrich, P.R., & Zeidner, M. (Ed.), Handbook of Self-Regulation (pp. 253-273). San Diego: Academic Press.
- Shaw, K., O'Rourke, P., Del Mar, C., & Kenardy, J. (2005). Psychological interventions for overweight or obesity. The Cochrane Collaboration, 3.
- Siewert, C. (2002). Consciousness and intentionality. Stanford Encyclopedia of Philosophy, Edited by Edward Zalta. Retrieved May 15, 2008 from <u>http://plato.stanford.edu</u>.
- Slentz, C. A., Duscha, B.D., Johnson, J.L., Ketchum, K., Aiken, L.B., Samsa, G.P., et al. (2004). Effects of the amount of exercise on body weight, body composition and measures of central obesity: STRRIDE-a randomized controlled study. Archives in Internal Medicine, 164, 31-39.
- Speroff, L., Glass, R, & Kase, N. (2001). Clinical gynecologic endocrinology and infertility (6th ed.). Philadelphia: Lippincott, Williams & Wilkins.

- Tacon, A., McComb, J, Caldera, Y, & Randoph, P. (2003). Mindfulness meditation, anxiety reduction and heart disease: a pilot study. Family Community Health, 26(1), 25-33.
- Teasdale, J., Segal, ZV, Williams, JM, Ridgewa, VA, Soulsby, JM, & Lau, MA. (2000). Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. Journal of Consulting and Clinical Psychology, 68(4), 615-623.
- Thomas, E. L., Jakicic, J.M., & Gallagher, K.I. (2004). Does social support for eating and exercise behaviors influence weight loss in overweight adults? Medicine & Science in Sports & Exercise, 36(5), S82.
- Thorne, S. (2000). Data analysis in qualitative research. Evidence-Based Nursing, 3(3), 68-70.
- Thorne, S., Kirkham, SR, & MacDonald-Emes, J. (1997). Interpretative Description: a noncategorical qualitative alternative for developing nursing knowledge. Research in Nursing & Health, 20, 169-177.
- Thorne, S., Paterson B, Russell C, & Schultz A. (2002). Complementary/alternative medicine in chronic illness as informed self-care decision making. International Journal of Nursing Studies, 39(7), 671-683.
- Timko, C., Perone, J, & Crossfield, A. (2006). Are you currently on a diet? What respondents mean when they say "yes". Eating Disorders, 14, 157-166.
- Tod, A., & Lacey, A. (2004). Overweight and obesity: helping clients to take action. British Journal of Community Nursing, 9(2), 59-66.
- Tsai, A. G., & Wadden, T.A. (2005). Systematic review: an evaluation of major commercial weight loss programs in the United States. Annals of Internal Medicine, 142(1), 56-66.
- Vaidya, V. (2006). Psychosocial aspects of obesity. Advanced Psychosomatic Medicine, 27, 73-85.
- Wadden, T. A., Berkowitz, R.I., Womble, L.G., Sarwer, D.B., Phelan, S., Cato, R.K., et al. (2005). Randomized trial of lifestyle modification and pharmacotherapy for obesity. The New England Journal of Medicine, 353(20), 2111-2120.
- Weiss, E. C., Galuska, D.A., Khan, L.K., & Serdula, M.K. (2006). Weight-control practices among U.S. adults, 2001-2002. American Journal of Preventative Medicine, 31(1), 18-24.
- Williams, K., Kolar, MM, Reger, BE, & Pearson, JC. (2001). Evaluation of a wellness-based mindfulness stress reduction intervention: a controlled trial. American Journal of Health Promotion, 15, 422-432.
- Wing, R.R. (1998). Behavioral approaches to the treatment of obesity. In G.A. Bray, C. Bouchard, & W.P.T. James (Eds.), Handbook of Obesity (pp. 855-873). New York: Marcel Dekker.

- Wing, R.R. (2002). Behavioral weight control. In T.A. Wadden & A.J. Stunkard (Eds.) Handbook of Obesity Treatment, (pp. 301-316), New York: Guilford Press.
- Wing, R. R., & Jeffery, R.W. (1999). Benefits of recruiting participants with friends and increasing social support for weight loss and maintenance. Journal of Consulting and Clinical Psychology, 67(1), 132-138.
- Wing, R. R., & Phelan, S. (2005). Long-term weight loss maintenance. American Journal of Clinical Nutrition, 82 (supplement), 222S-225S.
- Wing, R. R., Hamman, R.F., Bray, G.A., Delahanty, L. Edelstein, S.L., Hill, J.O., et al. (2004). The Diabetes Prevention Research Group: Achieving weight and activity goals among diabetes prevention program lifestyle participants. Obesity Research, 12, 1426-1434.
- York, M. (2007). A qualitative study into the experience of individuals involved in a mindfulness group within an acute inpatient mental health unit. Journal of Psychiatric and Mental Health Nursing, 14, 603-608.