# THE COMPARISON OF A TECHNOLOGY-BASED SYSTEM AND AN IN-PERSON BEHAVIORAL WEIGHT LOSS INTERVENTION IN OVERWEIGHT AND OBESE ADULTS


by

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**THE COMPARISON OF A TECHNOLOGY-BASED SYSTEM AND AN IN-PERSON BEHAVIORAL WEIGHT LOSS INTERVENTION IN OVERWEIGHT AND OBESE ADULTS**

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Standard behavioral weight loss programs typically result in a weight reduction of approximately 10%. These programs are generally intensive and therefore it is important to examine alternative methods, which may have the ability to enhance or produce similar outcomes. **PURPOSE:** To compare changes in body weight and physical activity between a technology-based system, an in-person behavioral weight loss intervention, and a combination of both over a 6-month period in overweight and obese adults. **METHODS:** Fifty-one subjects (Age: 44.2±8.7 years, BMI: 33.7±3.6 kg/m$^2$) participated in a 6-month behavioral weight loss program and were randomized to one of three groups: Standard Behavioral Weight Loss (SBWL), SBWL Plus Technology-Based System (SBWL+FIT), or Technology-Based System alone (FIT). SBWL attended weekly group or individual meetings, were prescribed a diet of 1200-1800 kcal/day, and progressed from 100-300 minutes/week of moderate intensity physical activity. SBWL+FIT received the same components as SBWL plus the use of the BodyMedia FIT System that included an armband, display, and website to monitor energy expenditure and caloric intake. FIT was given the BodyMedia FIT System and received monthly telephone calls. Body weight and physical activity were assessed at 0 and 6 months. **RESULTS:** A total of 39 out of 51 subjects completed the 6 month assessments, with significant differences in retention rates between groups (SBWL: 53%, SBWL+FIT: 100%, and FIT: 77%) (p<0.05). Intent-to-treat analysis revealed significant weight losses at 6 months in SBWL+FIT (-8.8±5.0kg, -8.7±4.7%), SBWL (-3.7±5.7kg, -4.1±6.3%), and FIT (-5.8±6.6kg, -6.3±7.1%) ($p<0.001$), with a trend for greater weight loss in SBWL+FIT compared to SBWL ($p=0.09$). Self-report physical activity increased significantly in SBWL (473.9±800.7 kcal/week), SBWL+FIT (713.9±1278.8 kcal/week), and FIT (1066.2±1371 kcal/week) ($p<0.001$), with no differences between groups ($p=0.25$). **DISCUSSION:** The technology-based system used in conjunction with monthly telephone calls, produced similar, if not greater weight losses and changes in physical activity than the standard in-person behavioral program at 6 months. Furthermore, the addition of the technology system enhanced participant retention. Thus the use of this technology may reduce participant attrition as well provide an effective alternative to the standard in-person behavioral weight loss intervention.

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# 1.0 INTRODUCTION

Approximately 68% of adults in the United States (U.S.) are overweight, which is defined as having a body mass index (BMI) between 25-29.9 $kg/m^2$ and over 33% are currently obese (BMI ≥ 30 $kg/m^2$)[1]. Overweight and obesity have been shown to be associated with higher rates of mortality[2] as well as numerous chronic diseases including cardiovascular disease[3-4], diabetes[3, 5-7], hypertension[4, 7], hyperlipidemia[7], and certain cancers[8-9]. In addition, body mass index is related to other health consequences such as gallstones[10], sleep apnea[11], and osteoarthritis[12-13]. With this strong evidence, linking excess body weight to a variety of chronic diseases, makes it critical to find further ways to lower the rates of overweight and obesity in the U.S.

In general, weight loss has been shown to decrease many health consequences of overweight and obesity. It has been suggested that even a modest weight loss of 5-10% from initial weight can produce beneficial health effects[14-15]. Blood glucose has been found to decrease while insulin sensitivity increases with weight loss[16]. In addition, the Diabetes Prevention Program (DPP) demonstrated that a lifestyle intervention which produced a 4.5% reduction in weight at 3 years decreased the risk of developing diabetes by 58% in individuals with impaired glucose tolerance[17]. Hypertension[16, 18] and blood lipid levels[19] have also been shown to decrease with weight loss in overweight individuals. Due to the known benefits of weight loss, the National Institutes of Health currently recommends weight loss for adults with a BMI ≥ 25 $kg/m^2$ with a starting weight loss goal of 10% of initial body weight[15]. However, despite recommendations and the health benefits from weight loss, a challenge still remains in developing effective ways to help individuals lose weight.

In general, body weight is determined by energy intake (calories consumed) and energy expenditure (calories burned). When energy intake and energy expenditure are equal, body weight remains stable. However, weight gain or weight loss occurs when these two factors are unbalanced. For example, when energy intake exceeds energy expenditure, weight increases. Conversely, when energy expenditure exceeds energy intake, weight loss is the result. Therefore, to achieve weight loss, treatment must focus on ways to increase energy expenditure and/or decrease energy intake.

## 1.1 SIGNIFICANCE

Guidelines for behavioral weight loss interventions by the American College of Sports Medicine[20] and the National Institutes of Health[15] focus on a reduction in caloric intake and increases in physical activity. This combination results in an energy deficit which produces weight loss. In addition, behavioral interventions typically include a behavior therapy component as suggested by the National Heart, Lung, and Blood Institute[15]. Behavioral weight loss interventions that include a combination of diet, exercise, and behavioral therapy have been found to be effective in producing approximately a 10% reduction in body weight over 30 weeks. Furthermore, approximately 80% of individuals will complete the standard 6 month weight loss intervention[21]. Although these interventions appear promising, not all participants reach this 10% weight loss goal. For example, a study conducted at the University of Pittsburgh on 197 overweight and obese women resulted in 44.7% of these individuals achieving at least 10%

weight loss at 6 months[22]. Thus, it is important to identify additional strategies to further assist individuals in behavioral interventions to achieve the minimum weight loss target of 10% of initial body weight.

### 1.1.1 Theoretical Rationale

Strategies used during behavioral weight loss interventions that have been found to be important in producing weight loss include goal setting, self-monitoring, and feedback on goal achievement[21, 23]. A theoretical model has been developed to demonstrate the proposed relationship between the above strategies and physical activity, dietary behaviors, and weight loss (Figure 1). The use of goal setting and self-monitoring, as well as receiving feedback on goal achievement, can positively influence both physical activity and dietary behaviors. For instance, setting a goal to increase physical activity participation can improve motivation to exercise. Self-monitoring physical activity will help demonstrate progress and receiving feedback on current levels of physical activity may provide additional strategies for overcoming barriers from obtaining additional exercise minutes each week. By increasing levels of physical activity and/or decreasing caloric intake, greater weight loss should be produced. In addition, the three strategies may reciprocally interact with each other in that improving goal setting may positively influence self-monitoring, which may also advance feedback on goal achievement. Overall, it is theorized that by enhancing goal setting, self-monitoring, and/or feedback on goal achievement, physical activity and dietary behaviors will improve resulting in greater weight loss.

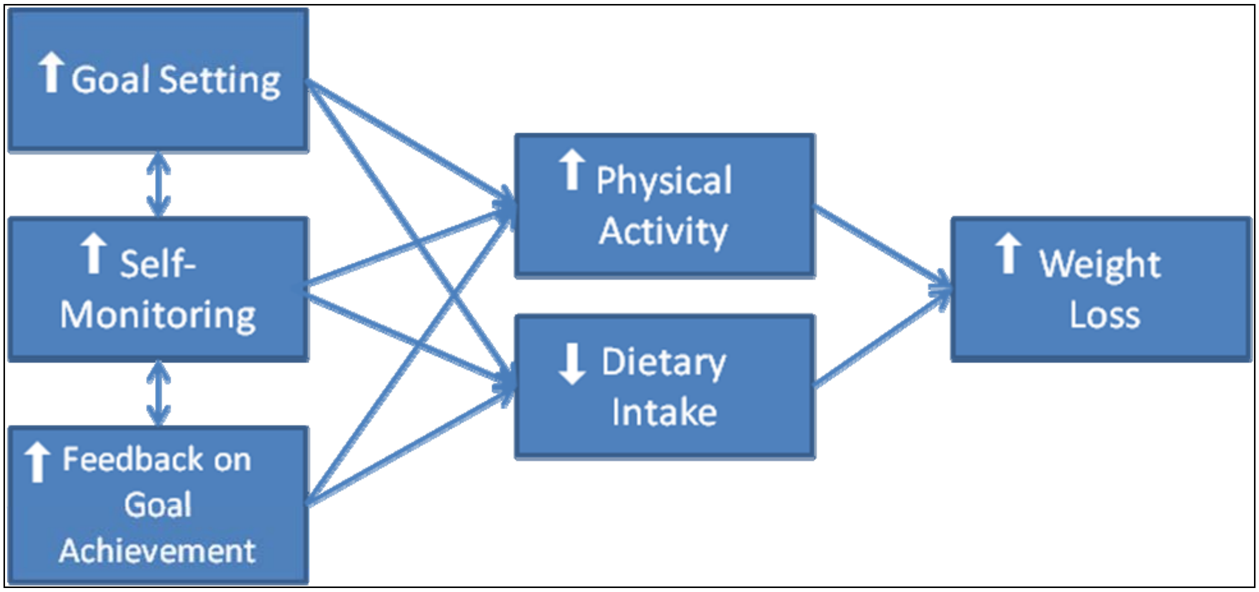



**Figure 1. Proposed Theoretical Model.**

### 1.1.2 Goal Setting

The Social Cognitive Theory, developed by Albert Bandura, identifies goal setting during self-regulation as an important strategy to behavior change. The theory states that goals help drive an individual's motivation to self-regulate toward a specific behavior change[23]. Goal setting is one of the essential characteristics of a behavioral weight loss intervention and involves participants setting specific goals with intervention staff to assist with their behavior change progress. Participants' goals should be detailed, measurable, and assessed regularly[21, 24]. Goal setting is an effective way to motivate and help participants focus on a specific behavior change[25]. For example, goal setting in adults has been found to have a significant beneficial effect on improving eating behaviors and increasing physical activity levels during an intervention[26]. Duncan and Pozehl[27] found that individuals who received an intervention that consisted of setting goals for the frequency and duration of structured and home-based exercise sessions, had significantly higher adherence to the number of exercise sessions completed (59.7 vs. 38.8 sessions) and to the duration of each session (35.2 vs. 25.9 minutes) than those who did not receive goals. In addition, Schnoll and Zimmerman[28] found that by setting specific goals for dietary fiber intake, individuals consumed 91% more fiber than those without any goals. Furthermore, setting goals specifically for diet or physical activity behaviors is associated more with the use of more strategies targeted on diet and activity behaviors than setting general weight-related goals[26]. Therefore, it is important that during weight loss interventions, participants aim to set behavior-related goals and work towards changing the behavior rather than just focusing on the outcome. In addition, the frequency of goal setting is associated with higher levels of change. For instance, Nothwehr and Yang[25] found that setting goals for diet or physical activity more frequently was positively related to the use of diet and activity-related strategies. Over the course of an intervention, numerous physical activity and dietary goals should be set to keep motivation levels high and participants engaged in their behavior changes.

### 1.1.3 Self-Monitoring

Social Cognitive Theory states that self-monitoring is an important strategy that aids in the self-regulation of behavior which is necessary for evaluating one's progress[23]. Behavioral weight loss interventions use self-monitoring as a crucial strategy for changing dietary intake and physical activity behaviors[21]. Self-monitoring includes keeping detailed records of daily food intake, physical activity, and body weight during the intervention. Participants typically record foods and beverages consumed, as well as the total number of calories and fat grams consumed throughout each day. In addition, participants record physical activity, time spent doing the activity, and ratings of perceived exertion. Self-monitoring has been associated with greater short-term weight control; individuals who were most consistent with self-monitoring lost approximately 64% more weight over 15 weeks than those who did not self-monitor[29]. Furthermore, Boutelle et al.[30] found that over holidays, increases in self-monitoring were related to additional weight loss, whereas individuals who not did self-monitor gained weight over this 8 week period. These results were consistent with findings by Baker and Kirschenbaum.[31] Individuals who were the least consistent with self-monitoring gained an average of 9 pounds over 18 weeks whereas those who regularly self-monitored dietary intake lost an average 31 pounds. Similarly, Boutelle and Kirschenbaum[32] found that over an 8 week program, individuals who consistently self-monitored lost approximately 1.5 pounds whereas those who were less consistent gained over 1 pound. In addition to monitoring eating behaviors, tracking physical activity has also been effective at increasing exercise participation. For example, Noland[33] found individuals who self-monitored ($M$ = 2.07) physical activity reported a significantly higher number of exercise sessions than those who did not self-monitor ($M$ = 1.36). In addition, regularly self-monitoring body weight has been shown to be important, particularly with regard to weight loss maintenance. According to the National Weight Control Registry, which consists of individuals who have lost more than 30 pounds and maintained the weight loss for over one year, approximately 75% of registry members weigh themselves at least once a week. Furthermore, approximately 38% report weighing themselves daily[34]. Highly consistent self-monitoring appears to effectively aid in improving weight loss behaviors (diet and physical activity) and weight maintenance; consequently, self-monitoring should be included in behavioral weight loss programs.

### 1.1.4 Feedback on Goal Achievement

Feedback is a strategy from Social Cognitive Theory that is used to enhance self-regulation and self-motivation[23]. Receiving feedback, particularly on one's accomplishments, is an effective way to increase an individual's self-efficacy for a specific behavior or task. Feedback regarding dietary intake, physical activity, and overall weight loss is essential during a behavioral weight loss intervention to continuously encourage and build self-efficacy for making these changes. Feedback can be helpful in measuring progress, setting or evaluating goals, overcoming barriers, and maintaining high levels of motivation.

As mentioned, self-monitoring is considered one of the most important aspects of behavioral weight loss interventions and providing feedback on self-monitoring may be effective in modifying eating and activity behaviors[21]. For instance, a pedometer, which gives participants immediate real-time feedback on how many steps are taken, is effective at increasing steps taken each day in adults[35] and children[36]. Specifically, a review by Bravata et al.[35] found that individuals given pedometers took an average of 2,183 steps more than baseline, and were almost 27% more physically active than those without pedometers. Mobile phones that are compatible with a Bluetooth wrist-worn accelerometer are a newer technology that provide real-time physical activity output on moderate, high, and very high intensity activities. These have been found to increase moderate intensity physical activity by more than 2 hours a week[37]. Receiving feedback on specific behaviors appears to be an important component to allow participants to make and maintain such changes.

### 1.1.5 Can technology improve weight loss?

The use of technology may be used to improve standard weight loss interventions by enhancing certain components of these interventions, which could result in improved weight loss[38]. The BodyMedia® FIT System (BodyMedia Inc., Pittsburgh, PA) is a new tool designed to help patients manage eating and activity behaviors while aiming to lose weight. The system includes an armband, digital display, and an activity manager website that incorporates the components of goal setting, self-monitoring, and methods to receive feedback on eating and activity goal achievement. If any of these components could be enhanced, greater weight losses may be produced.

The BodyMedia® FIT System has the potential to improve goal setting by providing individuals with the ability to program specific dietary and activity goals. Goals can be set by the individual or interventionist on total energy expenditure (calories burned), number of steps taken, and duration of physical activity. This information is shown on the digital display, that can be worn as a wristwatch or attached to clothing, and provides individuals with continuous access to their goals. On the activity manager website, individuals can set goals on caloric intake and have the ability to self-regulate and self-monitor progress on their goals throughout the day.

The BodyMedia® FIT System enhances self-monitoring by immediately transmitting up-to-the-minute physical activity information obtained by the armband to the digital display wristwatch. This information includes total energy expenditure (calories burned), steps taken, and the duration of moderate and vigorous intensity physical activity. Throughout the day, individuals have the ability to monitor energy expenditure in real-time using the digital display and decide whether they need to increase their activity throughout the remainder of the day to achieve their goal. Furthermore, the activity manager website allows the input of dietary intake and body weight and will display both dietary and physical activity patterns as well as overall calorie balance.

The BodyMedia® FIT System also allows the weight loss interventionist to view real-time activity and dietary information via the activity manager website. This allows the client's interventionist to provide specific feedback on both behaviors, as well as modify goals accordingly.

Although the BodyMedia® FIT System has not been examined during a published behavioral weight loss intervention, earlier versions including the Sensewear® Pro Armband have shown promising effects. For instance, Polzien et al.[39] found that adding this system continuously to a 12 week behavioral weight loss program resulted in a 2 kg greater weight loss than in those who did not receive the technology. Some of the key advancements the BodyMedia® FIT System has over earlier versions include the ability to provide up-to-the-minute energy expenditure information as well as allow the interventionist to have access to individuals' websites. Therefore, the interventionist can assist the individual in setting more appropriate goals based specifically on their information. These enhancements to goal setting, self-monitoring, and the ability to provide feedback have the potential to further improve weight loss for participants in a behavioral weight loss program by helping individuals increase exercise levels and monitor dietary intake more effectively.

Although behavioral weight loss interventions are capable of producing significant weight losses for some, this extensive treatment is not available to the general population for numerous reasons including cost, staffing, and time. Therefore, it is important to consider how different strategies could be used and applied to the general public. One solution may be the use of the BodyMedia® FIT System, which has the potential to provide individuals with many of the critical components of a behavioral weight loss intervention. Published data has not been available on the effectiveness of this system; therefore this study aimed to examine whether the BodyMedia® FIT System can enhance weight loss during a behavioral weight loss intervention as well as successfully produce weight loss in the general population without an extensive behavioral weight loss intervention.

## 1.2 SPECIFIC AIMS

The specific aims of this study were:

1.) To compare the changes in body weight between three intervention groups: standard behavioral weight loss (SBWL), standard behavioral weight loss plus BodyMedia® FIT System (SBWL+FIT), and BodyMedia® FIT System alone (FIT) during a 6 month behavioral weight loss intervention in overweight and obese adults.

2.) To compare the changes of moderate to vigorous intensity physical activity between three intervention groups: SBWL, SBWL+FIT, and FIT during a 6 month behavioral weight loss intervention in overweight and obese adults.

3.) To compare the changes in dietary intake between three intervention groups: SBWL, SBWL+FIT, and FIT during a 6 month behavioral weight loss intervention in overweight and obese adults.

4.) To compare the changes in cardiorespiratory fitness between three intervention groups: SBWL, SBWL+FIT, and FIT during a 6 month behavioral weight loss intervention in overweight and obese adults.

5.) To compare the changes in body composition (fat mass, muscle mass, bone mineral density, percent body fat, waist circumference, hip circumference, and waist-to-hip ratio) between three intervention groups: SBWL, SBWL+FIT, and FIT during a 6 month behavioral weight loss intervention in overweight and obese adults.

6.) To compare self-monitoring of dietary intake and physical activity between three intervention groups: SBWL, SBWL+FIT, and FIT during a 6 month behavioral weight loss intervention in overweight and obese adults.

## 1.3 HYPOTHESES

The specific hypotheses of this study included:

1.) The SBWL+FIT group will achieve a greater weight loss than the SBWL group and the SBWL group will achieve a greater weight loss than the FIT group.

2.) There will be greater increases in moderate to vigorous intensity physical activity in the SBWL+ FIT group than the FIT or SBWL groups.

3.) There will be greater reductions in caloric intake in the SBWL+ FIT group than the FIT or SBWL groups.

4.) There will be greater improvements in cardiorespiratory fitness in the SBWL+ FIT group than the FIT or SBWL groups.

5.) There will be greater improvements in body composition (fat mass, muscle mass, bone mineral density, percent body fat, waist circumference, hip circumference, and waist-to-hip ratio) in the SBWL+ FIT group than the FIT or SBWL groups.

6.) There will be a greater number of days that dietary intake and physical activity will be self-monitored in the SBWL+ FIT group than the FIT or SBWL groups.

# 2.0 REVIEW OF LITERATURE

## 2.1 INTRODUCTION

Obesity remains one of the leading health concerns in the United States, especially as the prevalence continues to remain elevated among adults and children[1, 40]. Behavioral weight loss interventions are one of the recommended treatment methods used to help individuals lose weight or prevent weight gain. Goal setting, self-monitoring, and feedback on goal achievement have been some of the key components of behavioral treatment for weight management, and although behavioral weight loss interventions are effective in producing a weight loss of 10% of initial body weight, these programs are not far reaching[21]. Alternative methods or various enhancements to traditional behavioral weight loss interventions are needed to determine new approaches for improving weight loss. One alternative to the standard behavioral weight loss treatment has been the use of technology. Computers and the Internet have become a viable option because increasingly more individuals are accessing the Internet[41]. This may be one method capable of targeting a larger portion of the population than the standard face-to-face behavioral weight loss treatment. Other forms of technology that may have the ability to enhance behavioral interventions include personal digital assistants (PDA)[42-43], Bluetooth accelerometers[37], and physical activity monitoring armbands[39].

This study evaluated the effectiveness of the BodyMedia® FIT System when used alone or in combination with a 6-month behavioral weight loss intervention in overweight and obese adults. The BodyMedia® FIT System is a new technology-based system that has the ability to enhance certain components of the standard behavioral weight loss intervention which may make the program more appealing to participants as well as easier to adhere to the behavior changes. Specifically, this technology simplifies self-monitoring by providing individuals with an objective measure of energy expenditure, activity duration and intensity. Once information is uploaded to a computer, the system automatically provides detailed reports displaying activity patterns and energy balance. Furthermore, this system allows individuals to set specific goals regarding their energy expenditure and activity levels and provides up-to-the-minute feedback on current, total, and active energy expenditure. The BodyMedia® FIT System also enhances the interventionist's ability to assist with weight loss because it provides daily objective data on physical activity and dietary intake that can be viewed remotely using a personalized website. Having this daily information allows the interventionist to provide immediate feedback on both dietary and activity behaviors. Although the BodyMedia® FIT System has not been examined during a clinical trial, it may have the capability of producing weight losses equivalent to the standard behavioral weight loss program or greater weight losses when combined with a weight loss intervention.

## 2.2 OBESITY

Classification of overweight and obesity is based on body mass index (BMI), which is calculated as weight in kilograms divided by the square of height in meters. A BMI of 25.0 to 29.9 $kg/m^2$ is considered overweight and a BMI equal to or greater than 30.0 kg/m$^2$ is classified as obese[15]. Based on data from the National Health and Nutrition Examination Survey (NHANES)[1, 44], the prevalence of overweight and obesity has increased significantly over the past several decades. Between 1999 and 2008, the overall prevalence of overweight and obesity in adults aged 20 years and older increased from 64.5% to 68.3%. Moreover, the prevalence of obesity alone has increased from 30.5% to 33.9% during the same time period. While these increases in obesity have been consistent among all ethnic and racial groups, as well as all children, adolescent, and adult age groups,[45] the prevalence of obesity among adult women appears to be leveling off[44].

Overweight and obesity are associated with many negative health effects including cardiovascular disease[3], diabetes[7], hypertension[4], and hyperlipidemia[7]. The risk of developing these conditions as well as overall mortality has been shown to be positively correlated to BMI. For instance, at a BMI of 30.0 kg/m$^2$, the risk of mortality increases by almost 30% compared to a BMI < 25 kg/m$^2$ [2]. It is estimated that obesity is associated with approximately 112,000 excess deaths a year[46].

Overweight and obesity results from numerous interactions between genetic, biological, and environmental factors[45]. Genetic predisposition increases the possibility of weight gain and although approximately 20 genes have been identified that may be linked to excess body fat, it is rarely the only cause of obesity[45]. It has been estimated that genes only explain between 25-40% of the variance in BMI[47]. Furthermore, it is unlikely that the increase over the years in the prevalence of overweight and obesity is due to changes in genetic composition, but instead due to changes in the social and cultural environment, particularly in regards to dietary and activity behaviors[47-48]. The environment currently promotes overconsumption of energy dense foods and a sedentary lifestyle which can result in weight gain[49]. It has been suggested that for successful weight loss, eating and activity behaviors should be modified as well as environmental cues to continue to promote and reinforce these healthy behavior changes[50].

## 2.3 BEHAVIORAL WEIGHT LOSS INTERVENTIONS

The National Heart, Lung, and Blood Institute recommends that behavioral interventions include a reduction in caloric intake, increases in physical activity, and behavior therapy[15]. Short-term behavioral weight loss interventions will produce on average a 10.7 kg weight loss (approximately 10% of initial weight) after 30 weeks of treatment[21]. In general, these behavioral interventions use methods and principles including classical conditioning and cognitive therapy to help modify eating and activity habits[24]. These two principles, in particular, help identify the cues or thoughts that are influencing negative or positive reactions or behaviors. Treatment aims to encourage reinforcement of positive behaviors and thoughts, while eliminating negative reactions and feelings[24]. This cognitive restructuring focuses on changing one's negative thoughts about achieving weight loss to more positive and less damaging thoughts[21]. This component may help individuals set more realistic goals and accepting the modest weight losses which are expected during behavioral weight loss interventions, rather than experiencing feelings of disappointment[51]. Although there are no data to support the use of cognitive restructuring to positively influence weight loss, some studies have suggested that cognitive therapy can improve body image in obese individuals regardless of actual weight loss[52-53].

Behavioral weight loss interventions usually include weekly group sessions for the first 16-26 weeks. Group sessions of approximately 10-20 individuals allow dietitians, exercise physiologists, or behavioral specialists to deliver behavioral, dietary, or physical activity lessons during a 60-90 minute time period[21, 50, 54]. Furthermore, these groups help provide individuals with additional social support, create friendly competition, and facilitate helpful group discussions.

Individual sessions, as used in the Diabetes Prevention Program,[55] allows tailoring of the intervention specifically to the participant. These sessions provide an opportunity for participants to address personal and emotional concerns, questions, or problems that they may not feel comfortable discussing during group sessions[56]. Furthermore, individual appointments allow interventionists to create a stronger bond with the participant as well as meet any specific cultural or ethnic needs[56].

Renjilian et al.[57] compared weight loss produced from individual or group therapy as well as the effects of matching participants to their preference of treatment. Group therapy resulted in a mean weight loss of 11.0 kg which was significantly greater than weight loss produced from individual therapy (9.09 kg) over 26 weeks. Interestingly, matching individuals to their treatment preference did not significantly enhance weight loss in either group (preferred -10.85 kg vs. nonpreferred -11.19 kg) or individual (preferred -8.48 kg vs. nonpreferred -9.61 kg) therapy.

Some interventions, including the Look AHEAD study, have used a combined approach of group and individual sessions for the first 6 months of treatment[56]. Participants in the Look AHEAD study attended 3 group sessions and 1 individual session a month. This provided individuals with additional social support while addressing specific needs. Although this approach has not been examined by randomized clinical trials, a combination of group and individual sessions has been effective in producing weight losses of approximately 8.6% of initial weight over 1 year[58]. Furthermore, it has been suggested that combining individual and group sessions helps to develop stronger relationships with participants and provides an alternative for those who want to stop attending the regular group sessions[56].

Dietary and physical activity modification are important components of behavioral weight loss interventions, however, additional techniques such as goal setting, self-monitoring, and feedback on goal achievement are crucial to making such modifications. These components and techniques will be discussed in further detail.

### 2.3.1 Dietary Modification

One of the critical components of behavioral weight loss interventions is dietary modification, which typically includes a reduction in daily calories (kcal) and fat grams. Current recommendations suggest that adults reduce caloric intake by 500-1,000 kcal/day to produce an approximate 1-2 pound weight loss per week[14]. In general, to produce this amount of weight loss, appropriate caloric intake recommendations for women and men are 1,200-1,500 kcal/day and 1,500-1,800 kcal/day, respectively[21]. The Diabetes Prevention Program developed four categories of specific calorie and fat gram goals that were based on initial body weight, and estimated to produce a 7% weight loss over 6 months[55]. The United States Department of Agriculture's 2005 Dietary Guidelines recommend a fat intake between 20-35% of daily calories[59].

Additional techniques used to modify dietary intake have been examined including very low calorie diets (VLCD), meal replacements, and structured meal plans[21, 50]. While following a VLCD, participants consume between 400-800 kcal/day, which typically produces a 20 kg weight loss over a 12 week period[60]. Although initially successful in enhancing weight loss, most patients regain 35-50% of their lost weight once the VLCD is stopped. In addition, individuals following a VLCD must be medically supervised which drastically raises costs[21, 50].

The use of meal replacements is another approach that has been shown to improve the dietary component of behavioral weight loss interventions. A meta-analysis by Heymsfield et al.[61] found individuals following a partial meal replacement plan consisting of 1-2 meal replacements per day, lost approximately 2.54 kg and 2.43 kg more at 3 months and 1 year respectively, than those who followed a conventional reduced calorie diet. Meal replacements generally simplify food choices and help individuals avoid problem foods which can aid in reducing caloric intake[21].

Structured meal plans have also been used in behavioral weight loss interventions to improve dietary compliance. A structured meal plan can be used as a specific example regarding how participants can follow a low calorie, low fat diet[50]. Wing et al.[62] found the provision of grocery lists and structured meal plans for 5 breakfasts and 5 dinners per week, produced significantly greater weight losses compared to groups with the same calorie goals but no structured meal plans or grocery lists at both 6 months (-12.0kg vs. -8.0kg) and 1 year (-6.9kg vs. -3.3kg).

The current investigation used some of the previous findings to develop the dietary modification component, which was based on the USDA's 2005 Dietary Guidelines that recommends a fat intake between 20-35% of daily calories[59]. Caloric intake recommendations were based on initial body weight as used by the Diabetes Prevention Program[55] which should produce a 1-2 pound weight loss per week. Furthermore, this investigation provided individuals with sample meal plans and recommended the use of meal replacements or portion-controlled meals and snacks.

### 2.3.2 Physical Activity

Physical activity has been found to be an important component of behavioral weight loss interventions and the American College of Sports Medicine (ACSM) and National Institutes of Health (NIH) suggest that weight loss interventions include a reduction in energy intake in combination with an increase in energy expenditure from daily physical activity and structured exercise[14-15]. Interventions consisting of an exercise component, and no dietary modifications, will produce modest weight losses of approximately 2 kg[63]. Based on a recent meta-analysis and literature review by the NIH, when exercise is combined with a dietary component, weight losses are approximately 1.1-1.9 kg greater than diet only conditions[15, 64]. Furthermore, Curioni and Lourenco[65] found that diet and exercise groups lost approximately 20% more than diet-only groups. Overall, physical activity appears to enhance weight loss when combined with dietary modification[20].

The ACSM and the American Heart Association recommend that all healthy adults between the ages of 18-65 years engage in moderate-intensity aerobic activity for a minimum of 30 minutes, five days per week, to promote and maintain health[66]. While this is enough activity to maintain health and prevent weight gain, it may not be enough to produce substantial weight loss. A modest weight loss of about 2-3 kg can be achieved with moderate intensity physical activity of 150-250 minutes a week[20]. For a weight loss of 5-7.5 kg, individuals should engage in 225-420 minutes per week of moderate intensity activity. Furthermore, approximately 200-300 minutes of weekly activity has been shown to improve long-term weight loss[20]. Physical activity and weight loss appear to follow a dose-response relationship in that higher levels of physical activity over a 12 month intervention produce greater weight losses than lower levels of activity[67]. Therefore, energy expenditure from physical activity of approximately 2,000 kcal/week (or 250-300 minutes/week of moderate intensity activity) should be included in behavioral weight loss interventions to produce greater weight loss and to sustain the weight loss long-term.

The current investigation used these findings and recommendations to establish physical activity goals. Individuals progressed from 100 to 300 weekly minutes of moderate intensity aerobic activity over the course of 24 weeks. This amount (ie. 300 min) is recommended to produce an energy expenditure of approximately 2,000 kcal/week, which will help enhance weight loss.

### 2.3.3 Goal Setting

Social Cognitive Theory has identified goal setting as an important strategy in self-regulation of behaviors[23]. Latham and Locke[68] developed the Goal Setting Theory which states human behavior is purposeful and regulated by individual's goals. This theory examines why some people perform better than others on a specific task and proposes the reason pertains to performance goals. Goal setting is a highly effective motivational mechanism that helps individuals gain a sense of mastery for a specific behavior when goals are met; this often results in increased self-efficacy[23, 69].

One explanation for how goals influence performance is that goals direct attention to the specific behavior and thus, more effort and persistence are put towards achieving the objective[70]. Goals that are specific and behavior focused have been found to be more effective than vague goals or no goals. Furthermore, specific goals are more helpful when measuring, tracking, and assessing progress[68-69].

Behavioral weight loss programs are goal and process orientated which means individuals determine the behavior they want to change, set goals, identify strategies to add, and remove barriers in an attempt to successfully adopt a new behavior[21]. Although previous research has been inconclusive, goals set during interventions are normally discussed and decided on by both the interventionist and the individual. Some studies have shown that assigned goals are more effective than self-set goals,[26] whereas others have shown there are no differences as long as the goal difficulty is the same[71]. Although uncertain, it may be beneficial for both the interventionist and participant to work together to set goals that are appropriate, realistic, and achievable.

During weight loss interventions, goals should focus specifically on changing behaviors rather than body weight because many factors influence body weight short term such as fluid, salt or humidity[24]. Nothwehr and Yang[25] examined whether frequent goal setting that focuses specifically on diet and exercise behaviors is more predictive of the use of dietary and physical activity strategies than setting a weight-related goal. Results found the specific goals for diet or physical activity to be more strongly predictive of the use of dietary and physical activity strategies than setting an overall weight loss goal. The authors suggest that setting goals for only body weight may not facilitate the attempt to change lifestyle habits, while setting specific diet and physical activity goals may encourage this change.

Dubbert and Wilson[72] examined the effect of setting either proximal or distal goals on caloric intake or expenditure on weight loss during a behavioral weight control program. Individuals who reported following either proximal or distal goals lost significantly more weight over a 19-week period than those who did not set any goals. Interestingly, there were no differences between those who set proximal or distal goals. The authors suggest that a potential reason for this finding is the lack of adherence to assigned goals.

### 2.3.4 Self-Monitoring

Self-monitoring is the systematic observation and recording of target behaviors. It has been suggested to be one of the most important components of behavioral treatment[21]. Self-monitoring is based on the self-regulative mechanism from the Social Cognitive Theory, which proposes that this technique provides the information required to set realistic goals, as well as evaluating individual progress[23]. Self-monitoring allows individuals to identify patterns that may not have been noticed previously. Furthermore, as treatment progression continues, individuals are more inclined to set goals for themselves, even when not prompted to do so[23].

During behavioral weight loss interventions, participants are encouraged to self-monitor food intake, physical activity, and body weight throughout treatment. Self-monitoring has been found to be associated with weight loss success. For instance, individuals who consistently self-monitor lose significantly more weight than those who do not self-monitor, or are not consistent[31-32, 73]. Over an 8-week period, Boutelle and Kirschenbaum[32] found that subjects who consistently self-monitored food intake lost approximately 2.56 kg more than those who did not consistently self-monitor. In addition, the authors suggest that in order to be most effective, food intake should be self-monitored at least 75% of the time. Self-monitoring success appears to increase, or improve progress toward, the desired behavior.

Although evidence demonstrates the importance of self-monitoring in behavioral weight loss interventions, it was suggested by Kazdin[74] that self-monitoring is more effective in helping individuals make behavior changes when they are also given a specific goal for that behavior.

Furthermore, as the individual progresses with the behavior change, weekly goals should be set based on the current level of behavior change achievement. Schnoll and Zimmerman[28] examined the effectiveness of incorporating goal setting and self-monitoring to increase dietary fiber intake. The combination of self-monitoring and goal setting resulted in a 91% higher consumption of dietary fiber than those who did not set any goals. These results suggest that goal setting should be combined with self-monitoring to significantly enhance behavior change.

Yon et al.[43] examined dietary self-monitoring with either a personal digital assistant (PDA) or the standard paper diary during a 6-month behavioral weight loss intervention. As with previous studies,[31-32, 73] frequent self-monitoring was significantly correlated with greater weight loss. Interestingly, there were no significant differences in weight loss or frequency of self-monitoring between those who used a PDA or paper diary to self-monitor dietary intake. It was suggested that no difference was found because of the technological barriers faced using the PDA (i.e. difficulty seeing the data screen and not having commonly consumed foods in the database). These burdens may have discouraged individuals from self-monitoring.

Accurately self-monitoring dietary intake has been recognized as a problem due to the underreporting of energy intake.[42, 75-76] Johnson et al.[75] examined the prevalence of underreporting dietary intake in overweight and obese women during a 6 month behavioral weight loss intervention. At baseline, approximately 40% of women were underreporting and by 6 months, prevalence increased to 60%. In addition, the severity of underreporting increased from -105 kcal per day to -415 kcal per day between baseline and 6 months.

Yon et al[42] examined whether the use of a PDA would improve the validity of self-monitoring as well as reduce the prevalence of underreporting energy intake in overweight and obese women. With the use of a PDA, 41% of women underreported energy intake by a mean of

-207 kcal/day. These findings are similar to those by Johnson et al[75] who noted an underreporting prevalence of 40%. Although self-monitoring, by either the use of a PDA or paper and pencil method, has been correlated with weight loss[31-32, 43, 73], underreporting continues to be an issue. Therefore, it is important to determine alternative methods to improve the accuracy and consistency of self-monitoring dietary intake.

### 2.3.5 Feedback on Goal Achievement

Feedback on goal achievement is used during behavioral weight loss interventions to inform participants of their current progress toward goal attainment and suggest effective strategies that may help minimize the discrepancy between target and actual behaviors. When goals are set, there is a specific performance standard that individuals strive to reach. Feedback assists in identifying the discrepancy and allows individuals to self-regulate their behaviors to obtain the target behavior[23].

A meta-analysis by Neubert[77] concluded that combining feedback and goal setting is more effective at influencing behavior than goal setting alone. One mechanism that may explain this relationship is that combing goal setting with feedback influences self-regulation of effort and persistence by identifying the discrepancy between the goal and current behavior. The difference between actual and goal behavior will typically motivate the individual to minimize the discrepancy and improve performance. A second mechanism as to why the relationship of goal setting and feedback is superior is that feedback on goal achievement provides information and strategies that may be necessary to adjust behaviors[77].

Latham and Locke[68] summarized the results of several studies[78-79] that examined the effects of isolating feedback from goal setting. The authors concluded that when feedback is provided without having any goals, performance is not affected. It was proposed that goal setting is a mediator of feedback's effects on performance. Erez[80] tested this prediction and examined the effects of goal setting and feedback on performance on a number comparison task. Individuals who received feedback ($M$ = 13.17) scored significantly higher during the second task than those who did not receive feedback ($M$ = 11.68). Feedback also resulted in a significantly stronger relationship between goal setting and performance ($r$ = .60) than the no feedback condition ($r$ = .01). In addition, approximately 40% of the variance in performance was accounted for when examining the feedback by goal interaction. The results demonstrated that feedback is necessary for goals to affect behavior. The combination of feedback and goal setting is more effective than either feedback or goal setting alone.[23, 68, 77]

Tang et al.[81] examined the effect of providing feedback on self-set goals for the number of anagrams that college students predicted they could solve during a timed test. After completion of the anagram-solving task, students randomly received bogus positive or negative feedback. On the next task, individuals who received positive feedback claimed that they had significantly higher ability ($M$ = 3.61) and thus, exerted more effort ($M$ = 6.26) toward the task than those in the negative feedback condition ($M$ = 2.76, 5.62, respectively). The authors suggest that positive feedback appears to enhance self-esteem which results in improvements in self-efficacy for this particular task. Furthermore, when self-efficacy increases, the amount of effort put toward this behavior increases. This suggestion is consistent with Latham and Locke[68] who stated that positive feedback will increase self-efficacy.

Ilies and Judge[82] examined how positive or negative performance feedback influences goal regulation during a task that involved college students listing as many words that they could think of that contained a specific letter. Furthermore, feedback was either comparative to others' performance or only concerned with their own performance. The authors found that performance feedback was predictive of the goal set for the second task in that negative feedback resulted in downward goal revision and positive feedback resulted in setting higher goals. In addition, the authors found that positive feedback that was concerned with their own individual performance was more strongly predictive of future goals than positive feedback that compared their performance to others. Consequently feedback, when concerned with an individual's performance, appears to strongly influence future goals, whether positive or negative.

Despite the noted importance of including feedback during behavioral weight loss interventions, limited research has examined this component. Krukowski et al.[83] examined the use of several features on a website during an Internet-based weight control program and found that the feedback factor, which consisted of past journals, progress graphs, and physiological calculators, was the best predictor of weight loss during active treatment. The authors suggest that feedback on self-monitoring is important, however difficult to determine individual significance given it was combined with other components.

### 2.4 COMPUTER AND INTERNET WEIGHT LOSS INTERVENTIONS

With increasing rates of overweight and obesity, alternative methods to enhance weight loss have been examined including the use of computers or the Internet, particularly since the number of individuals using computers and Internet have increased over the years. According to the U.S. Census Bureau in 2003, approximately 62% of U.S. households have at least one computer, which had increased from 56% in 2001. Furthermore, 88% of these households also have Internet access[84]. By 2010, the Pew Internet and American Life Project[41] reported that approximately 74% of adults were current Internet users, which was defined as occasionally using the Internet or sending or receiving e-mail. Computer and Internet-based interventions have the benefit of reaching a larger proportion of the population while still having the ability to tailor messages and information specifically for individuals.

McCoy et al.[85] developed an online weight loss program for diabetes prevention that emphasized diet and physical activity modification that was available to the general public. Overall, more than 800 individuals registered and used many of the online services available even though they were under no obligation to use the website. The authors suggest the high usage rate of the services available was due to the daily emailed newsletter which served as a reminder to return to the website. Although there is no data suggesting the effectiveness of the weight loss program, these results suggest that an automated website designed to promote awareness of diabetes prevention appears promising to successfully deliver a weight loss program solely over the Internet.

Marcus et al.[86] compared tailored Internet and print-based methods to increase physical activity participation in healthy sedentary adults. The Internet group received e-mail prompts to use the website to log in physical activity, set goals, and complete questionnaires. Once questionnaires were submitted online, individuals received immediate tailored feedback based on their responses. The print-based group received the same information via mail. Participants also completed the questionnaires and activity logs and were instructed to mail them back to investigators. There was also a third group which had access to the website, however they received no feedback and were given links to other physical activity websites. All groups increased their physical activity at 6 months (90-120 minutes/week) and 12 months (80-90 minutes/week), however there were no significant differences between the three groups at either time point. The authors suggest that the Internet, whether tailored or not, was just as effective as print-based materials. Consequently, the use of the Internet may be a faster and more cost-efficient for reaching a greater number of individuals in the general public than print-based materials.

Tate et al.[87] examined whether a structured Internet behavioral weight loss intervention would produce greater weight loss than the use of a weight loss education website. Individuals, who had the structured Internet weight loss program that included weekly e-mail messages from the interventionist, lost 2.3 and 2.5 kg more than the education group at 3 and 6 months, respectively. Furthermore, the Internet group had significantly greater reductions in waist circumference than the education group at 3 (6.7cm vs. 3.0cm) and 6 months (6.4cm vs. 3.1cm). This suggests that an Internet-based program combined with weekly interventionist feedback via e-mail, is effective in delivering and producing weight loss.

Tate et al[88] further examined the influence of weekly interventionist feedback and compared its effects on weight loss during an Internet-based weight loss program to either automated computer-tailored feedback, human e-mail feedback, or no feedback. At 3 months, automated (-5.3kg) and human feedback (-6.1kg) resulted in significant weight losses compared to those who did not receive feedback (-2.8kg), however there were no differences between the two feedback groups. By 6 months, the human feedback group (-7.3kg) lost significantly more weight than those who did not receive feedback (-2.6kg); however the automated feedback group (-4.9kg) did not differ significantly from either the human feedback or no feedback conditions. In addition, more than 50% of individuals in the human feedback condition achieved a 5% weight loss whereas, only approximately 34% of individuals in the automated feedback group reached this 5%. These results suggest that an Internet-based weight loss program, with either weekly human e-mails or automated feedback, can effectively produce weight loss.

Although the studies by Tate et al.[87,88] produced weight loss using the Internet, the amount of weight lost was not comparable to that produced during a standard face-to-face intervention. In general, standard weight loss interventions produce approximately 10 kg losses in 30 weeks, whereas these studies by Tate et al. resulted in losses between 4.5 and 7.3 kg over 6 months[87-88]. Future research needs to examine the addition of components from standard face-to-face interventions to Internet weight loss interventions to determine if this can enhance weight loss results.

Harvey-Berino et al.[89] tested the feasibility and acceptability of conducting a weight maintenance program over the Internet. After completion of a 15-week behavioral weight control program, participants were randomized to one of three conditions: 1.) no treatment control; 2.) in-person, therapist led; and 3.) Internet. The in-person group met bi-weekly for 22 weeks, had discussions, sessions, and received phone calls while the Internet group met on an Internet chat room, used e-mail to contact the interventionist, participated in group e-mail sessions, and could access therapist-led Internet video sessions. There were no significant differences in changes in weight, BMI, diet, or exercise between the three groups during the maintenance phase. In addition, although not significant, there were fewer individuals who attended all maintenance sessions in the Internet group (87%) than the in-person group (100%). Furthermore, individuals rated the in-person therapist-led group as more acceptable than an Internet group. However, the Internet may be a feasible option for weight maintenance programs, even though the Internet group had lower completion rates and was not viewed as the most acceptable method, the authors suggest it may have been due to participants having older computers and slower Internet connections, which may have discouraged them from continuing the protocol.

Harvey-Berino et al.[90] further compared weight maintenance over 18 months using Internet support, frequent in-person support, or minimal in-person support after the completion of a 6 month behavioral weight loss intervention. Those in the Internet group attended bi-weekly online chat room sessions, whereas those in the frequent in-person support groups attended bi-weekly meetings. During the off weeks, the group therapist contacted the Internet participants by e-mail while the frequent in-person group received phone calls. The minimal in-person support group met monthly for the first 6 months of the maintenance phase but did not have any contact during the remaining 6 months. Similar to Harvey-Berino et al.[89], there were no significant differences in weight loss between the three groups at 18 months. These results suggest that the Internet appears to be an effective way to promote and sustain long-term weight maintenance.

## 2.5 TECHNOLOGY-BASED SYSTEM

The BodyMedia® FIT was the technology-based system used during this study. The system was developed by BodyMedia Inc. and includes three components: the SenseWear® Minifly armband, SenseWear® display, and BodyMedia® FIT website. The armband is worn on the back of the upper left arm using an adjustable strap. The internal sensors include a 3-axis accelerometer, heat flux sensor, skin temperature sensor, and a galvanic skin response sensor[91]. Information obtained from the armband is downloaded onto the website which uses proprietary algorithms to calculate energy expenditure, steps taken, activity duration, and metabolic equivalents (METS).

The SenseWear® display is an electronic input/output device that is used in conjunction with the SenseWear® Minifly armband to provide the individual with daily targets and up-to-the-minute feedback on energy expenditure, steps taken, and activity duration. The display is water resistant and can be worn using a wrist watchband or on a clip, which can be attached to clothing such as a belt or shirt sleeve[92].

The BodyMedia® FIT activity manager website is used to display the uploaded data obtained from the armband. This information includes total and active energy expenditure, steps taken, and activity duration and level. In addition, the website allows manual input of daily food intake and body weight and will display calorie consumption as well as overall calorie balance. Interventionists can access this website and online data remotely, track progress, and adjust caloric and activity goals accordingly.

Several studies have examined the reliability and validity of the SenseWear® Pro armband at rest[93-94] and during exercise.[93-96] For instance, King et al.[96] compared the accuracy of five activity monitors, including the SenseWear® armband, at several treadmill walking and running speeds to indirect calorimetry. Compared to the other 4 activity monitors, the SenseWear® armband was the best for estimating total energy expenditures at most speeds on the treadmill except slow walking. The authors proposed that the armband was the most accurate in estimating energy expenditure because it was placed on the upper arm and includes heat production measurements in the algorithms.

Fruin and Rankin[94] examined the reliability and validity of the armbands energy expenditure estimate at rest and during 2 modes of exercise (cycle ergometer and treadmill) compared to indirect calorimetry in healthy, normal weight adults. At rest, there were no significant differences in estimates of energy expenditure between the armband and indirect calorimetry. In addition, between two resting trials, the armband estimates did not differ. Using the cycle ergometer, there were no significant differences in overall total energy expenditure between the armband and indirect calorimetry; however, when time points were split between early, mid, and late exercise, the two measurements were poorly correlated. On the treadmill, the armband significantly overestimated energy expenditure by 14-38% while walking on a flat surface and significantly underestimated energy expenditure by 22% when walking on an incline. These results are similar to those found in triaxial accelerometer studies.[97-98]

Jakicic et al.[95] examined the accuracy of the estimation of energy expenditure from the SenseWear® Pro armband compared to indirect calorimetry during four modes of exercises (walking, cycling, stepping, and arm ergometery) in healthy adults. Initially, using the generalized proprietary algorithm, the armband significantly underestimated total energy expenditure during walking, cycling, and stepping and overestimated total energy expenditure during arm ergometry. When exercise specific algorithms were used, there were no significant differences in total energy expenditure between the armband and indirect calorimetry. The authors suggest that it is necessary to use algorithms that are exercise specific to ensure accuracy of energy expenditure during exercise.

Welk et al.[99] compared the accuracy of various algorithms that are used with the SenseWear® armband or MTI accelerometer, which is one of the most widely used accelerometers, to the Intelligent Device for Estimating Energy Expenditure and Activity (IDEEA) monitor during free-living conditions. The armband had the highest correlations as well as the lowest estimation error when determining duration of physical activity. The authors suggest that the armband provides a more accurate estimation because its ability to discriminate between different movements as well as apply appropriate prediction equations based on the movement sensed.

While most validity studies on the SenseWear® armband were conducted using healthy, normal weight individuals, one study examined the reliability and validity of the armband at rest and during three modes of exercise (cycle ergometry, stair stepping, and treadmill walking) compared to indirect calorimetry in obese individuals[93]. The total energy expenditure estimates were highly repeatable in obese individuals, however resting energy expenditure was underestimated by approximately 9% and the three exercise energy expenditures were overestimated. Papazoglou et al[93] suggest that algorithms for rest and exercise should be developed specifically for obese subjects to estimate energy expenditure more accurately.

Although there have been no studies that evaluated the use of the BodyMedia® FIT system during a weight loss intervention, one study did examine an earlier version of the armband (SenseWear® Pro) which does not include the real-time digital display[39]. Polzien et al.[39] examined the efficacy of adding the armband continuously or intermittently throughout a 12 week behavioral weight loss intervention on weight loss. When the armband was continuously worn during treatment, weight losses at 12 weeks were significantly greater (6.2kg) than those who wore the armband intermittently (3.4kg). Furthermore, although there was no statistically significant difference, those who continuously wore the armband lost approximately 2 kg more than those in the standard weight loss intervention. The authors suggest that with a larger sample size, significant differences could have been detected. Overall however, these results suggest that this technology-based system is an effective way to enhance weight loss when worn continuously and combined with a behavioral weight loss intervention.

Interestingly, there was no difference in leisure time physical activity between the standard and two armband groups. One possible reason for this is that individuals could not actively monitor their activity throughout the day. Being blind to the data until it is downloaded to the computer may not provide enough motivation to increase activity levels. Having the ability to see real-time feedback regarding up-to-the-minute activity may provoke individuals to increase their activity.

## 2.6 SUMMARY

Currently, there are no studies that specifically evaluate the BodyMedia® FIT System's influence on weight loss when examined alone or in combination with a behavioral weight loss intervention. Polzien et al.[39] did examine the effectiveness of an earlier version of the SenseWear® armband on weight loss, however many differences exist. The first is that the previous version of the armband did not provide individuals with real-time feedback using the display. This new system significantly enhances an individual's ability to objectively monitor physical activity level and energy expenditure up-to-the-minute. This may have a positive effect on self-monitoring and goal setting.

Second, Polzien et al.[39] used a 12 week behavioral weight loss intervention, while the current investigation extended treatment to 6 months. In addition, the behavioral intervention in Polzien et al.[39] consisted of 7 individual meetings spread across 12 weeks. The current study followed a more intensive protocol that included three group sessions and one individual session per month. The enhancements that the BodyMedia® FIT System provides on goal setting, self-monitoring, and feedback on goal achievement may be strong enough to produce significant weight loss without an intensive behavioral intervention. In addition, this system may be able to greatly enhance weight loss when it is combined with a behavioral intervention. Therefore, the primary aim of this study was to evaluate the effectiveness of the BodyMedia® FIT System when used alone or in combination with a 6-month behavioral weight loss intervention in overweight and obese adults. This system is a promising new technology that may have the ability to help a greater number of individuals in the general population lose weight or significantly enhance weight loss during a behavioral weight loss intervention.

# 3.0 METHODOLOGY

## 3.1 SUBJECTS

A total of 51 men and women between the ages of 21-55 years were recruited to participate in this study. Subjects were sedentary and either overweight or obese with a body mass index between 25-40 kg/m$^2$. A BMI of 40 kg/m$^2$ was chosen as a cutoff point because morbid obesity is associated with increased risk of cardiovascular, metabolic, or respiratory complications[100]. Healthy subjects at low to moderate risk based on ACSM guidelines were recruited while individuals with conditions that may affect weight loss and/or are at high risk will be excluded from the study[101]. Subjects were excluded if they met any of the following criteria:

1. Currently pregnant, pregnant in the last 6 months, or plan on becoming pregnant in the next 6 months.
2. Currently participating in regular exercise for over 60 minutes/week.
3. Taking any medications that affect body weight or metabolism (e.g. synthroid).
4. Have any physical limitations that would prevent exercise.
5. Currently being treated for coronary heart disease, diabetes mellitus, hypertension, or cancer.
6. Have a history of myocardial infarction or other heart-related surgeries.

7. Have a resting systolic blood pressure $\geq$ 150 mmHg or diastolic blood pressure of $\geq$ 100 mmHg or currently taking any medications that affect blood pressure or heart rate (e.g. beta blockers).
8. Currently enrolled in a commercial weight loss program, participating in a weight loss study, or in a weight loss study in the last 6 months.
9. Have lost > 5% of current body weight in the past 6 months.
10. Currently being treated for any psychological problems or taking any psychotropic medication.
11. Currently do not have access to a computer and the Internet.

## 3.2 RECRUITMENT AND SCREENING

Subjects were recruited from newspaper, Craigslist, and television advertisements. Letters were also mailed to interested participants in the Obesity and Nutrition Research Center database. The University of Pittsburgh Institutional Review Board approved all recruitment materials. Interested participants were instructed to call the University of Pittsburgh's Physical Activity and Weight Management Research Center where trained staff and graduate students conducted telephone screenings to determine initial eligibility. The telephone screening included a description of the study and with participants' verbal consent, staff asked questions regarding their medical history and other questions that were relevant to the exclusion/inclusion criteria.

All eligible participants recruited from the telephone screenings were invited to attend an orientation session where complete details of the study were given. Subjects were encouraged to ask questions on the study's procedures. Interested subjects provided written informed consent to participate and were asked to complete a Physical Activity Readiness Questionnaire (PAR-Q) [102] and provide a medical history as recommended by the American College of Sports Medicine to detect those at high risk of participating in regular activity[101]. In addition, they were required to obtain physician's written consent to ensure that it is safe for the subject to participate in a weight loss intervention.

Eligible participants who obtained physician's consent underwent baseline assessments. Assessment procedures and measures included obtaining height, body weight, body composition, cardiorespiratory fitness, physical activity, and dietary intake. The assessment procedures will be described in further detail below. Eligible participants who completed all assessment procedures were randomized to one of three groups (See Figure 2). All study procedures were approved by the University of Pittsburgh Institutional Review Board.

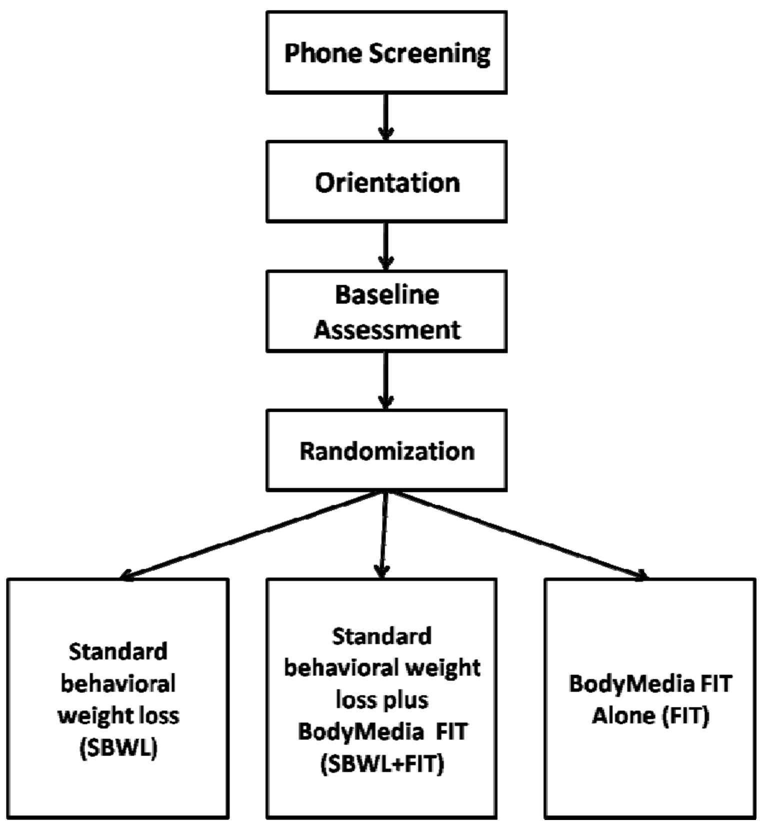



**Figure 2. Study Progression**

## 3.3 EXPERIMENTAL DESIGN

This was a randomized controlled trial that examined the effectiveness of the BodyMedia® FIT System on weight loss with or without participation in a behavioral weight loss intervention. This was a 6-month intervention that was conducted at the University of Pittsburgh Physical Activity and Weight Management Research Center. After completing baseline assessments, eligible participants were randomly assigned to one of three groups: 1) standard behavioral weight loss (SBWL), 2) standard behavioral weight loss plus BodyMedia® FIT System (SBWL+FIT), or 3) BodyMedia® FIT System alone (FIT). The groups will be discussed in further detail below. Assessments were completed at 0 and 6 months. The study timeline is illustrated in Figure 3.

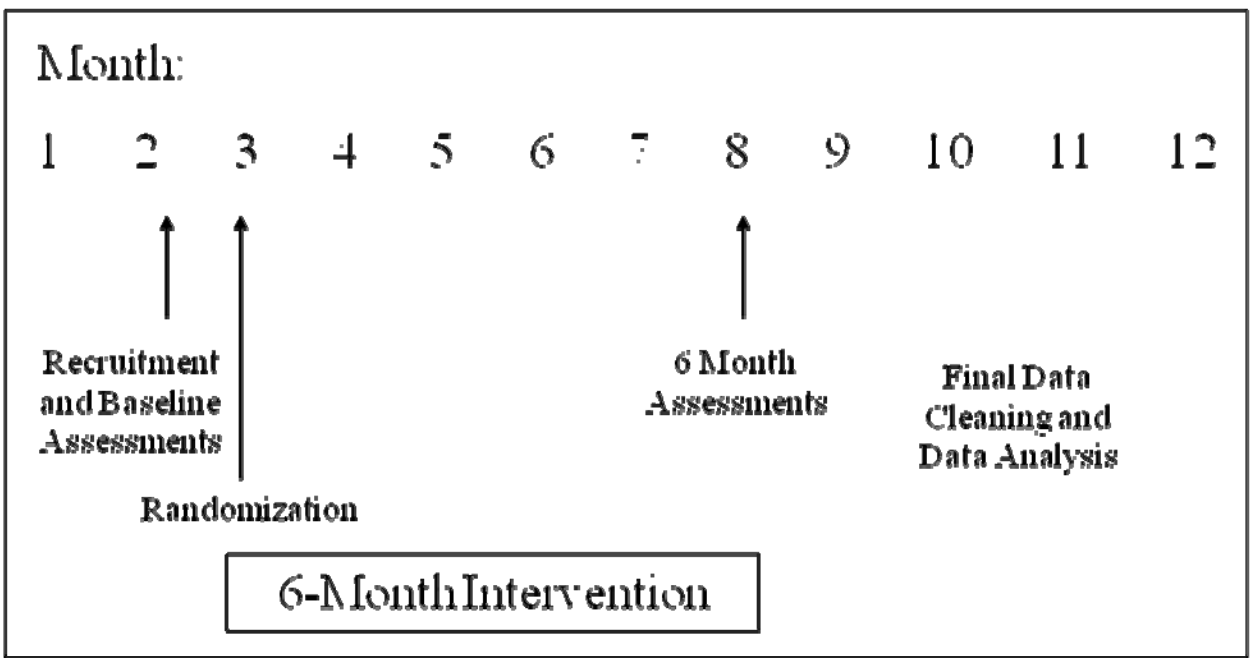



**Figure 3. Study Timeline**

## 3.4 STANDARD BEHAVIORAL WEIGHT LOSS INTERVENTION

The standard behavioral weight loss intervention was conducted at the University of Pittsburgh Physical Activity and Weight Management Research Center. The intervention included a 6-month program in which participants attended three weekly group meetings and one individual session each month. Group sessions ran approximately 30-45 minutes in length and were conducted by nutritionists and exercise physiologists with prior experience in conducting behavioral sessions. Topics of group lessons focused on behavioral strategies for changing eating and activity behaviors, which are primarily based on the Social Cognitive Theory. Individual sessions were approximately 20-30 minutes in length and were also conducted by interventionists. These sessions addressed individual barriers to changing physical activity and eating behaviors as well as setting specific behavior-related goals. All interventionists had experience in weight counseling as well as a background in nutrition, exercise physiology, or behavioral sciences. Staff were trained and supervised on how to conduct group and individual sessions, provide feedback on weekly dietary and physical activity diaries, and were familiar with using the BodyMedia® FIT System as well as common troubleshooting issues related to the armband, display, or website. Weekly meetings were held to discuss participant issues or treatment related concerns.

### 3.4.1 Dietary Component

Subjects were given a calorie and fat gram goal according to their initial body weight (Table 1). Subject's goals may have changed if they reduce to a different weight classification. The fat gram goals were set at 20% of total calories which falls within the USDA Dietary Guidelines range for fat at 20-35% of total calories[59].

**Table 1. Prescribed Calorie and Fat Goals by Body Weight**

| Starting Weight | Calorie Goal | Fat Goal |
|---|---|---|
| ≤ 174 pounds | 1200 | 26 |
| 175 - 219 pounds | 1500 | 33 |
| ≥ 220 pounds | 1800 | 42 |

Sample meal plans, recipes, and a copy of the 2009 edition of The Calorie King Calorie, Fat, and Carbohydrate Counter[103] were given to participants to assist with making healthy eating decisions. Group dietary lessons focused on lowering calorie and fat intake, reading food labels, choosing smaller portions, the MyPyramid, eating out, and self-monitoring dietary behaviors.

Subjects in the SBWL group recorded their daily dietary intake in a weekly food and activity diary. The diaries allowed participants to record the calories and fat grams of any meals and snacks that were consumed over the course of a day, as well as target any dietary goals that were set during individual sessions. Diaries were turned in weekly and reviewed by trained staff. Feedback was written on the diaries before returning them back to participants. In the case of a subject not recording behaviors for 7 consecutive days, an interventionist spoke with the participant at the next group or individual session or contacted the participant by telephone if he/she missed that session to determine why the individual stopped self-monitoring.

### 3.4.2 Exercise Component

Subjects were given weekly exercise goals starting with 100 minutes a week (20 minutes per day, 5 days a week) and progressing slowly to 300 minutes a week (60 minutes per day, 5 days a week) by 6 months (Table 2). Aerobic exercise, such as brisk walking, was recommended as the primary mode of exercise. This activity could have been done in long bouts or spread out across several short bouts that were at least 10 minutes in length. Non-aerobic activities including resistance training were discussed; however participants were instructed to engage in these activities in addition to their aerobic activity. Participants were encouraged to use the Borg Ratings of Perceived Exertion (RPE) scale[104] and exercise at moderate intensity at an RPE of 11-13 which is approximately 60 to 70% of aged-predicted maximal heart rate. Group exercise lessons focused on ways to increase lifestyle and structured physical activity and strategies to overcome barriers to activity.

**Table 2. Prescribed Exercise Progression**

| Weeks | Minutes/Day | Days/Week | Minutes/Week | Intensity (RPE) |
|---|---|---|---|---|
| 1-4 | 20 | 5 | 100 | 11-13 |
| 5-8 | 30 | 5 | 150 | 11-13 |
| 9-12 | 40 | 5 | 200 | 11-13 |
| 13-16 | 50 | 5 | 250 | 11-13 |
| 17-24 | 60 | 5 | 300 | 11-13 |

Participants in the SBWL group recorded the time of day, type of exercise, duration of the session, and intensity (RPE) of the activity in the food and exercise diary. If subjects did not exercise, the diary provided a space to list the reason for not exercising (e.g. lack of time, lack of motivation, or inconvenient).

## 3.5 STANDARD BEHAVIORAL WEIGHT LOSS PLUS BODYMEDIA® FIT SYSTEM (SBWL+FIT)

Participants in SBWL+FIT group participated in all of the components of the 6-month SBWL mentioned above which included following the same dietary and exercise goals as well as attending three weekly group meetings and one individual session each month. In addition, subjects were given the BodyMedia® FIT System that included the armband, digital display, and access to the activity manager website for the 6 month intervention period. Individuals were instructed to wear both the armband and display every day as well as download their physical activity information from the armband to the computer each day. The SBWL+FIT group was also instructed to primarily use the website to self-monitor dietary intake and body weight, however they were still given a paper food and exercise diary to use in case they did not immediately have access to a computer after a meal or exercise session.

At the first session of the intervention, an introductory lesson reviewed how to use all components of the BodyMedia® FIT System. Individuals were given confidential login identification codes which provided access to the activity manager website. Login procedures as well as uploading data from the armband to the computer were demonstrated using a computer and Internet. Detailed written instructions were also given illustrating the procedures for logging in, navigating on the website, and uploading to the computer.

Interventionists had access to an individual's activity manager website to evaluate their specific dietary and activity data. Interventionists used the information obtained from the BodyMedia® FIT System during individual sessions which aided in setting specific physical activity, energy expenditure, and diet related goals. In addition, interventionists monitored the website to ensure that participants are continuously self-monitoring. Each week, prior to the weekly session, the interventionist printed a summary sheet from each individual's website, provided written feedback regarding the past weeks eating and physical activity behaviors, and returned it to participants during sessions. In the case of a subject not recording behaviors for 7 consecutive days, an interventionist spoke with the participant at the next group or individual session or contacted the participant by telephone if he/she missed that session to determine why self-monitoring stopped.

## 3.6 BODYMEDIA® FIT SYSTEM ALONE (FIT)

The FIT group was given the same diet and exercise goals and was mailed the weekly behavioral lessons discussed in the SBWL, however they did not attend any group or individual sessions. Instead, individuals were provided with the BodyMedia® FIT System that included the armband, display, and access to the activity manager website for 6 months. Participants attended one introductory session similar to the SBWL+FIT which instructed individuals how to use all components of the BodyMedia® FIT System. In addition, FIT participants received a one hour lesson which reviewed basic information regarding weight loss. Calorie goals (1200-1800 kcal/day) based on their initial body weight and a daily fat gram goal of 20% of total calories were recommended. Participants were encouraged to gradually increase moderate intensity physical activity from 100-300 minutes/week across the 6-month intervention as well as self-monitor dietary intake, physical activity, and body weight using the BodyMedia® FIT activity manager website.

Participants also received one monthly 10 minute phone call from an interventionist, primarily for retention purposes. During this phone call, interventionists followed an individualized script which addressed any technological difficulties the individual was having with the BodyMedia® FIT System including armband, display, or website. The script also reviewed how often the technology-based system was used, current body weight, eating and activity behaviors, and the specific barriers for weight loss, dietary behaviors, physical activity, and technology use. Strategies to overcome these barriers were discussed briefly and all telephone call durations were recorded by the interventionist.

Interventionists had access to each individual's personal website to ensure that subjects were uploading their physical activity information and manually entering dietary intake, however feedback was not given. In the case of a subject not recording behaviors for 7 consecutive days, an interventionist contacted the participant by telephone with a specific script to determine why self-monitoring stopped.

## 3.7 ASSESSMENT PROCEDURES

Assessments were conducted at 0 and 6 months at the University of Pittsburgh Physical Activity and Weight Management Research Center. Assessments were held Monday thru Friday between the hours of 7:00AM – 11:00AM. The assessment procedures took approximately 90 minutes to complete and included height, body weight, body composition, cardiorespiratory fitness, and assessment of physical activity and dietary intake. Participants were also given questionnaires to complete at home prior to the assessment. These questionnaires were returned the day of the assessment.

### 3.7.1 Height, Body Weight, and Body Mass Index

Height was measured to the nearest 0.01 cm at the baseline assessment using a wall-mounted stadiometer (Perspective Enterprises, Portage, MI). Participants removed their shoes for this measurement. Body weight was measured to the nearest 0.1 kg on a Tanita WB-110A electronic scale (Tanita Corporation, Arlington Heights, IL) at 0 and 6 months with participants wearing a lightweight hospital gown. Body mass index was calculated using the height and weight measurements ($kg/m^2$). A questionnaire assessing the frequency of self-weighing per week was also given. Responses ranged from 0, 1-2, 3-4, 5-6, or 7 times per week.

### 3.7.2 Body Composition

Body composition was assessed at 0 and 6 months using a GE Lunar Prodigy dual-energy x-ray absorptiometer (DXA) (GE Healthcare, Madison, WI). Calibration and scanning speed was performed according to the manufacturer's instructions. Subjects wore a lightweight hospital gown and were asked to remove any jewelry or metal items. In addition, because small levels of radiation are involved with this procedure, all women underwent a urine sample pregnancy test prior to the scan. Pregnant women were excluded from the study. Individuals were instructed to lay motionless on the DXA scan table for a 10-15 minute period while the total body scan was performed. The DXA provides measurements of fat mass, lean mass, bone mineral density, and percent body fat. Analysis of the scan was performed by trained personnel.

### 3.7.3 Anthropometric Measurements

Abdominal adiposity, which has been found to be associated with heart disease as well as other health-related risk factors, was measured using waist girth and waist-to-hip ratio[105]. Measurements were taken at 0 and 6 months with subjects clothed in a lightweight hospital gown. Waist and hip circumferences were measured to the nearest 0.1 cm using a Gulick tape measure. Waist circumference was measured on the horizontal plane directly over the umbilicus. Hip circumference was measured at the largest part of the hips. Waist-to-hip ratio was calculated by dividing the waist measurement by the hip measurement. Two measures were taken at each site to ensure accuracy; however if these measures differed by more than 2.0 centimeters, a third measurement was taken. The mean value of each site was taken.

### 3.7.4 Cardiorespiratory Fitness

Cardiorespiratory fitness was assessed using a submaximal graded exercise test using a modified Balke protocol and was measured at 0 and 6 months. All exercise testing was conducted by an American College of Sports Medicine (ACSM) certified Exercise Specialist. The metabolic cart was calibrated prior to each test. Before each test, resting heart rate and blood pressure were obtained after a 5-minute rest period.

The exercise test was conducted using the following protocol: The speed of the treadmill began at 3.0 mph and remained constant throughout the test. The grade of the treadmill started at

0% and increased by 2.5% every 3 minutes. Heart rate and a 12-lead EKG were monitored continuously throughout the test. Blood pressure and ratings of perceived exertion (RPE) using the Borg Scale[104] were obtained during the last minute of each stage and at termination. Using a SensorMedics Vmax Metabolic Measuring Cart (SensorMedics, Yorba Linda CA), expired gas volumes and concentration were collected and measured continuously throughout the test. Termination of the test occurred at 85% of age-predicted maximal heart rate, which was determined by the equation of 220-age. Termination may have occurred earlier if any indications for terminating exercise testing as recommended by ACSM were presented[101]. After termination, subjects entered a 7-minute recovery period where heart rate and blood pressure continued to be monitored. The first 3 minutes of recovery were active at 2.0 mph and the last 4 minutes were in the seated position. A physician certified in EKG interpretation reviewed all exercise testing results to ensure there are no contraindications to participating in exercise during the intervention. All intervention staff assisting with exercise testing were CPR and AED certified and safety equipment was immediately accessible in the testing room.

### 3.7.5 Physical Activity

Physical activity was assessed at 0 and 6 months with the Paffenbarger Physical Activity Questionnaire[106]. This questionnaire can determine the daily average number of flights of stairs walked up and the number of city blocks walked for the sole purpose of exercise. In addition, any sport, recreational, fitness activities the subject engaged in over the previous week was reported. This questionnaire was administered by interview by trained personnel and results were reported in kilocalories per week from physical activity. This questionnaire has been validated and found to be a reliable measure of planned and lifestyle physical activity[107]

### 3.7.6 Dietary Intake and Eating Behaviors

Dietary intake was measured using the Block Food Frequency Questionnaire (FFQ) Version 2005, which assesses the usual frequency consumption of specific foods and typical portion sizes over a certain time period. The FFQ obtains information regarding daily energy intake and nutrient intake estimates and has been previously validated[108-109]. Dietary intake was assessed at 0 and 6 months.

Eating behaviors were measured using the Eating Behavior Inventory (EBI)[110]. This questionnaire assesses behaviors that may be related to weight loss such as self-monitoring of food intake and weight, refusing offers of food, shopping from a list, and eating in response to emotions. The EBI consists of 26 items that are rated with a 5-point scale ranging from never or hardly ever to always or almost always. The EBI has been established as a valid tool for measuring changes in weight related behaviors[110-111].

## 3.8 STATISTICAL ANALYSES

Statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS) software version 16.0. Statistical significance was defined at $P < 0.05$. The following analyses were conducted using individuals who completed assessments at 0 and 6 months and intention-to-treat analysis carrying the baseline data forward:

1.) Descriptive analyses were conducted to examine mean baseline characteristics (age, body weight, BMI), physical activity, body composition, and dietary intake.

2.) Additional descriptive analyses were conducted to examine process measures which include: attendance to weekly sessions, monthly telephone contact, dietary logging, self-reported caloric intake, energy expenditure, frequency of self-weighing, and armband time on body. A one way analysis of variance (ANOVA) was used to examine any differences in these process measures among group.

3.) A 3 x 2 mixed ANOVA were performed on weight loss as a function of group and time to determine if there were any differences between variables. The main effect of time examined any differences between 0 and 6 months. The main effect of group examined any differences among group randomization (SBWL, SBWL+FIT, FIT). The group x time interaction examined if the pattern of differences on weight loss among randomization groups was significantly different between 0 and 6 months. Post hoc pairwise comparisons were performed using the Bonferroni adjustment to examine the differences in weight loss between the 3 randomization groups.

4.) A 3 x 2 mixed ANOVA was performed on physical activity as a function of group and time to determine if there were any differences between variables. The main effect of time examined any differences between 0 and 6 months. The main effect of group examined any differences among group randomization (SBWL, SBWL+FIT, FIT). The group x time interaction examined if the pattern of differences on physical activity among randomization groups was significantly different between 0 and 6 months. Post hoc pairwise comparisons were performed using the Bonferroni adjustment to examine the differences in physical activity between the 3 randomization groups. In the case that data was not normally distributed, a nonparametric test (Kruskal-Wallis) was performed.

5.) A 3 x 2 mixed ANOVA was performed on dietary intake as a function of group and time to determine if there were any differences between variables. The main effect of time examined any differences between 0 and 6 months. The main effect of group examined any differences among group randomization (SBWL, SBWL+FIT, FIT). The group x time interaction examined if the pattern of differences on dietary intake among randomization groups was significantly different between 0 and 6 months. Post hoc pairwise comparisons were performed using the Bonferroni adjustment to examine the differences in dietary intake between the 3 randomization groups.

6.) A one way ANOVA was performed on the number of days dietary intake was self-monitored to determine if there were any differences among group randomization (SBWL, SBWL+FIT, FIT). Post hoc pairwise comparisons were performed using the Bonferroni adjustment to examine the differences in days dietary intake was self-monitored between the 3 randomization groups.

7.) A 3 x 2 mixed ANOVA was performed on cardiorespiratory fitness as a function of group and time to determine if there were any differences between variables. The main effect of time examined any differences between 0 and 6 months. The main effect of group examined any differences among group randomization (SBWL, SBWL+FIT, FIT). The group x time interaction examined if the pattern of differences on cardiorespiratory fitness among randomization groups was significantly different between 0 and 6 months. Post hoc pairwise comparisons were performed using the Bonferroni adjustment to examine the differences in cardiorespiratory fitness between the 3 randomization groups.

8.) A 3 x 2 mixed ANOVA was performed on body composition (fat mass, lean mass, bone mineral density, percent body fat, waist circumference, hip circumference, and waist-to-hip ratio) as a function of group and time to determine if there were any differences between variables. The main effect of time examined any differences between 0 and 6 months. The main effect of group examined any differences among group randomization (SBWL, SBWL+FIT, FIT). The group x time interaction examined if the pattern of differences on body composition among randomization groups was significantly different between 0 and 6 months. Post hoc pairwise comparisons were performed using the Bonferroni adjustment to examine the differences in body composition between the 3 randomization groups.

## 3.9 POWER ANALYSIS

The primary aim of this study was to compare the changes in body weight between the SBWL, SBWL+FIT, and FIT groups during a 6-month behavioral weight loss intervention in overweight and obese adults. This was the first study to examine this specific technology-based system and therefore it was proposed to randomize 25 subjects to each group. Although there are currently no published studies on the effectiveness of this specific technology-based system, and assuming an 8% dropout rate across groups and the variance estimates from a previous technology-based system by Polzien et al.[39] would be similar to what we would observe in this study (standard deviation = 3.4kg), we would need to observe differences in weight losses in SBWL+FIT compared to SBWL and SBWL compared to FIT by 2.21kg to achieve an effect size of .65 at 70% power, by 2.55kg to achieve an effect size of .75 at 80% power, and by 2.99kg to achieve an effect size of .88 at 90% power. Because this also assumes that weight loss will be greater in SBWL+FIT than SBWL and SBWL will be greater than FIT, these estimates are based on a one-tailed t-test with a type I error rate set less than or equal to 0.05.

We believe 25 subjects was a reasonable sample size to obtain variance estimates on the effectiveness of this specific technology-based system when combined or not combined with an in-person behavioral weight loss intervention. Although this study may not show significant group differences in weight loss, this technology-based system may result in clinically meaningful weight losses and could provide important data and information regarding the influence of this system.

# 4.0 RESULTS

The purpose of this study was to evaluate the effectiveness of a technology-based system when used alone or in combination with a 6-month behavioral weight loss intervention in overweight and obese adults. This was a pretest-posttest randomized controlled weight loss trial with assessments conducted at 0 and 6 months of participation. The results of this study are presented below:

## 4.1 SUBJECT CHARACTERISTICS

Fifty-one subjects between the ages of 21-55 years with a body mass index ranging from 25-39.9 $kg/m^2$ participated in this investigation at the University of Pittsburgh Physical Activity and Weight Management Research Center. Subjects were predominately female (86%), had a mean age of 44.2 ± 8.7 years, and mean body mass index (BMI) of 33.7 ± 3.6 $kg/m^2$ at the start of the program. Descriptive statistics of baseline characteristics are presented in Table 3. One-way analysis of variance (ANOVA) revealed a significant difference in baseline body weight ($p$=0.02) between treatment groups. Bonferroni post hoc analysis indicated a significantly higher baseline weight in SBWL+FIT compared to SBWL ($p$=0.02). There were no differences observed for baseline age, body mass index, waist and hip circumference, waist-to-hip ratio, body composition, dietary intake, and physical activity during analysis. Chi-square analyses revealed no baseline differences in gender or race. Analyses were repeated excluding males and no significant differences were detected between groups. (See Appendix A).

**Table 3. Differences in Baseline Characteristics by Treatment Group**

| Characteristics | Total (N=51) (mean± s.d.) | SBWL (N=17) (mean ± s.d.) | SBWL+FIT (N=17) (mean± s.d.) | FIT (N=17) (mean ± s.d.) | P-value |
|---|---|---|---|---|---|
| Age (years) | 44.2 ± 8.7 | 45.1 ± 9.4 | 43.3 ± 9.1 | 44.1 ± 8.1 | 0.85 |
| Weight (kg) | 94.3 ± 15.1 | 88.6 ± 12.5 | 102.1 ± 17.5 | 92.3 ± 12.1 | 0.02* |
| Body Mass Index (kg/m$^2$) | 33.7 ± 3.6 | 33.1 ± 3.8 | 34.7 ± 3.4 | 33.4 ± 3.6 | 0.42 |
| Waist Circumference (cm) | 112.5 ± 11.7 | 111.0 ± 12.9 | 114.3 ± 14.1 | 112.2 ± 7.4 | 0.73 |
| Hip Circumference (cm) | 119.2 ± 7.5 | 118.1 ± 8.8 | 122.2 ± 6.6 | 117.3 ± 6.6 | 0.13 |
| Waist-to-hip ratio | 0.94 ± 0.1 | 0.94 ± 0.1 | 0.93 ± 0.1 | 0.96 ± 0.1 | 0.60 |
| Body Composition (% fat) | 46.5 ± 4.9 | 47.7 ± 5.2 | 45.8 ± 4.6 | 46.0 ± 4.8 | 0.43 |
| Gender | | | | | 0.12 |
| % Males | 13.7% (N=7) | 0% (N=0) | 23.5% (N=4) | 17.6% (N=3) | |
| % Females | 86.3% (N=44) | 100% (N= 17) | 76.5% (N=13) | 82.4% (N= 14) | |
| Race | | | | | 0.41 |
| % African-American | 9.8% (N=5) | 17.6% (N=3) | 5.9% (N=1) | 5.9% (N=1) | |
| % Caucasian | 88.2% (N=45) | 76.5% (N=13) | 94.1% (N=16) | 94.1% (N=16) | |
| % Other | 2% (N=1) | 5.9% (N=1) | 0% (N=0) | 0% (N=0) | |
| Dietary Intake (kcal/day) | 1881.8 ± 778.0 | 2095.8 ± 1023.4 | 1693.4 ± 592.8 | 1856.2 ± 636.8 | 0.32 |
| Self-Reported Physical Activity (kcal/week) | 570.6 ± 567.6 | 517.2 ± 540.0 | 770.9 ± 741.6 | 423.7 ± 310.8 | 0.18 |

*SBWL < SBWL+FIT

## 4.2 RETENTION RATES

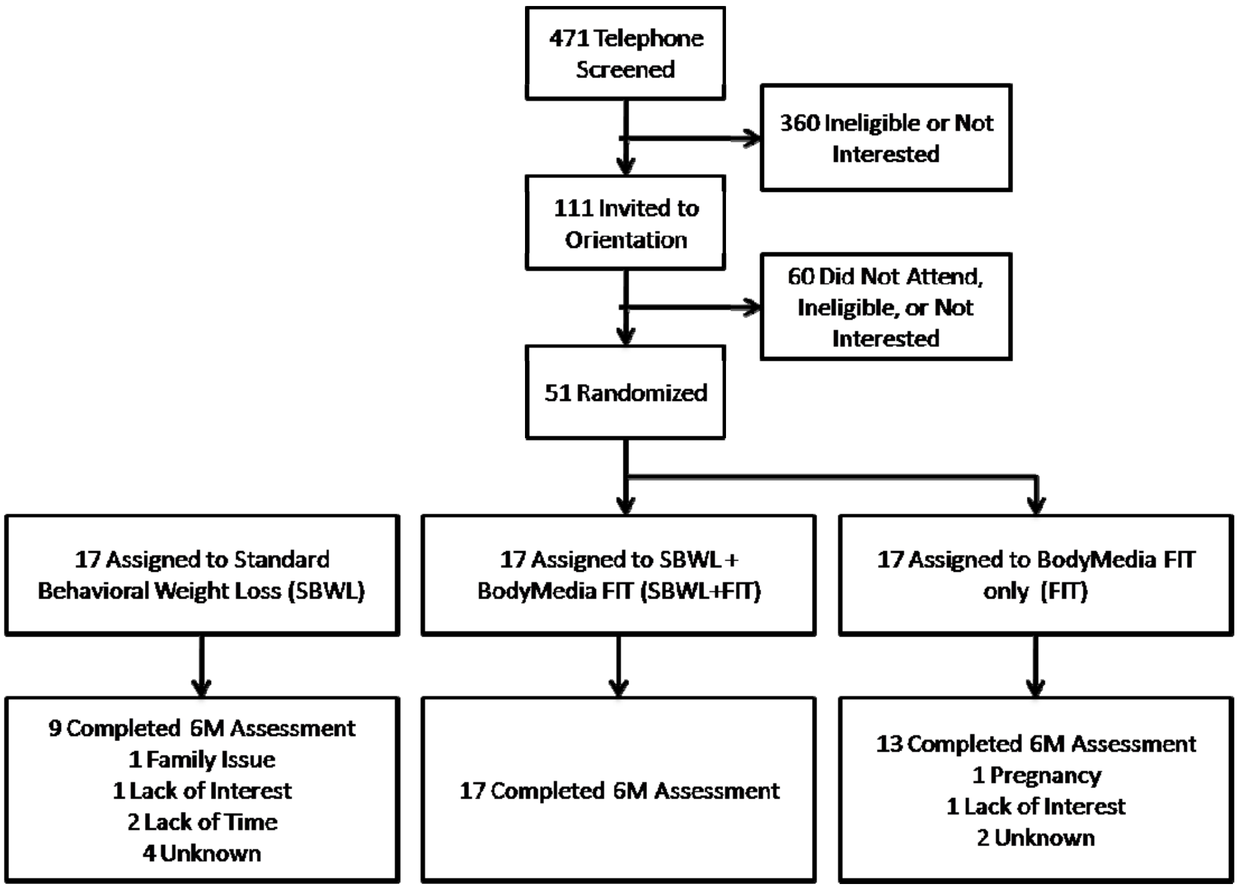



**Figure 4. Study Enrollment and Retention Across Groups**

Fifty-one subjects were randomized to one of three treatment groups (SBWL, SBWL+FIT, FIT). A total of 39 participants (76.5%) completed baseline and 6-month assessments and will be referred to as "completers." Participants who did not complete the 6-month assessment (N=12, 23.5%) will be referred to as "non-completers." Baseline characteristics between completers and non-completers are presented in Table 4. Independent samples t-tests revealed a significant difference between completers and non-completers in hip circumference at baseline (completers > non-completers, p=0.01). No differences were observed in any of the other baseline characteristics. Analyses with females only revealed similar results. (See Appendix B). When examined by treatment group (Table 5), significant differences were detected between the completers and non-completers in FIT for baseline waist-to-hip ratio ($p<0.05$) and dietary intake ($p<0.01$). When males were excluded, completers in FIT had significantly higher hip circumference and dietary intake at baseline than non-completers ($p<0.05$). Furthermore, chi square analysis revealed a significant difference among race in FIT between completers and non-completers ($p=0.047$). The results are shown in Appendix C.

Figure 4 illustrates subject enrollment, retention, and reasons for withdrawal, which included lack of interest in the program, pregnancy, and family issues. Overall, retention rates for each group were as follows: 53% for SBWL, 100% for SBWL+FIT, and 77% for FIT. Chi square analysis revealed a significant difference in retention rates among treatment groups ($p=0.005$).

**Table 4. Differences in Baseline Characteristics by Completers and Non-Completers**

| Characteristics | Total (N=51) (mean± s.d.) | Completers (N=39) (mean ± s.d.) | Non-Completers (N=12) (mean± s.d.) | P-value |
|---|---|---|---|---|
| Age (years) | 44.2 ± 8.7 | 44.4 ± 8.2 | 43.3 ± 10.5 | 0.69 |
| Weight (kg) | 94.3 ± 15.1 | 96.0 ± 14.4 | 88.8 ± 16.6 | 0.15 |
| Body Mass Index ($kg/m^2$) | 33.7 ± 3.6 | 34.0 ± 3.4 | 32.8 ± 4.3 | 0.32 |
| Waist Circumference (cm) | 112.5 ± 11.7 | 113.0 ± 11.4 | 110.7 ± 12.8 | 0.55 |
| Hip Circumference (cm) | 119.2 ± 7.5 | 120.7 ± 6.4 | 114.4 ± 9.1 | 0.01* |
| Waist-to-hip ratio | 0.94 ± 0.1 | 0.94 ± 0.1 | 0.97 ± 0.1 | 0.19 |
| Body Composition (% fat) | 46.5 ± 4.9 | 46.8 ± 4.8 | 45.8 ± 5.2 | 0.56 |
| Gender | | | | 0.54 |
| % Males | 13.7% (N=7) | 15.4% (N=6) | 8.3% (N=1) | |
| % Females | 86.3% (N=44) | 84.6% (N=33) | 91.7% (N=11) | |
| Race | | | | 0.12 |
| % African-American | 9.8% (N=5) | 5.1% (N=2) | 25.0% (N=3) | |
| % Caucasian | 88.2% (N=45) | 92.3% (N=36) | 75.0% (N=9) | |
| % Other | 2% (N=1) | 2.6% (N=1) | 0.0% (N=0) | |
| Dietary Intake (kcal/day) | 1881.8 ± 778.0 | 1940.7 ± 825.9 | 1690.3 ± 585.2 | 0.34 |
| Self-Reported Physical Activity (kcal/week) | 570.6 ± 567.6 | 575.6 ± 553.4 | 554.4 ± 637.3 | 0.36 |

* $p < 0.05$ Completer > Non-Completer

**Table 5. Baseline Characteristics by Completers and Non-Completers by Treatment Group**

| Characteristics | SBWL Completers (N=9) (mean± s.d.) | SBWL Non-Completers (N=8) (mean± s.d.) | SBWL+FIT Completers (N=17) (mean± s.d.) | SBWL+FIT Non-Completers (N=0) (mean± s.d.) | FIT Completers (N=13) (mean± s.d.) | FIT Non-Completers (N=4) (mean± s.d.) |
|---|---|---|---|---|---|---|
| Age (years) | 46.0 ± 9.3 | 44.1 ± 10.0 | 43.3 ± 9.1 | ---- | 44.8 ± 6.6 | 41.7 ± 12.8 |
| Weight (kg) | 90.1 ± 9.2 | 87.0 ± 15.9 | 102.1 ± 17.5 | ---- | 92.2 ± 9.8 | 92.4 ± 19.9 |
| Body Mass Index ($kg/m^2$) | 34.2 ± 3.1 | 31.9 ± 4.3 | 34.7 ± 3.4 | ---- | 33.0 ± 3.6 | 34.6 ± 4.1 |
| Waist Circumference (cm) | 112.7 ± 12.0 | 109.2 ± 14.5 | 114.3 ± 14.1 | ---- | 111.7 ± 6.9 | 113.8 ± 9.7 |
| Hip Circumference (cm) | 120.3 ± 7.3 | 115.6 ± 10.1 | 122.2 ± 6.6 | ---- | 119.0 ± 5.6 | 112.0 ± 7.5 |
| Waist-to-hip ratio | 0.93 ± 0.1 | 0.94 ± 0.1 | 0.93 ± 0.1 | ---- | 0.94 ± 0.1* | 1.0 ± 0.0* |
| Body Composition (% fat) | 48.9 ± 5.4 | 46.5 ± 4.9 | 45.8 ± 4.6 | ---- | 46.5 ± 4.4 | 44.3 ± 6.4 |
| Gender | | | | | | |
| % Males | 0% (N=0) | 0% (N=0) | 23.5% (N=4) | ---- | 15.4% (N=2) | 25% (N=1) |
| % Females | 100% (N=9) | 100% (N=8) | 76.4% (N= 13) | ---- | 84.6% (N=11) | 75% (N=3) |
| Race | | | | | | |
| % African-American | 11.1% (N=1) | 25.0% (N=2) | 5.9% (N=1) | ---- | 0.0% (N=0) | 25.0% (N=1) |
| % Caucasian | 77.8% (N=7) | 75.0% (N=6) | 94.1% (N=16) | ---- | 100% (N=13) | 75.0% (N=3) |
| % Other | 11.1% (N=1) | 0.0% (N=0) | 0.0% (N=0) | ---- | 0.0% (N=0) | 0.0% (N=0) |
| Dietary Intake (kcal/day) | 2271.3 ±1297.3 | 1898.3±621.7 | 1693.4±592.8 | ---- | 2035.2±625.5* | 1274.5±89.2* |
| Self-Reported Physical Activity (kcal/week) | 403.8 ± 300.6 | 644.8 ± 726.8 | 770.9 ± 741.6 | ---- | 439.0 ± 282.5 | 373.8 ± 218.8 |

* $p < 0.05$ for difference between completers and non-completers in FIT

## 4.3 CHANGES IN BODY WEIGHT AND BMI

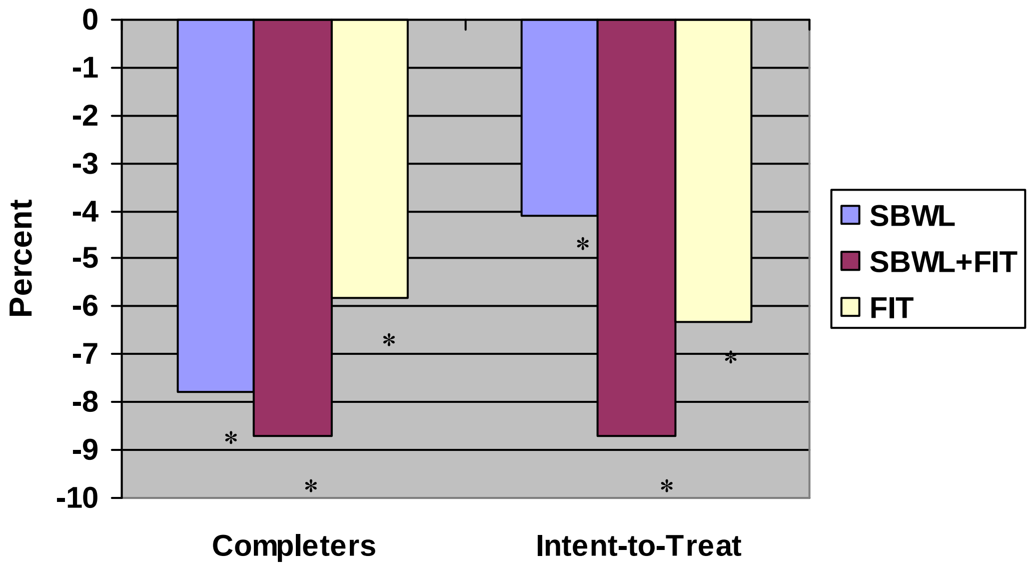
A 3 x 2 mixed ANOVA was performed to examine the changes in body weight and body mass index from baseline and 6 months between treatment groups. Results of the completers analysis indicated a significant weight loss from baseline to 6 months in SBWL (-7.1 ± 6.2 kg), SBWL+FIT (-8.8 ± 5.0 kg), and FIT (-7.6 ± 6.6 kg) ($p<0.001$), however there were no differences between groups (p=0.09). Results are shown in Table 6. The overall weight loss percentage among all conditions was -8.4 ± 5.9% with no differences between groups (SBWL: -7.8 ± 6.9%; SBWL+FIT: -8.7 ± 4.7%; FIT: -8.3 ± 7.1%) (See Figure 5). When baseline body weight was controlled, there were no differences observed between groups on percent weight change (p=0.970). Similarly, body mass index significantly decreased from baseline to 6 months (p<0.001), but there were no differences between groups (p=0.49). When males were excluded from analyses, similar results were found among body weight and body mass index. (See Appendix D).

**Table 6. Outcome Differences Between Treatment Groups at 6 Months - Completers Analysis**

| | | | | P-Values | | |
|---|---|---|---|---|---|---|
| Outcome Variable | SBWL (N=9) (mean± s.d.) | SBWL+FIT (N=17) (mean± s.d.) | FIT (N=13) (mean± s.d.) | Group Effect | Time Effect | Group X Time |
| Body Weight (kg) | | | | | | |
| 0 Months | 90.1 ± 9.2 | 102.1 ± 17.5 | 92.2 ± 9.8 | | | |
| 6 Months | 83.1 ± 10.6 | 93.3 ± 17.4 | 84.6 ± 11.7 | 0.086 | <0.001 | 0.722 |
| Body Mass Index ($kg/m^2$) | | | | | | |
| 0 Months | 34.2 ± 3.1 | 34.7 ± 3.4 | 33.0 ± 3.6 | | | |
| 6 Months | 31.4 ± 3.0 | 31.6 ± 3.4 | 30.3 ± 4.3 | 0.485 | <0.001 | 0.901 |
| $VO_2$ at 85% APMHR (ml/kg/min)+ | | | | | | |
| 0 Months | 22.1 ± 6.6 | 25.6 ± 4.8 | 25.0 ± 4.5 | | | |
| 6 Months | 24.9 ± 4.5 | 28.2 ± 6.2 | 27.5 ± 5.1 | 0.354 | <0.001 | 0.987 |
| Treadmill Time to reach 85% APMHR (seconds) + | | | | | | |
| 0 Months | 471.4 ± 284.9 | 626.7 ± 170.0 | 567.7 ± 261.3 | | | |
| 6 Months | 600.0 ± 218.8 | 760.0 ± 236.2 | 730.8 ± 293.8 | 0.350 | <0.001 | 0.811 |
| Self-Report Physical Activity (kcal/wk)§ | | | | | | |
| 0 Months | 403.8 ± 300.6 | 770.9 ± 741.6 | 457.0 ± 287.3 | | | |
| 6 Months | 1299.1 ± 837.1 | 1484.8 ± 792.9 | 1967.4±1483.0 | 0.344 | <0.001 | 0.548 |
| Dietary Intake (kcal/day) | | | | | | |
| 0 Months | 2271.3±1297.3 | 1693.4±592.8 | 2035.2±625.5 | | | |
| 6 Months | 1912.9±1100.3 | 1390.5±530.3 | 1473.6±552.4 | 0.171 | <0.001 | 0.524 |
| Eating Behavior Inventory | | | | | | |
| 0 Months | 65.1 ± 6.0 | 71.4 ± 9.0 | 68.7 ± 10.8 | | | |
| 6 Months | 86.8 ± 10.3 | 90.1 ± 7.8 | 85.4 ± 9.5 | 0.235 | <0.001 | 0.516 |

§ One subject (FIT) did not complete Paffenbarger Questionnaire at 6 months.
+ Four subjects (2 SBWL, 2 SBWL+FIT) did not complete treadmill test due to medical issues at 6 months and two subjects (1 SBWL+FIT, 1 FIT) did not complete VO2 collection at 0 or 6 months due to claustrophobia.
APMHR = Age predicted maximum heart rate

Intent-to-treat analysis was conducted using all randomized participants. In the case of an individual failing to complete the 6 month assessment, baseline data was carried forward to the 6 month assessment to assume no change from baseline. A 2 x 3 mixed ANOVA revealed a significant time effect ($p<0.001$) and group x time interaction ($p<0.05$) with body weight between baseline and 6 months for SBWL (-3.7 ± 5.7 kg), SBWL+FIT (-8.8 ± 5.0 kg), and FIT (-5.8 ± 6.6 kg) ($p<0.001$). Post hoc analysis revealed a trend for a greater weight loss in SBWL+FIT than SBWL ($p=0.089$). Results are shown in Table 7. The overall weight loss percentage was -6.4 ± 6.3% with no significant differences between groups (SBWL: -4.1 ± 6.3%; SBWL+FIT: -8.7 ± 4.7%; FIT: -6.3 ± 7.1%). (See Figure 5). When baseline body weight was controlled, there were no significant differences observed between groups on percent weight change ($p=0.214$). Body mass index significantly decreased between baseline and 6 months in SBWL (-1.5 ± 2.3 $kg/m^2$), SBWL+FIT (-3.0 ± 1.7 $kg/m^2$), and FIT (-2.1 ± 2.4 $kg/m^2$) ($p<0.001$), however there were no differences between groups ($p=0.77$). Similar results on body weight and body mass index were revealed when intent-to-treat analyses were repeated with females only (See Appendix E).




* Indicates significant change from baseline at p<0.001

Note: No statistical significance between groups in the completer or ITT analyses.

**Figure 5. Weight Loss Percentage Among Treatment Groups (Completers and ITT)**

**Table 7. Outcome Differences Between Treatment Groups at 6 Months - Intent-to-Treat Analysis**

| Outcome Variable | SBWL (N=17) (mean± s.d.) | SBWL+FIT (N=17) (mean± s.d.) | FIT (N=17) (mean± s.d.) | P-Values Group Effect | Time Effect | Group X Time |
|---|---|---|---|---|---|---|
| Body Weight (kg) | | | | | | |
| 0 Months | 88.6 ± 12.5 | 102.1 ± 17.5 | 92.3 ± 12.1 | | | |
| 6 Months | 84.9 ± 13.1 | 93.3 ± 17.4 | 86.4 ± 13.7 | 0.075 | <0.001 | 0.044 |
| Body Mass Index (kg/$m^2$) | | | | | | |
| 0 Months | 33.1 ± 3.8 | 34.7 ± 3.4 | 33.4 ± 3.6 | | | |
| 6 Months | 31.7 ± 3.6 | 31.6 ± 3.4 | 31.3 ± 4.5 | 0.768 | <0.001 | 0.102 |
| $VO_2$ at 85% APMHR (ml/kg/min)$^+$ | | | | | | |
| 0 Months | 22.5 ± 4.9 | 25.7 ± 4.6 | 25.8 ± 5.0 | | | |
| 6 Months | 23.7 ± 4.1 | 28.0 ± 5.9 | 27.6 ± 5.2 | 0.040* | <0.001 | 0.573 |
| Treadmill Time to reach 85% APMHR (seconds) | | | | | | |
| 0 Months | 491.8 ± 211.5 | 638.8 ± 167.3 | 572.9 ± 236.5 | | | |
| 6 Months | 544.7 ± 185.0 | 756.5 ± 224.5 | 697.6 ± 270.5 | 0.048* | <0.001 | 0.212 |
| Self-Report Physical Activity (kcal/wk) | | | | | | |
| 0 Months | 517.2 ± 540.0 | 770.9 ± 741.6 | 423.7 ± 310.8 | | | |
| 6 Months | 991.1 ± 833.6 | 1484.8 ± 792.9 | 1489.9 ±1459.6 | 0.224 | <0.001 | 0.246 |
| Dietary Intake (kcal/day) | | | | | | |
| 0 Months | 2095.8±1023.4 | 1693.4±592.8 | 1856.2±636.8 | | | |
| 6 Months | 1906.0 ± 880.1 | 1390.5±530.3 | 1426.7±487.8 | 0.114 | <0.001 | 0.476 |
| Eating Behavior Inventory | | | | | | |
| 0 Months | 66.9 ± 7.7 | 71.4 ± 9.0 | 69.2 ± 10.3 | | | |
| 6 Months | 78.4 ± 13.2 | 90.1 ± 7.8 | 82.0 ± 11.2 | 0.021* | <0.001 | 0.159 |

APMHR = Age predicted maximum heart rate
+ One subject (SBWL+FIT) did not complete $VO_2$ collection to claustrophobia (0 or 6 months)
* SBWL+FIT > SBWL

## 4.4 CHANGES IN CARDIORESPIRATORY FITNESS

Cardiorespiratory fitness was assessed during a submaximal graded exercise test and expressed as relative oxygen uptake ($VO_2$) and time to reach 85% of age-predicted maximal heart rate (APMHR). One subject was excluded from the analysis of oxygen update at baseline and two subjects at 6 months due to claustrophobia from wearing the mouthpiece. Four additional subjects were excluded from this analysis despite completing the intervention due to injury, recent surgery, and dizziness at 6 months. Results from a 2 x 3 mixed ANOVA revealed significant improvements in cardiorespiratory fitness at 6 months for completers in SBWL (2.8 ± 4.0 ml/kg/min), SBWL+FIT (2.6 ± 3.3 ml/kg/min), and FIT (2.5 ± 3.6 ml/kg/min) ($p<0.001$). Results are shown in Table 6. Likewise, there were significant increases in the time to reach 85% of APMHR in SBWL (128.6 ± 155.3 seconds), SBWL+FIT (133.3 ± 123.7 seconds), and FIT (163.1 ± 146.3 seconds) ($p<0.001$). There were no differences between groups in relative $VO_2$ ($p=0.35$) or time to reach 85% APMHR ($p=0.35$). Female only analyses revealed similar results on relative $VO_2$ and time to reach 85% of APMHR (See Appendix D).

Intent-to-treat analysis indicated significant increases in cardiorespiratory fitness at 6 months in SBWL (1.1 ± 2.8 ml/kg/min), SBWL+FIT (2.3 ± 3.2 ml/kg/min), and FIT (1.8 ± 3.2 ml/kg/min) ($p<0.001$). Results are shown in Table 7. There was also a significant group effect ($p<0.05$), with Bonferroni post hoc analysis revealing trends for a lower improvement in relative $VO_2$ in SBWL than SBWL+FIT ($p=0.076$) and FIT ($p=0.091$). One subject was excluded from the analysis of oxygen uptake at 0 and 6 months due to claustrophobia from wearing the mouthpiece. Intent-to-treat analysis also revealed significant improvements in the time to reach 85% of APMHR at 6 months in SBWL (52.9 ± 115.3 seconds), SBWL+FIT (117.6 ± 123.9 seconds), and FIT (124.7 ± 145.3 seconds) ($p<0.001$). Bonferonni post hoc analysis revealed significantly greater improvements in the time to reach 85% of APMHR in SBWL+FIT compared to SBWL ($p=0.048$). When males were excluded from the intent-to-treat analyses, similar time effects were observed on relative $VO_2$ or time to reach 85% of APMHR from baseline to 6 months, however no group differences were revealed. The results are shown in Appendix E.

## 4.5 CHANGES IN PHYSICAL ACTIVITY

Self-reported physical activity was not normally distributed and therefore the nonparametric (Kruskal-Wallis) test was performed. Significant increases in self-reported physical activity obtained from the Paffenbarger Physical Activity Questionnaire from baseline to 6 months were observed in SBWL (895.2 ± 926.3 kcal/week), SBWL+FIT (713.9 ± 1278.8 kcal/week), and FIT (1510.4 ± 1415.7 kcal/week) ($p<0.001$), however there were no significant differences detected between treatment groups ($p=0.55$). These results are shown in Table 6. Among all conditions, self-reported physical activity increased by 1008.4 ± 1270.1 kcal/week over the 6 month program. Analysis including only females revealed similar results (See Appendix D).

Intent-to-treat analysis indicated a significant increase in self-reported physical activity at 6 months in SBWL (473.9 ± 800.7 kcal/week), SBWL+FIT (713.9 ± 1278.8 kcal/week), and FIT (1066.2 ± 1371 kcal/week) ($p<0.001$) (See Table 7). Similar to the completers analysis, there were no differences between treatment groups ($p=0.25$). Overall, physical activity increased by 751 ± 1179.3 kcal/week from baseline to 6 months. Intent-to-treat analysis excluding males revealed similar results (See Appendix E).

## 4.6 CHANGES IN DIETARY INTAKE AND EATING BEHAVIORS

Results from a 3 x 2 mixed ANOVA indicated a significant difference in dietary intake from baseline to 6 months for completers in SBWL (-358.4 ± 1029.9 kcal/day), SBWL+FIT (-303.0 ± 248.4 kcal/day), and FIT (-561.6 ± 619.6 kcal/day) ($p<0.001$), however no differences existed between groups ($p=0.17$) (See Table 6). Weight loss eating behaviors, which was assessed from the Eating Behavior Inventory, significantly improved in all conditions from baseline to 6 months ($p<0.001$). No differences were observed between groups ($p=0.24$) (See Table 6). When analyses were repeated with females only, similar results were observed across time for dietary intake and eating behaviors, however, dietary intake was significantly greater in SBWL than SBWL+FIT ($p=0.04$). Results are presented in Appendix D.

Intent-to-treat analysis revealed significant reductions in dietary intake from baseline to 6 months in SBWL (-189.8 ± 751.2 kcal/day), SBWL+FIT (-303.0 ± 248.4 kcal/day), and FIT (-429.5 ± 590.1 kcal/day) ($p<0.001$). Results are shown in Table 7. There were no significant differences between treatment groups ($p=0.11$). Eating behaviors significantly improved from baseline to 6 months ($p<0.001$) with significant differences existing between groups ($p=0.02$). Post hoc analysis revealed a greater improvement in weight loss eating behaviors in SBWL+FIT than SBWL ($p=0.02$) (See Table 7). Intent-to-treat analyses excluding males revealed similar time effects for both dietary intake and eating behaviors. In addition, group differences were observed with SBWL reporting consumption of significantly more kilocalories each day and improving less on eating behaviors than SBWL+FIT ($p<0.05$). Results are shown in Appendix E.

## 4.7 CHANGES IN ANTHROPOMETRIC MEASUREMENTS AND BODY COMPOSITION

A 2 x 3 mixed ANOVA revealed significant reductions in waist and hip circumference at 6 months for completers in SBWL (waist: -8.4 ± 8.0 cm; hip: -7.8 ± 6.0 cm), SBWL+FIT (waist: -8.0 ± 5.7 cm; hip: -7.0 ± 3.6 cm), and FIT (waist: -7.3 ± 7.5 cm; hip: -8.1 ± 6.6 cm) ($p<0.001$)

(See Table 8). However, there were no differences observed between groups for change in waist, hip, or waist-to-hip ratio. Fat and lean mass significantly decreased at 6 months for SBWL (fat: -5.10 ± 5.10 kg; lean: -1.71 ± 2.12 kg), SBWL+FIT (fat: -6.81 ± 3.82 kg; lean: -1.64 ± 2.02 kg), and FIT (fat: -6.60 ± 5.88 kg; lean: -0.83 ± 1.51 kg) ($p<0.001$), however differences between groups were only observed with lean mass ($p=0.034$). Specifically, SBWL+FIT had a greater reduction in lean mass than SBWL ($p=0.037$). One-way ANOVA did not reveal any differences between groups on the percent of weight loss from lean body mass (SBWL: 35.7 ± 176.2%; SBWL+FIT: 16.3 ± 37.4%; FIT: 51.0 ± 191.2%) ($p=0.797$). Percent body fat significantly decreased from baseline to 6 months for completers in SBWL (-2.3 ± 3.1%), SBWL+FIT (-3.3 ± 2.2%), and FIT (-4.1 ± 3.8%) ($p<0.001$), however no differences were detected between treatment groups ($p=0.15$). Waist-to-hip ratio and bone mineral density did not significantly differ across time or group. Female only analyses revealed similar results for all body composition and anthropometric measurements except for a significant difference in lean body mass, which was no longer observed between groups ($p=0.37$). Results are presented in Appendix F.

**Table 8. Body Composition and Anthropometric Outcome Differences - Completers Analysis**

| Outcome Variable | SBWL (N=9) (mean± s.d.) | SBWL+FIT (N=17) (mean± s.d.) | FIT (N=13) (mean± s.d.) | P-Values Group Effect | Time Effect | Group X Time |
|---|---|---|---|---|---|---|
| Waist Circumference (cm) | | | | | | |
| 0 Months | 112.7 ± 12.0 | 114.3 ± 14.1 | 111.7 ± 6.9 | | | |
| 6 Months | 104.3 ± 8.9 | 106.3 ± 13.0 | 104.4 ± 9.9 | 0.841 | <0.001 | 0.935 |
| Hip Circumference (cm)^ | | | | | | |
| 0 Months | 120.3 ± 7.3 | 122.2 ± 6.8 | 119.0 ± 5.6 | | | |
| 6 Months | 112.6 ± 6.3 | 115.2 ± 6.0 | 110.9 ± 8.2 | 0.265 | <0.001 | 0.853 |
| Waist-to-Hip Ratio^ | | | | | | |
| 0 Months | 0.93 ± 0.1 | 0.93 ± 0.1 | 0.94 ± 0.1 | | | |
| 6 Months | 0.93 ± 0.1 | 0.92 ± 0.1 | 0.94 ± 0.1 | 0.895 | 0.429 | 0.722 |
| Fat Mass (kg) | | | | | | |
| 0 Months | 42.56 ± 7.59 | 45.18 ± 9.46 | 41.06 ± 4.47 | | | |
| 6 Months | 37.46 ± 7.82 | 38.38 ± 8.90 | 34.47 ± 6.09 | 0.345 | <0.001 | 0.684 |
| Lean Mass (kg) | | | | | | |
| 0 Months | 44.12 ± 4.86 | 53.22 ± 9.75 | 47.59 ± 8.14 | | | |
| 6 Months | 42.41 ± 4.51 | 51.58 ± 10.35 | 46.76 ± 8.09 | 0.034* | <0.001 | 0.433 |
| Body Fat (%) | | | | | | |
| 0 Months | 48.9 ± 5.4 | 45.8 ± 4.6 | 46.5 ± 4.4 | | | |
| 6 Months | 46.6 ± 4.7 | 42.5 ± 5.0 | 42.4 ± 4.8 | 0.152 | <0.001 | 0.407 |
| Bone Mineral Density ($g/cm^2$) | | | | | | |
| 0 Months | 1.2302 ± 0.122 | 1.2672 ± 0.119 | 1.2877 ± 0.069 | | | |
| 6 Months | 1.2242 ± 0.133 | 1.2600 ± 0.112 | 1.2923 ± 0.072 | 0.400 | 0.313 | 0.150 |

^ One subject (SBWL+FIT) missing hip measurement
* SBWL+FIT > SBWL

Intent-to-treat analysis indicated significant decreases in waist and hip circumference from baseline to 6 months in SBWL (waist: -4.4 ± 7.1 cm; hip: -4.1 ± 5.8 cm), SBWL+FIT (waist: -8.0 ± 5.7 cm, hip: -6.6 ± 3.9 cm), and FIT (waist: -5.6 ± 7.2 cm; hip: -6.2 ± 6.7 cm) ($p<0.001$). Results are shown in Table 9. Fat and lean mass significantly reduced at 6 months among all conditions ($p<0.001$). There was a trend for a group by time interaction for fat mass ($p=0.052$), however only significant differences were observed in lean mass with SBWL+FIT demonstrating greater decreases than SBWL ($p=0.012$). One-way ANOVA did not reveal any differences between groups on the percent of weight loss from lean body mass (SBWL: 18.9 ±

125.9%; SBWL+FIT: 16.3 ± 37.4%; FIT: 39.0 ± 167.0%) (p=0.841). Similarly, significant reductions in percent body fat were seen at 6 months for SBWL (-1.2 ± 2.5%), SBWL+FIT (-3.3 ± 2.2%), and FIT (-3.1 ± 3.8%) ($p<0.001$). No differences existed between groups or in waist-to-hip ratio and bone mineral density across time. Intent-to-treat analyses excluding males revealed similar results for waist, hip, waist-to-hip ratio, and bone mineral density. No difference in lean mass (p=0.07) was observed between groups, however significant group x time interactions were revealed for fat mass (p=0.043) and percent body fat (p=0.047). The results are presented in Appendix G.

**Table 9. Body Composition and Anthropometric Outcome Differences - Intent-to-Treat Analysis**

| Outcome Variable | SBWL (N=17) (mean± s.d.) | SBWL+FIT (N=17) (mean± s.d.) | FIT (N=17) (mean± s.d.) | P-Values Group Effect | Time Effect | Group X Time |
|---|---|---|---|---|---|---|
| Waist Circumference (cm) | | | | | | |
| 0 Months | 111.0 ± 12.9 | 114.3 ± 14.1 | 112.2 ± 7.4 | | | |
| 6 Months | 106.6 ± 11.7 | 106.3 ± 13.0 | 106.6 ± 10.4 | 0.932 | <0.001 | 0.305 |
| Hip Circumference (cm) | | | | | | |
| 0 Months | 118.1 ± 8.8 | 122.2 ± 6.6 | 117.3 ± 6.6 | | | |
| 6 Months | 114.0 ± 8.2 | 115.6 ± 6.1 | 111.1 ± 7.8 | 0.145 | <0.001 | 0.394 |
| Waist-to-Hip Ratio | | | | | | |
| 0 Months | 0.94 ± 0.1 | 0.93 ± 0.1 | 0.96 ± 0.1 | | | |
| 6 Months | 0.93 ± 0.1 | 0.92 ± 0.1 | 0.96 ± 0.1 | 0.471 | 0.384 | 0.654 |
| Fat Mass (kg) | | | | | | |
| 0 Months | 41.04 ± 9.03 | 45.18 ± 9.46 | 40.72 ± 5.94 | | | |
| 6 Months | 38.34 ± 9.02 | 38.38 ± 8.90 | 35.67 ± 7.26 | 0.430 | <0.001 | 0.052 |
| Lean Mass (kg) | | | | | | |
| 0 Months | 44.09 ± 4.97 | 53.22 ± 9.75 | 48.02 ± 8.75 | | | |
| 6 Months | 43.19 ± 4.88 | 51.58 ± 10.35 | 47.39 ± 8.76 | 0.012* | <0.001 | 0.223 |
| Body Fat (%) | | | | | | |
| 0 Months | 47.8 ± 5.2 | 45.8 ± 4.6 | 46.0 ± 4.8 | | | |
| 6 Months | 46.6 ± 4.6 | 42.5 ± 5.0 | 42.9 ± 5.1 | 0.126 | <0.001 | 0.082 |
| Bone Mineral Density ($g/cm^2$) | | | | | | |
| 0 Months | 1.2477 ± 0.103 | 1.2672 ± 0.119 | 1.2916 ± 0.107 | | | |
| 6 Months | 1.2445 ± 0.119 | 1.2600 ± 0.112 | 1.2951 ± 0.109 | 0.453 | 0.275 | 0.112 |

* SBWL+FIT > SBWL

## 4.8 PROCESS MEASURES

Descriptive analyses were conducted to examine process measures which included attendance at weekly sessions, monthly telephone contact, dietary logging, self-reported caloric intake, energy expenditure, frequency of self-weighing, and armband time on body. One way analysis of variance (ANOVA) and independent samples t-tests were used to examine any differences in these process measures among groups.

### 4.8.1 Attendance and Telephone Call Completion

Overall individual and group attendance was 84% among completers, with no differences observed between SBWL (85.7 ± 8.9%) and SBWL+FIT (83.2 ± 14.5%) ($p=0.59$). FIT, who did not attend meetings and instead received monthly telephone calls, had a telephone completion rate of 90.1 ± 15.9%. Results are presented in Table 10. Intent-to-treat analysis revealed an overall group and individual attendance of 72% with SBWL+FIT attending significantly more meetings (83.2 ± 14.5%) than SBWL (60.8 ± 30.8%) ($p=0.01$). Telephone completion rate in FIT was approximately 81%. Results are shown in Table 11.

**Table 10. Differences in Process Measures Among Groups - Completers Analysis**

| Variable | SBWL (N=9) (mean± s.d.) | SBWL+FIT (N= 17) (mean± s.d.) | FIT (N= 13) (mean± s.d.) |
|---|---|---|---|
| Percent Attendance | 85.7 ± 8.9 | 83.2 ± 14.5 | ---- |
| Percent Telephone Calls Completed | ---- | ---- | 90.1± 15.9 |
| Diaries Completed Per Person (diaries/week) | 0.80 ± 0.2 | ---- | ---- |
| Diet Logged (days/week)+ | 5.3 ± 2.8 [a] | 5.9 ± 2.2 [a, b] | 5.2 ± 2.7 [b] |
| Self-Reported Caloric Intake (kcal/day) + | 1233.1 ± 298.6 [a] | 1399.4 ± 392.3 [a, b] | 1316.1 ± 301.8 [b] |
| Total Energy Expenditure (kcal/day) + | ---- | 2696.6 ± 615.7 [b] | 2476.7 ± 381.1 [b] |
| Days Worn (days/week) + | ---- | 6.3 ± 1.3 | 6.5 ± 0.6 |
| Armband Time on Body (hrs/day) + | ---- | 16.2 ± 6.3 [b] | 17.4 ± 5.9 [b] |
| Self-Weighed (days/week) + | 5.0 ± 3.0 [a, c] | 3.3 ± 3.0 [a] | 3.2 ± 2.9 [c] |

Groups with same superscript across a given row are significantly different at $p<0.05$.
+ Data obtained from paper diary logging (SBWL) and website logging (SBWL+FIT and FIT).

**Table 11. Differences in Process Measures Among Groups - Intent-to-Treat Analysis**

| Variable | SBWL (N= 17) (mean± s.d.) | SBWL+FIT (N= 17) (mean± s.d.) | FIT (N= 17) (mean± s.d.) |
|---|---|---|---|
| Percent Attendance | 60.8 ± 30.8 [a] | 83.2 ± 14.5 [a] | ---- |
| Percent Telephone Calls Completed | ---- | ---- | 80.7 ± 23.7 |
| Diaries Completed Per Person (diaries/week) | 0.52 ± 0.4 | ---- | ---- |
| Diet Logged (days/week) + | 3.4 ± 3.4 [a, c] | 5.9 ± 2.2 [a, b] | 4.3 ± 3.1 [b, c] |
| Self-Reported Caloric Intake (kcal/day) + | 1246.5 ± 289.9 [a] | 1399.4 ± 392.3 [a, b] | 1302.1 ± 322.2 [b] |
| Total Energy Expenditure (kcal/day) + | ---- | 2696.6 ± 615.7 [b] | 2455.1 ± 397.7 [b] |
| Days Worn (days/week) + | ---- | 6.3 ± 1.3 | 5.6 ± 2.0 |
| Armband Time on Body (hrs/day) + | ---- | 16.2 ± 6.3 [b] | 14.6 ± 8.0 [b] |
| Self-Weighed (days/week) + | 3.1 ± 3.4 [c] | 3.3 ± 3.0 [b] | 2.5 ± 2.8 [b, c] |

Groups with same superscript across a given row are significantly different at $p<0.05$.
+ Data obtained from paper diary logging (SBWL) and website logging (SBWL+FIT and FIT).

### 4.8.2 Dietary Self-Monitoring

The percentage of food and activity diaries turned in by completers in SBWL was 80% with an average of 0.80 ± 0.2 diaries/week per person (See Table 10). One way ANOVA revealed significant differences in the number of days diet was recorded on either the paper food and activity diaries (SBWL) or on the BodyMedia FIT website (SBWL+FIT and FIT) ($p<0.001$). Post hoc analysis indicated that SBWL+FIT logged dietary intake (5.9 ± 2.2 days/week) significantly more days than SBWL (5.3 ± 2.8 days/week, $p<0.05$) or FIT (5.2 ± 2.7 days/week, $p<0.001$). Significant differences also were observed in daily self-reported caloric intake obtained from the paper diaries and website. Specifically, post hoc analysis revealed a lower caloric intake in SBWL (1233.1 ± 298.6 kcal/day) and FIT (1316.1 ± 301.8 kcal/day) compared to SBWL+FIT (1399.4 ± 392.3 kcal/day) ($p<0.001$ and $p<0.05$, respectively).

Intent-to-treat analysis revealed an average of 0.52 ± 0.4 diaries completed each week per person with an overall percentage of 52% (See Table 11) Significant differences were observed among all groups for the number of days dietary intake was self-monitored. SBWL+FIT (5.9 ± 2.2 days/week) recorded a significantly greater number of days than FIT (4.3 ± 3.1 days/week) who recorded a greater number of days than SBWL (3.4 ± 3.4 days/week) ($p<0.001$). Differences among groups was also observed in daily self-reported caloric intake with SBWL+FIT (1399.4 ± 392.3 kcal/day) consuming significantly more calories per day than FIT (1302.1 ± 322.2 kcal/day) or SBWL (1246.5 ± 289.9 kcal/day) ($p<0.05$).

### 4.8.3 Energy Expenditure

Total daily energy expenditure was obtained from armband data off the BodyMedia website (SBWL+FIT and FIT). Among completers, SBWL+FIT (2696.6 ± 615.7 kcal/day) expended significantly more calories each day than FIT (2476.7 ± 381.1 kcal/day) ($p<0.001$). Results are presented in Table 10. Intent-to-treat analysis revealed a significant difference in total daily energy expenditure. Specifically, SBWL+FIT expended significantly more calories per day (2696.6 ± 615.7 kcal/day) than FIT (2455.1 ± 397.7 kcal/day) ($p<0.001$). Results are presented in Table 11.

### 4.8.4 Armband Use

Among completers, the armband was worn for an average of 6.4 ± 1.0 days/week. There were no differences between groups ($p=0.55$), however, each day, FIT wore the armband significantly more hours (17.4 ± 5.9 hours/day) than SBWL+FIT (16.2 ± 6.3 hours/day) ($p=0.007$). Results are shown in Table 10.

Intent-to-treat analysis revealed no significant differences in the number of days the armband was worn (SBWL+FIT: 6.3 ± 1.3 days/week; FIT: 5.6 ± 2.0 days/week, $p=0.23$), however SBWL+FIT (16.2 ± 6.3 hours/day) wore the armband for more hours each day than FIT (14.6 ± 8.0 hours/day) across the 6 month program ($p=0.002$) (See Table 11). Overall combined, SBWL+FIT and FIT wore the armband for 15.4 ± 7.2 hours/day.

### 4.8.5 Self-Weighing

Participants, who completed the 6 month program, self-weighed an average of 3.6 ± 3.0 days/week. Significant differences were observed between groups, with post hoc analyses revealing SBWL self-weighed (5.0 ± 3.0 days/week) significantly more times per week than FIT (3.2 ± 2.9 days/week) or SBWL+FIT (3.3 ± 3.0 days/week) ($p<0.001$). Results are presented in Table 10. According to the self-weighing questionnaire, there was a significant increase in self-weighing among all treatment groups from baseline to 6 months ($p<0.001$), however no differences existed between groups ($p=0.732$). Specifically, the percentage of individuals weighing themselves daily at baseline and at 6 months increased from 11% to 78% in SBWL, 23.5% to 41% for SBWL+FIT, and from 15.4% to 54% for FIT.

Intent-to-treat analysis indicated a significant group difference with FIT self-weighing (2.5 ± 2.8 days/week) less frequently than SBWL (3.1 ± 3.4 days/week) and SBWL+FIT (3.3 ± 3.0 days/week) ($p<0.05$) (See Table 11). Based on the self-weighing questionnaire, there was a significant increase in the frequency of self-weighing from baseline to 6 months ($p<0.001$), however no group differences existed ($p=0.132$). The percentage of individuals weighing themselves daily at baseline and at 6 months increased from 6% to 41% for SBWL, 24% to 41% for SBWL+FIT, and 18% to 47% for FIT.

### 4.8.6 Correlations Between Process Measures and Weight Loss

Correlation analyses were performed on all process measures and weight loss at 6 month (calculated as body weight at 6 months minus baseline body weight). Completer's correlations are presented in Table 12. Intent-to-treat correlations are presented in Table 13.

### 4.8.6.1 Attendance and Telephone Call Completion

Completers analysis did not reveal any significant correlations among group/individual session attendance for SBWL (r=-0.54, p=0.13) or SBWL+FIT (r=-0.30, p=0.24) and weight loss at 6 months (See Table 12). Furthermore, no significant correlations were observed between telephone call completion and weight loss (r=0.10, p=0.76). Intent-to-treat analysis revealed a significant correlation between 6 month weight loss and group/individual session attendance in SBWL (r=-0.65, p=0.005), however no relationship was observed in SBWL+FIT (r=-0.30, p=0.24). Results are presented in Table 13. Telephone completion in FIT was not correlated to weight loss at 6 months (r=-0.14, p=0.60).

**Table 12. Correlations Between Process Measures and 6 Month Weight Loss - Completers**

| Variable | All (N=39) | SBWL (N=9) | SBWL+FIT (N= 17) | FIT (N= 13) |
|---|---|---|---|---|
| Percent Attendance | ---- | -0.543 | -0.300 | ---- |
| Percent Telephone Calls Completed | ---- | ---- | ---- | 0.095 |
| Diaries Completed Per Week | ---- | -0.635 | ---- | ---- |
| Diet Logged (days/week) + | -0.569** | -0.624 | -0.384 | -0.639* |
| Self-Reported Caloric Intake (kcal/day) + | -0.426** | -0.507 | -0.222 | -0.526 |
| Total Energy Expenditure (kcal/day) + | ---- | ---- | -0.060 | 0.008 |
| Days Worn (days/week) + | ---- | ---- | -0.349 | -0.459 |
| Armband Time on Body (hrs/day) + | ---- | ---- | -0.012 | -0.300 |
| Self-Weighed (days/week) + | -0.464** | -0.578 | -0.233 | -0.775** |

+ Data obtained from paper diary logging (SBWL) and website logging (SBWL+FIT and FIT).
*p<0.05
**p<0.01

**Table 13. Correlations Between Process Measures and 6 Month Weight Loss – Intent-to-Treat**

| Variable | All (N=51) | SBWL (N=17) | SBWL+FIT (N= 17) | FIT (N= 17) |
|---|---|---|---|---|
| Percent Attendance | ---- | -0.649** | -0.300 | ---- |
| Percent Telephone Calls Completed | ---- | ---- | ---- | -0.138 |
| Diaries Completed Per Week | ---- | -0.745** | ---- | ---- |
| Diet Logged (days/week) + | -0.705** | -0.755** | -0.384 | -0.703** |
| Self-Reported Caloric Intake (kcal/day) + | -0.629** | -0.683** | -0.222 | -0.625** |
| Total Energy Expenditure (kcal/day) + | ---- | ---- | -0.060 | 0.411 |
| Days Worn (days/week) + | ---- | ---- | -0.349 | -0.544* |
| Armband Time on Body (hrs/day) + | ---- | ---- | -0.012 | -0.532* |
| Self-Weighed (days/week) + | -0.598** | -0.737** | -0.233 | -0.824** |

+ Data obtained from paper diary logging (SBWL) and website logging (SBWL+FIT and FIT).
*p<0.05
**p<0.01

### 4.8.6.2 Dietary Self-Monitoring

There was no significant correlation between 6 month weight loss and diaries completed among completers in SBWL (r=-0.64, p=0.07). Results are presented in Table 12. The number of days dietary intake was logged was significantly related to weight loss at 6 months when all groups were combined (r=-0.57, p<0.001) and in FIT (r=-0.64, p=0.02), however no significant correlations between diet days and body weight were observed among SBWL (r=-0.62, p=0.07) and SBWL+FIT (r=-0.38, p=0.13). Self-reported caloric intake was significantly correlated to weight loss when all groups were combined (r=-0.57, p<0.001), however no significant relationships were observed among groups.

Intent-to-treat analysis revealed a significant relationship between diaries completed and weight loss in SBWL (r=-0.75, p=0.001) (See Table 13). Weight loss at 6 months was significantly correlated to the number of days dietary intake was monitored when all groups were combined (r=-0.71, p<0.001) as well as among SBWL (r=-0.76, p<0.001) and FIT (r=-0.70, p=0.002). Self-reported caloric intake was significantly correlated with weight loss when all groups were combined (r=-0.63, p=<0.001) and among SBWL (r=-0.68, p=0.003) and FIT (r=-0.63, p=0.007).

#### 4.8.6.3 Energy Expenditure

Daily total energy expenditure was not significantly related to weight loss at 6 months during completers (SBWL+FIT: r=-0.06, p=0.82; FIT: r=0.01, p=0.98) or intent-to-treat analysis (SBWL+FIT: r=-0.06, p=0.82; FIT: r=0.42, p=0.10). Results are presented in Tables 12 and 13.

#### 4.8.6.4 Armband Use

Completers analysis did not reveal any significant correlations between the average number of days or hours the armband was worn and 6 month weight loss in SBWL+FIT (days: r=-0.35, p=0.17; hours: r=-0.01, p=0.96) or FIT (days: -0.46, p=0.12; hours: r=-0.30, p=0.32). (See Table 12). Intent-to-treat analysis, however, revealed significant relationships in FIT between weight loss and the average number of days (r=-0.54, p=0.02) and hours per day (r=-0.53, p=0.03) the armband was worn (See Table 13).

#### 4.8.6.5 Self-Weighing

Completers analysis revealed a significant correlation between the number of days individuals self-weighed per week and weight loss at 6 months when all groups are combined (r=-0.46, p=0.003) and among FIT (r=-0.78, p=0.002). Results are presented in Table 12. Intent-to-treat analysis revealed significant correlations when groups were combined (r=-0.60, p<0.001) and among SBWL (r=-0.74, p=0.001) and FIT (r=-0.82, p<0.001) (See Table 13).

# 5.0 DISCUSSION

The current investigation sought to evaluate the effectiveness of a technology-based system when used alone or in combination with a 6-month behavioral weight loss intervention in overweight and obese adults on body weight, physical activity, dietary intake, cardiorespiratory fitness, body composition, and self-monitoring behaviors. Participants were randomized to one of three treatment groups: Standard Behavioral Weight Loss (SBWL), SBWL Plus Technology-Based System (SBWL+FIT), or Technology-Based System Alone (FIT).

The technology-based system used in the current investigation was the BodyMedia® FIT System which was developed by BodyMedia Inc. Previous research[39] using similar technology showed promise on producing weight loss short-term, however the use of this specific technology-based system has not been examined. Due to the advancements on goal setting, self-monitoring, and the ability to produce immediate feedback, it was hypothesized that adding this technology-based system to a behavioral weight loss program would produce an additive effect and enhance primary outcomes compared to the standard behavioral weight loss program or when the technology-based system was used alone.

## 5.1 PARTICIPANT RETENTION

In this current investigation, a total of 39 out of 51 randomized subjects completed the baseline and 6 month assessments. The retention rate was 76.5% which is slightly lower than the typical face-to-face behavioral weight loss program (80%)[21] as well as previous Internet or technology-based programs which ranged from 78-88%[39, 87-88, 112] after 6 months of treatment. Attrition rate did significantly differ between treatment groups with 47% for SBWL, 0% for SBWL+FIT, and 23% for FIT. When examining groups solely by the use of technology, individuals given the technology had a retention rate of 88% compared to 53% for SBWL. Despite differences in magnitude, this pattern of results are similar to data published by Polzien et al.[39] who observed lower retention rates among the standard group (84%) compared to those who were given use of the armband (89%).

## 5.2 BODY WEIGHT

At baseline, a significant difference existed in body weight between SBWL+FIT (102.1 ± 17.5 kg) and SBWL (88.6 ± 12.5 kg) ($p<0.05$). Although groups were randomly assigned, SBWL+FIT included four males whereas SBWL consisted of all females. This uneven gender distribution (although not statistically significant) may explain the differences in weight that were observed.

The current investigation was successful in producing weight loss among completers in all treatment groups (SBWL: -7.1 ± 6.2 kg; SBWL+FIT: -8.8 ± 5.0 kg; and FIT: -7.6 ± 6.6 kg) ($p<0.001$). The overall weight loss for groups combined was -8.4%. This is slightly lower than the standard behavioral weight loss program which averages approximately -10% over 30 weeks[21]. Based on the results of completers, the primary hypothesis that SBWL+FIT would achieve a greater weight loss than SBWL and SBWL would achieve a greater weight loss than FIT was not supported. Although not significantly different between groups, SBWL+FIT achieved the greatest weight loss (-8.7%) among groups, followed by FIT (-8.3%), and SBWL (-7.8%). Intent-to-treat analysis revealed a significant group x time interaction with a trend for a greater weight loss in SBWL+FIT compared to SBWL (p=0.089). At this time, there were no published studies examining this specific technology system when used alone or combined with a behavioral weight loss intervention. Polzien et al.[39] used an earlier version of this system and reported that a combination of the armband technology and face-to-face intervention produced a 2.1 kilogram greater weight loss at 3 months then the standard program. In the current study, SBWL+FIT's weight loss was greater than SBWL by 1.7 and 5.1 kilograms at 6 months based on analysis of completers and intention-to-treat, respectively. Although the current investigation included a more intensive in-person behavioral program, these findings appear to be consistent with previous research and suggest that the technology-based system may produce a slight additive effect on weight loss during the standard behavioral weight loss intervention.

Similar to previous findings and reviews[87-88, 112-114], this study confirms that weight loss programs can effectively be delivered over the Internet. The weight loss observed in the technology only group (FIT: -7.6 and -5.8 kg among completers and intent-to-treat analysis, respectively) is greater than prior Internet weight loss programs of comparable durations. For instance, Tate et al.[112] conducted an Internet weight loss program that included email behavioral counseling that resulted in a weight loss of -4.4 kg after 24 weeks. Similarly, in 2001, Tate et al.[87] produced a -4.1 kg weight loss after 6 months in an Internet behavior therapy group.

However, more recent findings from Tate et al.[88] revealed that a human email counseling weight loss program resulted in weight loss of -7.3 kg after 6 months.

In addition to the technology system, FIT attended one introductory/instructional meeting, received 7 telephone calls from interventionists, and visited the Center for assessments. Although phone calls completed was not associated with weight loss, the in-person contacts may have increased participants accountability and motivation to lose weight and thus, as Womble et al.[115] suggest this may be a best case scenario compared to those who use this technology system alone without interventionist contact. Overall however, this technology system shows promise for its ability to produce similar or greater weight losses than the standard in-person behavioral program with minimal interventionist contact. Future studies should continue to examine the use of this technology system with less contact time with interventionists.

## 5.3 CARDIORESPIRATORY FITNESS

Cardiorespiratory fitness, specifically relative $VO_2$ and time to reach 85% of APMHR, improved significantly among all groups during the 6 month program; however there were no differences between groups among completers. These findings do not support the hypothesis that the greatest improvements in cardiorespiratory fitness would be observed in SBWL+FIT, but are consistent with the lack of group differences in self-reported physical activity. Furthermore, the improvements observed in cardiorespiratory fitness are similar to previous 6 month behavioral weight loss or physical activity programs[67, 116]. Additionally, approximately 18% (N=7) of completers were unable to complete the graded exercise test or oxygen uptake analysis due to recent surgeries and medical conditions which may have further contributed to a lack of differences among groups. Intent-to-treat analysis revealed similar improvements in cardiorespiratory fitness, however trends suggest that SBWL+FIT and FIT had greater improvements in relative $VO_2$ than SBWL. Furthermore, SBWL+FIT showed significantly greater increases in the time to reach 85% APMHR than SBWL ($p<0.05$). Although all groups do not significantly differ from each other, the trend in improvements in treadmill time partially supports the hypothesis that the greatest improvements in cardiorespiratory fitness would be observed in SBWL+FIT.

## 5.4 PHYSICAL ACTIVITY

Self-reported physical activity from baseline to 6 months assessed using the Paffenbarger Physical Activity Questionnaire significantly increased by 1008 kcal/week in those who completed the program and by 751 kcal/week with the intent-to-treat analysis. There were no significant differences between groups among completers or intent-to-treat, and thus these results do not support the hypothesis that the SBWL+FIT would have greater increases in physical activity than SBWL or FIT. The overall increases in physical activity in the current study are similar to previous in-person behavioral programs[117] and higher than previous Internet-based programs[87-88, 112] at 6 months. The technology-based system used in this study, which included up-to-the-minute and visual feedback on energy expenditure, moderate and vigorous intensity activity and steps taken may have enhanced physical activity outcomes. Likewise, Polzien et al.[39] found similar improvements in physical activity with the use of an earlier version of the technology system as well as a lack of differences among groups. Trends, however were seen for the technology groups who used the armbands to have greater changes in physical activity

(+1287 and +1112 kcal/week) than the standard group (+282 kcal/week). Although not significant in the current study, yet consistent with the findings by Polzien et al.[39], both technology groups had greater increases in physical activity (FIT: +1066 kcal/week; SBWL+FIT: +714 kcal/week) than SBWL (+474 kcal/week) from baseline to 6 months. These results demonstrate that the technology system may have the ability to produce similar or greater increases in physical activity than the standard in-person behavioral weight loss program.

## 5.5 DIETARY INTAKE AND EATING BEHAVIORS

Across all treatment groups, the intervention produced a reduction in dietary intake from baseline to 6 months (completers: -402 kcal/day; intent-to-treat: -307 kcal/day). Significant differences were not observed between groups and the findings do not support the hypothesis that SBWL+FIT would show greater reduction in daily caloric intake than SBWL or FIT. These results are consistent with previous Internet[87-88, 112], technology based[39], and in-person behavioral[67, 118] programs that while a reduction is seen in daily caloric intake, no differences are observed between groups. Interestingly, similar to self-reported physical activity and although not significant, FIT demonstrated the greatest decrease in dietary intake (-562 kcal/day). Eating behaviors significantly improved (completers: +18.7, ITT: +14.3 on EBI scale) at 6 months. Furthermore, a greater improvement was observed in SBWL+FIT than SBWL ($p<0.05$). The increased use of weight loss eating behaviors observed in this study is similar to previous weight loss programs that have observed an average increase of 17.4 on the Eating Behavior Inventory[111]. The additional information and feedback SBWL+FIT received from the technology system may have significantly improved the adoption of weight loss eating behaviors such as self-monitoring dietary intake.

### 5.6 BODY COMPOSITION AND ANTHROPOMETIC MEASUREMENTS

Completers and intent-to-treat analyses revealed significant reductions in waist and hip circumference from baseline to 6 months, however no group differences were observed. These findings do not support the hypothesis that the greatest improvements in body composition would be observed in SBWL+FIT. Previous Internet based programs[87, 112] have demonstrated significant reductions in waist circumference (-4.6 to -7.2 cm) at 12 months which is similar to the reductions seen in SBWL, SBWL+FIT, and FIT (-4.4, -8.0, and -5.6 cm, respectively). The intervention did not result in any significant reductions in waist-to-hip ratio. Although waist-to-hip ratio has been associated with mortality rates[119-121], waist-to-hip ratios typically remain unchanged in exercise and weight loss interventions as both waist and hip circumferences decrease simultaneously[122-123]. Furthermore, NIH suggests the best measure of excess abdominal adiposity is the waist circumference[15] and thus, the current investigation included this measure in addition to waist-to-hip ratio.

The intervention resulted in significant reductions in fat and lean mass at 6 months, with intent-to-treat analysis indicating a greater reduction in lean mass among SBWL+FIT compared to SBWL; however, when the percent of weight loss from lean mass was analyized, there were no differences between groups. Percent body fat, which was obtained from DXA scans, significantly reduced from baseline to 6 months. Differences were not observed between groups, however, interestingly, the greatest reduction was seen in FIT (-4.1%). These findings further support the ability of this technology system to significantly reduce weight and body fat with minimal contact with interventionists.

Total bone mineral density decreased by 0.0030 $g/cm^2$ over the 6 month intervention, however the changes were not statistically significant. These findings conflict with previous research that shows weight loss is typically linked with bone loss[124-125]. One possible explanation for the inconsistency is that only whole body bone mineral density was examined rather than regional bone mineral density. Sites that are typically susceptible to fracture are often analyzed such as lumbar spine, total hip, or femoral neck[126] and thus, future studies should examine changes not only in total body but also regional sites bone mineral density. Another possibility is that the significant increases in physical activity observed in this study in addition to the caloric restriction prevented bone loss. For instance, Villareal et al.[126] showed that weight loss induced by caloric restriction resulted in a decrease in total and regional bone mineral density whereas an exercise induced weight loss group did not demonstrate any change. The current findings may provide additional support that increased exercise participation with caloric restriction during weight loss may help preserve bone mineral density. Future studies should continue to examine the addition of exercise during weight loss on bone loss.

## 5.7 PROCESS MEASURES

### 5.7.1 Attendance and Telephone Completion

Among completers, differences were not observed in overall attendance; however intent-to-treat analysis indicated that SBWL+FIT (83%) attended significantly more in-person meetings than

SBWL (61%). The attendance is comparable to the findings by Wing and Jeffery[127] who observed group attendance of 66% in the standard group and 89% in the enhanced group who received food provisions. Similar to the food provisions, additional components added to the intention such as the technology system may improve participant compliance to attend group and individual sessions more than those who did not receive the enhanced program. Compared to the study by Polzien et al.[39], completer's attendance in the current investigation was lower in both the standard and technology groups. The current attendance may have been lower due to the longer treatment (12 vs. 24 months) and more intensive protocol (7 vs. 21 in-person meetings).

Group and individual session attendance was significantly related to weight loss at 6 months for SBWL. This link between attendance and weight loss is consistent with previous research[127-128]. Interestingly, neither attendance nor telephone completion was related to weight loss for SBWL+FIT or FIT. The technology may have provided these two groups with the tools necessary to lose weight and thus, were not as reliant on the information and social support provided by the in-person meetings or telephone contact as the standard group.

### 5.7.2 Dietary Self-Monitoring

The number of days that participants logged dietary intake, which was obtained from paper food and activity diaries completed (SBWL) or the BodyMedia website (SBWL+FIT and FIT) was significantly different among groups. Post hoc analysis supports the hypothesis that SBWL+FIT would record significantly more days than SBWL or FIT. The BodyMedia website includes a searchable food database that automatically calculates dietary information such as caloric intake and fat which may make self-monitoring less burdensome. In addition, by regularly self-monitoring dietary intake, individuals using the website could receive feedback on overall calorie balance which could be beneficial when trying to lose weight. Polzien et al.[39] did not observe any differences among self-monitoring behaviors between the technology or standard groups. There may be inconsistent findings among the two studies due to the greater amount of in-person contact and weekly feedback received in the current investigation. Although the technology system alone did not improve dietary self-monitoring, the combination of weekly in-person lessons, regular feedback from coaches, and the use of the website may have contributed to the higher dietary monitoring compliance in SBWL+FIT compared to SBWL or FIT.

Previous studies have demonstrated that website usage was significantly associated with greater weight losses[83, 88, 112, 115]. Although this current study did not examine the number of times individuals logged into the website or used a paper diary, the number of days dietary intake was logged can give a good estimate. Thus, overall among all groups, the number of days food intake was monitored was significantly related to greater weight losses at 6 months. Similarly, higher weight losses were related to the number of paper diaries completed in SBWL. Consistent with previous reports[21, 31], self-monitoring dietary intake is an essential and effective component to weight loss programs.

Caloric intake obtained from weekly self-report data was significantly higher in SBWL+FIT than FIT and SBWL. Similar to the difference in days dietary intake was monitored, the combination of in-person meetings and the use of the technology may have motivated individuals more to self-monitor than when only given in-person meetings or the technology. Furthermore, self-reported caloric intake was related to weight loss among all participants. Specifically, when all subjects were combined, those who reported a higher caloric intake each day had the greatest weight losses at 6 months. Interestingly, among completers, the Food Frequency Questionnaire reported an average of 1538 kcal/day whereas self-reported data showed a caloric intake of 1339 kcal/day. Furthermore, our findings are consistent with previous reports that individuals tend to underreport energy intake when using paper diaries or personal digital assistants[42, 75-76].

### 5.7.3 Energy Expenditure Monitoring

Total daily energy expenditure, which was obtained from the two technology groups, was significantly greater in SBWL+FIT than FIT (intent-to-treat). One possible explanation for the overall difference is that at baseline, SBWL+FIT weighed significantly more than FIT and thus, would have had higher energy expenditures at rest and during activity. In addition, SBWL+FIT wore the armband for significantly more hours each day than FIT. The armband estimates energy expenditure during the hours the armband is not worn and therefore may underestimated activity for FIT. Previous studies have examined total energy expenditure from an earlier version of the armband in healthy[129] and diabetic[130] populations, however to our knowledge, there have not been any studies that examined total energy expenditure during a behavioral weight loss program. Overall, average daily energy expenditure obtained from the armband was not associated with weight loss at 6 months. Future studies should examine this relationship over shorter time periods as weight loss will result in lowered energy expenditure.

### 5.7.4 Armband Use

Armbands were worn for an average of 16.7 hours/day by completers and 15.4 hours/day with intent-to-treat. While there were no differences between groups with days the armband was worn, FIT completers wore the armband for significantly more hours than SBWL+FIT. Intent-to-treat analysis indicated that SBWL+FIT wore the armband more hours than FIT. Previous research using the earlier version of the armband indicated the armband was worn for 64 to 71 hours per week which averages approximately 9-10 hours per day over 12 weeks[39]. The current study may have observed greater on body time due to the smaller and more comfortable design. In addition, SBWL+FIT may have felt more obligated to wear the armband as they had regular face-to-face contact with intervention staff than FIT.

The average number days per week and hours per day the armband was worn was significantly associated with weight loss at 6 months in FIT, which is consistent with previous findings by Polzien et al.[39]. Interestingly, no relationship existed between weight loss and armband time on body in SBWL+FIT. While it appears that FIT may be reliant on information obtained from the technology system and SBWL is reliant on in-person contacts, SBWL+FIT may use both information sources which may explain the lack of relationship between attendance or armband on body time and weight loss. Overall however, as participants were instructed to remove the armband during any water activities (bathing, showering, swimming) and only wear the armband during waking hours (16-19 hours/day), these findings demonstrate excellent compliance of approximately 81-96%. This technology system appears to be widely accepted by participants and may be recommended as an effective system to produce weight loss.

### 5.7.5 Self-Weighing

Daily self-weighing was significantly higher among SBWL than SBWL+FIT or FIT completers based on weekly self-reported logging, however the increases in frequency of self-weighing from baseline to 6 months was not significant between groups. Overall, intent-to-treat analysis revealed the frequency of individuals who daily self-weighed increased from 16% to 43%. This percentage is similar to results from the National Weight Control Registry which indicated that approximately 44% of successful losers weigh themselves daily[34]. Furthermore, correlation analysis revealed those who weighed themselves more frequently lost the most weight at 6 months. This finding is consistent with previous reports that daily self-weighing is associated with greater weight loss and weight maintenance[131-133]. Future studies should continue to place emphasis on the importance of frequent self-weighing on weight loss.

## 5.8 LIMITATIONS AND FUTURE RESEARCH

This was the first study that examined the use of this specific technology-based system when used alone or in combination with an in-person behavioral weight loss and thus served as a pilot study. Furthermore, there are several limitations to the current investigation which may have impacted the main outcomes. Therefore, the results should be interpreted with caution and future studies should consider these recommendations.

1. The sample size was small particularly at the end of the program and may have not been sufficient enough to detect significant differences in body weight, physical activity, and body composition among treatment groups. Future studies should examine the use of this technology system when used alone or during an in-person behavioral program in a larger sample size.
2. There was low minority representation which may have been a result of the requirement to have internet access to participate. Although Internet use continues to rise, the "digital divide" issue continues to

exist. Minority individuals, particularly African Americans, have some of the highest rates of overweight and obesity but consequently also have lower rates of Internet use, especially broadband[1, 41]. Future studies should consider higher minority representation.

3. The technology alone group visited the Physical Activity and Weight Management Research Center on three occasions (twice for assessments and one time for an introductory weight loss class and instruction on how to use the technology-based system). Furthermore, they received weekly lessons in the mail and 7 telephone contacts to improve participant retention. Future investigations should consider alternative methods to reduce contact time while continuing to collect objective outcome measures to further determine the effect of the technology system alone on weight loss.
4. The current study was 6 months in duration and may not have been long enough to detect more significant differences among groups. Furthermore, it is unknown whether the novelty of wearing the armband would wear off past 6 months. Future studies should examine the use of this technology system long-term.

## 5.9 CONCLUSION

In conclusion, the current investigation was successful in producing weight loss, increasing physical activity, and improving fitness and body composition. Although the primary hypothesis that the use of the technology system would produce an additive effect on weight loss to the standard behavioral weight loss program was not supported, several important findings can be drawn from this study. First, the use of technology-based system, combined with monthly telephone calls has the ability to produce similar, if not greater changes in body weight, physical activity, body composition, and fitness than the standard in-person behavioral weight loss intervention. Second, the attrition rate was higher in the standard group than either of the two groups that used the technology system, and thus this system may improve participant retention. Third, both technology groups self-monitored dietary intake more frequently than the standard group. Self-monitoring plays a critical role in weight loss and this study provided additional support that greater consistency with dietary logging is associated with higher weight losses. Overall, this technology system demonstrates great promise on producing similar outcomes on weight, enhancing participant retention, and increasing the frequency of dietary monitoring. As standard behavioral weight loss programs are not typically available or accessible to everyone, the use of this technology system may be a feasible and effective way for more individuals to lose weight. This investigation served as a pilot study and thus, additional studies should be completed to further examine and replicate the results observed on the effects of the use of this technology system alone or when combined with an in-person behavioral weight loss intervention on body weight. In addition, future studies should examine the use of this system to determine whether these findings are sustainable past 6 months.

## APPENDIX A

## DIFFERENCES IN BASELINE CHARACTERISTICS BY TREATMENT GROUP (FEMALES ONLY)

| Characteristics | Total (N=44) (mean± s.d.) | SBWL (N=17) (mean ± s.d.) | SBWL+FIT (N=13) (mean± s.d.) | FIT (N=14) (mean ± s.d.) | P-value |
|---|---|---|---|---|---|
| Age (years) | 45.0 ± 8.5 | 45.1 ± 9.4 | 45.0 ± 9.2 | 45.0 ± 7.4 | 0.99 |
| Weight (kg) | 91.0 ± 11.8 | 88.6 ± 12.5 | 95.7 ± 13.1 | 89.3 ± 9.0 | 0.22 |
| Body Mass Index (kg/m$^2$) | 33.3 ± 3.4 | 33.1 ± 3.8 | 33.8 ± 3.5 | 33.2 ± 2.8 | 0.83 |
| Waist Circumference (cm) | 111.2 ± 11.6 | 111.0 ± 12.9 | 111.4 ± 14.6 | 111.1 ± 6.3 | 0.99 |
| Hip Circumference (cm) | 119.0 ± 7.8 | 118.1 ± 8.8 | 121.8 ± 7.1 | 117.6 ± 7.0 | 0.32 |
| Waist-to-hip ratio | 0.93 ± 0.1 | 0.94 ± 0.1 | 0.91 ± 0.1 | 0.95 ± 0.1 | 0.47 |
| Body Composition (% fat) | 46.5 ± 4.9 | 47.7 ± 5.2 | 47.0 ± 4.1 | 47.4 ± 4.0 | 0.89 |
| Race | | | | | |
| % African-American | 11.4% (N=5) | 17.6% (N=3) | 7.7% (N=1) | 7.1% (N=1) | |
| % Caucasian | 86.3% (N=38) | 76.5% (N=13) | 92.3% (N=12) | 92.9% (N=13) | 0.58 |
| % Other | 2.3% (N=1) | 5.9% (N=1) | 0% (N=0) | 0% (N=0) | |
| Dietary Intake (kcal/day) | 1854.8 ± 799.6 | 2095.8 ± 1023.4 | 1450.3 ± 373.9 | 1937.9 ± 670.7 | 0.08 |
| Self-Reported Physical Activity (kcal/week) | 560.3 ± 600.5 | 517.2 ± 540.0 | 808.9 ± 840.1 | 381.7 ± 289.5 | 0.17 |

## APPENDIX B

## DIFFERENCES IN BASELINE CHARACTERISTICS BY COMPLETERS AND NON-COMPLETERS (FEMALES ONLY)

| Characteristics | Total (N=44) (mean± s.d.) | Completers (N=33) (mean ± s.d.) | Non-Completers (N=11) (mean± s.d.) | P-value |
|---|---|---|---|---|
| Age (years) | 45.0 ± 8.5 | 45.1± 8.2 | 44.6 ± 9.8 | 0.87 |
| Weight (kg) | 91.0 ± 11.8 | 92.6 ± 10.6 | 86.1 ± 14.4 | 0.12 |
| Body Mass Index ($kg/m^2$) | 33.3 ± 3.4 | 33.7 ± 3.1 | 32.2 ± 4.0 | 0.22 |
| Waist Circumference (cm) | 111.2 ± 11.6 | 111.8 ± 11.4 | 109.2 ± 12.3 | 0.53 |
| Hip Circumference (cm) | 119.0 ± 7.8 | 120.7 ± 6.4 | 114.0 ± 9.5 | 0.01* |
| Waist-to-hip ratio | 0.93 ± 0.1 | 0.93 ± 0.1 | 0.96 ± 0.1 | 0.19 |
| Body Composition (% fat) | 46.5 ± 4.9 | 47.8 ± 4.1 | 46.2 ± 5.3 | 0.31 |
| Race<br>% African-American<br>% Caucasian<br>% Other | <br>11.4% (N=5)<br>86.3% (N=38)<br>2.3% (N=1) | <br>6.1% (N=2)<br>90.9% (N=30)<br>3.0% (N=1) | <br>27.3% (N=3)<br>72.7% (N=8)<br>0.0% (N=0) | 0.14 |
| Dietary Intake (kcal/day) | 1854.8 ± 799.6 | 1901.0 ± 857.6 | 1716.5 ± 606.3 | 0.51 |
| Self-Reported Physical Activity (kcal/week) | 560.3 ± 600.5 | 576.3 ± 592.7 | 512.2 ± 650.6 | 0.76 |

* $p < 0.05$ Completer > Non-Completer

# APPENDIX C

## BASELINE CHARACTERISTICS BY COMPLETERS AND NON-COMPLETERS BY TREATMENT GROUP (FEMALES ONLY)

| Characteristics | SBWL Completers (N=9) (mean± s.d.) | SBWL Non-Completers (N=8) (mean± s.d.) | SBWL+FIT Completers (N=13) (mean± s.d.) | SBWL+FIT Non-Completers (N=0) | FIT Completers (N=11) (mean± s.d.) | FIT Non-Completers (N=3) (mean± s.d.) |
|---|---|---|---|---|---|---|
| Age (years) | 46.0 ± 9.3 | 44.1 ± 10.0 | 45.0 ± 9.2 | ---- | 44.7 ± 6.7 | 46.2 ± 11.3 |
| Weight (kg) | 90.1 ± 9.2 | 87.0 ± 15.9 | 95.7 ± 13.1 | ---- | 90.9 ± 8.1 | 83.7 ± 11.7 |
| Body Mass Index ($kg/m^2$) | 34.2 ± 3.1 | 31.9 ± 4.3 | 33.8 ± 3.5 | ---- | 33.2 ± 2.8 | 33.1 ± 3.5 |
| Waist Circumference (cm) | 112.7 ± 12.0 | 109.2 ± 14.5 | 111.4 ± 14.6 | ---- | 111.5 ± 6.7 | 109.4 ± 5.1 |
| Hip Circumference (cm) | 120.3 ± 7.3 | 115.6 ± 10.1 | 121.8 ± 7.1 | ---- | 119.8 ± 5.3* | 109.7 ± 7.2* |
| Waist-to-hip ratio | 0.93 ± 0.1 | 0.94 ± 0.1 | 0.91 ± 0.1 | ---- | 0.93 ± 0.1 | 1.0 ± 0.0 |
| Body Composition (% fat) | 48.9 ± 5.4 | 46.5 ± 4.9 | 47.0 ± 4.1 | ---- | 47.9 ± 2.8 | 45.4 ± 7.3 |
| Race | | | | | | |
| % African-American | 11.1% (N=1) | 25.0% (N=2) | 7.7% (N=1) | ---- | 0.0% (N=0) * | 25.% (N=1) * |
| % Caucasian | 77.8% (N=7) | 75.0% (N=6) | 92.3% (N=12) | ---- | 100% (N=11) * | 75% (N=2) * |
| % Other | 11.1% (N=1) | 0% (N=0) | 0% (N=0) | ---- | 0.0% (N=0) * | 0.0% (N=0) * |
| Dietary Intake (kcal/day) | 2271.3 ±1297.3 | 1898.3±621.7 | 1450.3 ± 373.9 | ---- | 2130.5±628.0* | 1231.9±32.3* |
| Self-Reported Physical Activity (kcal/week) | 403.8 ± 300.6 | 644.8 ± 726.8 | 808.9 ± 840.1 | ---- | 442.5 ± 296.7 | 158.7 ± 98.3 |

* $p < 0.05$ for difference between completers and non-completers in FIT

## APPENDIX D

## OUTCOME DIFFERENCES BETWEEN TREATMENT GROUPS AT 6 MONTHS – COMPLETERS ANALYSIS (FEMALES ONLY)

| Outcome Variable | SBWL (N=9) (mean± s.d.) | SBWL+FIT (N=13) (mean± s.d.) | FIT (N=11) (mean± s.d.) | P-Values Group Effect | Time Effect | Group X Time |
|---|---|---|---|---|---|---|
| Body Weight (kg) | | | | | | |
| 0 Months | 90.1 ± 9.2 | 95.7 ± 13.0 | 90.9 ± 8.1 | | | |
| 6 Months | 83.1 ± 10.6 | 86.2 ± 10.9 | 82.3 ± 9.4 | 0.474 | <0.001 | 0.654 |
| Body Mass Index ($kg/m^2$) | | | | | | |
| 0 Months | 34.2 ± 3.1 | 33.8 ± 3.5 | 33.2 ± 2.8 | | | |
| 6 Months | 31.4 ± 3.0 | 30.5 ± 3.0 | 30.1 ± 3.9 | 0.707 | <0.001 | 0.828 |
| $VO_2$ at 85% APMHR (ml/kg/min)$^+$ | | | | | | |
| 0 Months | 22.1 ± 6.6 | 23.9 ± 3.7 | 23.4 ± 2.6 | | | |
| 6 Months | 24.9 ± 4.5 | 26.1 ± 4.9 | 26.1 ± 3.6 | 0.733 | 0.001 | 0.915 |
| Treadmill Time to reach 85% APMHR (seconds) $^+$ | | | | | | |
| 0 Months | 471.4 ± 284.9 | 581.7 ± 148.6 | 496.4 ± 213.5 | | | |
| 6 Months | 600.0 ± 218.8 | 696.7 ± 212.8 | 672.7 ± 275.9 | 0.589 | <0.001 | 0.571 |
| Self-Report Physical Activity (kcal/wk)$^§$ | | | | | | |
| 0 Months | 403.8 ± 300.6 | 808.9 ± 840.1 | 464.4 ± 303.3 | | | |
| 6 Months | 1299.1 ± 837.1 | 1597.5 ± 835.4 | 2022.8±1633.2 | 0.319 | <0.001 | 0.374 |
| Dietary Intake (kcal/day) | | | | | | |
| 0 Months | 2271.3±1297.3 | 1450.3±373.9 | 2130.5±628.0 | | | |
| 6 Months | 1912.9±1100.3 | 1220.0±317.0 | 1498.5±597.8 | 0.039* | 0.001 | 0.337 |
| Eating Behavior Inventory | | | | | | |
| 0 Months | 65.1 ± 6.0 | 73.0 ± 9.2 | 68.2 ± 11.8 | | | |
| 6 Months | 86.8 ± 10.3 | 90.0 ± 8.3 | 86.6 ± 9.8 | 0.241 | <0.001 | 0.569 |

§ One subject (FIT) did not complete Paffenbarger Questionnaire at 6 months.
+ Four subjects (2 SBWL, 2 SBWL+FIT) did not complete treadmill test due to medical issues at 6 months and two subjects (1 SBWL+FIT, 1 FIT) did not complete VO2 collection at 0 or 6 months due to claustrophobia.
APMHR = Age predicted maximum heart rate
*p=<0.05 SBWL>SBWL+FIT

## APPENDIX E

## OUTCOME DIFFERENCES BETWEEN TREATMENT GROUPS AT 6 MONTHS – INTENT-TO-TREAT ANALYSIS (FEMALES ONLY)

| Outcome Variable | SBWL (N=17) (mean± s.d.) | SBWL+FIT (N=13) (mean± s.d.) | FIT (N=14) (mean± s.d.) | P-Values Group Effect | P-Values Time Effect | P-Values Group X Time |
|---|---|---|---|---|---|---|
| Body Weight (kg) | | | | | | |
| 0 Months | 88.6 ± 12.5 | 95.7 ± 13.0 | 89.3 ± 9.0 | | | |
| 6 Months | 84.9 ± 13.1 | 86.2 ± 10.9 | 82.6 ± 9.4 | 0.457 | <0.001 | 0.043 |
| Body Mass Index ($kg/m^2$) | | | | | | |
| 0 Months | 33.1 ± 3.8 | 33.8 ± 3.5 | 33.2 ± 2.8 | | | |
| 6 Months | 31.7 ± 3.6 | 30.5 ± 3.0 | 30.7 ± 3.9 | 0.939 | <0.001 | 0.079 |
| $VO_2$ at 85% APMHR (ml/kg/min)$^+$ | | | | | | |
| 0 Months | 22.5 ± 4.9 | 24.0 ± 3.5 | 24.2 ± 3.7 | | | |
| 6 Months | 23.7 ± 4.1 | 26.0 ± 4.7 | 26.1 ± 4.0 | 0.285 | 0.001 | 0.676 |
| Treadmill Time to reach 85% APMHR (seconds) | | | | | | |
| 0 Months | 491.8 ± 211.5 | 584.6 ± 142.6 | 500.0 ± 188.1 | | | |
| 6 Months | 544.7 ± 185.0 | 690.8 ± 204.9 | 638.6 ± 251.8 | 0.244 | <0.001 | 0.192 |
| Self-Report Physical Activity (kcal/wk) | | | | | | |
| 0 Months | 517.2 ± 540.0 | 808.9 ± 840.1 | 381.7 ± 289.5 | | | |
| 6 Months | 991.1 ± 833.6 | 1597.5 ± 835.4 | 1494.8 ±1612.1 | 0.197 | <0.001 | 0.367 |
| Dietary Intake (kcal/day) | | | | | | |
| 0 Months | 2095.8±1023.4 | 1450.3±373.9 | 1937.9±670.7 | | | |
| 6 Months | 1906.0 ± 880.1 | 1220.0±317.0 | 1441.4±536.6 | 0.028* | 0.002 | 0.329 |
| Eating Behavior Inventory | | | | | | |
| 0 Months | 66.9 ± 7.7 | 73.0 ± 9.2 | 69.1 ± 11.3 | | | |
| 6 Months | 78.4 ± 13.2 | 90.0 ± 8.3 | 83.6 ± 11.3 | 0.027** | <0.001 | 0.455 |

APMHR = Age predicted maximum heart rate
+ Two subjects (1 SBWL+FIT, 1 FIT) did not complete $VO_2$ collection to claustrophobia at 0 or 6 months
*p<0.05 SBWL > SBWL+FIT
**p<0.05 SBWL+FIT > SBWL

## APPENDIX F

## BODY COMPOSITION AND ANTHROPOMETRIC OUTCOME DIFFERENCES – COMPLETERS ANALYSIS (FEMALES ONLY)

| Outcome Variable | SBWL (N=9) (mean± s.d.) | SBWL+FIT (N=13) (mean± s.d.) | FIT (N=11) (mean± s.d.) | P-Values | | |
|---|---|---|---|---|---|---|
| | | | | Group Effect | Time Effect | Group X Time |
| Waist Circumference (cm) | | | | | | |
| 0 Months | 112.7 ± 12.0 | 111.4 ± 14.6 | 111.5 ± 6.7 | | | |
| 6 Months | 104.3 ± 8.9 | 102.5 ± 11.9 | 103.7 ± 10.3 | 0.944 | <0.001 | 0.932 |
| Hip Circumference (cm)^ | | | | | | |
| 0 Months | 120.3 ± 7.3 | 121.8 ± 7.5 | 119.8 ± 5.3 | | | |
| 6 Months | 112.6 ± 6.3 | 113.8 ± 5.7 | 110.9 ± 8.7 | 0.650 | <0.001 | 0.875 |
| Waist-to-Hip Ratio^ | | | | | | |
| 0 Months | 0.93 ± 0.1 | 0.91 ± 0.1 | 0.93 ± 0.1 | | | |
| 6 Months | 0.93 ± 0.1 | 0.90 ± 0.1 | 0.94 ± 0.1 | 0.595 | 0.541 | 0.690 |
| Fat Mass (kg) | | | | | | |
| 0 Months | 42.56 ± 7.59 | 43.73 ± 9.08 | 41.83 ± 4.22 | | | |
| 6 Months | 37.46 ± 7.82 | 36.46 ± 7.98 | 34.34 ± 6.58 | 0.748 | <0.001 | 0.523 |
| Lean Mass (kg) | | | | | | |
| 0 Months | 44.12 ± 4.86 | 48.56 ± 4.77 | 45.48 ± 4.93 | | | |
| 6 Months | 42.41 ± 4.51 | 46.65 ± 4.51 | 44.63 ± 4.92 | 0.107 | <0.001 | 0.349 |
| Body Fat (%) | | | | | | |
| 0 Months | 48.9 ± 5.4 | 47.0 ± 4.1 | 47.9 ± 2.8 | | | |
| 6 Months | 46.6 ± 4.7 | 43.5 ± 5.0 | 43.3 ± 4.7 | 0.368 | <0.001 | 0.256 |
| Bone Mineral Density ($g/cm^2$) | | | | | | |
| 0 Months | 1.2302 ± 0.122 | 1.2255 ± 0.089 | 1.2937 ± 0.070 | | | |
| 6 Months | 1.2242 ± 0.133 | 1.2210 ± 0.082 | 1.2981 ± 0.075 | 0.144 | 0.499 | 0.329 |

^ One subject (SBWL+FIT) missing hip measurement

# APPENDIX G

## BODY COMPOSITION AND ANTHROPOMETRIC OUTCOME DIFFERENCES – INTENT-TO-TREAT ANALYSIS (WOMEN ONLY)

| Outcome Variable | SBWL (N=17) (mean± s.d.) | SBWL+FIT (N=13) (mean± s.d.) | FIT (N=14) (mean± s.d.) | P-Values Group Effect | Time Effect | Group X Time |
|---|---|---|---|---|---|---|
| Waist Circumference (cm) | | | | | | |
| 0 Months | 111.0 ± 12.9 | 111.4 ± 14.6 | 111.1 ± 6.3 | | | |
| 6 Months | 106.6 ± 11.7 | 102.5 ± 11.9 | 104.9 ± 9.5 | 0.900 | <0.001 | 0.239 |
| Hip Circumference (cm) | | | | | | |
| 0 Months | 118.1 ± 8.8 | 121.8 ± 7.5 | 117.6 ± 7.0 | | | |
| 6 Months | 114.0 ± 8.2 | 113.8 ± 5.7 | 110.6 ± 8.1 | 0.352 | <0.001 | 0.239 |
| Waist-to-Hip Ratio | | | | | | |
| 0 Months | 0.94 ± 0.1 | 0.91 ± 0.1 | 0.95 ± 0.1 | | | |
| 6 Months | 0.93 ± 0.1 | 0.90 ± 0.1 | 0.95 ± 0.1 | 0.345 | 0.506 | 0.635 |
| Fat Mass (kg) | | | | | | |
| 0 Months | 41.04 ± 9.03 | 43.73 ± 9.08 | 40.85 ± 6.07 | | | |
| 6 Months | 38.34 ± 9.02 | 36.46 ± 7.98 | 34.96 ± 7.36 | 0.735 | <0.001 | 0.043* |
| Lean Mass (kg) | | | | | | |
| 0 Months | 44.09 ± 4.97 | 48.56 ± 4.77 | 45.06 ± 4.35 | | | |
| 6 Months | 43.19 ± 4.88 | 46.65 ± 4.51 | 44.39 ± 4.35 | 0.071 | <0.001 | 0.132 |
| Body Fat (%) | | | | | | |
| 0 Months | 47.8 ± 5.2 | 47.0 ± 4.1 | 47.4 ± 4.0 | | | |
| 6 Months | 46.6 ± 4.6 | 43.5 ± 5.0 | 43.7 ± 5.1 | 0.436 | <0.001 | 0.047* |
| Bone Mineral Density ($g/cm^2$) | | | | | | |
| 0 Months | 1.2477 ± 0.103 | 1.2255 ± 0.089 | 1.2776 ± 0.088 | | | |
| 6 Months | 1.2445 ± 0.119 | 1.2210 ± 0.082 | 1.2810 ± 0.091 | 0.314 | 0.527 | 0.323 |

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