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Efficacy of three eight-week lifestyle interventions on weight loss and cardiovascular disease risk factors in obese adults

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Efficacy of three eight-week lifestyle interventions on weight loss and cardiovascular disease risk factors in obese adults

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ABSTRACT

There is little consensus on the most effective approach to promote weight loss and weight maintenance. Guided weight loss programs utilizing motivational interviewing (MI) have shown positive results for weight loss but they can be time consuming and expensive. New self-monitoring devices such as the SenseWear Pro mini-fly Armband (SWA) may provide alternative approaches for facilitated weight loss. The primary purpose of this study was to determine the relative effectiveness of a guided weight loss program (Bon), the SWA monitor with associated weight management system (SWA), or a combination of both strategies (Bon + SWA) on weight loss and clinical risk factor change.

Seventy-eight obese adults (31 male and 47 female) were enrolled in the study and randomized to one of the three conditions. The 8-week intervention consisted of either weekly health coach meetings in conjunction with a behavior change curriculum (BonSanté), utilization of the SWA monitor with minimal health coaching, or a combination of weekly meetings and SWA. Changes in weight and clinical risk factors (blood pressure, fasting glucose, total cholesterol, HDL, LDL, and triglyceride concentrations) were assessed using multivariate ANOVAs. Results indicate that there was a significant weight reduction seen in all three conditions (-4.21 ± 3.08 kg; $p < 0.0001$); however, there was no significant difference across conditions. There were general tendencies for larger effects in the group that received the combination of programs. Secondary analyses revealed that change in risk factors were proportional to the degree of weight loss ($r=0.40$); however, there was evidence that some risk factor change may occur independently of weight loss.

The results suggest that a self-monitoring device may be as beneficial as a guided intervention to facilitate weight loss and behavior change. Positive changes in risk factors can occur without a decrease in weight, but these changes are associated with the magnitude of weight reduction. Follow-up analyses of this sample will provide insights about the impact of these intervention approaches on maintenance of effects.

Keywords: weight loss intervention, self-monitoring, energy expenditure monitor, motivational interviewing, health promotion, SenseWear Armband

CHAPTER 1. INTRODUCTION

The rising prevalence of overweight and obese people in the world has become a serious problem over the past decades. According to the World Health Organization (2008), there are over 1 billion people that are overweight (categorized as a Body Mass Index (BMI) = 25-29.9 kg/m^2) and over 350 million people who are obese (BMI $\geq$ 30 kg/m^2). The World Health Organization (2008) predicts the prevalence of overweight people will be greater than 1.5 billion by 2015. The occurrence of overweight and obese people in the United States is approximately 68% of the total population, with over 30% of the population being obese and 14% of people considered to be grade 2 obesity or above (BMI $\geq$ 35 kg/m^2) (Flegal et al, 2010). Overweight and obesity results in 2.5 million preventable deaths, through complications such as type 2 diabetes mellitus, stroke, cardiovascular problems, and different forms of cancer. Estimates suggest a 5-10% weight reduction will reduce the risk of some of these complications (Goldstein et al, 1992; Pansinisi et al, 2001).

Considerable research has been done to evaluate the effectiveness of various intervention programs aimed at preventing and treating obesity in all populations. These interventions include caloric or nutrient restrictions and diet modifications (Torgerson et al, 1997; Wadden et al, 1993), programming to promote physical activity for weight loss (Wallman et al, 2009), combined diet and exercise interventions (Carels et al, 2005; Racette et al, 2009), as well as various behavioral programs aimed at lifestyle change (Martins et al, 2009). These programs have shown both positive (Torgerson et al, 1997; Carels et al, 2005) and negative weight loss results (Racette et al, 2009) and there is currently little consensus

on the most effective approach for weight loss and maintenance. Wadden et al (1993) demonstrated that most dieters return to their baseline weight in about 3-5 years after initial weight loss and removal of treatment, with one third of this weight gain happening one year after the intervention has finished.

A variety of behaviorally-based weight loss programs have been developed but most have not been evaluated using controlled randomized designs. The BonSanté weight loss intervention program focuses on weight loss and maintenance, along with healthy behavior and lifestyle changes. The program uses motivational interviewing techniques to facilitate healthy diet modifications, with a recommendation to include meal replacement items, to teach correct portion control, and increase fiber, fruit, and vegetable consumption, increase physical activity, and incorporate self-monitoring techniques to build behavioral skills needed for weight loss and long term weight maintenance. The BonSanté guided weight loss program has never been evaluated through controlled, clinical trials. The present study uses a modified BonSanté program to evaluate the relative importance of different components on weight loss outcomes. Additional detail is provided on the BonSanté program before describing the specific purpose.

Background on the BonSanté Program

The BonSanté program is a behaviorally-based weight loss program that emphasizes the use of more frequent, small meals (meal replacements) and instruction on behavioral skills needed for weight loss. Meal replacements have been shown to be helpful in initial weight loss (Anderson et al, 2005) and weight loss maintenance (Ashley et al,

2001). It has also been noted that participants who consume meal replacements have an increase in dietary intake of essential nutrients (Ashley et al, 2007). These studies have concluded that meal replacements may be beneficial for people with a busy, on-the-go lifestyle.

Motivational interviewing is the core behavior change strategy employed in the BonSanté program. Motivational interviewing (MI) has become one of the most widely used (and studied) components in a variety of intervention programs, including substance abuse and improvement in medication adherence, and it has been shown to have positive effects when used in weight loss interventions (Martins et al, 2009). Motivational interviewing is a patient-based approach to examine and assess the patient's goals, willingness to change, and perceived barriers to these changes. The health professional who administers MI should include reflective listening and summarization of the patient, and allow the patient to build individualized goals while helping to make these goals realistic and attainable (Dilillo et al, 2003). When patients at high risk for coronary heart disease had the option of attending individualized MI sessions, all patients who attended the sessions showed an increase in physical activity (+245 met-min/wk) and weight loss (-0.7 kg) and a decrease in blood pressure (systolic blood pressure -4.8 mmHg and -3.45 mmHg for diastolic blood pressure) and cholesterol (-0.23 mmol/L); however, a greater reduction was seen in patients who attended MI sessions more frequently (Hardcastle et al, 2008). MI strengthens the patient's self-efficacy in not only weight loss, but problem solving as well. Self-efficacy is a person's belief that he or she can accomplish a specific task or overcome a challenge. Self-efficacy can help build skills and behaviors needed to

overcome barriers and to resolve problematic situations that may arise after the program has ceased (Dilillo et al, 2003).

While MI sessions can hold participants accountable during the intervention it may not provide a sufficient dose of training to promote lasting behavior change. Self-monitoring is another key behavioral skill that is important for the adoption and maintenance of healthy behaviors. Self-monitoring is used to track behavior, thoughts, and emotions over a period of time to help increase awareness barriers to behavior change may arise throughout daily living. The use of pedometers as a self-monitoring tool for promoting activity has been shown to increase physical activity in various populations (i.e. low-income, overweight and obese, and in both men and women) (Tudor-Locke and Lutes, 2009). The tracking of activity or diet in daily logs has been shown to be important for promoting healthy behavior changes in the population (Clarke et al, 2007; Racette et al, 2009; Carels et al, 2005). Self-monitoring helps participants build self-efficacy through visualized feedback (Tudor-Locke and Lutes, 2009) and identify lifestyle barriers, which could eventually derail people from long-term behavioral maintenance (Carels et al, 2005).

Self-monitoring is another component of the BonSanté program. In this intervention self-monitoring was assessed using personal written diaries and logs or a technology based monitor. The SenseWear Pro Mini-Fly Armband (Body Media Inc.) (SWA) is a technology-based self-monitoring device that provides estimates of the amount of physical activity completed (both moderate and vigorous), steps taken, and calories expended. An associated software tool, the FIT Weight Management System (WMS), enables users to enter food consumed and obtain an estimate of energy intake. By

integrating daily estimates of energy intake and energy expenditure, an individual may be able to monitor their behavior more objectively. The SenseWear monitor and WMS offer promise for facilitated weight loss programming but it is not clear if it can be effectively used independently or if it needs to be used in combination with a guided weight loss program that includes training on behavioral skills. The BonSanté program has developed an integrated approach that includes the coordinated use of the SWA and motivational interviewing sessions, but it is not clear whether the guided program or the use of self-monitoring is a more important component for weight loss and behavior change.

Purpose of the Study

The primary purpose of this study was to determine the relative effectiveness on weight loss and clinical outcomes of the combined use of the BonSanté guided weight loss program with the SenseWear monitor and WMS; as well as the effectiveness of the BonSanté program and the use of the SenseWear Pro monitor and WMS independently. The secondary purpose was to evaluate the extent to which clinical outcomes are related to weight loss. It is hypothesized that wearing a self-monitoring device (SWA) in conjunction with a guided weight loss program (BonSanté) will result in a larger weight reduction than the use of either component alone. It is also hypothesized that changes in clinical measures will correspond more closely, but will not be dependent on, changes in weight.

CHAPTER 2. REVIEW OF LITERATURE

Obesity Epidemic

Obesity is a rising epidemic throughout the United States and the world. According to the Center for Disease Control (CDC) (2004) overweight and obesity is the second leading cause of preventable death in the United States, but is increasing at such a rapid rate it could eventually surpass smoking to become the number one cause of preventable deaths. In 1990, no state in the U.S. had a prevalence of obesity greater than 15% of their population. As of 2009, only one state (Colorado at 18.9%) had an obesity prevalence of less than 20% of the population, with the highest incidence reported in Mississippi at 35.3% (BRFFS, 2009).

Obesity is defined as an excess accumulation of fat in the body. There are numerous instruments and methods to determine if a person is considered overweight or obese. A simple calculation that can be used for the general population is the Body Mass Index (BMI). This calculation takes into account height and weight of the individuals by using the equation weight in kilograms (kg) divided by height in meters squared (m^2) (Corral et al, 2008). The World Health Organization (2008) classifies individuals into different categories based upon BMI ranges: healthy individuals range from 18.5 – 24.9 kg/m^2, overweight individuals range from 25 – 29.9 kg/m^2, Grade I obesity ranges from 30 – 34.9 kg/m^2 and Grade II obesity is categorized as $\geq$ 35 kg/m^2. According to Corral et al (2008), after evaluating data from the National Health and Nutrition Evaluation Survey (NHANES) there was good specificity and a positive prediction value of percent body fat in

people who had a BMI $\geq$ 30 kg/m^2, but was not as accurate in adults with a BMI < 30 kg/m^2. BMI has also been known to be less accurate in the elderly (Corral et al, 2008), athletes (Ode et al, 2007), and children (Heymsfield et al, 2007) because it does not take into account body composition and the amount of lean body mass in individuals. The direct benefit of assessing BMI is that it is a noninvasive, simple calculation that can be used to evaluate the health status of the general population (Corral et al, 2008).

Complications Related to Obesity

Individuals categorized as either overweight or obese are at an increased risk for numerous health complications, both physically and psychologically. Being overweight or obese can lead to various cardiovascular problems, type 2 diabetes mellitus, stroke, cancer (Goldstein et al, 1992; Pi-Sunyer, 2002), depression, anxiety, mood swings, and other psychological problems (Puhl & Heuer, 2010). An excess amount of adipose tissue can also lead to an increase in proinflammatory cytokines released by adipocytes. These cytokines can cause a person who is obese to be in a low-grade inflammatory state. This constant inflammation increases the risk of fatal coronary heart disease (CHD) events (Logue et al, 2011). It is estimated that these complications can be reduced with a 5-10% weight reduction (Goldstein et al, 1992; Pansinisi et al, 2001).

Walter et al (2009) showed that in older populations (> 55 years of age), being overweight or obese increased the onset and duration of disability, defined as an inability to perform activities of daily living, especially in females. Therefore, the need to prevent and reduce the prevalence for overweight and obesity is relevant for health complications now as well as in an individual's future. Consequently, obesity can affect an individual's

family as well. Whitaker and colleagues (1997), found that a child with at least one obese parent was twice as likely to be obese in young adulthood than was a child without an obese parent.

Metabolic Syndrome

Metabolic syndrome is a common consequence of obesity and is defined as a clustering of risk factors associated with atherosclerosis and CHD. There are different variations of diagnostic criteria for metabolic syndrome. The National Cholesterol Education Program Adult Treatment Panel III (NCEP III) (2001) evaluates waist circumference measures ($\geq$ 102 cm in men and $\geq$ 88 cm in women), fasting triglyceride ($\geq$ 150 mg/dl) and HDL concentrations (< 40 mg/dl in men and < 50 mg/dl in women), blood pressure levels ($\geq$ 130 mmHg systolic and/or $\geq$ 85 mmHg diastolic pressure) and fasting blood glucose concentrations ($\geq$ 110 mg/dl) to diagnosis metabolic syndrome. An individual who has 3 or more of these elevated risk factors is diagnosed with metabolic syndrome. Each of the components evaluated are known cardiovascular disease risk factors as well. It has been observed that people who are identified as having metabolic syndrome have a twofold higher risk of having CHD than people without metabolic syndrome (Alexander et al, 2003; Pajunen et al, 2010) and an even higher association is seen with the incidence of type 2 diabetes mellitus (Pajunen et al, 2010). These individual risk factors of metabolic syndrome are at least partially mediated by obesity (Wijndaele et al, 2006).

Cardiovascular Disease

Cardiovascular disease (CVD) is highly associated with obesity and an increase in adiposity. CVD includes coronary heart disease (CHD), angina pectoris, hypertension, hypercholesterolemia, and an increase in triglyceride concentration. Reducing adiposity can be a preventative measure and can help decrease CVD risk at an individual and a population level (Wilson et al, 2002).

Determining effective weight loss and maintenance strategies is a necessary tool for the global population in order to reduce the amount of preventable deaths in the world and allow people to have an increased quality of life.

Weight Loss and Maintenance Interventions

There are numerous intervention programs developed for weight loss and reduction in cardiovascular disease risk factors. Programs including caloric and nutrient dietary restrictions (Torgerson et al, 1997; Wadden et al, 1993), promotion of physical activity (Wallman et al, 2009), combined diet and physical activity programs (Carels et al, 2005; Racette et al, 2009), and behavioral based programs (Martins et al, 2005) are among the most commonly evaluated approaches. Maintenance of healthy behaviors and weight loss after an intervention program can be problematic for many people. Wadden et al (1993) showed that participants regain an average of one third of their initial weight loss one year after a typical weight loss intervention.

Mediators for Weight Loss and Maintenance

A recent study by Teixeira et al (2010) evaluated the mediators to weight loss maintenance in participants one year after a weight loss intervention. The main mediators shown to maintain weight loss were self-efficacy in exercise, intrinsic exercise motivation, fewer perceived exercise barriers, and lower emotional eating. Mattfeldt-Beman and colleagues (1999), surveyed participants after a weight loss intervention focused on self-management of energy intake, exercise, and individually set behavior goals. The study targeted a weight loss of 10 lbs and examined maintenance over 18 months. During the weight loss phase participants met with a health professional at least once a week, and during the maintenance phase had monthly meetings. After the intervention, the participants were given a survey to evaluate what was most beneficial about the program. Overall, participants were satisfied with the structure of regularly scheduled meetings, but preferred more creative ways to maintain this contact. Participants who successfully maintained the weight loss believed goal-setting and continued self-monitoring of energy intake and output were the most beneficial components, and also reported having a larger social support system. Other evaluations varied with each participant; emphasizing the importance of individuality throughout an intervention while goal setting and discussing behavior maintenance strategies (Mattfeldt-Beman et al, 1999).

Benefits of Healthy Behavior Change

Studies have evaluated the "*fitness versus fatness*" theory to determine if positive physiological effects can occur independent of weight loss. Many have noted improvements in physiological values in response to healthy behavior change with the

absence of weight loss (Ekelund et al, 2007; Larson-Meyer et al, 2010; Ekblom-Bak et al, 2010; Stevens et al, 2002). A number of studies have demonstrated that healthy behavior changes (e.g. an increase in the amount of physical activity or consumption of a calorie restricted/nutrient dense diet) can lead to a variety of positive metabolic and cardiovascular changes including decreased fasting glucose (Ekelund et al, 2007; Larson-Meyer et al, 2010), decreased waist circumference (Ekelund et al, 2007; Ross, 2000), decreased systolic and diastolic blood pressure (Ekelund et al, 2007), decreased low density lipoprotein (LDL) cholesterol concentration (Larson-Meyer et al, 2010), decreased total cholesterol concentration (Larson-Meyer et al, 2010), and decreased triglyceride concentration (Ekblom-Bak et al, 2010; Ekelund et al, 2007; Johnson et al, 2009; Larson-Meyer et al, 2010; Stevens et al, 2002). Improvement in these physiological values lead to a lower risk for several diseases associated with obesity and metabolic syndrome; such as, cardiovascular disease and diabetes.

The BonSanté Guided Weight Loss Program

The BonSanté guided weight loss program is based on motivational interviewing techniques to help individuals find the most beneficial and efficient approach to weight loss and healthy lifestyle changes. This program includes a recommended diet filled with nutrient dense foods, such as the incorporation of meal replacement items, fruits, vegetables, and fiber, strategies to increase physical activity, and skills to integrate behavior modifications into daily life. Weekly sessions facilitated by a health coach are used to assess individual's motivation, perceived barriers, and progress with the program

through continual goal setting and self-monitoring. These components will allow the participant to maintain the skills learned to problem solve and overcome barriers once the intervention has ceased. Specific components of the BonSanté program are described in more detail since it is the basis of the behavioral weight loss intervention.

Motivational Interviewing

Motivational interviewing is one of the core components of the BonSanté guided weight loss program. Motivational interviewing is a client-based form of intervention that allows the client to identify goals, barriers, and skills to maintain lifestyle changes. The health professional is there to help guide the patient through the phases of the intervention; while keeping goals specific, realistic, and attainable and enhancing the client's self-efficacy (DiLillo et al, 2003). Compared to a traditional counseling session which is typically centered on problem solving through solutions given by the professional (Wood, 1990), motivational interviewing is based on the patient's assessments of realistic solutions to various lifestyle challenges and barriers to behavior change (DiLillo et al, 2003). While appropriate under certain conditions, traditional problem-solving strategies focus on active problem solving and short term solutions rather than strategies needed for long term, sustained weight loss. (Wood et al, 1990; DiLillo et al, 2003; Schiller et al, 1998). Instead of making specific recommendations for the individual's perceived obstructions to change, the health coach actively listens to the client and guides them to the solutions that would allow them to solve and maintain these positive changes (DiLillo et al, 2003). Martins et al (2009) found that the more MI sessions are attended, the more likely behavior change will be seen and maintained.

Overall, the main goal of MI is to implement a sense of self-control and self-efficacy in the client in order to maintain the positive lifestyle changes that were achieved even after the intervention sessions have stopped (DiLillo et al, 2003).

Meal Replacements

In the BonSanté program, meal replacements are recommended to help the individual with calorie control and correct portion size recognition. In other dietary weight loss intervention programs, the inclusion of meal replacements have shown to be beneficial in initial weight loss (Anderson et al, 2005) and weight loss maintenance (Ashley et al, 2001). When either soy (Scan-Diet™) or milk based (Slim Fast®) commercial meal replacements were consumed, both saw a similar weight loss of 8.5% over 12 weeks, with minimal other lifestyle interventions (Anderson et al, 2005).

Ashley and colleagues (2001) indicated that consumers of meal replacements maintained a larger percent of their weight loss compared to people who lost weight without the use of meal replacements over a 2 year period. These participants met on a regular basis with a physician-nurse combination or with a dietitian for informational sessions as well (Ashley et al, 2001). Ashley et al (2007) also noted that participants who consumed meal replacements, instead of traditional foods with similar amounts of calories and macronutrient distribution, had an increase in essential micronutrient intake. Finally, meal replacement consumption was shown to decrease fat mass and weight while improving high density lipoprotein (HDL) cholesterol in U.S. military officers, who did not meet the U.S. army standards for weight and percent body fat. This suggests that using

meal replacements as a weight loss tool may be valuable for people with a busy lifestyle (Smith et al, 2009).

Self-Monitoring of Diet and Physical Activity

A third component of the comprehensive BonSanté approach is self-monitoring. Self-monitoring has been shown to be an important behavioral skill for promoting healthy diets and increased physical activity levels in diverse populations (Tudor-Locke and Lutes, 2009; Racette et al, 2009; Clarke et al, 2007; Carels et al, 2005). By logging or recording tendencies and habits, self-monitoring helps participants identify lifestyle barriers, which could eventually disrupt long-term behavior change maintenance (Carels et al, 2005) and build self-efficacy through visualized feedback (Tudor-Locke and Lutes, 2009).

Paper Records

An inexpensive way to promote self-monitoring is the use of written paper diaries for diet and physical activity habits. Baker and Kirschebaum (1998) found that people who consistently filled out a paper food record lost more weight during an intervention than did individuals who did not record their meals or only did so periodically. There has been evidence supporting the link between frequency of self-monitoring and weight loss. Even though paper records are inexpensive and easy to use, they do have limitations. For example, participants must be literate. This becomes a problem because evidence has noted that there is a higher prevalence of obesity in people with lower education levels (Everson et al, 2002). Secondly, recording every food item eaten and every minute of activity each day can be tedious and become a burden on the participant, eventually resulting in a deterioration of compliance. However, it is important to note that

participants in a weight loss intervention who were required to provide very descriptive and detailed logs had no difference in the amount of weight loss compared to people who filled out more general and simpler food and physical activity logs. Therefore, people should be encouraged to do any form of recording because detailed logs may not be necessary to enhance weight loss when a simpler log displayed comparable, positive results (Helsel et al, 2007). Finally, about 50% of self-reported paper records are inaccurate. This could be caused by delayed recording and poor recollection of consumption or from under- or over-reporting due to social norms and biases (Burke et al, 2005). In an 18-month study, only 5 participants were able to maintain adequate paper logs after the initial intervention program ceased. This displays that documenting on paper diaries may be beneficial for short-term weight loss, but is not sustainable over time (Burke et al, 2009)

Electronic Device Logs

The use of an electronic device to promote self-monitoring can be much more convenient for participants when corresponded with nutritional software (i.e. the USDA nutrient database) which provides nutrient compositions for a variety of foods. Increased adherence to consistent self-monitoring is seen with electronic logs compared to paper logs (Burke et al, 2005). When providing direct feedback along with the electronic software, there was $\geq$ 5% increase in weight reduction than with just the electronic logging alone, demonstrating that immediate feedback can be a motivating factor (Burke et al, 2011).

Pedometers

Pedometers are a simple, noninvasive way to assess physical activity in the general population. Pedometers also have the ability to give direct feedback for the amount of steps taken each day, which can often be a motivational tool for participants to increase activity levels. It has been noted by Tudor-Locke and colleagues (2004) that pedometers are acceptable and sustainable for long term use, as evidenced by a year-long study where participants wore the devices 365 days, with an adherence rate of 98%. Participants explained that the pedometers were not considered a burden (Tudor-Locke et al, 2004). Therefore, pedometers can provide long-term sustainability of physical activity assessment through the estimation of the amount of steps taken each day. In the same study, a seasonal difference in step count was also detected; with an increase in steps/day in spring and summer compared to the winter months (Tudor-Locke et al, 2004). When these were incorporated into an 8-week behavioral intervention program for low-income mothers, steps were increased by 63.5% and there was a significant decrease in body weight, percent body fat, and waist circumference as well (Clarke et al, 2007). While pedometers are noninvasive, inexpensive, and easy to use there are many known limitations. For example, unlike accelerometers, pedometers cannot distinguish between exercise intensity, pattern of physical activity, or type of activity (i.e. running vs. walking uphill or upper body exercises). Also, if pedometers are rotated off the vertical plane it will impair measurement function, which could be problematic for individuals with excess abdominal adiposity who wear pedometers on their waistband (Tudor-Locke and Lutes, 2009).

Accelerometers

While logs and pedometers can be motivating factors for people to begin healthy behaviors, more detail may be needed in order to enhance positive changes, increase knowledge, and consequently improve maintenance of healthy behaviors. Napolitano and colleagues (2010) found that wearing a single axis accelerometer in conjunction with an individualized health intervention program increased minutes of physical activity compared to a control group who were only told to meet the physical activity guidelines. In a similar study with patients who were diagnosed with type 2 diabetes, Paschali et al (2005) found that people who received an accelerometer had increased physical activity; effects were enhanced when immediate feedback was available for the participants. This shows that the information as well as immediate feedback from the accelerometers is most beneficial.

SenseWear Pro Mini-fly Armband

The SenseWear Armband (SWA) monitor (BodyMedia®, Pittsburgh, PA www.bodymedia.com) is a non-invasive, wireless, multi-sensor monitor that is worn over the triceps muscle on the back of the right arm with an adjustable strap. The SWA records data from five sensors including a 3-axis accelerometer, heat flux sensor, galvanic skin response sensor, skin temperature sensor, and near body ambient temperature sensor. Internal algorithms determine the predominant type of movement taking place and the estimated energy expenditure cost of the activity.

Validity

A number of studies have supported the utility of the SWA monitor in estimating resting (Fruin & Rankin, 2004; McClain et al, 2005) and exercise energy expenditure (Fruin & Rankin, 2004; King et al, 2004). It has also been shown to provide accurate estimates of resting energy expenditure in both lean and overweight individuals (Papazoglou et al, 2006). Over the past few years, members of our research team have conducted a series of field based studies that have supported the utility and accuracy of the SWA (Welk et al, 2007; Calabro et al, 2007). The most recent study (Johannson et al, 2010) evaluated the validity of the SWA using doubly labeled water (DLW) as the criterion measure. The average total energy expenditure estimates from the SenseWear Mini (latest version of the SWA) were within 22 kcals/day. The absolute error rates (computed as average absolute value of the individual errors) were 8.3 ± 6.5% with an intra-class correlation analysis that revealed significant agreement between the Mini and DLW (ICC = 0.85, 95% CI: 0.92, 0.76).

Corresponding Weight Management System

A unique feature of the SWA monitor is that it is designed to work with an integrated software tool called the Weight Management System (WMS). The WMS allows participants to log their diet behaviors and produces an estimate of energy intake. By combining this information with the objective data on energy expenditure it is possible to obtain an estimate of daily energy balance. Recent work with the SWA and WMS (McGuire, 2010) demonstrated that the WMS provides accurate estimates of energy balance when participants provide sufficiently detailed diet logs. The detailed and integrated feedback

from the SWA and WMS may also facilitate self-monitoring and manage daily diet and activity to promote weight loss.

SWA Combined with Weight Loss Interventions

The effect of the SWA and WMS on facilitated weight loss has only been evaluated in a single study (Polzien et al., 2007). In this study, the SenseWear Pro armband was used in combination with a short-term behavioral weight loss program. The investigators found that the groups wearing the armband continuously lost more weight than participants that wore the monitor intermittently, which supports the idea that self-monitoring with the SWA may facilitate weight loss. It is not clear, however, if the feedback from the SWA and WMS only is sufficient to promote weight loss. This study will evaluate the independent and additive effect of the SWA and WMS system when used as part of a guided behavioral weight loss program.

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CHAPTER 3. EFFICACY OF THREE EIGHT WEEK LIFESTYLE INTERVENTIONS ON WEIGHT LOSS AND CARDIOVASCULAR DISEASE RISK FACTORS IN OBESE ADULTS

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Abstract

There is little consensus on the most effective approach to promote weight loss and weight maintenance. Guided weight loss programs utilizing motivational interviewing (MI) have shown positive results for weight loss but they can be time consuming and expensive. New self-monitoring devices such as the SenseWear Pro mini-fly Armband (SWA) may provide alternative approaches for facilitated weight loss. The primary purpose of this study was to determine the relative effectiveness of a guided weight loss program (Bon), the SWA monitor with associated weight management system (SWA), or a combination of both strategies (Bon + SWA) on weight loss and clinical risk factor change.

Seventy-eight obese adults (31 male and 47 female) were enrolled in the study and randomized to one of the three conditions. The 8-week intervention consisted of either weekly health coach meetings in conjunction with a behavior change curriculum (BonSanté), utilization of the SWA monitor with minimal health coaching, or a combination of weekly meetings and SWA. Changes in weight and clinical risk factors (blood pressure, fasting glucose, total cholesterol, HDL, LDL, and triglyceride concentrations) were assessed using multivariate ANOVAs. Results indicate that there was a significant weight reduction seen in all three conditions (-4.21 $\pm$ 3.08 kg; $p < 0.0001$); however, there was no significant difference across conditions. There were general tendencies for larger effects in the group that received the combination of programs. Secondary analyses revealed that change in

risk factors were proportional to the degree of weight loss (r=0.40); however, there was evidence that some risk factor change may occur independently of weight loss.

The results suggest that a self-monitoring device may be as beneficial as a guided intervention to facilitate weight loss and behavior change, but the combined use of both strategies may enhance effectiveness. Positive changes in risk factors can occur without a decrease in weight, but these changes are associated with the magnitude of weight reduction. Follow-up analyses of this sample will provide insights about the impact of these intervention approaches on maintenance of effects.

Keywords: weight loss intervention, self-monitoring, energy expenditure monitor, motivational interviewing, health promotion, SenseWear Armband

Introduction

Approximately 68% of the population in the United States is categorized as overweight or obese, with over 30% of the population being obese (BMI $\geq$ 30 kg/m^2) and 14% being grade 2 obesity or higher (BMI $\geq$ 35 kg/m^2) (Flegal et al, 2010). Consequently, this results in 2.5 million preventable deaths, through complications such as type 2 diabetes mellitus, stroke, cardiovascular problems, and cancer (CDC, 2004). Estimates suggest a 5-10% weight reduction will reduce the risk of these complications (Goldstein et al, 1992; Pansinisi et al, 2001). Considerable research has been done to evaluate the effectiveness of various lifestyle and behavior change intervention programs aimed at preventing and treating obesity. However, there is little consensus on the most effective approach for weight loss and maintenance.

Motivational interviewing (MI) is a commonly used strategy to facilitate behavior change (Martins et al, 2009). MI is a patient-based approach that involves assessing a patient's goals, willingness to change, and perceived barriers to these changes. A counselor employing MI strategies helps to strengthen the patient's self-efficacy and helps to build skills and behaviors that can be utilized to resolve problematic situations (DiLillo et al, 2003). Hardcastle and colleagues (2008) showed that participants who attended more MI sessions had larger increases in physical activity (+245 MET-min/wk), greater weight loss (-0.7 kg) and larger reductions in blood pressure (systolic blood pressure: -4.8 mmHg; diastolic blood pressure: -3.45 mmHg) and total cholesterol (-0.23 mmol/L); compared to people who attended sessions less frequently.

While MI sessions create accountability for participants, it may not provide a sufficient dose of training to promote long-term behavior change. Self-monitoring is another key skill for the adoption and maintenance of healthy behaviors. Daily tracking of diet or activity has been shown to promote healthy dietary and lifestyle changes (Clarke et al, 2007; Racette et al, 2009; Carels et al, 2005), along with the use of pedometers and accelerometers for activity promotion (Tudor-Locke and Lutes, 2009). Self-monitoring helps participants to build self-efficacy through visualized feedback (Tudor-Locke and Lutes, 2009) and identify lifestyle barriers, which could eventually disrupt long-term behavioral maintenance (Carels et al, 2005).

The SenseWear Pro Mini-Fly Armband (Body Media Inc.) (SWA) is a physical activity and energy expenditure assessment tool that provides opportunities for self-monitoring through an associated web tool called the FIT Weight Management System (WMS). The

monitor integrates estimates of energy expenditure with estimates of energy intake (obtained by self-reported diet assessments) to provide feedback on daily energy balance and progress towards weight loss goals. Research on the SWA has shown it to be accurate when assessing resting energy expenditure (Fruin et al, 2004; McClain et al, 2005) as well as exercise; such as treadmill walking and running and stair stepping (Fruin et al, 2004; King et al, 2004; Papazoglou et al, 2006) and free living energy expenditure (Calabro et al, 2007; Johannson et al, 2010; Welk et al, 2007). The WMS also has been shown to accurately assess energy and nutrient distribution in foods when compared to an established dietary assessment system (Nutritionist Pro) (McGuire, 2010). By integrating information on energy intake and energy expenditure an individual may be able to monitor their behavior and energy balance more objectively. The utilization of the SWA and WMS has been shown to facilitate behavior change and weight loss when used in conjunction with a guided intervention program (Polzien et al, 2007). However, it is not clear if the SWA and WMS would be more beneficial if used in conjunction with a guided program.

The primary purpose of this study was to determine the independent and interactive benefits of the BonSanté guided weight loss program and SWA monitoring program on weight loss and clinical outcomes in obese adults. The secondary purpose was to evaluate whether clinical outcomes are related to weight loss or to behavioral changes as assessed through the BonSanté program and the SWA/WMS. It is hypothesized that wearing a self-monitoring device (SWA) in conjunction with the guided weight loss program (BonSanté) will result in a larger weight reduction than the use of either component alone.

It is also hypothesized that changes in clinical measures will correspond more closely, but not be dependent on, changes in weight.

Methods

This study was conducted as part of an ongoing weight loss and maintenance study at the Iowa State University Nutrition and Wellness Research Center (NWRC).

Study Design

The study was designed as a randomized clinical trial to evaluate the relative effectiveness of three different weight loss programs. Participants were recruited through campus mailings and interested participants attended an information session where a diet and medical history questionnaire was completed to review for possible exclusions. This study was approved by the Institutional Review Board at Iowa State University.

Participants had to be over 18 years of age with a BMI $\geq$ 30 kg/m^2 to be included in this study. Participants were excluded if they were diabetic, a smoker, pregnant or planning to become pregnant, anorexic or bulimic, or if they have had bariatric surgery, a heart attack or angina, recent or recurrent strokes, cancer, thrombophlebitis, peptic ulcer disease, or chronic use of corticosteroids, within the past 3 months. All participants had approval from their primary care physician to enter a weight loss program and signed an informed consent form before beginning. A diagram depicting the tracking of participants in the study is provided in Figure 1.

Eligible participants were enrolled in the study and had a second visit where height, weight, BMI, percent body fat, waist circumference, and blood pressure were measured. A

fasted blood draw was taken, followed by a small breakfast. Participants were then randomized using a computer-automated randomization sequence. Participants were randomized (using a random number generator) to a trained health coach and one of three conditions: (1.) BonSanté program, (2.) SenseWear Armband (SWA) with FIT Weight Management System (WMS) and (3.) BonSanté + SWA.

The health coaches were six graduate students who were trained and supervised on the BonSanté program, motivational interviewing, and the SWA/WMs by registered dietitians and research staff members. Health coaches coordinated the delivery of the programs but were not considered part of the intervention because participants had the same amount of contact with their health coach despite condition. Each participant met face-to-face with the health coach on at least three separate occasions, the initial meeting, the halfway point, and the last week of the intervention. Coaches and participants were required to have a minimum of one contact per week, via telephone, email communication, or in-person meetings. Participants receiving the BonSanté program had in-person meetings each week unless situations arose that did not allow this to happen, such as travel or illness; in this case other plans for communication were arranged. Participants in the SWA condition received only weekly email communications except during weeks 1, 2, 4 and 8. These emails were to inquire about any problems that may have arisen and to provide an encouraging statement about achieving goals. Because the health coaching was randomly assigned and standardized across conditions (health coaches had an even distribution of participants in each condition), the differences in weight loss

outcomes can be attributed to the distinctions among the program components.

Descriptions of Interventions

Group 1: BonSanté Condition. The BonSanté guided weight loss program provided participants with a structured 8-week intervention. The participants received dietary advice, weekly skills and behavioral guidelines through an educational booklet and motivational interviewing given by the health coach. The BonSanté program emphasizes six small meals per day, to help control caloric intake and portion size. An increase or maintenance of adequate fiber and fruit and vegetable consumption, physical activity, and food and activity logs are the main features in the BonSanté program.

Group 2: SWA and WMS Condition. The SWA and WMS condition provided participants with access to the SenseWear armband monitor and instructions on how to use the associated WMS program. The monitor was worn on the back of the left triceps. Participants were also given a wristwatch display that provided real-time estimates of calories expended, minutes of vigorous and moderate physical activity, and number of steps taken during the day. The display provided immediate feedback but emphasis was placed on training participants to utilize the integrated computer system. Participants were trained to download the monitor onto the computer, enter dietary intake, and view reports of energy balance, nutrition, physical activity, sleep duration, and sleep efficiency. After the first visit participants were advised to wear the armband as much as possible but were required to wear it during the first, fourth, and eighth weeks of the intervention. They also received public resources (i.e., mypyramid.gov) as references for healthy lifestyle changes but were not taught the behavioral skills covered in the BonSanté program.

Group 3: BonSanté and SWA/WMS Condition. Participants in the BonSanté + SWA/WMS condition received both the BonSanté program and the SenseWear monitor and WMS computer program. The BonSanté program was delivered in the same way as condition 1 but participants were also taught how to use the armband and WMS system to monitor their activity level and daily energy balance. Unlike group 2, participant's randomized to group 3 received feedback on the SWA/WMS information from their health coach.

Participants in groups 2 and 3 were required to wear and download the armband the 1st, 4th, and 8th weeks of the intervention but were encouraged to wear and download the data every week. A detailed description of each condition and a weekly breakdown of the intervention are displayed in Figure 2.

Outcome Measures and Data Collection Procedures

A variety of outcome measures were used to evaluate the effectiveness of the programs for promoting weight (and fat) loss and decreasing cardiovascular risk factors.

Anthropometric Measures

Anthropometric measures were collected at baseline, week 4, week 8, and at a 4 month follow-up assessment. All measures were assessed at least twice and averaged if accurate (within 0.1 units of each other). Height and weight were assessed without shoes using an electronic scale and a stadiometer mounted to the wall. Body mass index (BMI) was calculated by taking weight (in kilograms) divided by the height (in meters) squared. Percent body fat was measured using an Omron handheld Bioelectrical Impedance Analysis

(BIA). Waist circumference was measured at the umbilical region of participants (using a standard measuring tape) by a trained laboratory staff member.

Physiological Measures

Blood pressure was measured at all four time points (baseline, week 4, week 8 and 4-month follow-up). It was assessed twice in the sitting position after a 10 minute resting period, and the average of the two measures was determined. Fasting blood draws were assessed at baseline, week 8, and after the 4-month follow-up assessment. At each of the three time points, venous blood was drawn from the antecubital vein after a 10-hour overnight fast. Approximately 30 ml blood samples were drawn by a phlebotomist from the antecubital vein and were and sent to a clinical laboratory for assessment, which included total cholesterol, high density lipoprotein cholesterol (HDL), triglycerides, and blood glucose. Low density lipoprotein (LDL) was calculated using the Friedewald equation (Friedewald et al, 1972).

Risk factors were evaluated using standards established in the Third Report of the National Cholesterol Education Program Expert Panel on Detects, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III) (2001). The specific values used to classify individual CVD risk factors were as follows: elevated blood pressure levels (systolic $\geq$ 130 mmHg and/or diastolic $\geq$ 85 mmHg), elevated triglycerides ($\geq$ 150 mg/dl) low HDL cholesterol (< 40 mg/dl in men and < 50 mg/dl in women), elevated fasting plasma glucose levels ($\geq$ 110 mg/dl), and elevated abdominal adiposity (waist circumference $\geq$ 102 cm in men and $\geq$ 88 cm in women). Metabolic syndrome was defined as an elevated risk in 3 or more of the above risk factors.

Process Measures

Participants were evaluated each week to measure their progress throughout the intervention period. Each health coach rated the participants using a general rating system. Individuals were given a score from 0-2 based on attendance, motivation, and willingness to make lifestyle changes (0= did not attend meeting, no motivation and/or no effort to make lifestyle changes). This health coach rating (HCR) was used to evaluate compliance.

Statistical Analysis

The primary goal of the study was to determine the relative effectiveness of the BonSanté guided weight loss program, the use of the SenseWear Pro monitor and WMS program, and the combined use of BonSanté with the SenseWear monitor and WMS. Group differences for changes in weight, BMI, percent body fat, waist circumference and various cardiovascular disease risk factors (Total cholesterol, HDL and LDL cholesterol, triglycerides, blood pressure and fasting blood glucose) were assessed using a series of two-way (Group x Time) analyses of variance (ANOVA). Significant main effects for Group were located with post hoc comparisons to examine the differences among the three groups. The Time effects would show changes in outcomes over time while the interaction terms would determine if the changes over time varied across groups.

A secondary aim of the study was to examine whether changes in cardiovascular disease risk factors occurred independently of changes in weight. To evaluate this, individual changes in weight were correlated with changes in clinical risk factors. These analyses used a continuous metabolic syndrome score (MetS) that was computed by

examining the relative changes in metabolic syndrome risk scores across the 8 week intervention (Eisenmann, 2008). Correlations were computed between the change in weight and the change in MetS. Analyses were conducted using individuals who completed the 8-week program. Significance was defined as a *p* value of < 0.05. Data analyses were completed using Statistical Analysis Software (SAS) version9.1.

Results

Descriptive statistics (means $\pm$ SD) for the 78 subjects included in the data analysis are provided in Table 1. A majority of the participants were well educated (69% with $\geq$ 4-year degree) and the distribution of race was representative of the community where participants were recruited. All participants were considered obese (BMI $\geq$ 30 kg/m^2) at baseline and 25% of participants (13 male, 6 female) were considered to have metabolic syndrome based on established definitions from the NCEP ATP III (2001) definition.

Participants were guided through the weight loss programming in two separate cohorts (one in the fall and one in the spring). A preliminary 3-way ANOVA (Cohort x Group x Gender) was conducted to test if there were significant cohort effects. There was a significant difference in weight loss between the two cohorts ($p = .044$) with larger amounts of weight loss observed in cohort 2 (5.00 kg) compared with cohort 1 (3.41 kg). There were no significant two way or three way interactions with cohort which suggests that the intervention operated similarly, but with larger average outcomes in the spring cohort. The remaining analyses were conducted using 2 way ANOVAs (group x gender) to streamline the reporting of the findings. The overall trial effects are shown in Table 2.

Significant trial effects were observed for weight ($p < 0.0001$), BMI ($p < 0.0001$), percent body fat ($p = 0.0008$), waist circumference ($p < 0.0001$), diastolic blood pressure ($p = 0.0004$), glucose ($p = 0.0001$), total cholesterol ($p = 0.0003$), triglycerides ($p = 0.0001$), and metabolic syndrome ($p<0.0001$). Non-significant differences were found for systolic blood pressure ($p = 0.0953$), HDL cholesterol ($p = 0.0954$), and LDL cholesterol ($p = 0.0760$).

There were no significant ($p > .05$) differences in anthropometric or clinical outcomes across the treatment groups (see Appendix 1 – Table 7 and 9). However, there were general tendencies for larger effects in the group that received the combination of programs. For example, weight loss for Bon + SWA was -4.88 kg ($\pm$ 3.21) while the Bon condition had a weight change of -3.69 kg ($\pm$ 3.14) and the SWA condition reported -4.05 kg ($\pm$ 2.87). Similar results were seen for clinical outcomes as well. For example, change in systolic blood pressure for the Bon + SWA condition was - 4.19 mmHg vs. -2.38 and -0.46 mmHg for the Bon and SWA condition respectively. Changes were also considerably larger in the combined group for diastolic blood pressure (-5.88 mmHg vs. -4.66 and -2.85), total cholesterol (-11.81 mg/dl vs. -4.38 and -5.73), glucose (-5.88 mg/dl vs. -0.69 and -2.65), LDL cholesterol (-2.72 mg/dl vs. + 0.18 and -1.61), and triglycerides (-38.15 mg/dl vs. -10.69 and -15.04). While these values are not statistically significant, the degree of these differences may be clinically meaningful. A plot of the change for weight loss difference is shown in Figure 3 and the difference in metabolic syndrome is displayed in Figure 4. Descriptive statistics for Group and Gender differences are reported in Appendix 2 (Table 9).

Lack of statistical significance between conditions may be due to the relatively small sample size in each group ($n = 26$). Therefore, Effect sizes were calculated to provide an

alternative indicator of group and gender differences in anthropometric and clinical outcomes between conditions (Table 3). The effect sizes were low to moderate in magnitude with the largest effects evident for changes in metabolic syndrome (*d* = -0.76 and -0.54 for difference between Bon+SWA and Bon and SWA, respectively), glucose (*d* = -0.70 for difference between Bon+SWA and Bon condition) and triglycerides (*d* = -0.62 and -0.51 for comparisons between Bon+SWA and Bon and SWA, respectively). The effect sizes for group differences were also computed separately by gender and these comparisons revealed some notable gender differences. In general, the effect sizes for differences between the Bon+SWA and Bon conditions were larger in men than women for weight (*d* = -0.48 vs. *d* = -0.02), BMI (*d* = -0.42 vs. *d* = -0.07), and body fat (*d* = -0.93 vs. *d* = 0.16). The group x gender interaction terms were not significant for any of the weight loss differences but these differences suggest some tendency for differential gender effects in weight loss outcomes between conditions. Interestingly, the differences in gender effects on the clinical outcomes were considerably larger for females than males for most of the clinical outcomes (glucose, total cholesterol, LDL cholesterol, triglycerides, and metabolic syndrome). Females had large effect size for differences between the Bon+SWA and Bon conditions for glucose (*d* = -0.76), total cholesterol (*d* = -0.77), LDL cholesterol (*d* = -0.61), triglycerides (*d* = -0.56), and metabolic syndrome (*d* = -0.57). The differences between the Bon + SWA and SWA conditions were also large for glucose (*d* = -0.62), total cholesterol (*d* = -0.92), LDL cholesterol (*d* = -0.58), and triglycerides (*d* = -1.19). These values were considerably larger than the similar comparisons for men suggesting that there were some notable gender differences in effects, despite the lack of statistically significant findings.

The effects from the intervention can be influenced by the degree of involvement and compliance. Process measures and compliance data collected during the intervention were used to examine the impact of these variables on the outcomes. The average health coach rating (HCR) was used as the indicator of overall compliance. At the end of the 8 weeks participants were categorized by their average HCRs (scale of 0 – 2; 0 = did not attend, no motivation or effort to change 2 = excellent attendance, motivation and effort). Participants were categorized into three HCR groups, by tertiles. Participants in HC 1 had an average HCR of < 1.25, HC 2 had an average rating of = 1.25 – 1.75, and HC 3 had an average HCR of > 1.75 over the entire 8 weeks. There were significant changes from baseline reported in all three conditions for weight (HC 1 $p = 0.0003$; HC 2 and HC 3 $p < 0.0001$). A significant mean difference was also reported between HC 3 compared to HC 1 and HC 2 in weight loss (-2.44 and -2.17 kg [$p<0.05$]). There was no difference between HC 1 and HC 2 (Table 4). HCR was also moderately correlated with weight change ($r= -0.37$) and BMI change ($r= -0.40$). Therefore, participants who were more compliant and willing to make lifestyle changes saw the largest decrease in weight loss compared to participants who were less compliant with the intervention.

The second purpose of the study was to determine if changes in risk factors would be seen without changes in weight loss. Correlations were computed among the various anthropometric variables and clinical outcomes (Table 5). The correlations were highly variable but generally low to moderate in magnitude. The largest correlation to weight loss were found for change in triglycerides ($r =0 .43$) and metabolic syndrome risk score ($r =0 .40$). To further examine the effect of weight loss on the changes in risk factors,

participants were divided into 5 arbitrary weight loss groups (Group1: < 1.0 kg; Group 2: -1.01 – 3 kg; Group 3: -3.01 – 5 kg; Group 4: -5.01 – 7 kg; Group 5: > 7 kg). Descriptive statistics for changes in outcomes were calculated for each of the groups and significance is noted in Table 6. Participants in Group 1 showed the least amount of risk factor reduction whereas participants in Group 5 showed the largest amounts of risk reduction. The changes in metabolic syndrome are displayed in Figure 6 to show the general effects but detailed values are reported in Appendix 3. In general, the results indicate that moderate weight reduction (as seen in Groups 2 – 4) yield similar effects in changes in clinical risk factors. Larger reductions in risk were evident in people with larger weight loss but little or no changes were evident in participants who gained weight or lost < 1.00 kg.

Discussion

The study examined the independent and interactive outcomes of a guided weight loss program and the use of a technological self-monitoring device on weight loss. No significant differences were found in weight loss and clinical outcomes across treatment groups, but significant changes occurred over the intervention period for the guided weight loss, self-monitoring, and interactive conditions. Overall weight loss was 9.24 lbs. (4.21 kg) over the 8 weeks. This change in weight was within the recommended guidelines of healthy, gradual weight loss of 1-2 lbs/week.

These results were similar to other guided weight loss intervention programs. For example, a 3-month internet weight loss intervention using MI through email showed a moderate weight loss in men (-4.8 kg) and a decrease in waist circumference by 5.2 cm

(Morgan et al, 2009). In another intervention of the same duration, participants with an individualized program based on their resting metabolic rate had similar weight loss outcomes (-4.2 kg) as participants in a usual care intervention (-4.7kg) (McDoniel et al, 2009). Carels et al (2005) evaluated a longer (6-month) group behavioral weight loss intervention and reported an average weight change of -7.6 kg. Carels and colleagues (2005) found that participants who recorded more daily logs had an increase in weight loss, amount of exercise/week, and lower perceived difficulties with exercise. This is similar to findings in the present study that showed larger effects in participants that were more compliant with the health coaching. Carels et al. (2007) also evaluated the effectiveness of weight loss programming with and without MI components. The authors reported larger weight loss in groups who received MI (4.5 kg) than those that did not receive MI (2.1 kg). This study indicated that MI is an important component of behavioral weight loss interventions. Most published weight loss studies have been conducted over longer periods of time so the average weight loss of 4.2 kg in the present 8- week study is noteworthy.

Previous research suggested that the combination of self-monitoring and MI can enhance the effectiveness of weight loss programming (Carels, 2005). Therefore, it was hypothesized that the combination of treatments would yield the largest effects in the study. While the difference in conditions were not significant, there was a tendency for men in the combined (Bon + SWA) condition to show a greater reduction in weight loss compared to the independent use of either component alone. Despite lack of statistical significance this increased reduction could be clinically meaningful and implies that the

combined effect is greater than the individual use of either constituent. The collective utilization of these strategies may provide a new, innovative way to promote healthy behavior change.

Polzien and colleagues (2007) reported similar findings in a study designed to evaluate the additive effects of continuous and intermittent use of the SWA monitor when combined with a behavioral weight loss program. Over the 12-week intervention significant differences between baseline and final measures were reported, but no treatment effect was detected. Similar to the present study, the authors noted a larger reduction in weight with continuous SWA treatment combined with the guided weight loss program despite lack of statistical significance. The Polzien guided weight loss program included 7 in-person meetings over the 12-week period (compared to 8 meetings over an 8 week interval for the present study). The similar results suggest that continuous meetings with a health professional may not be necessary to enhance the efficacy of behavioral based programs. Finally, the continuous use of the SWA was more beneficial than intermittent use throughout the 12-weeks. However, the independent effects of the use of the SWA were not evaluated.

A similar study at the University of South Carolina also yielded comparable results (Personal Communication, Dr. Steven Blair). In this 9-month study, participants were randomized into 4 treatments: standard care with self-directed weight loss, a group-based behavioral weight loss program using MI sessions (comparable to individual MI sessions in the present study), the use of SWA only, and a combination of the group behavioral program and the SWA (Barry et al, 2010). Preliminary results showed that the participants

who had the combination of the SWA and a behavioral weight loss program lost three times more weight than those who only received standard care after 4-months; average weight loss was approximately 7.5 lbs. over the 4-month intervention for the combined condition (Sui et al, 2010). In our study participants lost an average of 9.2 lbs. (4.2 kg) in the combined Bon and SWA/WMS condition over an 8-week intervention period. This suggests that individual behavioral sessions may be more beneficial at promoting weight loss than group based sessions.

Some studies have used a simpler form of self-monitoring devices (i.e. pedometers) to promote weight loss. LeCheminant and colleagues (2011) used a guided weight loss program with weekly meetings for three months in conjunction with pedometers and daily diet and activity records to promote weight loss in a university program. Participants lost an average of 0.4 – 2.1 lbs/week and maintained the weight loss 3 months after the program ceased. There was no comparison to a standard behavioral weight loss program only. However, implications for this study may allow a more practical purpose since pedometers are fairly inexpensive and easy to access for the general community and may produce similar weight loss to those who used the SWA for self-monitoring in the current study.

The secondary purpose of the current study was to evaluate whether clinical outcomes are dependent on weight loss. Clinically significant weight loss is defined as weight loss that improves known obesity-related complications. This may be hard to quantify without numerous tests. An accepted standard definition of clinically significant weight loss is said to be $\geq$ 5% of initial body weight (Stevens et al, 2006). In the current

study, participants had an average weight loss of -3.8% of their initial weight (with the largest percentage seen in the Bon + SWA condition of -4.2% compared to -3.6% for both Bon and SWA conditions). This weight loss is close to clinically significant as defined by Stevens and colleagues (2006), but experts now typically recommend evaluating risk factor reduction rather than solely weight loss.

In the present study, there were relationships between change in weight and change in risk factors. In general, participants who lost the most weight saw the most reduction in clinical risk factors. However, it is difficult to determine the specific contributions of weight loss to change in these risk factors. All participants saw reduction of at least one clinical outcome regardless of whether they lost weight or not. Surprisingly, the largest declines in LDL cholesterol were found in those that gained weight or lost $\leq$ 1 kg. Most interesting is that participants in all three conditions and all 5 weight loss categories had large reduction in waist circumference. Ross et al (2000) reported that exercise reduced waist circumference and visceral fat independent of weight loss. Data on visceral fat loss was not available in this study but the changes in waist circumference may reflect changes in abdominal obesity. There is considerable research demonstrating that excess fat in the abdomen region is a stronger predictor of CVD and type 2 diabetes than obesity alone (Després and Lemieux, 2006; Berentzen et al, 2010). Thus, it is clearly possible for metabolic risks to change independent of weight loss. The present study demonstrated that changes in risk factors are related to change in weight; however, this does not discount the possibility that risk factor changes can also occur independently. The design of the study makes it difficult to draw definitive conclusions about this issue.

There were recognized limitations in this study. Generalizability is limited to the people represented within our participants. This type of intervention may not be effective for certain populations; for example, it may be necessary for participants to be literate and have internet access or a general fluency with technology. Also, physical activity and food records were not assessed prior to study initiation. Thus, there was no way to identify baseline behaviors prior to the start of the intervention. It is noted that the use of students as health coaches could be seen as a limitation since they are not trained health professionals. However, all student health coaches were trained by the registered dietitian that developed the program. Student health coaches had also taken a nutrition counseling class through the university and met weekly with a separate RD and other research staff to discuss issues and experiences with health coaching. Detailed exit interviews of the participants by an independent member of the research staff indicated very favorable reports on the quality of coaching from the students.

Finally, the length of 8-weeks for an intervention program may not be sufficient time to acquire and maintain behavior change. Most studied weight loss interventions typically are $\geq$ 12-weeks. Few studies have evaluated a shorter program. An 8-week program was evaluated to provide evidence to support the idea that 2 months would be a sufficient amount of time to facilitate behavior change. In a population of overweight and obese low-income mothers, an 8-week intervention using pedometers and weekly lessons for health recommendations (Clarke, 2007) resulted in an increase in the number of steps/day to 9,757 (close to the recommended 10,000/day) and an increase in exercise self-efficacy similar to those of a healthy-weight status. Four months post-intervention,

the participants were evaluated again and furthered their weight loss by an average of -6.9 lbs. This supports that 8-weeks is an adequate time period to acquire and maintain healthy behavioral changes.

In summary, this was one of the first studies to assess the efficacy of a technological self-monitoring device when used independently and combined with a guided weight loss program over 8-weeks. Significant weight reductions were seen for all treatment conditions. The study was not able to detect statistical differences between groups but larger effects were consistently observed for men in the group who received both components of the intervention. The study resulted in significant changes in clinical risk factors and these changes were associated to some degree with the degree of weight loss. It is possible that some changes in risk factors may have resulted independently of weight or fat loss but the lack of detailed behavioral data (i.e. diet and physical activity logs) prevented a full evaluation of these changes.

The results of this study show that use of a technological self-monitoring device can lead to weight loss and changes in risk factors that are equivalent to that obtained through guided health coaching. A key issue in weight loss studies is to evaluate the maintenance of weight loss over time. Follow-up analyses of this sample will provide insights about the impact of these intervention approaches on maintenance of effects.

Future research is needed to determine the optimal intervention length, modality and frequency of MI sessions. Research may also help to determine if certain individuals respond better to a specific type of treatment approach.

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Table 1. Descriptive Characteristics of Participants at Baseline

			Treatment Group		
Characteristic		All (N = 78)	Bon (*n* = 26)	SWA (*n* = 26)	Bon + SWA (*n*= 26)
Gender (*n* [%])					
	Male	31 [39.7%]	3 [11.5%]	13 [50%]	15 [57.7%]
	Female	47 [60.3%]	23 [88.5%]	13 [50%]	11 [42.3%]
Age (yrs)		38.6 ± 14.0	38.5 ± 14.4	33.6 ± 14.5	38.1 ± 12.9
	Range	18 - 72	19 - 65	18 - 72	19 - 67
Race (*n*[%])					
	White	74 [94.9%]	25 [96.2%]	25 [96.2%]	24 [92.3%]
	Black	3 [3.9%]	1 [3.8%]	1 [3.8%]	1 [3.8%]
	Asian	1 [1.2%]	0 [0%]	0 [0%]	1 [3.8%]
Height (cm)					
	Male	181.0 ± 5.9	176.4 ± 5.0	181.9 ± 5.4	181.1 ± 6.4
	Female	166.8 ± 5.7	166.6 ± 5.4	167.9 ± 6.6	165.9 ± 5.7
Weight (kg)					
	Male	121.0 ± 19.3	112.7 ± 7.7	117.1 ± 17.7	125.9 ± 21.6
	Female	102.6 ± 18.2	102.6 ± 16.0	106.7 ± 21.5	97.9 ± 19.0
BMI (kg/m^2)					
	Male	36.7 ± 5.2	36.1 ± 0.9	35.2 ± 4.5	38.2 ± 6.0
	Female	36.7 ± 5.7	36.9 ± 5.6	37.5 ± 5.9	35.4 ± 5.9

All values are means ± standard deviation (SD)
Bon: BonSanté guided weight loss condition
SWA: SenseWear Armband only condition
Bon + SWA: Combination BonSanté and SWA condition

Table 2. Changes in Anthropometric and Clinical Outcomes

	Baseline	8 – week	Change	p
Weight (kg)	109.9 ± 20.6	105.7 ± 20.0	-4.2 ± 3.1	< 0.0001
BMI (kg/m^2)	36.7 ± 5.5	35.3 ± 5.5	-1.4 ± 1.0	< 0.0001
Body Fat (%)	38.1 ± 6.5	37.3 ± 6.4	-0.8 ± 2.0	0.0008
Waist Circumference (cm)	120.1 ± 13.8	115.8 ± 14.0	-4.3 ± 3.6	< 0.0001
Systolic BP (mmHg)	116.6 ± 12.1	114.3 ± 11.1	-2.4 ± 9.7	0.0953
Diastolic BP (mmHg)	76.3 ± 7.6	71.8 ± 8.6	-4.5 ± 8.6	0.0004
Glucose (mg/dl)	93.7 ± 8.2	90.5 ± 7.4	-3.1 ± 7.1	0.0003
Total Cho (mg/dl)	191.2 ± 32.5	183.9 ± 36.3	-7.3 ± 20.3	0.0003
HDL Cho (mg/dl)	48.7 ± 13.6	47.1 ± 11.9	-1.7 ± 5.7	0.0954
LDL Cho (mg/dl)	110.2 ± 28.9	108.8 ± 29.8	-1.4 ± 17.7	0.076
Triglyceride (mg/dl)	161.2 ± 75.3	139.9 ± 75.4	-21.3 ± 42.9	0.0001

All values are means ± standard deviation

Table 3. Effect Size by Condition and Gender

		Male	Female	Total
Weight Change				
	Bon+SWA vs Bon	-0.48	-0.04	-0.37
	Bon+SWA vs SWA	-0.50	0.02	-0.27
Waist Change				
	Bon+SWA vs Bon	0.22	-0.21	-0.17
	Bon+SWA vs SWA	0.16	0.27	0.24
BMI Change				
	Bon+SWA vs Bon	-0.42	-0.07	-0.28
	Bon+SWA vs SWA	-0.50	-0.04	-0.28
% Body Fat				
	Bon+SWA vs Bon	-0.93	0.16	-0.05
	Bon+SWA vs SWA	-0.51	0.23	0.00
Systolic BP				
	Bon+SWA vs Bon	-0.33	0.07	-0.21
	Bon+SWA vs SWA	-0.74	0.01	-0.38
Diastolic BP				
	Bon+SWA vs Bon	-0.25	0.15	-0.14
	Bon+SWA vs SWA	-0.85	0.18	-0.36
Glucose				
	Bon+SWA vs Bon	-0.27	-0.76	-0.70
	Bon+SWA vs SWA	-0.31	-0.62	-0.43
Total Cho				
	Bon+SWA vs Bon	0.76	-0.77	-0.35
	Bon+SWA vs SWA	0.08	-0.92	-0.35
HDL Cho				
	Bon+SWA vs Bon	-0.1	-0.09	0.17
	Bon+SWA vs SWA	0.14	-0.21	-0.05
LDL Cho				
	Bon+SWA vs Bon	1.09	-0.61	-0.15
	Bon+SWA vs SWA	0.4	-0.58	-0.07
Triglycerides				
	Bon+SWA vs Bon	-0.27	-0.56	-0.62
	Bon+SWA vs SWA	-0.5	-1.19	-0.51
MetSyndrome				
	Bon+SWA vs. Bon	-0.33	-0.57	-0.76
	Bon+SWA vs. SWA	-0.80	-0.20	-0.54

Table 4. Mean Difference for Weight change by Health Coach Ratings

	Mean difference	95% confidence interval
HC 2 - HC 1	0.26	(-1.78 - 2.31)
HC 2 - HC 3	2.44	(0.73 - 4.15)*
HC 1 - HC 2	-0.26	(-2.31 - 1.78)
HC 1 - HC 3	2.17	(0.08 - 4.26)*
HC 3 - HC 2	-2.44	(-4.15 - -0.73)*
HC 3 - HC 1	-2.17	(-4.26 - -0.08)*

* $p < 0.05$. HC 1: HCR < 1.25; HC 2: HCR= 1.25 – 1.75; HC 3: HCR of > 1.75

Table 5. Correlation Coefficients for Risk Factors

	Waist Diff	BMI Diff	BodyFat Diff	Systolic Diff	Diastolic Diff	Glucose Diff	TG Diff	Chol Diff	HDL Difference	LDL Difference	MetS Diff
Weight Difference	0.41	0.98	0.43	0.30	0.20	0.19	0.43	0.21	0.08	0.10	0.40
Waist Difference		0.40	0.06	0.02	-0.03	0.04	0.29	0.15	0.09	0.01	0.23
BMI Difference			0.45	0.30	0.21	0.19	0.42	0.19	0.10	-0.02	0.40
BodyFat Difference				0.29	0.17	-0.17	0.21	-0.02	-0.14	-0.08	0.15
Systolic Difference					0.66	0.16	0.18	0.03	-0.14	-0.01	0.63
Diastolic Difference						0.11	0.16	-0.03	-0.17	-0.05	-0.66
Glucose Difference							0.26	0.16	-0.06	0.08	0.65
TG Difference								0.28	-0.21	-0.10	0.62
Chol Difference									0.38	0.89	0.09
HDL Difference										0.21	-0.40
LDL Difference											0.06

Table 6. Change in Measurements by Weight Loss Group

	Weight Group				
	1 (n=9)	2 (n=23)	3 (n=20)	4 (n=11)	5 (n=15)
Weight (kg)	0.3 ± 1.1	-2.0 + 0.6	-4.2 ± 0.7	-6.1 ± 0.7	-9.0 ± 1.3
Waist Circumference (cm)	-2.1 ± 2.5	-3.5 ± 3.5**	-3.4 ± 3.9**	-6.6 ± 2.2**	-6.1 ± 2.8**
BMI (kg/m^2)	0.1 ± -0.5	-0.7 ± 0.3**	-1.4 ± 0.3**	-2.0 ± 0.3**	-2.9 ± 0.6**
Bodyfat (%)	1.1 ± 3.7	-0.4 ± 0.8*	-1.0 ± 0.8**	-1.6 ± 3.4	-1.8 ± 1.0**
Systolic (mmHg)	1.7 ± 11.4	-0.1 ± 8.9	-3.3 ± 8.3	-1.8 ± 10.7	-7.3 ± 9.8*
Diastolic (mmHg)	-1.1 ± 5.8	-3.5 ± 10.8	-4.9 ± 7.3**	-5.2 ± 8.8	-6.8 ± 7.8**
Glucose (mg/dL)	-2.1 ± 6.3	-1.4 ± 7.4	-4.1 ± 6.3**	-4.8 ± 9.1	-3.7 ± 6.6*
Triglyceride (mg/dL)	-8.7 ± 25.02	-3.4 ± 32.0	-14.1 ± 28.3*	-42.6 ± 51.2*	-50.3 ± 57.0**
Chol (mg/dL)	-16.7 ± 21.3*	1.4 ± 15.8	-3.6 ± 13.9	-8.4 ± 15.7	-19.2 ± 28.8*
HDL (mg/dL)	-1.8 ± 6.6	-1.1 ± 5.6	-2.0 ± 6.0	0.6 ± 4.6	-3.7 ± 5.8
LDL (mg/dL)	-13.2 ± 17.3	3.2 ± 12.1	1.3 ± 13.3	-0.5 ± 16.7	-5.5 ± 27.2
MetSyndrome	-0.4 ± 0.9	-0.7 + 1.7	-1.3 ± 1.5	-2.2 ± 2.4	-2.2 ± 2.0

*p<0.05; ** p<0.01 Values are percent change from baseline measures.
Weight group 1: participants who lost ≤ 1kg; Weight Group 2: participants who lost 1.01 – 3kg; Weight group 3: participants who lost 3.01 – 5kg;Weight group 4: participants who lost 5.0 1 – 7kg; Weight group 5: participants who lost >7kg over 8 weeks

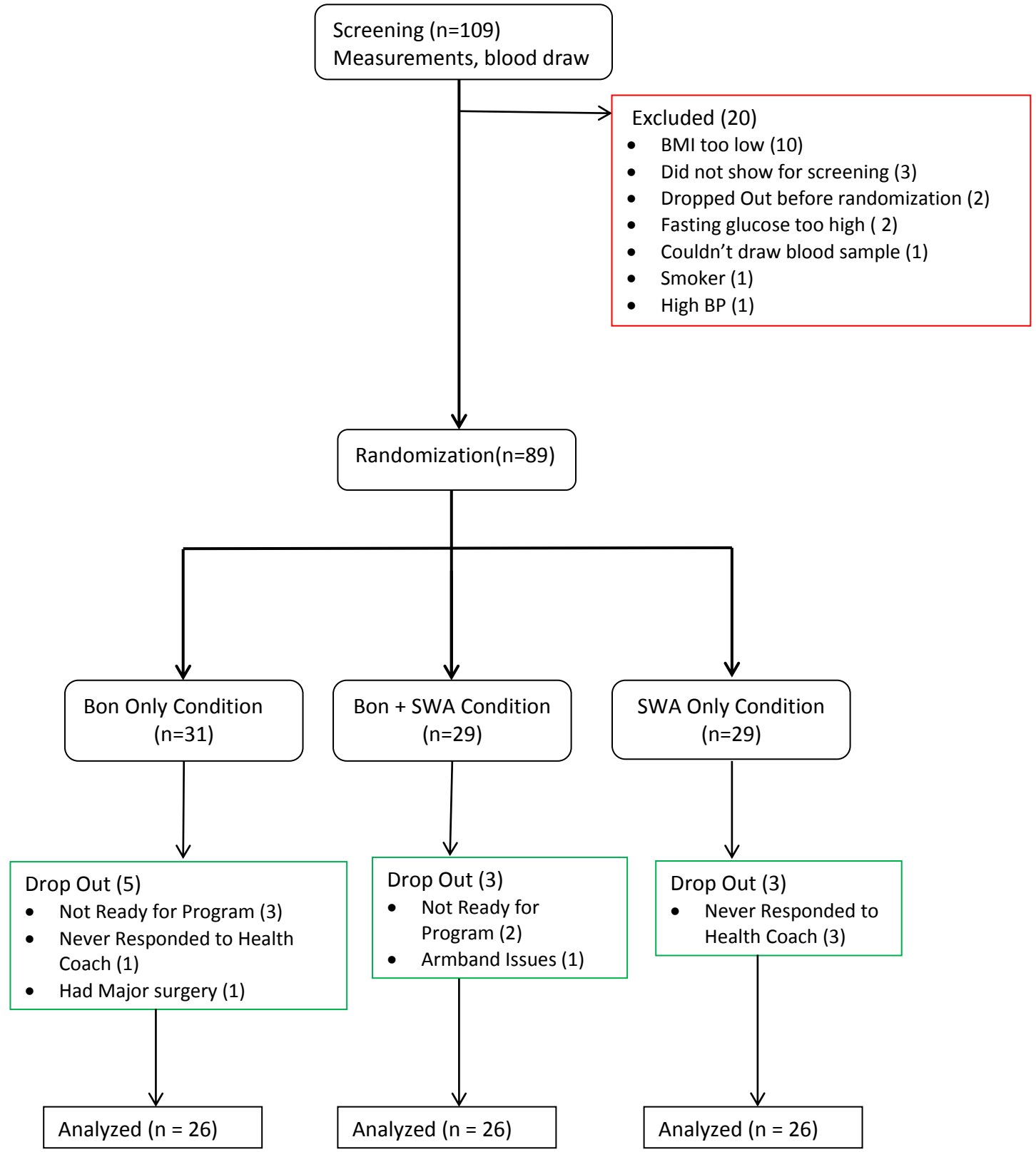

Figure 1. Participants Flow from Screening to Randomization

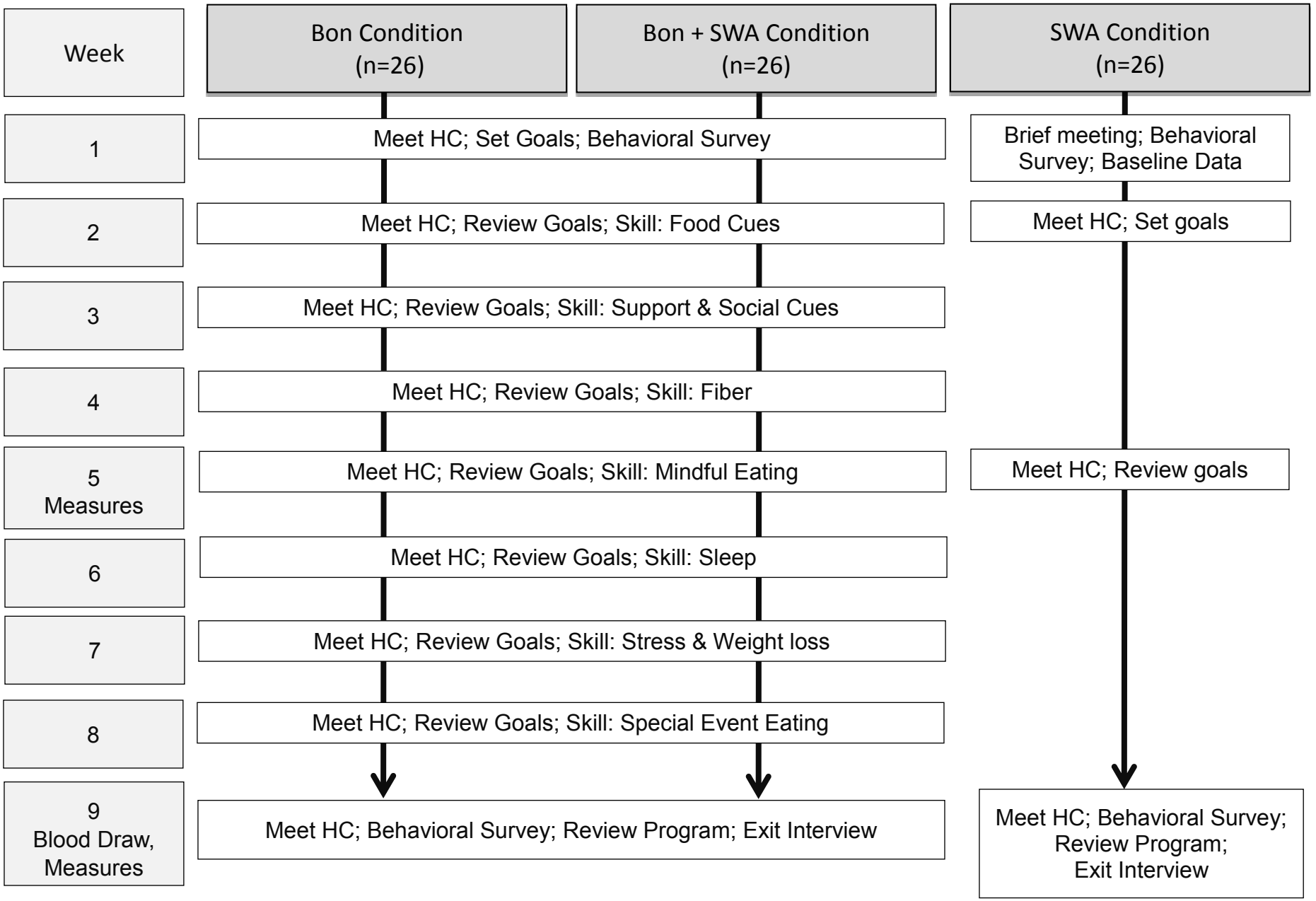

Figure 2. Weekly Breakdown of Intervention Methods
HC: Health Coach; Bon: BonSanté; SWA: SenseWear Armband

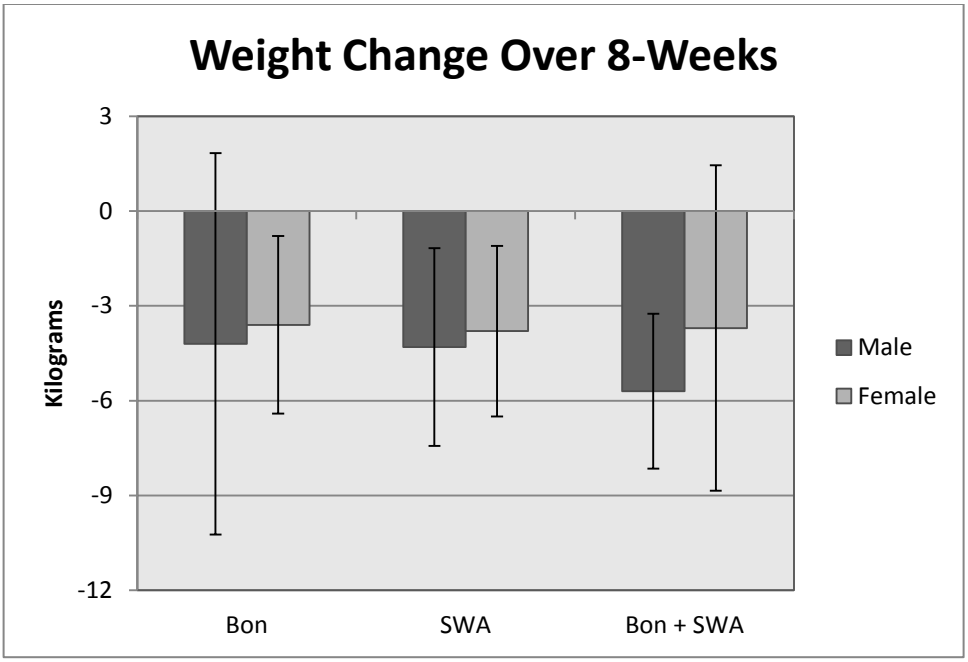

Figure 3. Changes in Weight by Condition. Mean weight change (± SD) from baseline to 8-weeks between the BonSanté guided weight loss condition (Bon), the SenseWear Armband condition (SWA), and the combined condition (Bon + SWA). Values are weight in kilograms (kg).

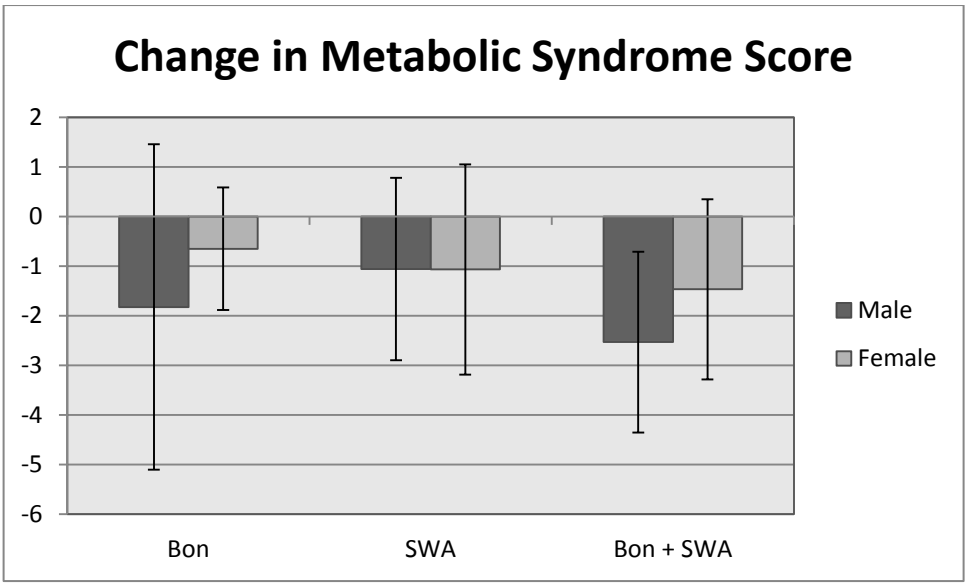

Figure 4. Change in Metabolic Syndrome by Condition and Gender. Mean metabolic syndrome change (± SD) from baseline to 8-weeks between the BonSanté guided weight loss condition (Bon), the SenseWear Armband condition (SWA), and the combined condition

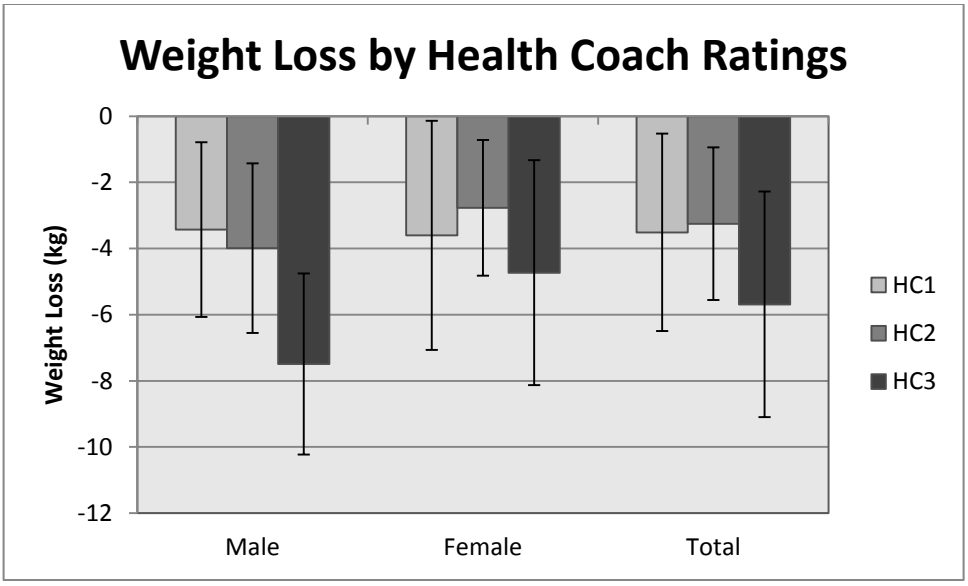

Figure 5. Change in Weight by Health Coach Rating by Gender. Health coach (HC) ratings were averaged each week based on participant level of motivation, willingness to change, and attendance/responsiveness. Participants in HC group 1 had the lowest ratings. Values are change from baseline

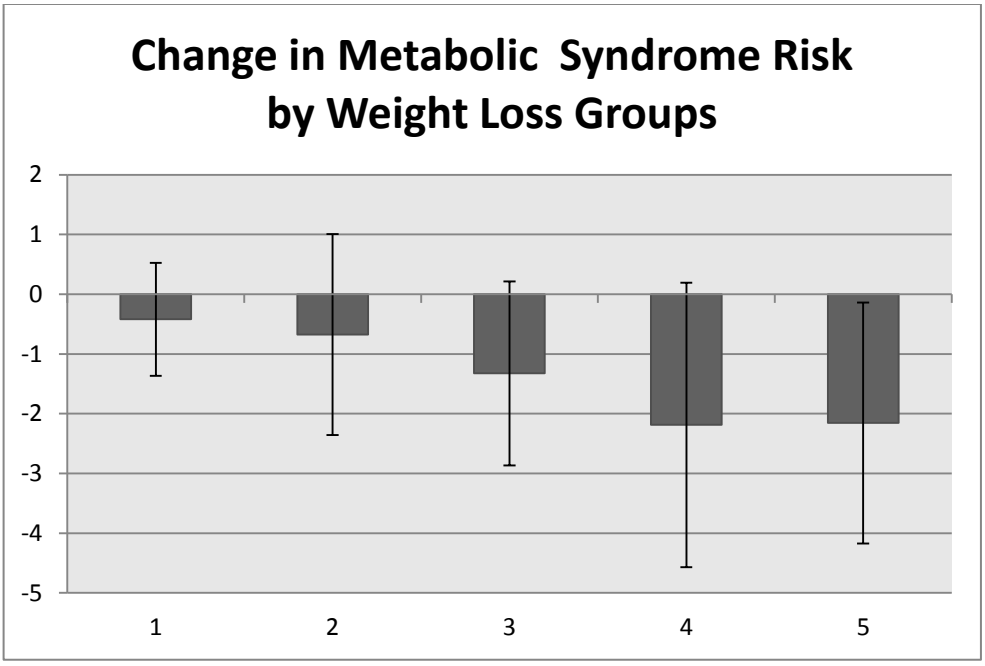

Figure 6. Change in Metabolic Syndrome Risk by Weight Loss Groups. Change in continuous Metabolic Syndrome score (± SD) (Eisenmann, 2008) from baseline to week 8. Group 1: participants who lost ≤ 1kg; Group 2: participants who lost 1.01 – 3kg; Group 3: participants who lost 3.01 – 5kg; Group 4: participants who lost 5.01 – 7kg; Group 5: participants who lost >7kg

CHAPTER 4. GENERAL CONCLUSIONS

Numerous techniques for weight loss have been studied and tested in the recent years, but there is no general consensus on the most beneficial technique. Self-monitoring devices have been shown to increase weight loss and physical activity. Technological self-monitoring devices (such as the SenseWear Armband) can give detailed feedback on energy expenditure, use of an integrative software for energy intake, and consequently energy balance. There is very limited research on whether the use of self-monitoring devices is enough to promote weight loss or if it is needed in conjunction with a guided weight loss program.

In this study, there was no significant difference in weight loss between participants who only received a guided weight loss program, those who only received the SWA, and a combination of the guided weight loss program and the SWA. This suggests (and reinforces previous evidence) that the use of a self-monitoring device alone is beneficial for moderate weight loss over 8-weeks; however, these results may possibly be enhanced when combined with a guided behavioral weight loss program.

APPENDIX 1. CHANGES BY CONDITION

Table 7. Changes in Anthropometric and Blood Pressure Variables by Condition

Treatment	Baseline	8 - Week	Change	P
Weight (kg)				
Bon (*n* = 26)	103.8 ± 15.5	100.1 ± 15.3	- 3.7 ± 3.1	<0.0001
SWA (*n* = 26)	111.9 ± 20.0	107.8 ± 19.3	- 4.1 ± 2.9	<0.0001
Bon + SWA (*n* = 26)	114.1 ± 24.6	109.2 ± 23.9	- 4.9 ± 3.2	< 0.0001
BMI (kg/m^2)				
Bon	36.8 ± 5.3	35.5 ± 5.5	-1.3 ± 1.1	<0.0001
SWA	36.4 ± 5.3	35.0 ± 5.3	- 1.3 ± 0.9	<0.0001
Bon + SWA	37.0 ± 6.0	35.4 ± 5.9	-1.6 ± 1.1	<0.0001
Body Fat (%)				
Bon	41.1 ± 5.2	40.4 ± 4.8	-0.7 ± 2.3	0.1193
SWA	37.0 ± 7.0	36.2 ± 7.0	-0.9 ± 0.9	< 0.0001
Bon + SWA	36.2 ± 6.4	35.4 ± 6.3	-0.9 ± 2.6	0.1025
Waist Circumference (cm)				
Bon	119.9 ± 13.9	116.3 ± 13.8	- 3.6 ± 3.8	< 0.0001
SWA	120.6 ± 13.0	115.5 ± 14.0	- 5.0 ± 3.4	< 0.0001
Bon + SWA	119.8 ± 14.9	115.6 ± 14.8	- 4.2 ± 3.5	< 0.0001
Systolic BP (mmHg)				
Bon	114.5 ± 12.3	112.1 ± 11.2	- 2.4 ± 9.3	0.2042
SWA	116.5 ± 11.8	116.0 ± 12.9	-0.5 ± 11.8	0.8431
Bon + SWA	118.9 ± 12.2	114.7 ± 9.0	- 4.2 ± 7.5	0.0083
Diastolic BP (mmHg)				
Bon	75.7 ± 7.6	71.0 ± 10.1	- 4.7± 8.9	0.0131
SWA	76.3 ± 6.8	73.4 ± 8.6	- 2.9 ± 8.8	0.1132
Bon + SWA	76.9 ± 8.6	71.0 ± 7.0	- 5.9 ± 8.2	0.0011

Values are means ± standard deviation

Table 8. Change in Clinical Metabolic Risk Variables by Condition

	Treatment	Baseline	8 – week	Change	p
Glucose (mg/dl)					
	Bon (*n* = 26)	92.5 ± 9.5	91.8 ± 7.1	-0.7 ± 6.7	0.6031
	SWA (*n* = 26)	92.0 ± 7.2	89.3 ± 7.4	-2.7 ± 6.7	0.0528
	Bon + SWA (*n* = 26)	96.9 ± 7.0	91.0 ± 7.6	-5.9 ± 8.2	0.0003
Total Cho (mg/dl)					
	Bon	193.2 ± 32.0	188.8 ± 38.6	-4.4 ± 25.2	0.3831
	SWA	192.0 ± 33.9	186.2 ± 39.8	-5.7 ± 17.7	0.1116
	Bon + SWA	188.5 ± 32.6	176.7 ± 30.1	-11.8 ± 17.1	0.0017
HDL Cho (mg/dl)					
	Bon	50.0 ± 10.1	47.6 ± 9.6	-2.4 ± 4.7	0.0151
	SWA	48.0 ± 14.8	46.9 ± 13.5	-1.1 ± 5.7	0.3310
	Bon + SWA	48.1 ± 15.8	46.7 ± 12.8	-1.5 ± 6.7	0.2779
LDL Cho (mg/dl)					
	Bon	111.4 ± 30.2	111.6 ± 30.2	0.2 ± 21.5	0.9669
	SWA	112.7 ± 30.3	111.1 ± 33.3	-1.6 ± 15.9	0.6109
	Bon + SWA	106.5 ± 26.9	103.8 ± 25.7	-2.7 ± 15.8	0.3880
Triglyceride (mg/dl)					
	Bon	158.5 ± 69.9	147.9 ± 75.5	-10.7 ± 33.4	0.1148
	SWA	156.0 ± 74.6	140.9 ± 78.6	-15.0 ± 36.1	0.0435
	Bon + SWA	169.2 ± 7.0	131.0 ± 74.1	-38.2 ± 53.0	0.0011

Values are means ± standard deviation

APPENDIX 2. CHANGES BY GENDER

Table 9. Gender differences in change by condition over 8 - weeks

Characteristic		Treatment Group: Bon (M=3, F=13)	SWA (M=13, F =13)	Bon + SWA (M=15, F=11)	Total (M=31, F=37)
Weight (kg)					
	Male	-4.2 ± 6.0	-4.3 ± 3.1	-5.7 ± 2.5	-5.0 ± 3.1
	Female	-3.6 ± 2.8	-3.8 ± 2.7	-3.8 ± 3.9	-3.7 ± 3.0
BMI (kg/m^2)					
	Male	-1.3 ± 2.0	-1.3± 0.9	-1.7 ± 0.8	-1.5 ± 1.0
	Female	-1.3 ± 1.0	-1.3 ± 0.9	-1.4 ± 1.4	-1.3 ± 1.0
% Body Fat					
	Male	-0.6 ± 1.0	-0.8 ± 1.1	-1.3 ± 0.7	-1.0 ± 0.9
	Female	-0.8 ± 2.5	-0.9 ± 0.6	-0.3 ± 3.9	-0.7 ± 2.5
Waist Circumference (cm)					
	Male	-4.5 ± 2.4	-4.5 ± 2.6	-4.1 ± 1.8	-4.3 ± 2.2
	Female	-3.5 ± 4.0	-5.6 ± 4.0	-4.4 ± 5.2	-4.3 ± 4.3
Systolic BP (mmHg)					
	Male	-2.7 ± 21.6	1.0 ± 11.7	-5.9 ± 6.6	-2.7 ± 10.8
	Female	-2.4 ± 7.5	-1.9 ± 12.2	-1.8 ± 8.2	-2.1 ± 9.0
Diastolic BP (mmHg)					
	Male	-5.3 ± 13.6	-0.8 ± 7.3	-7.7 ± 8.8	-4.6 ± 9.0
	Female	-4.6 ± 8.5	-4.9 ± 10.0	-3.4 ± 6.7	-4.4 ± 8.4
Glucose (mg/dl)					
	Male	-4.3 ± 5.8	-4.0 ± 7.0	-6.3 ± 7.5	-5.1 ± 7.0
	Female	-0.2 ± 6.8	-1.3 ± 6.3	-5.4 ± 6.9	-1.7 ± 6.9
Total Cho (mg/dl)					
	Male	-24.3 ± 50.7	-9.1 ± 21.6	-7.6 ± 13.7	-9.8 ± 9.0
	Female	-1.8 ± 20.6	-2.4 ± 12.8	-17.6 ± 20.1	-5.6 ± 19.5
HDL Cho (mg/dl)					
	Male	0.3 ± 2.1	-0.6 ± 4.0	-0.1 ± 4.1	-0.3 ± 3.8
	Female	-2.8 ± 4.9	-1.6 ± 7.2	-3.4 ± 9.1	-2.6 ± 6.6
LDL Cho (mg/dl)					
	Male	-18.7 ± 39.9	-4.5 ± 16.8	1.4 ± 12.8	-3.0 ± 18.2
	Female	2.6 ± 18.1	1.3 ± 15.0	-8.4 ± 18.2	-0.3 ± 17.52
TG (mg/dl)					
	Male	-29.7 ± 43.7	-19.8 ± 38.9	-44.7 ± 57.3	-32.8 ± 49.1
	Female	-8.2 ± 32.2	-10.3 ± 33.8	-29.2 ± 47.7	-13.7 ± 36.9

Values are means ± standard deviation

BMI: Body Mass Index, BP: Blood Pressure, Cho: Total Cholesterol, HDL Cho: High Density Lipoprotein Cholesterol, LDL Cho: Low Density Lipoprotein Cholesterol, TG: Triglycerides

APPENDIX 3. PERCENTAGE OF CHANGE BY WEIGHT LOSS

Table 10. Percentage of Change from Baseline by Weight Loss Groups

	Weight Group				
	1	2	3	4	5
Weight	0.3%	-3.7%	-3.9%	-5.7%	-7.7%
Waist	-1.6%	-3.1%	-2.9%	-5.7%	-5.1%
BMI	0.4%	-2.0%	-4.0%	-5.7%	-7.7%
Bodyfat	4.4%	-0.93%	-2.8%	-3.7%	-5.0%
Systolic	2.0%	-0.4%	-3.1%	-1.5%	-5.4%
Diastolic	-0.9%	-1.8%	-6.2%	-6.6%	-7.9%
Glucose	-1.8%	-1.5%	-4.8%	-4.4%	-3.6%
TG	-6.5%	-2.9%	-7.9%	-23.2%	-25.5%
Chol	-7.8%	0.2%	-1.6%	-4.1%	-10.1%
HDL	-2.2%	-2.1%	-2.7%	3.4%	-6.3%
LDL	-10.8%	2.8%	2.8%	0.6%	-4.5%

Percent change in outcome measures from baseline to week 8. Group 1: participants who lost $\leq$ 1kg; Group 2: participants who lost 1.01 – 3kg; Group 3: participants who lost 3.01 – 5kg; Group 4: participants who lost 5.01 – 7kg; Group 5: participants who lost >7kg

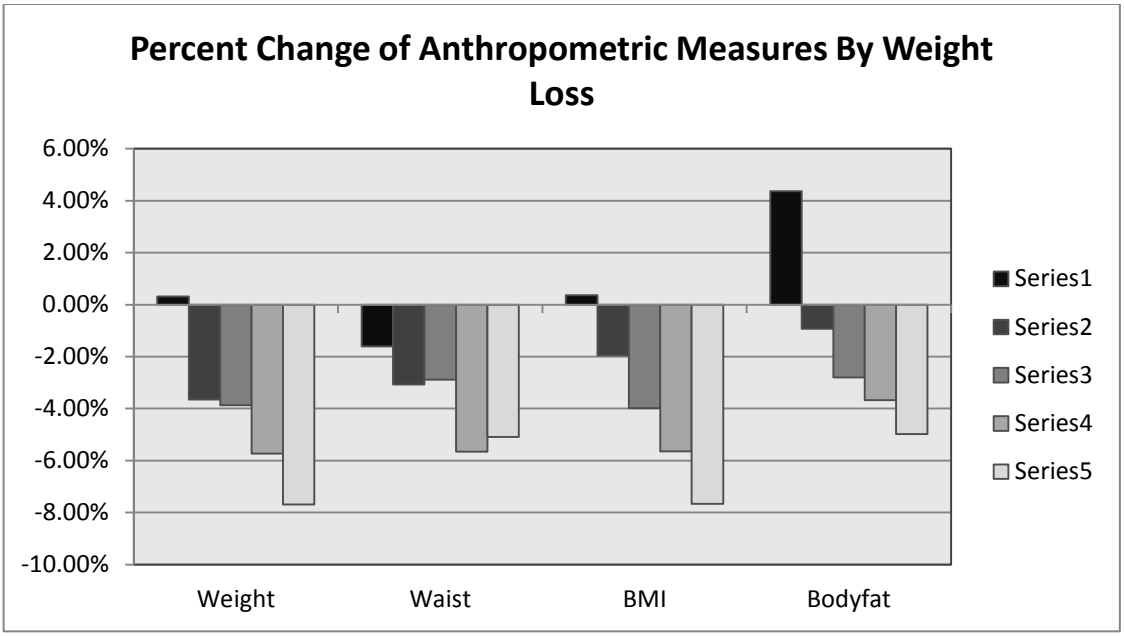

Figure 7a. Values are anthropometric measures where percent change = (end value – baseline value)/baseline. Group 1: participants who lost ≤ 1kg; Group 2: participants who lost 1.01 – 3kg; Group 3: participants who lost 3.01 – 5kg; Group 4: participants who lost 5.01 – 7kg; Group 5: participants who lost >7kg

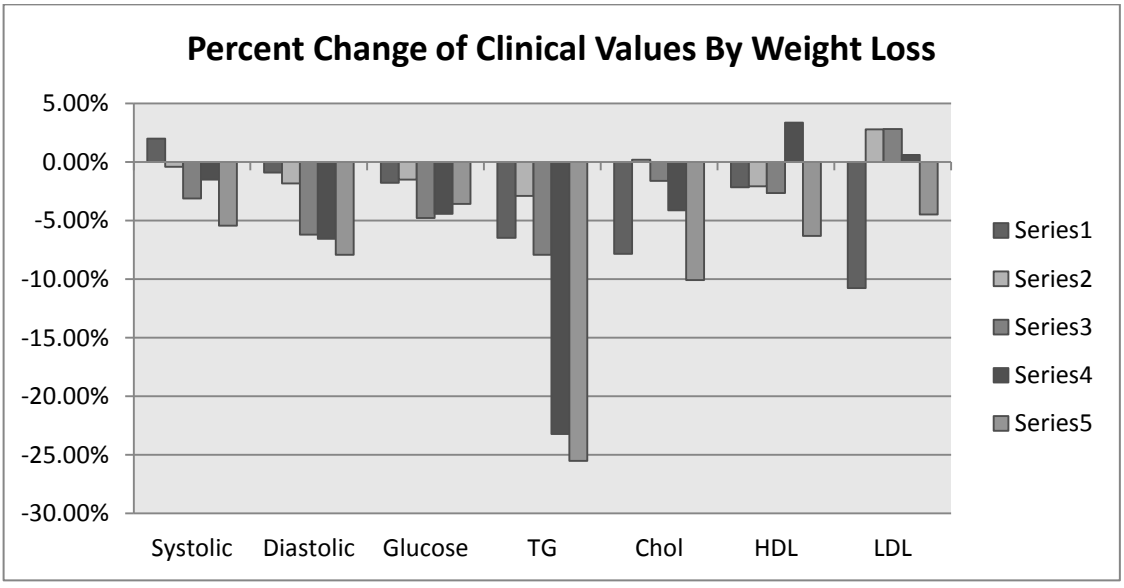

Figure 7b. Values are clinical measures where percent change = (end value – baseline value)/baseline. TG: triglycerides, Chol: total cholesterol; HDL: High density lipoprotein lipase cholesterol; LDL: Low-density lipoprotein lipase cholesterol; Group 1: participants who lost ≤ 1kg; Group 2: participants who lost 1.01 – 3kg; Group 3: participants who lost 3.01 – 5kg; Group 4: participants who lost 5.01 – 7kg; Group 5: participants who lost >7kg

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