The Comparison of a Technology-based System and In-person Behavioral Weight Loss Intervention in the Severely Obese

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THE COMPARISON OF A TECHNOLOGY-BASED SYSTEM AND IN-PERSON BEHAVIORAL WEIGHT LOSS INTERVENTION IN THE SEVERELY OBESE

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A technology-based system incorporating a physical activity monitor and a web interface to monitor dietary intake and body weight combined with monthly telephone contact has been shown to be an effective intervention for weight loss. Whether this type of intervention is effective for individuals with Class II (BMI = 35.0 to <40.0 kg/m^2) or III (BMI $\geq$40 kg/m^2) obesity has not been examined. Continuous enhancements in technology require ongoing evaluation of the effectiveness of these interventions. **PURPOSE:** To examine weight loss in response to standard behavioral weight loss (SBWL), technology (TECH), and an enhanced technology (TECH-BT) interventions in adults with Class II or III obesity. **METHODS:** Subjects were 39 adults (age: 39.0±9.7, BMI: 39.5±2.8kg/m^2) randomized to SBWL (n=14), TECH (n=12), or TECH-BT (n=13). The prescription for all subjects included decreases in energy intake (1500-2100kcal/d), and increases in physical activity (200min/wk). SBWL attended weekly in-person group intervention sessions. TECH was provided with a wearable activity monitor that interfaced with a web-based program to monitor dietary intake and body weight (BodyMedia FIT®), also with one 10-minute intervention telephone call per month. TECH-BT received the same component as TECH, with the technology enhanced with Bluetooth® capability to allow for real-time monitoring of energy balance (intake and expenditure)(BodyMedia LINK®). **RESULTS:** Body weight was significantly reduced (p<.001) from 110.9±9.1 to 107.7±8.8kg in SBWL (-3.2±3.1kg; -2.9±2.9%), 112.2±10.5 to 107.2±10.5kg in TECH (-5.0±3.7kg; 4.9±3.8%), and 108.8±15.0 to 104.0±16.2kg in TECH-BT

(-3.3±4.2kg; 3.5±4.8%) from 0 to 3 months. However, weight loss was not significantly different between the intervention groups. While significant improvements ($p<.05$) were found in waist and hip circumferences, percent body fat, physical activity, and dietary intake, there were no group significant group differences. **CONCLUSIONS:** These findings suggest that significant short-term weight loss can be achieved in individuals with Class II or III obesity with less in-person contact using a technology-based system combined with monthly telephone contact. These findings may have significant clinical implications for effective delivery of weight loss interventions for severely obese adults. Whether these findings extend beyond the initial 3 months of intervention and the long-term acceptability of a technology-based intervention warrants further investigation.

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PREFACE

To my Mother and Father, who always believed that I could do anything.

1.0 INTRODUCTION

Age-adjusted estimates from the National Health and Nutritional Examination Survey (NHANES) in 2007-2008 indicate that 68% of the United States population is overweight or obese as defined by a Body Mass Index (BMI) of ≥ 25 kg/m^2, with 33% of that representing the obesity prevalence at a BMI of ≥ 30 kg/m^2 [1]. The health-related consequences of increased BMI are of public concern as excess body weight has been shown to be associated with higher rates of mortality[2-5], along with chronic diseases including cardiovascular disease[6-9], diabetes[9-11], and certain cancers[12-14]. In addition, overweight and obesity are related to increased risk of developing other health consequences such as osteoarthritis[15-17], gall stones[10, 18] and sleep apnea[19-21]. In 2010, it was estimated that $117 billion was spent on the treatment of obesity and obesity-related comorbidities. Projections based on the rate of increase estimate that the cost of treating these conditions will be approximately $221 billion by 2020[22]. Given the high prevalence of overweight and obesity in the United States, along with the strong body of evidence linking excess body weight to health consequences and chronic diseases, it is evident there is a need to develop novel approaches to reducing overweight and obesity.

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1.1 BACKGROUND

Improvements in health consequences related to overweight and obesity have been demonstrated with modest reductions in body weight[23-24]. In overweight and obese individuals, weight loss has produced reductions in hypertension[25-26] and blood lipids[27]. In addition, blood glucose has been shown to decrease, and insulin sensitivity has been shown to increase[28]. The Diabetes Prevention Program demonstrated a 58% reduction in risk of developing diabetes in individuals with impaired glucose tolerance that had an initial weight loss after one year of 7.2%, with 4.5% loss maintained after 3 years[28]. More recently the multi-center Look AHEAD Study has shown that similar magnitudes of weight loss at one and four years in adults with type 2 diabetes can result in improvements in numerous traditional cardiovascular disease risk factors[29-30]. Thus, lifestyle interventions are recommended to reduce body weight that can result in improvements in health risk.

Interventions that focus on reducing energy intake (diet) and increasing energy expenditure (exercise or physical activity) are typically most effective if combined with behavioral strategies to facilitate engagement in and maintenance of these behaviors. This approach is consistent with the clinical guidelines for obesity treatment issued by the National Institutes of Health (NIH)[24] and other leading professional organizations including the American College of Sports Medicine[23], the American Dietetic Association[31] , and the American Heart Association[32--33]. These types of interventions have demonstrated a reduction of initial body weight of approximately 8-10% across a period of 21-24 weeks[34]. Traditionally, these interventions have required onsite face-to-face contact between patients and weight loss counselors, which can result in patient burden and make these approaches less appealing to some patients.

There has been an increase in the use of technology and alternative delivery channels (mail, web-based, telephone), and these interventions have resulted in significant weight loss without requiring in-person contact between the patient and counselor. Recently, Pellegrini et al.[35] reported that the use of a technology-based system that included a wearable device to monitor energy expenditure and a web-based interface to report dietary intake, combined with one brief monthly telephone call from a weight loss counselor resulted in similar changes in body weight (-5.8 ± 6.6 kg, 6.3 ± 7.1%) when compared to an in-person intervention that did not include this technology (-3.7 ± 5.7 kg, -4.1 ± 6.3%). However, these findings warrant replication, which was one of the specific aims of this proposed study. Moreover, examining whether additional enhancements to this technology-based intervention would result in even greater weight loss would be of clinical significance thus was an additional aim of this study.

1.2 THEORETICAL RATIONALE SUPPORTING THE EFFECTIVENESS OF TECHNOLOGY FOR WEIGHT LOSS

Behavioral weight loss programs typically integrate the concept of self-regulation as a crucial strategy for changing dietary intake and physical activity behaviors[34]. Based on the Social Cognitive Theory of Self-regulation developed by Bandura, two key components to self-regulation include self-monitoring and feedback on the progress of behaviors[36]. Thus, part of the effectiveness of the technology-based intervention (BodyMedia® FIT System, Pittsburgh, PA) implemented by Pellegrini et al.[35] may be explained by the technology facilitating self-monitoring and feedback of key weight loss behaviors, namely physical activity and dietary intake. The BodyMedia® FIT System includes a wearable device to monitor physical activity and energy expenditure in real-time, a display device to provide feedback on achievement of energy expenditure and physical activity goals, and a web-based software program to provide self-monitoring of dietary intake and to provide feedback on goal achievement. Moreover, the intervention staff was able to access this information via a web-interface and provide further feedback on goal achievement of these key behaviors during monthly telephone counseling contact.

Self-monitoring of dietary behaviors has consistently been shown in the literature to be associated with greater reductions in weight compared to not self-monitoring[33-34], or self-monitoring less frequently[37-41]. Noland et al. reported that individuals who self-monitored physical activity reported a significantly greater number of exercise sessions compared to those that did not[42]. Regular self-weighing of body weight has also been shown to be associated with improved weight loss outcomes[39]. Feedback in reference to self-monitoring of dietary and physical activity behaviors may be an effective strategy to promote weight loss[43]. Within Social Cognitive Theory[36], Bandura states that knowledge of how one is doing, in the form of feedback, may alter subsequent behaviors potentially triggering self-reactive influences towards achieving goals. Feedback offers important information specifically related to reaching more direct decisional considerations, increasing engagement, increasing motivation, and providing comparison and norms to base future goals upon[44]. The success of self-regulation relies partly on the temporal proximity of feedback related to self-monitoring[36].

Figure 1 represents a theoretical model depicting the pathway by which both self-monitoring and feedback may contribute to behavior change resulting in weight loss. Within the model, goals for both dietary modification and physical activity are established that should result in weight loss. Key in this concept is the need to self-monitor each of these behaviors. Self-monitoring results in feedback on achievement of behavioral goals, and depending on goal achievement, additional changes to these key behaviors are undertaken by the individual.

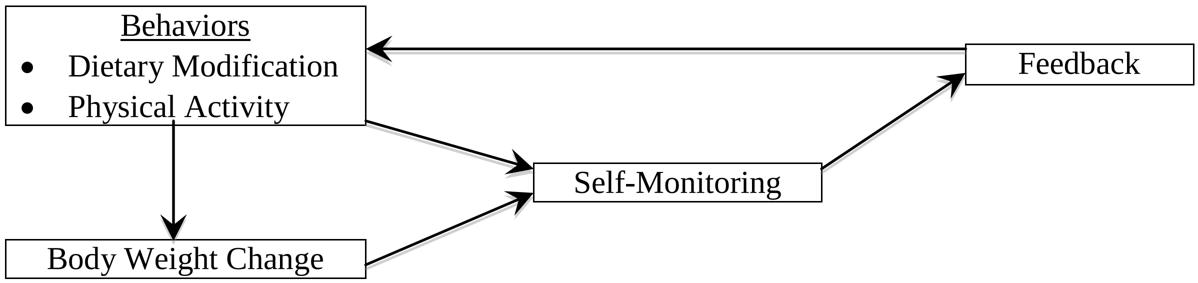


Figure 1. Self-regulation within behavioral weight loss interventions

The findings of Pellegrini et al. [35] show that use of the BodyMedia® FIT System in combination with monthly intervention contact via telephone was as effective as a more intensive in-person weight loss intervention, and this may be a result of the technology enhancing the components of self-regulation, specifically self-monitoring and feedback. These findings needed replication, which was a focus of this proposed study. In addition, the technology used by Pellegrini et al. [35] required individuals to use a computer to self-monitor eating behavior, which prohibited this from occurring in real-time and may have reduced effectiveness. Moreover making the physical activity data available to the counselor also required the participant to upload the data from the armband to the website using a computer, which again may have reduced effectiveness. More recent developments allow the participant to use smart phones to self-monitor eating behavior in real-time and to have the physical activity visible without connecting to a computer, which may improve the effectiveness of this technology. However, these enhancements in the technology had not been evaluated within the context of an intervention for weight loss, which was the second focus of this proposed study.

1.3 SPECIFIC AIMS

1. To examine the effect of standard behavioral weight loss (SBWL), BodyMedia® FIT System combined with a monthly intervention telephone call (TECH), and an Enhanced BodyMedia® FIT System combined with a monthly intervention telephone call (TECH-BT) on weight loss across 3 months in overweight and obese adults.
2. To examine the effect of SBWL, TECH, and TECH-BT on change in body composition as measured with percent body fat, waist circumference, and hip circumference across 3 months in overweight and obese adults.
3. To examine the effect of SBWL, TECH, and TECH-BT on changes in moderate-to-vigorous intensity physical activity across 3 months in overweight and obese adults.
4. To examine the effect of SBWL, TECH, and TECH-BT on changes in dietary intake across 3 months in overweight and obese adults.
5. To examine the effect of SBWL, TECH, and TECH-BT on self-monitoring of diet, physical activity, and body weight across 3 months in overweight and obese adults.

1.4 HYPOTHESES

1. It was hypothesized that TECH-BT would result in a significantly greater weight loss compared to SBWL and TECH across a 3-month intervention.
    a. An exploratory hypothesis was that there was no significant difference for weight loss between SBWL and TECH.

2. It was hypothesized that TECH-BT would result in a significantly greater reduction in percent body fat, waist circumference, and hip circumference compared to SBWL and TECH across a 3-month intervention.
    a. An exploratory hypothesis was that there would be no significant difference in these measures between SBWL and TECH.
3. It was hypothesized that TECH-BT would result in a significantly greater amount of moderate-to-vigorous physical activity compared to SBWL and TECH across a 3-month intervention.
    a. An exploratory hypothesis was that there would be no significant difference in moderate-to-vigorous physical activity between SBWL and TECH.
4. It was hypothesized that TECH-BT would result in significantly greater improvement in dietary intake and eating behavior compared to SBWL and TECH across a 3-month intervention.
    a. An exploratory hypothesis was that there would be no significant difference in these measures between SBWL and TECH.
5. It was hypothesized that TECH-BT would self-monitor (dietary intake, physical activity, and body weight) at a greater frequency compared to SBWL and TECH across a 3-month intervention.
    a. An exploratory hypothesis was that there would be no significant difference in these measures between SBWL and TECH.

2.0 REVIEW OF THE LITERATURE

2.1 OBESITY: DEFINITION AND PREVALENCE

Overweight and obesity is defined as having excess body weight or body fat. Body mass index (BMI) is calculated by weight in kilograms divided by height in meters squared[24]. Overweight is defined as a BMI of 25.0 to < 30.0 kg/m^2 with obesity defined as a BMI of ≥ 30.0 kg/m^2. Obesity can be divided into classes based on severity: Class I, BMI of 30.0 to < 35.0 kg/m^2; Class II, BMI of 35.0 to < 40.0 kg/m^2; and Class III, BMI of ≥ 40.0 kg/m^2 [24, 44]. Age-adjusted estimates from the National Health and Nutritional Examination Survey (NHANES) in 2007-2008 indicate that 68% of the United States population is overweight or obese, and 33% of that represents the obesity prevalence.[1] The epidemic of overweight and obesity is demonstrated with high prevalence rates found across the United States impacting both genders, the majority of racial and ethnic groups, and all socioeconomic tiers[44-46].

2.2 CONSEQUENCES OF OBESITY

The consequences of obesity have influenced health and quality of life in addition to having a large economic impact on society. Consistently, the literature has established that a higher BMI is related to increased risk of mortality [2-5]. Age-adjusted analyses in the Nurses' Health Study[2] demonstrate a J-shaped association between increasing BMI and mortality, with women having a BMI of 19.0 to 26.9 kg/m^2 at the lowest risk. Results indicate a positive association with increasing BMI and relative risk of mortality from all causes[3-5]. The American Cancer Society's Cancer Prevention Studies I and II[3, 4] demonstrated similar trends in the relationship between increasing BMI and risk of mortality with highest rates associated with a BMI of ≥ 32.0 kg/m^2 in men and women (2.68, 95% CI: 1.76-4.08; and 1.89, 95% CI: 1.62-2.21). The risk of death increased with higher BMI in all age groups and for all cause of death categories. Flegal et al.[5] examined cause-specific relative risks of mortality in relation to BMI using NHANES data combined with cause of death data from the 2004 United States vital statistics. Results from this study demonstrated a significant and positive association between excess mortality and cardiovascular disease (CVD) mortality in obese, but not overweight BMI categories.

The development of chronic health conditions related to overweight and obesity has a similar pattern of associated risk. High levels of body fat have been shown to be involved in the pathogenesis of hypertension, insulin resistance, hyperlipidemia, and certain cancers [6-14, 48]. Excess body fat is also considered a risk factor for cardiovascular disease [49]. After 26 years of follow-up in the Framingham Heart Study, the risk of cardiovascular death increased by 1% for every pound increase in body weight for subjects 30-42 years of age, and by 2% for subjects between the ages of 50 and 62[50]. Overweight and obesity have also been related to increased risk of developing other health consequences such as osteoarthritis [15-17], gallstones [10,18], and sleep apnea [19-21]. Central adiposity has been shown to be an independent risk factor for co-morbidities related to overweight and obesity[24]. Evidence from the Nurses' Health Study shows that after adjusting for BMI and other cardiac risk factors, a waist circumference of ≥ 96.5 cm (38 in) in women was associated with a greater relative risk of developing coronary heart disease (3.06, 95% CI: 1.54-6.10) [51].

Overweight and obesity have also been linked with lower health-related quality of life (HRQL) and physical limitations. Studies have demonstrated significant decreases in quality of life as a result of obesity. The Behavioral Risk Factor Surveillance System (BRFSS) shows that the severely obese (BMI $\geq$ 35 kg/m^2) and obese (BMI 30.0 kg/m^2) were more likely to experience unhealthy days affecting physical health (OR=1.87 and 1.11), mental health (OR=1.41 and 1.17), and activity limitations (OR=1.73 and 1.22) compared to a normal weight reference (BMI < 25.0 kg/m^2)[52]. Compared to age-matched men of normal weight (BMI < 25.0 kg/m^2), Larsson et al. found that men in the highest category of BMI (30.0 to <40.0 kg/m^2) had significantly lower HRQL scores for physical functioning (94.4, SE=1.5, $p \leq .05$), general health (73.5, SE=2.5, $p \leq .01$) , vitality (61.0, SE=2.9, $p \leq .01$), and social functioning (84.4, SE=2.9, $p \leq .05$). Compared to age-matched women of normal weight (BMI < 25.0 kg/m^2), women in the highest category of BMI (30.0 to < 40.0 kg/m^2) had significantly lower HRQL scores for physical functioning (90.8, SE=21.9, $p \leq .01$), bodily pain (72.5, SE=3.2, $p \leq .05$), and general health (50.0, SE=1.0, $p \leq .01$)[53]. Compared to normal weight subjects, obese subjects (BMI >30.0 kg/m^2) have also reported a higher prevalence of falls (27% vs. 15%) and ambulatory stumbling (32% vs. 14%), with HRQL scores significantly lower in terms of physical functioning, vitality, bodily pain, and general health [54].

It is suggested that obesity is related to depressive disorders along with other mental illnesses [44, 55]. Overweight subjects (BMI $\geq$ 25.0 kg/m^2) demonstrate a higher prevalence of depression compared to those with a BMI of < 25.0 kg/m^2. Compared to non-overweight controls, the odds ratio for overweight individuals to have depression and bodily dissatisfaction is 4.63 and 2.25, respectively[55].

In addition to the adverse effects on health, the high prevalence of overweight and obesity has adverse effects on the economy. Obesity-related conditions are among the most expensive health care problems as treatment of these comorbidities is associated with greater cost and use of health care services[56]. A reported 36% increase in medical expenditures is related to the treatment of obesity-related conditions when compared to medical expenses from normal-weight patients[57]. In 2010, it was estimated that $117 billion was spent on the treatment of obesity and obesity-related comorbidities. Projections based on the rate of increase estimate that the cost of treating these conditions to be approximately $221 billion by 2020[22]. A large portion of this cost is covered through government supported medical providers such as Medicare and Medicaid costing taxpayers approximately $175.00 to a projected $200.00 or greater per person per year[22,58].

2.3 WEIGHT LOSS AND IMPROVED HEALTH CONSEQUENCES

Improvements in health consequences related to overweight and obesity have been demonstrated with modest reductions in body weight[23-24]. In overweight and obese individuals, weight loss has produced reductions in hypertension[25-26], blood lipids[27], and blood glucose has been shown to decrease, and insulin sensitivity has been shown to increase[26]. The Diabetes Prevention Program demonstrated a 58% reduction in risk of developing diabetes in individuals with impaired glucose tolerance that had an initial weight loss after one year of intervention of 7.2%, with 4.5% loss maintained after 3 years[28]. More recently the multi-center Look AHEAD Study has shown that similar magnitudes of weight loss at one and four years in adults with type 2 diabetes can result in improvements in numerous traditional cardiovascular disease risk factors[29-30].

An early review of the medical benefits of weight loss suggests that improvements in insulin resistance, serum glucose levels, and systolic and diastolic blood pressures can be achieved in the short-term[25]. MacMahon et al. reported that a significant decrease in systolic and diastolic blood pressure (13 and 10 mmHg) was associated with a mean group weight loss of 7.4 kg after 21 weeks[59]. Ross et al. have demonstrated improvements in glucose disposal following diet- (5.6mg/kg skeletal muscle/min) and exercise-induced (7.2mg/kg skeletal muscle/min) weight loss across 12 weeks[60]. Four-month improvements in insulin sensitivity (5.9 ± 0.4 to 7.3 ± 0.5 mg/fat-free mass/min) have been demonstrated by Goodpaster et al. following significant weight losses (baseline 100.2 ± 2.6 to 4-month 85.5 ±2.1 kg)[61]. Goodpaster et al. have also demonstrated significant improvements in fasting insulin levels following diet (baseline 15.83 to 6-month 11.61 uU/mL, $p < 0.001$) and diet plus exercise (baseline 17.07 to 6-month 12.06 uU/mL, $p < 0.001$) weight loss interventions[62].

2.4 INTERVENTIONS FOR WEIGHT LOSS

2.4.1 Standard Behavioral Weight Loss Interventions

Lifestyle interventions that focus on reducing energy intake (diet) and increasing energy expenditure (exercise or physical activity) are typically most effective if combined with behavioral strategies to facilitate engagement in and maintenance of these behaviors. This approach is consistent with the clinical guidelines for obesity treatment issued by the National

Institutes of Health (NIH)[24] and other leading professional organizations including the American College of Sports Medicine[23], the American Dietetic Association[31] , and the American Heart Association[32-33]. These types of interventions have demonstrated a reduction of initial body weight of approximately 8-10% across a period of 21-24 weeks[34]. Early work by Wing et al. demonstrated that after 10 weeks of basic dietary intervention without specific caloric prescription, weight loss programs produced a 4.5 kg weight loss[63].

Changes to behavioral weight loss intervention in the last 20 years have included dietary prescriptions reducing daily calories by approximately 500-1,000 kcal/day[23], and gradually increasing physical activity energy expenditure to 1,000[34] to 1,500 kcals[63] per week. This combination produces a negative energy balance creating a 1-2 pound weight loss per week [23]. According to Wing et al. participants in behavioral weight loss programs in the 1990's lost 9.0 kg, or approximately 10% of initial body weight[34].

A more recent trial demonstrated similar changes in body weight when examining differences in intermittent (-9.3 ± 4.5 kg) versus continuous (-10.2 ± 4.2 kg) exercise within a behavioral weight loss intervention[64]. Jakicic et al. have shown similar results in a later trial with participants losing 8.1 ± 5.0 kg (-9.3 ± 5.6%) of initial body weight across 6 months[65]. In a population of severely obese adults (BMI: 43.5 ÷ 4.8, 43.7 ± 5.9 kg/m^2) across 6 months, Goodpaster et al. demonstrated significant changes in body weight in diet only (-8.2 kg) versus to diet plus exercise (-10.9 kg) interventions, with approximately a 2 kg additional change in body weight found in the diet plus exercise condition[62]. The addition of exercise to dietary weight loss interventions has been shown to produce an additive 2-3 kg change in body weight as compared to diet interventions alone[67].

2.4.2 Technology-based Weight Loss Interventions

In the past 10 years, there has been an increase in the use of technology to deliver weight loss interventions. The availability of the Internet, with 73% of adults having access in 2011, has led to its incorporation in the delivery of weight loss interventions [68]. Web-based interventions have resulted in significant weight losses while reducing in-person contact.

Tate et al. examined the use of the Internet to deliver education on weight loss compared to a behavioral weight loss intervention[69]. Participants in the Internet behavior group lost significantly more weight than those in the education group from baseline to 3 months (p = .001), with 45% of the participants in the Internet behavior group losing ≥ 5% of initial body weight. In the Internet behavior group, the total number of self-monitoring diaries submitted online was correlated with weight loss (r =-.05, p =.001).[69]

A pilot study by Gold et al. compared changes in body weight from an interactive behavioral weight loss website and a commercial website[70]. Repeated measures analysis showed that the behavioral weight loss website group (-8.3 ±7.9 kg) lost significantly more weight than the commercial website group (-4.1 ± 6.2 kg) (p = .004) after 6 months.

Tate et al. also examined the role of counseling using the Internet within a weight loss intervention[71]. In addition to having access to an interactive website, participants in this design were randomized to receive no counseling, automated email counseling generated by a computer, or personalized email counseling from a human counselor. At 3-months, the two groups receiving email feedback had similar magnitudes of weight loss whether by computer (-5.3 ± 4.2 kg) or counselor (-6.1 ±3.9 kg), and a greater loss compared to no counseling controls across 3 months. However, at 6 months, the group receiving human email counseling had a significantly greater weight loss (-7.3 ± 6.2 kg) compared both the computer email group (-4.9 ± 5.9 kg) and no counseling controls (-2.6 ± 5.7 kg). In both computer and counselor feedback groups, the total number of self-monitoring diaries submitted online was associated with weight loss (r = -.69 and -.56, p<.001).

To understand the level of in-person contact needed to support technology-based interventions, Micco et al[72] randomized 183 participants into two groups, Internet only or Internet plus in-person treatment. Results showed no significant difference in weight loss between the groups at 6 months (-6.8 ± 7.8 kg vs -5.1 ± 4.8 kg, p=.15). More recently, Harvey-Berino et al.[73] conducted a study to compare traditional in-person, interactive Internet, and a hybrid intervention incorporating both in-person contact and interactive Internet interventions. Conditions differed significantly in mean weight loss (-8.0 ± 6.1 kg, -5.5 ± 5.6 kg, -6.0 ± 5.5 kg; p<.01) for in-person, Internet, and hybrid, respectively. The in-person group had a significantly higher proportion of participants achieving a 7% weight loss (56.3%) as compared to hybrid (44.4%) and Internet (37.3%) conditions. These results suggest that in-person contact had a greater impact on weight loss; however, it should be noted that even though not significantly different from the other group, the hybrid intervention provided a trend towards an increase in weight loss as compared to Internet alone.

The magnitude of weight loss in the Internet-based studies appears to be less than that observed in SBWL interventions; however, recent technology enhancements integrating a wearable physical activity monitor have shown promising results. The BodyMedia® FIT System incorporates a physical activity monitor worn on the upper arm that works in conjunction with a web-interface for self-monitoring of daily energy expenditure and energy intake. In a 12-week study examining the efficacy of this system, Polzien et al., compared a standard in-person intervention to a standard in-person plus the technology-based system used both intermittently and continuously[74]. Results from this study demonstrated that greater weight losses were reported when the technology was used continuously, (-6.2 ± 4.0 kg) compared to intermittent usage (-3.4 ± 3.4 kg); however, the addition of the technology-based system produced a non-significant (p = 0.08) 2 kg decrease in body weight compared to in-person intervention alone. A significant correlation was observed between change in body weight from self-monitoring of physical activity (armband time on body) in both intermittent technology (r = -.68, p < .01) and continuous technology (r = -.71, p < .01) groups, and change in body weight from self-monitoring of meals on the web-interface in the continuous technology group (r = -.50, p < .05).

Pellegrini et al. examined the use of a similar technology-system with a once per month telephone intervention[35]. This study reported greater weight losses in the standard in-person plus technology group (-8.8 ± 5.0 kg) compared to standard in-person intervention (-7.1 ± 6.2 kg), and consistent with Polzien et al.[74], the use of the technology system assisted with an additional 2 kg decrease in body weight. Subjects in the standard plus technology group self-monitored eating behaviors significantly more (5.9 ± 2.2 days/week) than those in the standard alone group (5.3 ± 2.8 days/week) with dietary intake significantly related to weight loss at 6 months (r = -.57, p<.01). The technology plus telephone intervention group had similar changes in body weight (completers: -5.8 ± 6.6 kg, intent-to-treat: -6.3 ± 7.1%) when compared with in-person intervention that did not include the technology (completers: -3.7 ± 5.7 kg, intent-to-treat: -4.1 ± 6.3%).

Using the same technology system in a weight loss intervention, Shuger et al.[75] randomized subjects into 4 groups: self-directed standard care (SC), group-based weight loss (GWL), GWL plus armband technology (GWL+SWA), and armband technology used alone

(SWA-alone). There was a significant reduction in body weight in SWA-alone from baseline (101.15 ± 2.95 kg) to 4 months (98.48 ± 2.97 kg) and in GWL+SWA (baseline 100.32, ± 2.97 kg to 4 months 96.83 ± 2.99 kg). Significant reductions in waist circumference were also seen after 4 months in SWA-alone (baseline 105.91 ± 2.18 cm to 4 months 102.99 ± 2.21 cm) and GWL+SWA (baseline 106.04 ± 2.19 to 4 months 102.12 ± 2.21 cm). No differences in body weight were found between the intervention groups, however results after 9 months showed a significant body weight reduction in GWL+SWA compared to SC (p = .0004). The lower magnitude of weight loss in the SWA-alone group may be explained by the complete removal of contact as compared to the Pellegrini study[35] in which a once-monthly telephone contact was made with participants. Conflicting results from Shuger et al.[75] and Pellegrini et al.[35] suggest that the efficacy of this type of technology-based system used with minimal in-person contact should be further investigated.

2.5 SELF-MONITORING AND FEEDBACK

Based on the Social Cognitive Theory of Self-regulation developed by Bandura, two key components to self-regulation include self-monitoring and feedback on the progress of behaviors[36]. Self-monitoring is defined as the systematic observation and recording of target behaviors[76] that promotes self-awareness[77-79]. Within the Social Cognitive Theory of Self-Regulation, Bandura states that it is difficult for people to influence their own motivation and actions if they do not pay adequate attention to their behavior performance[36]. Thus self-monitoring provides information needed for realistic and progressive goal setting, while assisting with the evaluation of goal achievement to better influence behavior change[36,77-79]. It has been suggested that self-monitoring is one of the most critical components of behavior change[78,80], and it is frequently used as a strategy when modifying behaviors associated with weight loss. Early research by Fisher et al. emphasized self-monitoring in weight management. Findings from this study show that those who did not self-monitor over a 3-week holiday gained approximately 5.7 times as much weight as those that sustained self-monitoring behaviors[81]. Work by Kirschenbaum et al. [78,82-83] supports these findings suggesting that the discontinuation of self-monitoring results in discontinuation or failure of self-regulation.

Baker et al.[84] examined the relationship between self-monitoring and weight change. Results after 12-weeks demonstrate that six variables: monitoring of any food consumed (r=.42, p<0.001) monitoring of all foods eaten in a day (r=.44, p<0.001), monitoring of time food was eaten (r=.44, p<0.001), monitoring of the quantity of food (r=.41, p<0.001), monitoring grams of fat consumed (r=.35, p<0.01) and not self-monitoring (r= -.41, p<0.01) were significantly correlated with weight change. Additional analysis divided subjects into high and low categories based on overall consistency and completeness of self-monitoring, with the highest category losing significantly more weight than the category with the lowest level of monitoring (p < .01). When divided into self-monitoring quartiles after 12 weeks, greater percentages of subjects lost weight in the quartiles that reflected greater levels of consistency and completeness. Boutelle et al. replicated these findings over an 8-week period demonstrating that the most consistent self-monitors lost more weight than the least consistent self-monitors[85].

Carels et al.[86] examined the relationship between exercise self-monitoring and weight loss. After 15.8 ± 6.2 weeks of exercise monitoring, a significant and positive relationship was shown between higher levels of self-monitoring and greater weight losses (r = .44, p < .05), and greater cumulative exercise minutes (r = .52, p <. 01). Secondary analyses examining consistent versus inconsistent exercise self-monitoring revealed that consistent self-monitors lost significantly more weight ($p < .05$); participated in greater cumulative exercise minutes ($p < .01$); and reported fewer difficulties with exercise ($p < .01$).

Burke et al. in a qualitative analysis of participants within a weight reduction program concluded that individualizing self-monitoring strategies may improve adherence to the behavior [87]. Among the current self-monitoring strategies utilized, paper diaries have classically been used within weight loss interventions[88-93], however reports use of electronic diaries[69,71,92-93] and personal digital assistant (PDAs)[94-97] have recently emerged. These technological enhancements in self-monitoring may simplify the process and allow for temporal and meaningful feedback consistent with constructs of the Social Cognitive Theory of Self-Regulation [36]. Bandura also states that feedback, or knowledge of how one is doing, may alter subsequent behaviors potentially triggering self-reactive influences towards achieving goals. A review of the literature supporting the role of feedback in behavior change concludes that feedback offers important information specifically on reaching more direct decisional considerations, increasing engagement, increasing motivation, and providing comparison and norms upon which to base future goals[44].

2.6 SUMMARY

Overweight and obesity is of major concern due to the high prevalence[1] and consequences affecting physical[6-21,48-50] and mental health[45,.54], along with quality of life and physical and mental function[52-55]. Improvements in health outcomes related to overweight and obesity have been demonstrated with modest reductions in body weight[23-24], and behavioral weight loss interventions have been successful at producing the magnitude of weight loss necessary to see these changes[28-30,35,62,65,67]. Recent technology advances have demonstrated that significant weight loss can potentially be achieved with less in-person contact[35]. The benefit of this technology is the potential to improve the temporal proximity of self-monitoring which is consistent with Bandura's Social Cognitive Theory of Self-Regulation[36]. When applying this model to a weight loss intervention, goals for both dietary modification and physical activity are established that should result in weight loss. Key in this concept is the need to self-monitor each of these behaviors. Self-monitoring results in feedback on achievement of behavioral goals, and depending on goal achievement, additional changes to these key behaviors are undertaken by the individual. This study is designed to examine whether recent enhancements to the existing technology may facilitate self-monitoring and feedback on goal achievement, ultimately resulting in improved weight loss compared to alternative weight loss interventions. The theoretical pathway to be examined in this study is shown in Figure 2.

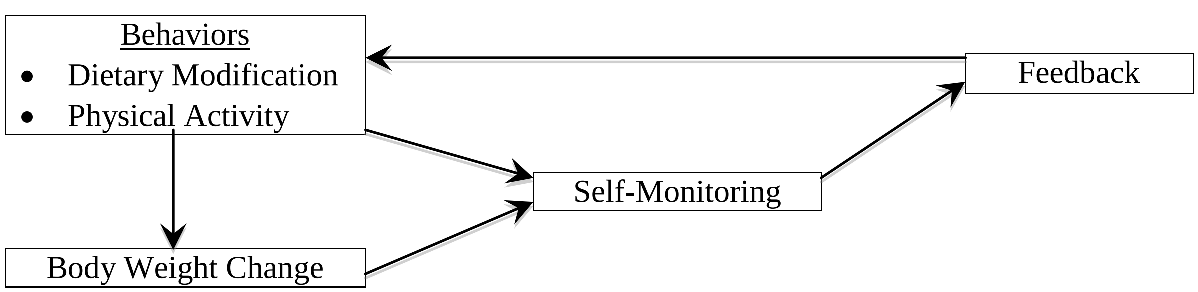


Figure 2. Self-regulation within behavioral weight loss interventions

3.0 METHODOLOGY

3.1 SUBJECTS

Eighty four (N=84) men and women between the ages of 21-55 years were recruited to participate in this study. Subjects were sedentary and classified as Class II and Class III obese adults based on Body Mass Index (BMI) (35.0 – 45.0 kg/m^2). While severe obesity has been shown to be associated with a greater number of comorbidities[24], only one study included adults with Class III obesity when examining the effectiveness of the BodyMedia® FIT system for weight loss[75]. Subjects meeting the American College of Sports Medicine (ACSM) criteria for classification of low to moderate risk were eligible for participation in this study, with those classified as high risk excluded from the study[49]. Additionally, individuals meeting the following conditions were excluded:

1. Reported not having access to a computer, access to the Internet, or the availability to download software onto a computer.
    a. Rationale: The BodyMedia® FIT System required the usage of a computer with the above capabilities. Not having this access would result in the reduced ability to utilize the technology as a tool to assist with monitoring of weight loss behaviors. Funds were not available to provide a compatible computer to participants in this study.

2. Reported not having a smart phone that is compatible with the BodyMedia® FIT Bluetooth® System that was examined in this study.
    a. Rationale: Not having access to this technology prohibited use of the technology system that is being examined in one of the intervention conditions for this study. Funds were not available to provide the necessary smart phone device to participants in this study.
3. Had a physical limitation that prevented engaging in physical activity.
    a. Rationale: The ability to perform physical activity was a necessary component in all three intervention groups. This type of limitation reduced the capability of assessing changes to physical activity behaviors as a part of the weight loss study.
4. Participated in structured aerobic exercise for $\geq$ 60 minutes per week over the prior $\geq$ 3 months.
    a. Rationale: The inclusion of only sedentary individuals allowed for the examination of changes in physical activity behaviors over the course of the study. Recruiting individuals who were already physically activity would limit the influence of the proposed interventions on improvements in this behavior.
5. Reported being treated for a current medical condition that could affect body weight. These may have included the following: cancer; diabetes mellitus; hyperthyroidism; inadequately controlled hypothyroidism; chronic renal insufficiency; chronic liver disease; gastrointestinal disorders including ulcerative colitis, Crohn’s disease, or malabsorption syndromes, etc.
    a. Rationale: The presence of these medical conditions would confound the results of this study.

6. Reported current congestive heart failure, angina, uncontrolled arrhythmia, symptoms indicative of increase risk of an acute cardiovascular event, coronary artery bypass grafting or angioplasty, prior myocardial infarction, and conditions requiring anticoagulation therapy (i.e. deep vein thrombosis).
    a. <u>Rationale:</u> Individuals with these types of medical conditions require additional clearance, supervision, and changes in the prescription of dietary and physical activity goals, which was outside of the projected scope of this study. These types of alterations would be different from the standard procedures used within the intervention groups being proposed.
7. Had a resting systolic blood pressure $\geq$ 150 mmHg or resting diastolic blood pressure of $\geq$ 100 mmHg or taking medications to control blood pressure.
    a. <u>Rationale:</u> Hypertension at these levels may have contraindicated participation in the prescribed physical activity as a part of the weight loss study or may require additional screening or medical management.
8. Treatment for any psychological issues (i.e., depression, bipolar disorder, etc) or taking psychotropic medications within the previous 12 months.
    a. <u>Rationale:</u> Interventions for psychological issues may have affected compliance, potentially confound the effect of the proposed intervention, or may require additional medical monitoring throughout the study period. Psychotropic medications are exclusionary, as certain types have been shown to affect body weight.
9. Had taken prescription or over-the-counter medications that affect body weight and metabolism.

a. Rationale: Medications that affect body weight may have confounded the results of this study.

10. Had lost > 5% of current body weight in the prior 3 months and maintained that weight loss at the time of recruitment.

    a. Rationale: Previous experiences with this type of intervention have shown that maintained weight losses > 5% in the previous 3 months tend to move the intervention to focus to the prevention of weight regain as opposed to weight loss, which was one of the primary outcomes of the proposed study.

11. Was a participant in an exercise or weight control study, had participated in an exercise or weight control study within the previous 6 months, or was a current participant in a commercial weight reduction program.

    a. Rationale: Concurrent involvement in these types of programs or research studies may have confounded the weight loss intervention proposed for this study.

12. Had undergone bariatric surgery (e.g., gastric bypass, lap-band) for weight loss.

    a. Rationale: Bariatric surgery may have required alterations in the proposed diet and physical activity intervention, and may have confounded the outcome variables for this study.

13. Had been treated for an eating disorder.

    a. Rationale: The presence of an eating disorder may have required additional medical monitoring and may have confounded the results of this study.

14. Was pregnant, pregnant in the last 6 months, breast feeding in the last 3 months, lactating, or planning on becoming pregnant in the next 3 months.

a. Rationale: Pregnancy would have required modification to the intervention and may have required additional medical monitoring. Recent pregnancy or breast feeding may have confounded the outcomes of this study.

15. Planned to relocate outside of the greater Pittsburgh area within 3 months.

    a. Rationale: Individuals planning on relocating may have not completed the study, which would have increased attrition.

3.2 RECRUITMENT

Subjects were recruited through local flier mailings and television advertisements. Additionally, letters were mailed to individuals meeting eligibility requirements registered in the Obesity and Nutrition Research Center database. All recruitment materials were approved by the University of Pittsburgh Institutional Review Board (IRB).

Potential participants were instructed to contact the Physical Activity and Weight Management Research Center by telephone where trained staff and graduate students conducted telephone screenings to determine eligibility. A description of the study and telephone screening procedures were first provided to the potential participant. Upon receiving verbal consent, the individual answered a series of questions to determine initial eligibility, which included questions regarding demographics (age, BMI, etc.), physical health, and medical history (Appendix A).

Individuals that appeared eligible based on the telephone screening were invited to attend an orientation session in which participants learned about the details of the study from the Principal Investigator (PI), and had the opportunity to ask questions about any components of the study and to have these questions answered to their satisfaction. After attendance at an orientation session, those interested in participating in the study were asked to read and sign the informed consent document that was approved by the University of Pittsburgh IRB. After providing written informed consent, participants completed a Physical Activity Readiness Questionnaire (PAR-Q)[97] and medical history, and provided medical clearance from their primary care physician prior to being eligible to undergo additional baseline assessments. The baseline assessments included measures of height, body weight, Body Mass Index (BMI), regional adiposity by anthropometry, blood pressure, heart rate, bioelectrical impedance analysis (BIA) for percent body fat, physical activity, and dietary intake and behaviors.

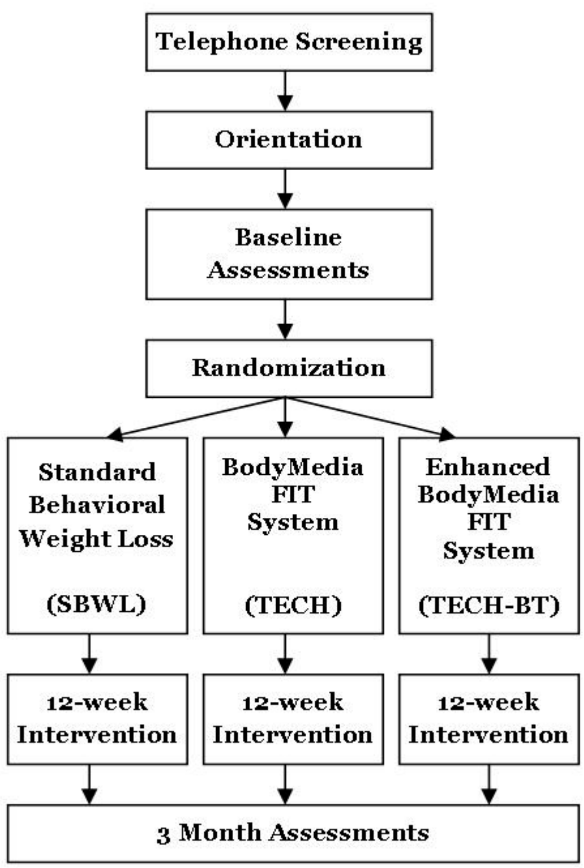


Figure 3. Study progression

3.3 EXPERIMENTAL DESIGN AND STUDY TIMELINE

This study used a randomized pretest and post-test design. Eligible participants were randomized to one of three intervention groups: Standard Behavioral Weight Loss (SBWL), BodyMedia® FIT System combined with a monthly intervention telephone call (TECH), or Enhanced BodyMedia® FIT System combined with a monthly intervention telephone call (TECH-BT). Outcome assessments were performed at baseline (0 months) and following a 3-month intervention. Figure 3 illustrates the study progression with the timeline illustrated in Figure 4. The interventions and assessments are described in detail below. All study procedures were approved by the University of Pittsburgh IRB prior to implementation.

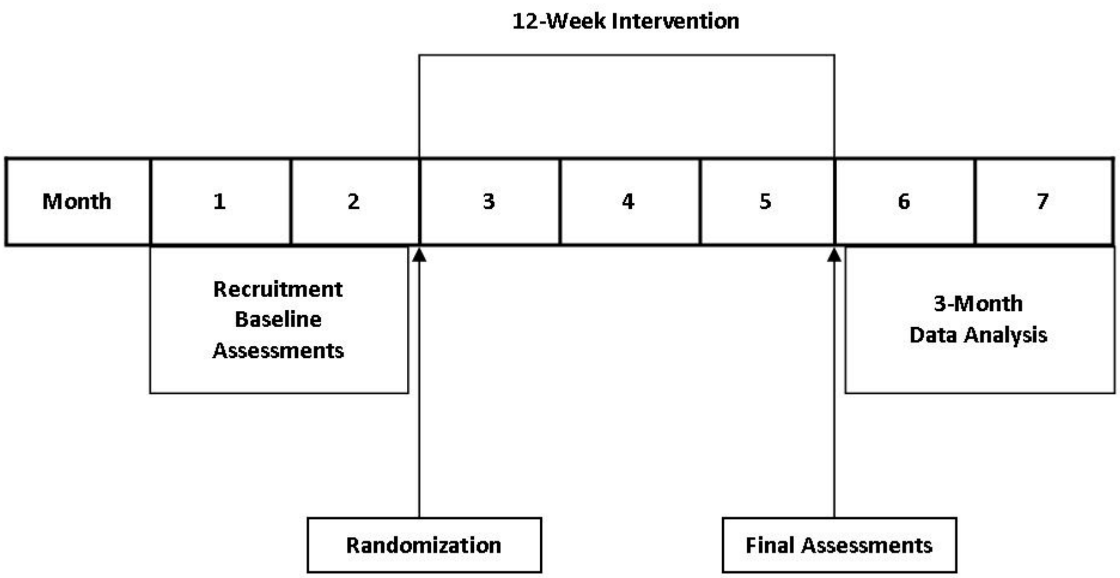


Figure 4. Study timeline

3.4 DESCRIPTION OF INTERVENTIONS

3.4.1 Interventions Components Common to All Randomized Groups

3.4.1.1 Dietary Component

Dietary recommendations were based on the subjects' baseline body, with calorie and fat intake goals shown in Table 1. The calorie goals were based on intake recommendations that have been shown to result in successful short-term weight loss [35,62,64-65,], with fat intake goals consistent with the USDA Dietary Guidelines[98].

Table 1. Calorie and fat intake goals based upon body weight

Body Weight (lbs)	Caloric Intake Goal (kcal)	Fat Intake Goal (grams)
<175	1200	27-40
175-219	1500	33-50
220-249	1800	40-60
≥250	2100	47-70

To facilitate adoption and maintenance of these dietary intake goals, participants were provided with meal plans and sample recipes. In addition, participants were taught how to read food labels and were provided with The Calorie King Calorie, Fat, and Carbohydrate Counter[99] to facilitate self-monitoring of calorie and fat intake. Participants were instructed to self-monitor techniques described below that were specific to each of the randomized intervention groups. Printed intervention lessons also included information related to behavior strategies for achieving the desired calorie and fat intake goals.

3.4.1.2 Physical Activity Component

The physical activity component included unsupervised home-based exercise, and was recommended at a moderate intensity defined as 3-6 metabolic equivalents (METS), which is similar to brisk walking. To facilitate adoption of this intensity of physical activity, participants were provided both a target heart rate (60-70% of age-predicted maximal heart rate) and rating of perceived exertion (11-13 on the 15-category Borg Scale)[100]. Duration was initially be prescribed at 100 minutes per week and progressed to 200 minutes per week by 9th week of the intervention, which was consistent with the recommendation of the American College of Sports Medicine (ACSM) [23]. The weekly exercise progression is shown in Table 2. Participants were encouraged to complete the prescribed doses of physical activity each week, with daily goals achieved by performing the activity in one continuous bout or accumulated across several shorts bouts that are each at least 10 minutes in duration[64]. Printed intervention lessons included information related to behavior strategies for achieving the desired activity goals for this study.

Table 2. Prescribed physical activity progression

Week	Minutes/Week	Minutes/Day	Days/Week	Intensity (RPE)
1-4	100	20	5	11-13
5-8	150	30	5	11-13
9-12	200	40	5	11-13

3.4.2 Intervention Components Specific to the Standard Behavioral Weight Loss Group (SBWL)

The standard behavioral weight loss (SBWL) intervention took place across 3-months in which participants attended weekly group meetings. Group sessions ran approximately 30-45 minutes in length. The intervention strategies were modeled after constructs included in the Social Cognitive Theory[33], Problem Solving Theory [101], and Relapse Prevention[102]. The primary focus of these sessions addressed barriers associated with altering physical activity participation and dietary intake. Intervention staff conducting the group sessions had experience in weight counseling with backgrounds in exercise physiology, nutrition, and/or behavioral sciences. Staff was trained in administering the sessions prior to the start of the intervention. Group discussions were facilitated by the interventionist and interactive participation was encouraged. Participants were provided with written materials at each meeting to supplement group discussions. Assessment of body weight occurred on an individual basis before or after the weekly meeting, and self-monitoring of body weight was emphasized during group sessions. In the event that a participant missed a group meeting, an interventionist engaged the participant by telephone initially with the goal of scheduling an in-person make-up session.

Diaries were provided each week to assist participants with self-monitoring of calorie and fat consumption. The diaries also contained sections for recording daily physical activity minutes and intensity (RPE). On days when a participant was not physically active, space within the diary allowed the participant to indicate a reason (i.e., lack of time, inconvenient, lack of motivation, needed rest). Participants returned the diary to the intervention staff each week for review. Constructive feedback was provided in regards to healthier food choices, portion control, calorie and fat goals, physical activity and other considerations pertinent to the content presented at the previous group meeting.

3.4.3 BodyMedia® FIT System Combined with a Monthly Intervention Telephone Call (TECH)

Participants in TECH did not attend the weekly group sessions. However, the identical intervention materials provided to SBWL were also provided, with these materials mailed weekly to the participants. Participants in this group were provided with the BodyMedia® FIT System (BodyMedia®, Pittsburgh, PA). The BodyMedia® FIT System included a wearable device that monitored physical activity and energy expenditure, a display device that provided feedback on achievement of energy expenditure and physical activity goals, and a web-based software program that assisted with self-monitoring of dietary intake and to provide feedback on goal achievement. This technology required that energy expenditure data from the armband monitor be downloaded via USB connection to a computer in order to view information regarding calories expended, and time and intensity of physical activities.

Participants attended one introductory session in which a tutorial of the components of the FIT System that was provided. In addition, this group initially received a one-hour lesson on basic guidelines of the weight loss intervention. At this time, caloric goals and weekly physical activity recommendations were explained. To support weight loss behaviors, participants were encouraged to use the BodyMedia® FIT System to self-monitor dietary intake, physical activity, and body weight.

Participants in the TECH group also received a scheduled intervention telephone call one-time per month (weeks 3, 7, 11). This telephone call took approximately 10 minutes and was completed by a member of the intervention staff that was experienced using the BodyMedia® FIT System and trained in delivering telephone interventions. Strategies to overcome weight-loss barriers were primarily discussed, and a standardized script served as a guide to address technical difficulties using the FIT System, frequency of system usage, participant goals, barriers to diet and physical activity, and self-monitoring of body weight (Appendix B). Interventionists had access to the information uploaded to the web-interface, and this allowed the interventionist to review this information prior to facilitate interactions with participants during the monthly telephone calls. The length of each telephone intervention was recorded.

3.4.4 Enhanced BodyMedia® FIT System Combined with a Monthly Intervention Telephone Call (TECH-BT)

Participants in TECH-BT did not attend the weekly group sessions. However, the identical intervention materials provided to SBWL and TECH were also provided, with these materials mailed weekly to the participants. Participants in this group were provided with the enhanced BodyMedia® FIT System (BodyMedia®, Pittsburgh, PA). In contrast to the previous version of the system being used by TECH, enhancements to the BodyMedia® FIT System included Bluetooth® technology which allowed participants to receive real-time feedback without having to use a personal computer or USB cable to upload physical activity data. Participants received the enhanced armband technology with Bluetooth® capabilities that transmitted real-time feedback on calories expended and physical activity time and intensity directly to a smart phone application (app) containing the web-interface. In addition, the smart phone app supported self-monitoring of dietary behaviors to provide real-time feedback of goal achievement. The enhancements to the FIT system allowed for self-monitoring of physical activity and dietary intake to occur in real-time and in one convenient location.

The remaining procedures follow that of TECH. Participants attended one introductory session in which a tutorial of the components of the FIT System were provided. In addition, this group initially received a one-hour lesson on basic guidelines of the weight loss intervention. At this time, caloric goals and weekly physical activity recommendations were explained. To support weight loss behaviors, participants were encouraged to use the enhanced BodyMedia® FIT System to self-monitor dietary intake and physical activity.

Participants in the TECH-BT group received a scheduled intervention telephone call one-time per month (weeks 3, 7, 11). This telephone call took approximately 10 minutes and was completed by a member of the intervention staff that was experienced using the enhanced BodyMedia® FIT System and was trained in delivering telephone interventions. Strategies to overcome weight-loss barriers were primarily discussed, and a standardized script served as a guide to address technical difficulties using the FIT System, frequency of system usage, participant goals, barriers to diet and physical activity, and self-monitoring of body weight (Appendix B). Interventionists had access to the information transmitted to the web-interface, and this allowed the interventionist to review this information prior to facilitate interactions with participants during the monthly telephone calls. The length of each telephone intervention was recorded.

3.5 ASSESSMENT PROCEDURES

Assessment measures occurred at 0 and 3 months at the University of Pittsburgh, Physical Activity and Weight Management Research Center, Monday through Friday between the hours of 7:30am and 12:30pm. Assessments took approximately 45 minutes to complete. Assessments for this study included measures of height, body weight, body mass index (BMI), regional adiposity by anthropometry, body composition, blood pressure, heart rate, physical activity and dietary intake and behaviors.

3.5.1 Height, Body Weight and BMI

Prior to height and weight measurements, participants changed into a lightweight hospital gown and removed footwear. Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer (Perspective Enterprises; Portage, MI). Body weight was measured to the nearest 0.1 kg on a Tanita WB-110A digital scale (Tanita Corporation; Arlington Heights, IL). Duplicate measurements were taken and a third was completed if the initial two measurements differ by > 0.5 cm and > 0.2 kg for height and weight respectively. BMI was calculated as the body weight in kilograms divided by the height squared in meters (kg/m^2). At baseline, BMI was used to determine eligibility and baseline heights were carried forward for calculation of BMI at the 3-month assessment point.

3.5.2 Regional Adiposity by Anthropometry

Anthropometric measurements were taken in a lightweight hospital gown and measured to the nearest 0.1 cm using a Gulick tape measure. Duplicate measurements were taken at each site and a third was completed if the initial two measurements differ by > 1.0 cm. Waist circumference were taken at the level of the iliac crest. Measurements were taken while standing in front of the participant and a horizontal circumference was taken at the peak of the iliac crest as palpated from the mid-axillary line. Hip circumferences were taken from the side while making a horizontal circumference at the maximal protrusion of the gluteal muscles.

3.5.3 Blood Pressure and Heart Rate

Prior to assessment of resting blood pressure and heart rate, a circumference measure at the midpoint of the distance between the acromion and olecranon processes of the left arm was taken to determine the appropriate size of the blood pressure cuff. Resting blood pressure and heart rate measurements were obtained using the DINAMAP V100 automated blood pressure cuff (GE Medical System Technologies; Milwaukee, WI) following a 5-minute seated rest period. Two measures of blood pressure and heart rate were obtained with a one-minute rest period between measures. A third blood pressure was taken if the systolic blood pressure is ≥ 10 mmHg or if the diastolic blood pressure is ≥ 6 mmHg.

3.5.4 Body Composition

Body composition was assesses using bioelectrical impedance analysis (BIA). Measurements were taken in a lightweight hospital gown following the removal of all jewelry from the right side of the body. Electrodes were placed in four locations: (1) midpoint of styloid processes at the right wrist; (2) joint between the knuckles of the index and middle fingers of the right hand; (3) midpoint of the lateral and medial malleoli of the right ankle; and (4) joint at the base of the great and second toes on the right foot. The participant was asked to lay in a supine position. Electrical impedance of body tissues was determined by obtaining measurements of resistance and reactance. Lean body mass (LBM) was estimated from BIA using the equation proposed by Segel et al[103], and this equation also incorporated measure of height, weight, age, and gender. Percent body fat was computed as [(weight –LBM)/weight] x 100.

3.5.5 Physical Activity

The Global Physical Activity Questionnaire (GPAQ)[104-105] was used to assess leisure and recreational physical activity at all assessment time points. In addition, sedentary time was assessed at the all assessment periods. The questionnaire was completed in a non-interview format during each assessment period. Results are reported as hours per week of total physical activity.

3.5.6 Dietary Intake and Eating Behaviors

Dietary intake was assessed using the Block Food Frequency Questionnaire (FFQ) (Block, 2005.1). This questionnaire has been validated[106-107] in estimating daily caloric intake. Data are represented as daily caloric intake and percent of calories consumed from dietary fat.

The Eating Behavior Inventory (EBI) is a 26-point checklist that was used to measure eating behaviors[108].This questionnaire assesses behaviors that may be related to successful weight loss such as self-monitoring of intake, refusing food, shopping practices, and emotional eating. The items on the questionnaire were rated on 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 body weight related food behaviors[109].

3.6 DEFINING SELF-MONITORING DATA FOR STATISTICAL ANALYSIS

As defined in the specific aims, self-monitoring was compared in the 3 intervention groups (SBWL, TECH, and TECH-BT). Below, defined *a priori* criteria for self-monitoring of dietary intake, physical activity, and body weight was provided for data analysis.

3.6.1 SBWL

1. <u>Dietary Intake:</u> Dietary intake was self-monitored in a paper diary. Total frequency of self-monitoring days, average days per week, and self-reported caloric intake across the 12-week intervention was measured.

2. Physical Activity: Physical activity will be self-monitored in a paper diary. Included in these measures were the total days, days per week, and minutes per week when physical activity behaviors were recorded.
3. Body Weight: Body weight was self-monitored in a paper diary. Total frequency of self-weighing days and the average number of days per week that body weight is self-monitored across the 12-week intervention will be measured.

3.6.2 TECH and TECH-BT

1. Dietary Intake: Dietary intake was self-monitored using the web-based software program. Total frequency of self-monitoring days, average days per week, and self-reported caloric intake across the 12-week intervention was measured.
2. Physical Activity: Physical activity was self-monitored based on armband wear-time as measured by the number of total days, days per week, total hours, hours per day, and percent time on-body.
3. Body Weight: Body weight was self-monitored using the web-based software program. Total frequency of self-weighing days and the average number of days per week that body weight is self-monitored was measured.

3.7 STATISTICAL ANALYSES

Statistical analyses were completed using the Statistical Package for the Social Sciences (IBM-SPSS, version 20.0). Statistical significance was defined at $p < 0.05$. For missing data at the 3 month assessment, baseline data were carried forward to allow for intention-to-treat analyses. The following outlines the analyses conducted for each of the proposed outcome variables.

3.7.1 Descriptive Analyses

1. Descriptive analyses were conducted to examine mean baseline characteristics such as age, body weight, BMI and adiposity along with measures of physical activity, and dietary intake.
2. Descriptive analyses were conducted to examine process measures such as: intervention contact, dietary and physical activity self-monitoring, frequency of self-weighing, and armband time-on-body.

3.7.2 Data Analyses

1. A 3 x 2 repeated measures (group by time) analysis of variance (ANOVA) was performed on body weight. A significant interaction effect (group by time) was further examined with *post-hoc* comparisons using Bonferroni adjustment to explore for the TECH-BT versus SBWL and TECH-BT versus TECH. An exploratory comparison of SBWL vs. TECH was also performed if a significant interaction effect (group by time) was observed in the ANOVA.
2. A 3 x 2 repeated measures (group by time) analysis of variance (ANOVA) was performed for body composition. A significant interaction effect (group by time) was further examined with *post-hoc* comparisons using Bonferroni adjustment to explore for the TECH-BT versus SBWL and TECH-BT versus TECH. An exploratory comparison of SBWL vs. TECH was also performed if a significant interaction effect (group by time) was observed in the ANOVA.

3. A 3 x 2 repeated measures (group by time) analysis of variance (ANOVA) was performed for physical activity assessed by questionnaire. A significant interaction effect (group by time) was further examined with *post-hoc* comparisons using Bonferroni adjustment to explore for the TECH-BT versus SBWL and TECH-BT versus TECH. An exploratory comparison of SBWL vs. TECH was also performed if a significant interaction effect (group by time) was observed in the ANOVA.
4. A 3 x 2 repeated measures (group by time) analysis of variance (ANOVA) was performed for dietary intake. A significant interaction effect (group by time) was further examined with *post-hoc* comparisons using Bonferroni adjustment to explore for the TECH-BT versus SBWL and TECH-BT versus TECH. An exploratory comparison of SBWL vs. TECH was also performed if a significant interaction effect (group by time) was observed in the ANOVA.
5. Descriptive statistics were performed for self-monitoring data (dietary intake, physical activity, and body weight) in SBWL, and independent samples t-tests were performed on self-monitoring data (dietary intake, physical activity, and body weight) in TECH and TECH-BT. Separate one-way ANOVAs were performed for self-monitoring data (self-report dietary intake) between SBWL, TECH, and TECH-BT. *Post-hoc* comparisons using Bonferroni adjustment was conducted to compare TECH-BT versus SBWL and TECH-BT versus TECH. An exploratory comparison of SBWL vs. TECH was also performed for self-reported dietary intake.

3.8 POWER ANALYSIS

The primary aim of this study was to examine if TECH-BT had greater change in body weight compared to both SBWL and TECH. Based on other studies that have been 12 weeks in duration conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh, it was estimated that the standard deviation for weight loss in each of the intervention conditions was 3.0 kg. It was proposed that a clinically meaningful difference in weight loss between TECH-BT and either SBWL or TECH would be 2.5 kg. The type I error rate was 0.05; however this was adjusted to 0.025 to allow for the two primary comparisons (TECH-BT vs. SBWL) and (TECH-BT vs. TECH). Based on these assumptions, a sample size of 25 subjects per group would allow for 75% power to detect the proposed differences in weight loss between the intervention conditions. To allow for the potential of 10% attrition, 84 subjects were suggested for recruitment. However, as described in detail in Chapter 4, 54 individuals consented to participant in this study, with 39 completing baseline assessments and being eligible for randomization to one of the three treatment groups (SBWL, TECH, TECH-BT).

4.0 RESULTS

The purpose of this study was to examine the effectiveness of a technology –based, enhanced technology-based and standard behavioral weight loss intervention in Class II and III obese adults. This was a pretest-posttest randomized controlled weight loss trial with assessments conducted at 0 and 3 months of participation. The results of this study are presented below.

4.1 SUBJECT CHARACTERISTICS

Thirty-nine subjects between the ages of 21 to 55 years with a body mass index (BMI) ranging from 35.3 to 44.6 kg/m^2 participated in this investigation at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. Subjects had a mean BMI of 39.5 ± 2.8 kg/m^2 at baseline and were predominantly female (79.5%). One-way analysis of variance (ANOVA) determined no significant differences between treatment groups for baseline age, body weight, BMI, systolic blood pressure (SBP), diastolic blood pressure (DBP), waist circumferences at both the umbilicus and iliac crest sites, hip circumference, percent body fat, self-reported moderate-to-vigorous physical activity (MVPA), and sedentary time. (Table 3) Significant differences were revealed for baseline resting heart rate (RHR) (p=.036) between treatment groups. Bonferroni *post hoc* analysis indicated a significantly higher baseline RHR in TECH compared to SBWL (p=.038).

Table 3. Differences in Baseline Characteristics by Treatment Group

Characteristics	Total (N=39) (mean±SD)	SBWL (N=14) (mean±SD)	TECH (N=12) (mean±SD)	TECH-BT (N=13) (mean±SD)	*p*-value
Age (years)	39.0 ± 9.7	39.7 ± 10.4	40.6 ± 9.5	39.5 ± 9.7	.957
Weight (kg)	111.5 ± 11.5	110.9 ± 9.1	112.2 ± 10.5	111.6 ± 15.0	.959
Body Mass Index (kg/m^2)	39.5 ± 2.8	39.5 ± 2.6	39.7 ± 2.9	39.3 ± 3.2	.950
Systolic Blood Pressure (mmHg)	121.4 ± 9.7	119.5 ± 6.6	124.0 ± 13.2	121.0 ± 9.1	.495
Diastolic Blood Pressure (mmHg)	73.0 ± 7.7	73.1 ± 8.1	74.6 ± 8.7	71.4 ± 6.5	.606
Resting Heart Rate (beats/min)	70.9 ± 9.4	66.0 ± 7.9[a]	75.2 ± 9.5[a]	72.2 ± 9.2	.036
Waist Circumference Umbilicus (cm)	126.8 ± 8.5	125.9 ± 7.1	128.4 ± 7.3	126.3 ± 11.1	.744
Waist Circumference Iliac Crest (cm)	121.3 ± 9.0	119.1 ± 6.5	122.8 ± 8.7	122.3 ± 11.6	.532
Hip Circumference (cm)	132.0 ± 7.8	132.9 ± 8.1	131.8 ± 7.0	131.3 ± 8.7	.868
Body Composition (% body fat)	45.8 ± 4.0	46.2 ± 4.5	45.9 ± 4.6	45.4 ± 2.9	.881
Self-Reported Moderate-to-Vigorous Physical Activity (hours/wk)	1.7 ± 2.7	1.9 ± 4.0	1.3 ± 1.5	1.8 ± 2.1	.845
Self-Reported Sedentary Time (hours/day)	8.7 ± 4.0	10.1 ± 3.1	7.5 ± 4.8	8.4 ± 3.9	.230

Superscript indicates significant between group differences at $p<0.05$.

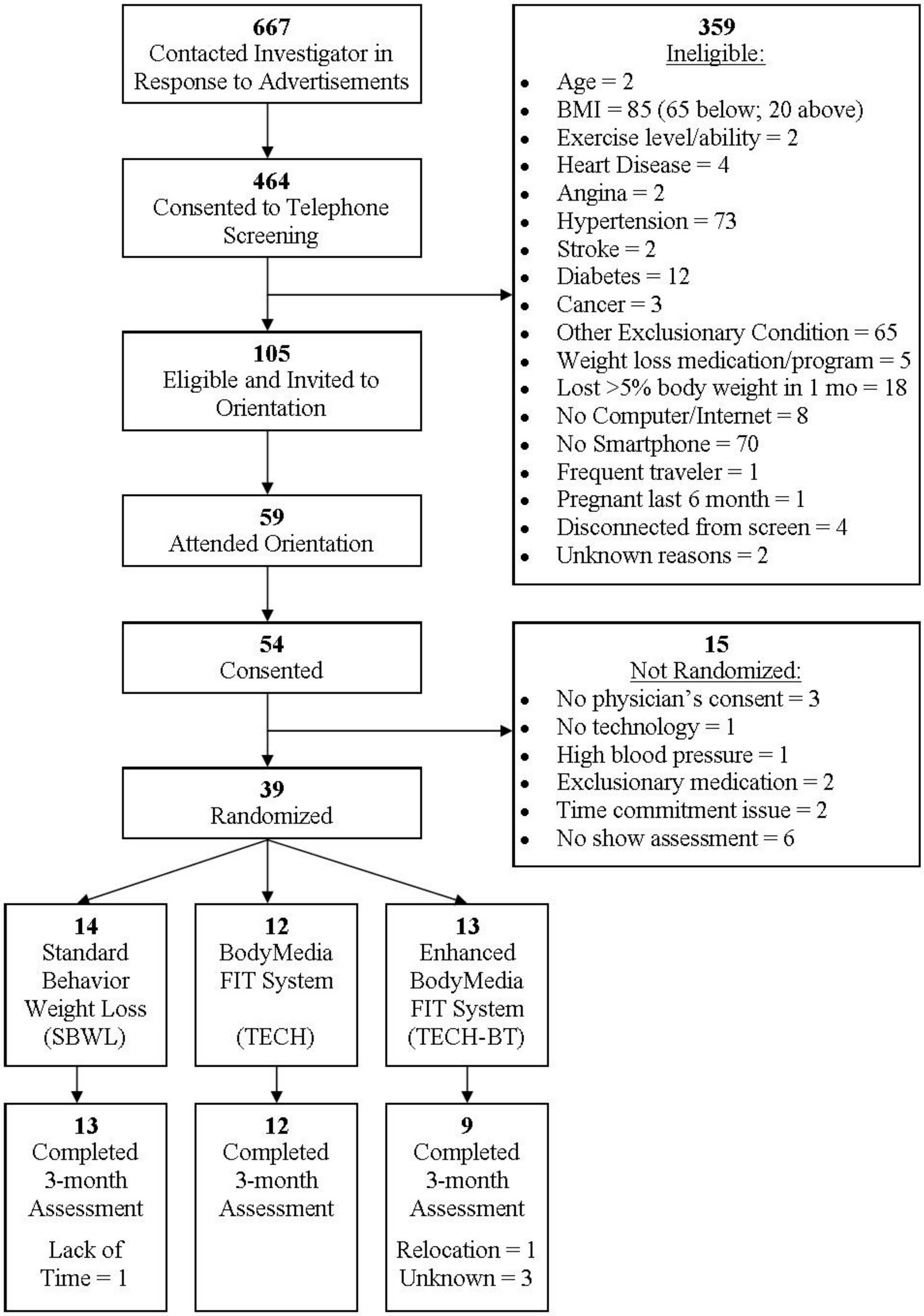


Figure 5. Study recruitment, randomization and retention

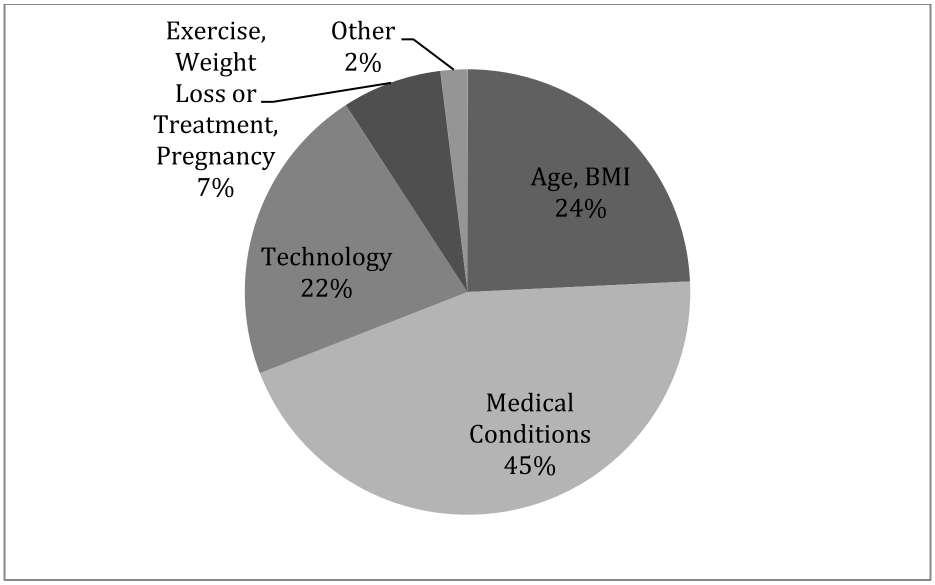


Figure 6. Reasons for ineligibility based on telephone screening

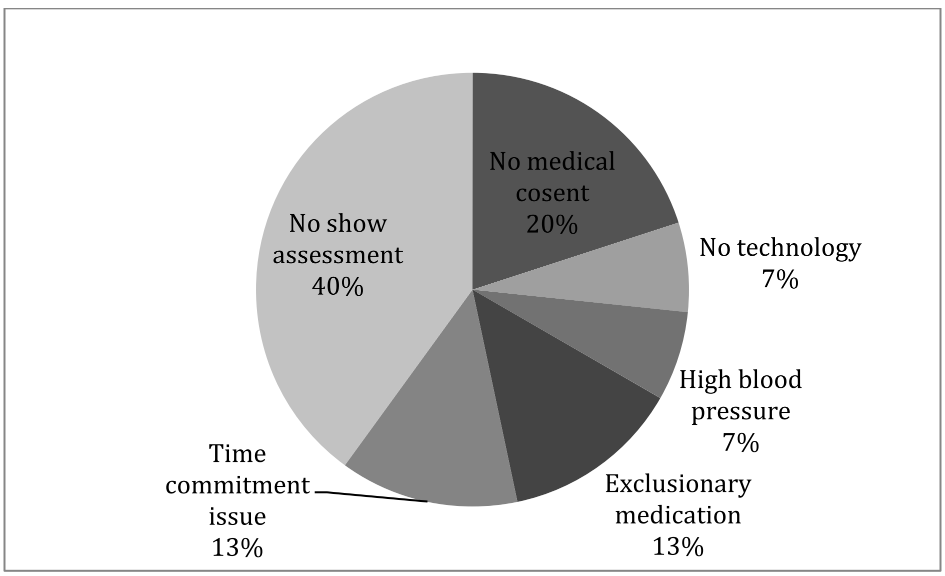


Figure 7. Reasons consented participants were not randomized

Figure 5 illustrates subject recruitment, randomization and retention. Six-hundred sixty-seven participants were initially called for a telephone screening and 464 (69.6%) participants consented to be screened after receiving information about the study. Of those screened, 105 (22.6%) were eligible to participate and 359 (77.4%) were not. Fifty-nine participants attended an orientation and 54 consented to be a part of the study. Following completion of baseline assessments, 39 subjects were randomized to one of the three treatment groups (SBWL, TECH, TECH-BT). Reasons for ineligibility are shown in Figures 5 and 6, and reasons for not being randomized after providing informed consent are shown in Figure 7.

A total of 34 participants (87.2%) completed baseline and 3-month assessments and will be referred to as completers. Participants who did not complete the 3-month assessment (N=5, 12.8%) will be referred to as non-completers. Comparison of retention rates between groups using Pearson Chi-Square resulted in $\chi^2 = 5.9$ ($p = 0.052$). Baseline characteristics between completers and non-completers are presented in Table 4. Independent samples t-tests showed no significant differences between completers and non-completers in any of the baseline characteristics.

4.2 CHANGE IN BODY WEIGHT AND BMI

A 3 x 2 repeated measures (group by time) ANOVA was performed to examine change in body weight and BMI from baseline to 3 months between the treatment groups. Results of the completers analysis indicated a significant weight loss from baseline to 3 months in SBWL (-3.4 ± 3.1 kg), TECH (-5.0 ± 3.7 kg), and TECH-BT (-4.8 ± 4.3 kg) (p<.001); however, there were no significant differences between the groups (p=.812) or group X time interaction (p=.499). (Table 5). Percent weight loss was -4.3 ± 3.8% with no differences between treatment groups (SBWL: -3.2 ± 2.8%; TECH: -4.9 ± 3.8%; TECH-BT: -5.0 ± 5.1%) (Figure 8). Body mass index also significantly decreased from baseline to 3 months (p<.001); however, there were also no significant differences between treatment groups (p=.963) or group X time interaction (p=.466).

Intent-to-treat analysis was conducted using all randomized participants with baseline data carried forward when 3-month data were missing. A 3 x 2 repeated measures (group by time) ANOVA was performed to examine body weight and BMI changes from baseline to 3 months between the treatment groups. Results of the intent-to-treat analysis indicated a significant time effect for weight loss from baseline to 3 months in SBWL (-3.2 ± 3.1 kg) TECH (-5.0 ± 3.7 kg), and TECH-BT (-3.3 ± 4.2 kg) (p<.001); however, there were no significant differences between the groups (p=.990) or group X time interaction (p=.387) (Table 6). Percent weight loss was -3.7 ± 3.9% with no differences between treatment groups (SBWL: -2.9 ± 2.9%; TECH: -4.9 ± 3.8%; TECH-BT: -3.5 ± 4.8%) (Figure 8). Body mass index also significantly decreased from baseline to 3 months (p<.001); however, there were no significant differences between treatment groups (p=.981) or group X time interaction (p=.417).

Table 4. Differences in baseline characteristics by completers and non-completers

Characteristics	Total (N=39) (mean ± SD)	Completers (N=34) (mean ± SD)	Non-Completers (N=5) (mean ± SD)	*p*-value
Age (years)	39.0 ± 9.7	40.5 ± 9.1	35.8 ± 13.5	.316
Weight (kg)	111.5 ± 11.5	110.7 ± 11.2	117.6 ± 12.9	.211
Body Mass Index (kg/m^2)	39.5 ± 2.8	39.5 ± 2.8	39.7 ± 2.7	.863
Systolic Blood Pressure (mmHg)	121. ± 9.7	122.0 ± 9.8	117.3 ± 9.1	.322
Diastolic Blood Pressure (mmHg)	73.0 ± 7.7	73.3 ± 8.1	70.7 ± 4.1	.483
Resting Heart Rate (beats/min)	70.9 ± 9.4	71.0 ± 9.9	70.2 ± 5.3	.862
Waist Circumference Umbilicus (cm)	126.8 ± 8.5	126.9 ± 8.6	125.7 ± 9.3	.764
Waist Circumference Iliac Crest (cm)	121.3 ± 9.0	121.1 ± 8.9	122.8 ± 10.7	.697
Hip Circumference (cm)	132.0 ± 7.8	131.6 ± 8.2	135.2 ± 3.1	.347
Body Composition (% body fat)	45.8 ± 4.0	45.9 ± 4.1	45.3 ± 3.2	.751
Self-Reported Moderate-to-Vigorous Physical Activity (hours/wk)	1.7 ± 2.7	1.7 ± 2.8	1.5 ± 2.6	.856
Self-Reported Sedentary Time (hours/day)	8.7 ± 4.0	9.2 ± 4.0	5.7 ± 2.5	.070

Table 5. Completers analyses for change in outcomes between treatment groups at 3 months (mean±SD)

Outcome Variable	SBWL (N=13)	TECH (N=12)	TECH-BT (N=9)	*p*-values Group Effect	Time Effect	Group X Time
Body Weight (kg)						
0 Months	110.5 ± 9.4	112.2 ± 10.5	108.8 ± 15.0			
3 Months	107.1 ± 8.8	107.2 ± 11.8	104.0 ± 16.2	.812	<.001	.499
Body Mass Index (kg/m^2)						
0 Months	39.4 ± 2.6	39.7 ± 2.9	39.4 ± 3.4			
3 Months	38.2 ± 2.7	37.9 ± 3.5	37.6 ± 3.9	.963	<.001	.466
Systolic Blood Pressure (mmHg)						
0 Months	120.1 ± 6.4	124.0 ± 13.2	121.9 ± 9.2			
3 Months	119.6 ± 9.6	119.7 ± 8.7	117.4 ± 6.9	.796	.016	.305
Diastolic Blood Pressure (mmHg)						
0 Months	73.3 ± 8.4	74.6 ± 8.7	71.7 ± 7.4			
3 Months	67.8 ± 8.1	71.6 ± 7.7	68.9 ± 5.8	.609	.001	.432
Resting Heart Rate (beats/min)						
0 Months	65.7 ± 8.1	75.2 ± 9.5	73.1 ±10.5			
3 Months	62.5 ± 6.6	71.5 ± 9.0	67.2 ± 12.0	.024*	.009	.772
Waist Circumference: Umbilicus (cm)						
0 Months	126.4 ± 7.2	128.4 ± 7.3	125.9 ± 12.1			
3 Months	122.0 ± 9.4	121.6 ± 9.8	117.0 14.7	.692	<.001	.100
Waist Circumference: Iliac Crest (cm)						
0 Months	119.7 ± 6.4	122.8 ± 8.7	120.8 ± 12.5			
3 Months	116.0 ± 7.3	116.4 ± 9.6	115.4 ± 12.7	.875	<.001	.594
Hip Circumference (cm)						
0 Months	132.3 ± 8.1	131.8 ± 7.0	130.2 ± 10.4			
3 Months	128.7 ± 6.2	126.5 ± 8.2	124.9 ± 10.7	.708	<.001	.366
Percent Body Fat (%)						
0 Months	46.2 ± 4.7	45.9 ± 4.6	45.7 ± 2.8			
3 Months	45.1 ± 5.5	44.7 ± 5.8	43.9 ± 3.7	.925	<.001	.690
Self-Reported Moderate-to-Vigorous Physical Activity (hours/week)						
0 Months	2.0 ± 4.1	1.3 ± 1.5	1.8 ± 1.8			
3 Months	3.2 ± 3.3	1.8 ± 1.9	3.7 ± 3.0	.433	.020	.533
Self-Reported Sedentary Time (hours/day)						
0 Months	10.3 ± 3.1	7.5 ± 4.8	9.8 ± 3.6			
3 Months	8.5 ± 2.7	6.4 ± 4.0	7.3 ± 2.9	.147	.010	.683
Dietary Intake (kcal/day)						
0 Months	1639.6±545.3	2076.8±783.3	1942.5±676.5			
3 Months	1365.3±526.1	1804.1±882.9	1739.4±482.8	.162	.037	.963
Dietary Intake (% kcal from fat)						
0 Months	38.7 ± 4.7	39.8 ± 7.1	36.0 ± 6.9			
3 Months	37.1 ± 4.3	37.2 ± 5.0	32.8 ± 9.1	.223	.016	.806
Eating Behavior Inventory						
0 Months	71.5 ± 7.8	65.8 ± 6.2	65.6 ± 5.4			
3 Months	86.0 ± 9.8	80.5 ± 14.5	80.9 ± 12.3	.158	<.001	.985

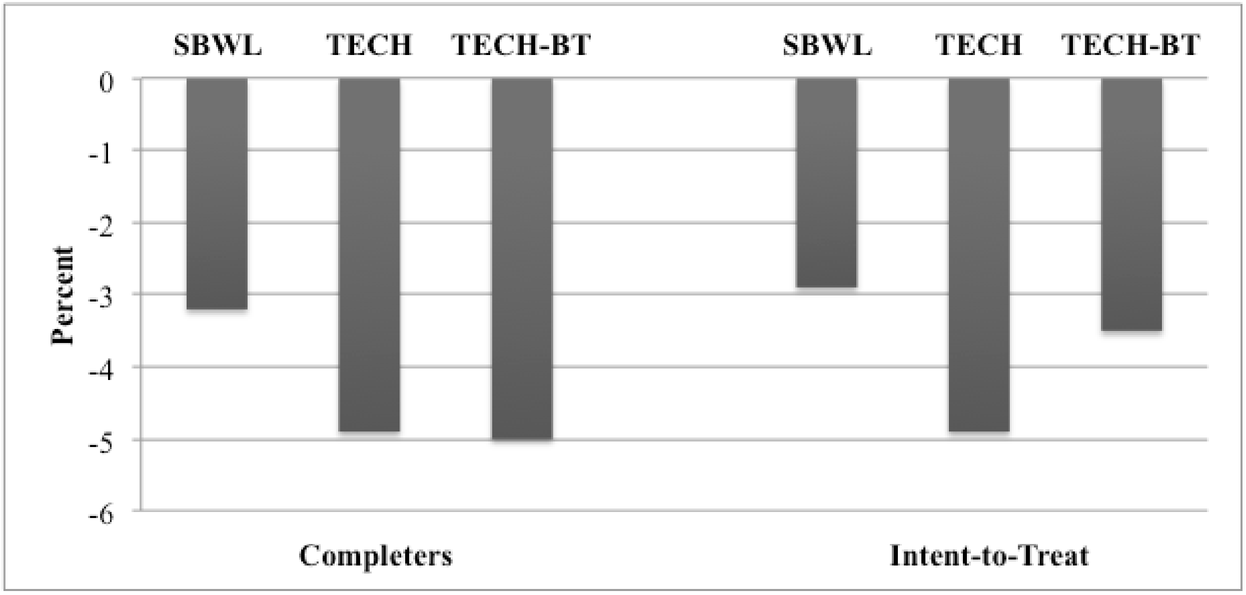
*SBWL < TECH

Table 6. Intent-to-treat analyses for change in outcomes between treatment groups at 3 months (mean±SD)

Outcome Variable	SBWL (N=14)	TECH (N=12)	TECH-BT (N=13)	*p*-values Group Effect	Time Effect	Group X Time
Body Weight (kg)						
0 Months	110.9 ± 9.1	112.2 ± 10.5	111.6 ± 15.0			
3 Months	107.7 ± 8.8	107.2 ± 11.8	108.3 ± 16.6	.990	<.001	.387
Body Mass Index (kg/m²)						
0 Months	39.5 ± 2.6	39.7 ± 2.9	39.3 ± 3.2			
3 Months	38.4 ± 2.7	37.9 ± 3.5	38.1 ± 3.6	.981	<.001	.417
Systolic Blood Pressure (mmHg)						
0 Months	119.5 ± 6.6	124.0 ± 13.2	121.0 ± 9.1			
3 Months	119.0 ± 9.5	119.7 ± 8.7	117.8 ± 7.5	.695	.019	.326
Diastolic Blood Pressure (mmHg)						
0 Months	73.1 ± 8.1	74.6 ± 8.7	71.4 ± 6.5			
3 Months	72.7 ± 8.7	73.8 ± 8.7	71.3 ± 6.4	.670	.031	.462
Resting Heart Rate (beats/min)						
0 Months	66.0 ± 7.9	75.2 ± 9.5	72.2 ± 9.2			
3 Months	63.0 ± 6.6	71.5 ± 9.0	68.1 ± 10.4	.020*	.012	.945
Waist Circumference: Umbilicus (cm)						
0 Months	125.9 ± 7.1	128.4 ± 7.3	126.3 ± 11.1			
3 Months	121.9 ± 9.0	121.6 ± 9.8	120.1 ± 13.9	.895	<.001	.362
Waist Circumference: Iliac Crest (cm)						
0 Months	119.1 ± 6.5	122.8 ± 8.7	122.3 ± 11.6			
3 Months	115.7 ± 7.1	116.4 ± 9.6	118.6 ± 12.5	.663	<.001	.448
Hip Circumference (cm)						
0 Months	132.9 ± 8.1	131.8 ± 7.0	131.3 ± 8.7			
3 Months	129.6 ± 6.8	126.5 ± 8.2	127.6 ± 9.7	.773	<.001	.332
Percent Body Fat (% fat)						
0 Months	46.2 ± 4.6	45.9 ± 4.6	45.4 ± 2.9			
3 Months	45.2 ± 5.3	44.7 ± 5.8	44.2 ± 3.5	.874	<.001	.958
Self-Reported Moderate-to-Vigorous Physical Activity (hours/week)						
0 Months	1.9 ± 4.0	1.3 ± 1.5	1.8 ± 2.1			
3 Months	3.0 ± 3.2	2.4 ± 1.8	3.2 ± 2.9	.766	.005	.960
Self-Reported Sedentary Time (hours/day)						
0 Months	10.1 ± 3.1	7.5 ± 4.8	8.4 ± 3.9			
3 Months	8.5 ± 2.6	6.4 ± 4.0	6.7 ± 2.9	.141	.013	.880
Dietary Intake (kcal/day)						
0 Months	1897.4±1097.9	2067.8±783.3	2227.3±987.4			
3 Months	1642.8±1154.7	1804.1±882.9	2086.7±960.0	.572	.031	.841
Dietary Intake (% kcal from fat)						
0 Months	38.5 ± 4.6	39.8 ± 7.1	35.6 ± 6.0			
3 Months	37.0 ± 4.1	37.2 ± 5.0	33.4 ± 7.8	.136	.018	.872
Eating Behavior Inventory						
0 Months	71.7 ± 7.5	65.8 ± 6.2	64.8 ± 5.0			
3 Months	85.1 ± 10.0	80.5 ± 14.5	75.4 ± 13.3	.034**	<.001	.682

*SBWL < TECH

**TECH-BT < SBWL



Note: No statistical difference between groups in the completers and intent-to-treat analyses.

Figure 8. Percent weight loss at 3 months among treatment groups: completers and intent-to-treat

Chi-square analysis showed no differences between groups for those subjects achieving ≥5% weight loss (χ^2= 2.26, *p*=.323). The frequencies of those achieving ≥5% weight loss across 3 months are shown in Table 7.

Table 7. Frequencies by group for achieving ≥5% weight loss at 3 months

	Total (N=39)	SBWL (N=14)	TECH (N=12)	TECH-BT (N=13)
Frequency	13	4	6	3
Percent of Total	33.3%	28.5%	50.0%	23.1%

4.3 CHANGES IN SYSTOLIC AND DIASTOLIC BLOOD PRESSURE AND RESTING HEART RATE

A 3 x 2 repeated measures (group by time) ANOVA was performed to examine changes from baseline to 3 months in systolic blood pressure (SBP), diastolic blood pressure (DBP) and RHR between the treatment groups. Completers analyses results are found in Table 5. Results indicated a significant time effect in SBP from baseline to 3 months in SBWL (-0.5 ± 5.3 mmHg), TECH (-4.3 ± 9.0 mmHg), and TECH-BT (-4.6 ± 6.4 mmHg) (p=.016); however, there were no significant differences between the groups (p=.796) or group X time interaction (p=.305). Likewise, DBP significantly decreased from baseline to 3 months in SBWL (-5.5 ± 5.7 mmHg), TECH (-3.0 ± 6.0 mmHg), and TECH-BT (-2.8 ± 4.6 mmHg) (p=.001); however, there were no significant differences between the groups (p=.609) or group X time interaction (.432). RHR significantly decreased from baseline to 3 months in SBWL (3.2 ± 8.0 beats/min), TECH (3.7 ± 11.1 beats/min), and TECH-BT (5.9 ± 6.0 beats/min) (p=.009). There was a significant group effect for RHR (p=.024) with Bonferroni *post hoc* analysis demonstrating a lower RHR in SBWL compared to TECH (p=.022).

Intent-to-treat analysis indicated a significant time effect in SBP in SBWL (-.5 ± 5.1 mmHg), TECH (-4.3 ± 9.0 mmHg), and TECH-BT (-3.2 ± 5.7 mmHg)(p=.019), with no differences between groups (p=.695) or group X time interaction (.326). Likewise, there was a significant time effect for DBP in SBWL (-0.4 ± 1.0 mmHg), TECH (-0.8 ± 1.9 mmHg), and TECH-BT (-0.2 ± 0.6 mmHg) (p=.031), and no differences between groups (p=.670) or group X time interaction (.462). RHR significantly decreased from baseline to 3 months in SBWL (3.0 ± 7.7 beats/min), TECH (3.7 ± 11.1 beats/min), and TECH-BT (4.1 ± 5.7 beats/min) (p=.012). There was a significant group effect for RHR (p=.020) with Bonferroni *post hoc* analysis demonstrating a lower RHR in SBWL compared to TECH (*p*=.022). These results are shown in Table 6.

4.4 CHANGES IN ANTHROPOMETRIC MEASURES AND BODY COMPOSITION

A 3 x 2 repeated measures (group by time) ANOVA demonstrated significant reductions in waist circumferences at both the umbilicus (*p*<.001) and iliac crest (*p*<.001) sites at 3 months for completers in SBWL (umbilicus: -4.3 ± 3.8 cm, iliac: -3.7 ± 5.6 cm), TECH (umbilicus: -6.8 ± 4.7 cm, iliac: -6.4 ± 8.3 cm), and TECH-BT (umbilicus: -8.9 ± 5.9 cm, iliac: -5.4 ± 5.0 cm). No group differences were observed between groups for umbilicus (*p*=.692) and iliac (*p*=.875) sites or group X time interactions (umbilicus: *p*=.100, iliac: *p*=.594). Similarly, a significant time effect was found for reduction in hip circumference in SBWL (-3.6 ± 3.6 cm), TECH (-5.3 ± 2.8 cm) and TECH-BT (-5.3 ± 3.5 cm) (*p*<.001), with no group differences observed (*p*=.708) or group X time interaction (*p*=.366). A significant time effect was found for reductions in percent body fat in SBWL (-1.1 ± 1.8%), TECH (-1.2 ± 2.0%), and TECH-BT (-1.7 ± 1.7%) (*p*<.001), with no group differences (*p*=.925) or group X time interaction (.690). Results are shown in Table 5.

Intent-to-treat analysis revealed significant reductions in waist circumferences at both the umbilicus (*p*<.001) and iliac crest (*p*<.001) sites at 3 months for completers in SBWL (umbilicus: -4.0 ± 3.9 cm, iliac: -3.5 ± 5.5 cm), TECH (umbilicus: -6.8 ± 4.7 cm, iliac: -6.4 ± 8.3 cm), and TECH-BT (umbilicus: -6.1 ± 6.4 cm, iliac: -3.8 ± 4.9 cm). No group differences were observed between groups for umbilicus (*p*=.895) and iliac (*p*=.663) sites, or group X time interactions (umbilicus: *p*=.362, iliac: *p*=.448). A significant time effect was also found for reduction in hip circumference in SBWL (-3.4 ± 3.6 cm), TECH (-5.3 ± 2.8 cm), and TECH-BT (-3.7 ± 3.8 cm) (*p*<.001), with no group differences observed (*p*=.773) or group X time interactions (*p*=.332). A significant time effect was found for reductions in percent body fat in SBWL (-1.0 ± 1.7%), TECH (-1.2 ± 2.0%), and TECH-BT (-1.2 ± 1.6%) (*p*<.001), with no group differences observed (*p*=.874) or group X time interaction (*p*=.958). Results are shown in Table 6.

4.5 CHANGES IN PHYSICAL ACTIVITY

A 3 x 2 repeated measures (group by time) ANOVA was performed to examine changes from baseline to 3 months in MVPA (hours/wk) and sedentary time (hours/day) between the treatment groups. Completers analyses results are found in Table 5. Results indicated a significant time effect for both MVPA (*p*=.020) and sedentary time (*p*=.010), with MVPA increasing and sedentary time decreasing from baseline to 3 months. However, there were no significant differences between the groups (*p*=.147 and .766) or group X time interactions (*p*=.533 and .683) for either MVPA or sedentary time respectively. Intention-to-treat analyses showed similar patterns for both MVPA and sedentary time (Table 6).

4.6 CHANGES IN DIETARY INTAKE AND EATING BEHAVIOR

A 3 x 2 repeated measures (group by time) ANOVA was also performed to examine changes from baseline to 3 months in energy intake measured from a food frequency questionnaire between the treatment groups. Results for the completers analysis are found in Table 5. Results indicated a significant time effect (p=.037) for reduction in energy intake with a mean of 254.9±640.6 kcal/day. However, there were no significant differences between the groups (p=.162) or group X time interactions (p=.963). A similar pattern of results were shown for the intent-to-treat analysis (Table 6).

A 3 x 2 repeated measures (group by time) ANOVA was also performed to examine changes from baseline to 3 months in percent of calories consumed as dietary fat measured from a food frequency questionnaire between the treatment groups. Results for the completers analysis are found in Table 5. Results indicated a significant time effect (p=.223) for reduction in percent dietary fat intake with a mean of 2.4±5.5%. However, there were no significant differences between the groups (p=.162) or group X time interactions (p=.806). A similar pattern of results were shown for the intent-to-treat analysis (Table 6).

A 3 x 2 repeated measures (group by time) ANOVA was performed to examine changes from baseline to 3 months in Eating Behavior Index (EBI) scores between the treatment groups. Results for the completers analysis are found in Table 5. Results indicated a significant time effect (p<.001) for improvement in score. However, there were no significant differences between the groups (p=.158) or group X time interactions (p=.985). Intent-to-treat analysis (Table 6) demonstrated a significant time effect (p<.001) for improvement in score as well. There was also a significant group effect (p=.034) with Bonferroni *post hoc* analysis demonstrating a difference between TECH-BT and SBWL (p=.032).

4.7 PROCESS MEASURES

Descriptive analyses were used to examine process measures of attendance at weekly group meetings, monthly telephone call completion, and self-monitoring of dietary intake, physical activity, and weight. Due to differences in these measures across group interventions, independent samples t-test were used to examine differences in the process measures between the technology groups (TECH, TECH-BT), and descriptive statistics were used for SBWL.

Table 8. Completers Analyses: Differences in process measures between groups

Characteristics	SBWL (N=13) (mean ± SD)	TECH (N=12) (mean ± SD)	TECH-BT (N=9) (mean ± SD)
Percent Group Attendance	72.4 ± 19.9	---	---
Percent Telephone Call Completed	---	91.7 ± 15.1	74.1 ± 27.8
Diaries Completed per Person (# diaries)	7.9 ± 4.1	---	---
Dietary Intake Recorded (total days)	53.3 ± 27.5	52.2 ± 23.0	54.0 ± 29.4
Dietary Intake Recorded (days/week)	4.4 ± 2.3	4.3 ± 1.9	4.5 ± 2.4
Self-Reported Caloric Intake (kcal/day)	1112.9 ± 489.4	969.6 ± 607.2	873.4 ± 521.0
Physical Activity Self-monitored Diary			
Total Days	30.7 ± 22.5	---	---
Days/Week	2.6 ± 1.9	---	---
Minutes/Week	104.6 ± 84.3	---	---
Physical Activity Self-monitored Armband (wear-time)			
Total Days	---	68.8 ± 18.7	69.0 ± 19.7
Days/Week	---	5.7 ± 1.6	5.8 ± 1.6
Total Hours	---	1098.2 ± 393.6	1058.3 ± 446.3
Hours/Day	---	14.0 ± 5.4	13.3 ± 5.6
Percent Time On-Body	---	58.4 ± 22.6	55.4 ± 23.3
Energy Expenditure (kcal/day)	---	2886.8 ± 881.7	2807.0 ± 539.1
Self-Weighed			
Total Days	5.2 ± 9.2	16.6 ± 14.6	13.3 ± 7.1
Days/Week	0.4 ± 0.8	1.4 ± 1.2	1.1 ± 0.6

Table 9. Intent-to-treat analyses: differences in process measures between groups

Characteristics	SBWL (N=14) (mean ± SD)	TECH (N=12) (mean ± SD)	TECH-BT (N=13) (mean ± SD)
Percent Group Attendance	69.0 ± 23.0	---	---
Percent Telephone Call Completed	---	91.7 ± 15.1[a]	64.1 ± 28.7[a]
Diaries Completed per Person (# diaries)	7.6 ± 4.1	---	---
Dietary Intake Recorded (total days)	51.5 ± 27.3	52.2 ± 23.0	41.9 ± 30.8
Dietary Intake Recorded (days/week)	4.3 ± 2.3	4.3 ± 1.9	3.5 ± 2.6
Self-Reported Caloric Intake (kcal/day)	1070.4 ± 493.0	969.6 ± 607.2	674.5 ± 535.4
Physical Activity Self-monitored Diary			
Total Days	28.9 ± 22.6	---	---
Days/Week	2.4 ± 1.9	---	---
Minutes/Week	98.3 ± 84.3	---	---
Physical Activity Self-monitored Armband (wear-time)			
Total Days	---	68.8 ± 18.7	59.5 ± 26.5
Days/Week	---	5.7 ± 1.6	5.0 ± 2.2
Total Hours	---	1098.2 ± 393.6	889.1 ± 513.4
Hours/Day	---	14.0 ± 5.4	11.2 ± 6.5
Percent Time On-Body	---	58.4 ± 22.6	46.8 ± 27.2
Energy Expenditure (kcal/day)	---	2886.8 ± 881.7	2560.0 ± 969.3
Self-Weighed			
Total Days	5.5 ± 8.9	16.6 ± 14.6	10.5 ± 7.3
Days/Week	0.5 ± 0.7	1.4 ± 1.2	0.9 ± 0.6

Superscript indicates significant between group differences at $p<0.05$.

4.7.1 Attendance and Telephone Call Completion

Attendance at weekly group meetings was 72.4 ± 19.9% among completers in SBWL. TECH and TECH-BT did not attend weekly meetings and instead received monthly telephone calls. Telephone call completion rates were 91.7 ± 15.1% and 74.1 ± 27.8% for TECH and TECH-BT respectively, with no differences between groups (p=.077) (Table 8). Intent-to-treat analysis revealed a weekly group attendance of 69.0 ± 23.0% for SBWL. Telephone call completion rates were 91.7 ± 15.1% and 64.1 ± 28.7% for TECH and TECH-BT respectively, with TECH completing significantly more telephone calls compared to TECH-BT (p=.007) (Table 9).

4.7.2 Dietary Self-monitoring

The total number of self-monitoring paper diaries completed for completers in SBWL was on average 7.9 ± 4.1 diaries (66%) across 12 weeks (Table 8). SBWL recorded dietary intake in a paper diary 53.3 ± 27.5 total days or 4.4 ± 2.3 days/week. TECH used the online website and TECH-BT used the online website or smartphone device to self-monitor dietary intake. Total days of dietary intake self-monitoring were 52.2 ± 23.0 (TECH) and 54.0 ± 29.4 (TECH-BT), and days per week of dietary intake self-monitoring were 4.3 ± 1.9 (TECH) and 4.5 ± 2.4 (TECH-BT) with no differences between groups (p=.874). The mean self-reported caloric intake was 1112.9 ± 489.4 kcal/day, 969.6 ± 607.2 kcal/day, and 873.4 ± 521.0 kcal/day for SBWL, TECH and TECH-BT, respectively, with no differences between groups (p=.707). One-way ANOVA was used to determine mean differences between SBWL, TECH, and TECH-BT. No significant differences were found between groups for total days self-monitored (p=.572), days per week self-monitored (p=.572), and mean self reported caloric intake (p=.173).

Intent-to-treat analysis revealed that the total number of self-monitoring paper diaries completed for SBWL was 7.6 ± 4.1 diaries (63%) across 12 weeks (Table 9). SBWL recorded dietary intake in a paper diary 51.5 ± 27.3 total days and 4.3 ± 2.3 days/week. Self-monitoring of dietary intake for the technology groups was 52.2 ± 23.0 and 41.9 ± 30.8 total days for TECH and TECH-BT respectively; and 4.3 ± 1.9 and 3.5 ± 2.6 days/week for TECH and TECH-BT respectively. No differences were reported between groups (*p*=.360). Average caloric intake for SBWL was 1112.9 ± 489.4 kcal/day, and caloric intake for the technology groups was 969.6 ± 607.2 and 864.5 ± 535.4 kcals per day for TECH and TECH-BT respectively. No differences were reported between the technology groups (*p*=.209).

4.7.3 Physical Activity Self-monitoring

Using the paper diary, completers in SBWL self-monitored physical activity 30.7 ± 22.5 total days; 2.6 ± 1.8 days per week; and reported 104.6 ± 84.3 minutes per week (Table 8). Different from SBWL, the technology groups (TECH, TECH-BT) used the armband to self-monitor physical activity. The armband was worn for 68.8 ± 18.7 and 69.0 ± 19.7 total days for TECH and TECH-BT respectively; and 5.7 ± 1.6 and 5.8 ± 1.6 days per week for TECH and TECH-BT respectively. No differences were observed between groups (*p*=.977). Total hours of armband wear-time were 1098.2 ± 393.6 (TECH) and 1058.3 ± 446.3 (TECH-BT), with no differences between groups (*p*=.431). The armband was worn on average 14.0 ± 5.4 and 13.3 ± 5.6 hours per day for TECH and TECH-BT respectively, with no difference between groups (*p*=.332). Percent time on-body for TECH was 58.4 ± 22.6% and 55.4 ± 23.3% for TECH-BT, with no differences between groups (*p*=.759).

Intent-to-treat analysis revealed that SBWL self-monitored physical activity in the paper diary 28.9 ± 22.6 total days; 2.4 ± 1.9 days per week; and 98.3 ± 84.3 minutes per week (Table 9). The technology groups (TECH, TECH-BT) wore the armband for 68.8 ± 18.7 and 59.5 ± 26.5 total days for TECH and TECH-BT respectively; and 5.7 ± 1.6 and 5.0 ± 2.2 days per week for TECH and TECH-BT respectively. No differences were observed between groups (*p*=.329). Total hours of armband wear-time were 1098.2 ± 393.6 (TECH) and 889.1 ± 513.4 (TECH-BT), with no differences between groups (*p*=.268). The armband was worn on average 14.0 ± 5.4 and 11.2 ± 6.5 hours per day for TECH and TECH-BT respectively, with no difference between groups (*p*=.260). Percent time on-body for TECH was 58.4 ± 22.6% and 46.8 ± 27.2% for TECH-BT, with no differences between groups (*p*=.260).

4.7.4 Energy Expenditure

Total daily energy expenditure was obtained from armband data for TECH and TECH-BT. Among completers, energy expenditure was not different between TECH (2886.8 ± 881.7 kcal/day) and TECH-BT (2807.0 ± 539.1 kcal/day) (*p*=.814) (Table 8). Intent-to-treat analysis also demonstrated no significant differences between TECH (2886.8 ± 881.7 kcal/day) and TECH-BT (2560.0 ± 969.3 kcal/day) (*p*=0.388) (Table 9).

4.7.5 Self-weighing

Completers analysis revealed that SBWL self-weighed 5.2 ± 9.2 total days across 12-weeks and an average of 0.4 ± 0.8 days per week (Table 8). There was no difference in total days self-weighed in TECH (16.6 ± 14.6 days) and TECH-BT (13.3 ± 7.1 days) (*p*=.546), and no difference in self-weighing days per week in TECH (1.4 ± 1.2 days/week) and TECH-BT (1.1 ± 0.6) (p=.546).

Intent-to-treat analysis revealed that SBWL self-weighed 5.5 ± 8.9 total days across 12-weeks and an average of 0.5 ± 0.7 days per week (Table 9). There was no difference in total days self-weighed in TECH (16.6 ± 14.6 days) and TECH-BT (10.5 ± 7.3) (p=.197), and no difference in self-weighing days per week in TECH (1.4 ± 1.2 days/week) and TECH-BT (0.9 ± 0.6) (p=.197).

4.8 CORRELATIONS BETWEEN PROCESS MEASURES AND WEIGHT CHANGE

Correlations were performed for completers (Table 10) and intent-to-treat (Table 11) analyses for 3-month change in body weight and all process measures.

4.8.1 Attendance and Telephone Call Completion

Percent group meeting attendance in SBWL was not significantly related to weight loss at 3 months in completers (r=.311, p=.301) or intent-to-treat (r=.410, p=.145) analyses. The technology groups were significantly correlated to telephone call completion in completers (TECH: r=.646, p=.023; TECH-BT: r=.736, p=.024), and intent-to-treat (TECH: r=.646, p=.023; TECH-BT: r=.782, p=.002) analyses. Results are presented in Tables 10 and 11.

Table 10. Completers analyses: correlations between process measures and 3-month weight loss

Characteristics	SBWL (N=13)	TECH (N=12)	TECH-BT (N=9)
Percent Group Attendance	.311	---	---
Percent Telephone Call Completed	---	.646*	.736*
Diaries Completed per Person (# diaries)	.905**	---	---
Diet Intake Recorded (total days)	.893**	.112	.218
Diet Intake Recorded (days/week)	.893**	.112	.218
Self-Reported Caloric Intake (kcal/day)	.830**	-.018	.229
Physical Activity Self-monitored Armband (wear-time)			
Total Days	---	.414	.723*
Days/Week	---	.414	.723*
Total Hours	---	-.033	.457
Hours/Day	---	-.122	.400
Percent Time On-Body	---	-.122	.400
Energy Expenditure (kcal/day)	---	.402	.314
Self-Weighed			
Total Days	.224	.492	.883**
Days/Week	.224	.492	.883**

*indicates significant at $p<.05$

**indicates significant at $p<.01$

Table 11. Intent-to-treat analyses: correlations between process measures and 3-month weight loss

Characteristics	SBWL (N=14)	TECH (N=12)	TECH-BT (N=13)
Percent Group Attendance	.410	---	---
Percent Telephone Call Completed	---	.646*	.782**
Diaries Completed per Person (# diaries)	.911**	---	---
Diet Intake Recorded (total days)	.900**	.112	.477
Diet Intake Recorded (days/week)	.900**	.112	.477
Self-Reported Caloric Intake (kcal/day)	.848**	-.018	.470
Physical Activity Self-monitored Armband (wear-time)			
Total Days	---	.414	.674*
Days/Week	---	.414	.674*
Total Hours	---	-.033	.554*
Hours/Day	---	-.122	.506
Percent Time On-Body	---	-.122	.506
Energy Expenditure (kcal/day)	---	.402	.338
Self-Weighed			
Total Days	.169	.492	.909**
Days/Week	.169	.492	.909**

*indicates significant at p<.05

**indicates significant at p<.01

4.8.2 Dietary Self-monitoring

Completers analysis revealed significant correlations for SBWL between weight loss at 3 months and number of diaries completed (r=.905, *p*<.001), total days intake recorded (r=.893, *p*<.001), days per week intake recorded (r=.893, *p*<.001), and average caloric intake per day (r=.830, *p*=.001) (Table 10). Weight loss in the technology groups was not significantly correlated with total days intake recorded (TECH: r=.112, *p*=.728; TECH-BT: r=.218, *p*=.574), days per week intake recorded (TECH: r=.112, *p*=.728; TECH-BT: r=.218, *p*=.574), and average caloric intake per day (TECH: r=-.018, *p*=.955; TECH-BT: r=.229, *p*=.554).

Intent-to-treat analysis demonstrated similar results (Table 11). SBWL significantly correlated 3-month change in body weight to number of diaries completed (r=.911, *p*>.001); total days intake recorded (r=.900, *p*<.001); days per week intake recorded (r=.990, *p*<.001); and average caloric intake per day (r=.848, *p*<.001). However, weight loss in the technology groups was not significantly correlated with total days intake recorded (TECH: r=.112, p=.728; TECH-BT: r=.477, *p*=.099); days per week intake recorded (TECH: r=.112, p=.728; TECH-BT: r=.477, *p*=.099); and average caloric intake per day (TECH: r=-.018, *p*=.955; TECH-BT: r=.470, *p*=.105).

4.8.3 Armband Usage

Completers analysis did not reveal any significant correlations for TECH between weight loss and total days worn (r=.414, *p*=.180); days per week worn (r=.414, *p*=.180); total hours worn (r=-.033, *p*=.918); hours per day worn (r=-.122, *p*=.706); and percent time on-body (r=-.122, *p*=.706) (Table 10). TECH-BT had a significant correlation between weight loss and total days the armband was worn (r=.723, *p*=.028) and days per week the armband was worn (r=.723, *p*=.028); however, there was no significant relationship with change in body weight and total hours worn (r=.457, *p*=.216); hours per day worn (r=.400, *p*=.286); and percent time on-body (r=.400, *p*=.286).

Intent-to-treat analysis revealed the same pattern of results. For TECH, the correlations were not statistically significant between weight loss and total days the armband was worn (r=.414, *p*=.180), days per week the armband was worn (r=.414, *p*=.180), total hours the armband was worn (r=-.033, *p*=.918), hours per day the armband was worn (r=-.122, *p*=706), and percent time on-body for the armband (r=-.122, *p*=.706) (Table 11). For TECH-BT, the correlations were significant between weight loss and total days armband the armband was worn (r=.674, *p*=.012), days per week the armband was worn (r=.674, *p*=.012), and total hours worn the armband was worn (r=.554, *p*=.050); however, no significant relationship was observed between change in body weight and hours per day the armband was worn (r=.506, *p*=.077) or percent time on-body for the armband (r=.506, *p*=.077).

4.8.4 Energy Expenditure

Daily energy expenditure was not significantly related to weight loss at 3 months in completers (TECH: r=.402, *p*=.195; TECH-BT: r=.314 , *p*=.410) or intent-to-treat (TECH: r=.402, *p*=.195; TECH-BT: r=.338, *p*= .259) analyses (Tables 10 and 11).

4.8.5 Self-weighing

Completers analysis did not reveal any significant correlations between weight loss and total days of self-weighing for SBWL (r=.224, *p*=.462) and TECH (r=.492, *p*=.104); however, the correlation was significant in TECH-BT (r=.723, *p*=.028) (Table 10). Likewise, weight loss for SBWL (r=.224, *p*=.462) and TECH (r=.492, *p*=.104) were not significantly correlated with days per week of self-weighing; however, these were significantly correlated for TECH-BT (r=.723, *p*=.028).

Intent-to-treat analysis demonstrated similar results (Table 11). Weight loss in SBWL (r=.169, *p*=.563) and TECH (r=.492, *p*=.104) was not correlated with total days of self-weighing; however, these variables were significantly correlated in TECH-BT (r=.674, *p*=.012). A similar pattern of results was observed for the correlation between weight loss and days per week of self-weighing (SBWL: r=.169, *p*=.563; TECH: r=.492, *p*=.104; TECH-BT: r=.674, *p*=.012).

5.0 DISCUSSION

The purpose of this study was to examine the effectiveness of a technology-based, enhanced technology-based and standard behavioral weight loss intervention across 3 months in Class II and Class III obese adults. The technology-based system used in the investigation is the BodyMedia FIT System (BodyMedia Inc., Pittsburgh, PA). Previous research using this type of technology alone has shown promising results in creating significant weight losses across 4-month[75] and 6-month[76] interventions. Pellegrini et al[35] found significant magnitudes of weight loss using this type of technology combined with monthly telephone contact with outcomes comparable to standard in-person interventions. The current investigation examined the efficacy of this type of technology-based system with minimal in-person contact within Class II and Class III obese adults. Technology enhancements allowing for improved temporal proximity of self-monitoring of dietary intake and feedback on energy balance have recently been added to the BodyMedia FIT System, allowing this study to further investigate the effectiveness of these technology improvements on weight loss and behavior change.

5.1 PARTICIPANT RETENTION

A total of 34 out of 39 randomized subjects completed the baseline and 3 month assessments, reflecting retention of 87% of subjects at 12 weeks. This level of retention is comparable to what is reported for short-term face-to-face weight loss interventions[80], and is also within the range observed in previous studies using armband technology (71.1-89.2%)[35,74,75]. Attrition rates were 7% for SBWL, 0% for TECH, and 31% for TECH-BT. The higher observed attrition for TECH-BT may present an interesting finding, further investigation is needed to determine if this is due the different technology available to subjects in TECH-BT compared to TECH. The technology groups (TECH, TECH-BT) had a combined retention rate of 84% compared to 93% in SBWL. These results differ from those published by Polzien et al.[74] and Pellegrini et al.[33] which found lower retention rates among the standard in-person groups (53% and 84%) compared to those groups given armband technology (88% and 89%). Whether this is a result of the currently study examining only individuals with Class II or III obesity is unable to be determined and warrants further investigation.

5.2 BODY WEIGHT AND BMI

The current investigation was successful in producing weight loss across all treatment groups in completers (SBWL: -3.4 ± 3.1 kg; TECH: -5.0 ± 3.7 kg; TECH-BT:-4.8 ± 4.3 kg) (p<.001), and intent-to-treat (SBWL: -3.2 ± 3.1 kg; TECH: -5.0 ± 3.7 kg; TECH-BT: -3.3 ± 4.2 kg) (p<.001) analyses. Overall combine weight change was -4.3% (completers) and -3.7% (intent-to-treat). This is within the range of weight loss expected following 10-12 weeks of a behavioral weight loss intervention (-4-5%)[34] for completers, and slightly lower than expected with intent-to-treat analysis. Based on the results of completers and intent-to-treat analyses, the primary hypothesis that TECH-BT will result in a significantly greater weight loss compared to SBWL and TECH was not supported. Similar to previous studies using armband technology[35,74], there were no differences between groups for changes in body weight when comparing technology to standard in-person interventions. Thus, the TECH and TECH-BT interventions show promise in their ability to produce changes in body weight that are similar to what is achieved in SBWL programs.

The weight loss achieved in both the TECH and TECH-BT interventions exceeds the weight loss achieved with the BodyMedia FIT System reported by Shuger et al[75]. This may be a result of the current study combining the technology in TECH and TECH-BT with a brief once per month telephone call delivered by the intervention staff, whereas this telephone contact was not included in the intervention implemented by Shuger et al[75]. Additionally, the importance of these telephone calls may be further reflected in the finding that showed that the number of completed telephone calls was associated with weight loss achieved at 3-months. While not decided to disentangle the influence of the technology from the telephone calls, it is possible that the telephone calls may have increased accountability, engagement, and motivation[44] of the participants resulting in improved weight loss compared to what would have been achieved with the technology when not coupled with the telephone calls. Other studies have also reported that the addition of personalized intervention contact to a technology-based intervention improves weight loss when compared to a technology program alone. For example, within the context of a web-based intervention, Tate et al.[71] found greater weight loss after 6 months when personalized feedback was provided via email from a counselor compared to automated computer feedback delivery.

The technology enhancements in TECH-BT, which allowed for real time feedback of weight loss behaviors using a smart phone, did not further enhance the effectiveness of the technology for producing greater magnitudes of weight loss compared to TECH and SBWL as originally hypothesized. However, this does not suggest that this technology is not necessary or appealing to achieve weight loss. Rather, it is possible that some individuals would prefer the TECH-BT system over the TECH system. Thus, the finding that the TECH and TECH-BT groups achieved comparable weight loss, and that weight loss was also similar to what was achieved in SBWL suggests that all of these interventions can be used effectively. Moreover, recent estimates indicate that approximately 50% of adult consumers in the United States own a smart phone,[110] which was a component of the TECH-BT intervention. Thus, while not more effective than either SBWL or TECH, TECH-BT may appeal to a segment of the population who find this technology appealing to use within the context of a health behavior change intervention program. Therefore, there are options for delivery of effective weight loss interventions, and decisions on which intervention approach to use may need to be based on the intervention that is most appealing to the participant.

Although significant weight loss was achieved in all intervention conditions, it is important to note that on average the subjects of this study still remain categorized with Class II obesity following the 3-month intervention. Thus, interventions of longer duration appear necessary to effectively reduce BMI in this population. Moreover, whether the TECH and TECH-BT can continue to effectively reduce weight beyond 12 weeks in adults with Class II or III obesity warrants additional investigation.

5.3 PROCESS MEASURES

There were no differences between groups for the amount of self-monitoring of dietary intake that was done across the 3-month intervention, which does not support the a-priori hypothesis that TECH-BT would self-monitor dietary behaviors more frequently than TECH and SBWL. The finding that the technology used in this study did not improve self-monitoring of dietary intake is consistent with the findings of other investigators[35]. It is also important to note that the technology did not hamper the ability of participants to self-monitor their eating behaviors when compared to the use of more traditional self-monitoring diaries. These findings are important because self-monitoring of dietary behaviors has frequently been highlighted as being a key component of weight loss interventions[36,76-84]. Unfortunately, the data collection methodology does not allow for additional analyses related to the quality or accuracy of the self-monitoring that occurred in this study, and whether this may have differed by intervention condition.

There were no also differences between groups for the number of total days and days per week that body weight was self-monitored for both completers and intent-to-treat analyses. These results do not support the original hypothesis that TECH-BT would self-monitor body weight more frequently than TECH and SBWL. These results differ from those of Pellegrini et al.[35] in which the technology-alone groups had a significantly lower number of days per week of self-weighing compared to the in-person intervention for both completers and intent-to-treat analyses. The results of this particular study do not show the hypothesized increase in frequency of self-weighing in the TECH-BT group; however, it should be noted that self-monitoring of body weight was not possible through the smart phone technology; only through the website interface. Given this limitation, it is not surprising that the TECH and TECH-BT groups had similar frequency of self-weighing days. Of note compared to the Pellegrini study[35], the frequency of self-weighing in all groups was lower. Further investigation may be necessary to understand the reason for the overall reduced frequency of self-weighing in the Class II and III obese subjects.

Direct comparisons cannot be made between SBWL and the technology groups (TECH, TECH-BT) for process measures related to physical activity self-monitoring due to major differences in techniques used between the intervention conditions. However, armband wear-time was able compared between TECH and TECH-BT. In this study, there were no differences between groups for armband wear-time for total days worn, days per week worn, total hours worn, hours per day worn, and percent time on-body for completers and intent-to-treat analyses. Completers analysis indicated that the technology subjects in this study worn the armband 5.7 days per week (TECH) and 5.6 days per week (TECH-BT), for 14.0 hours per day (TECH) and 13.3 hours per day (TECH-BT), which equates to a time on-body percent of 58.4% (TECH) and 55.4% (TECH-BT). Similar results were seen with intent-to-treat analysis. Results from both analyses are similar to those reported by others for armband wear-time[35]. These results also reflect that adults with Class II or III obesity will use the armband technology to monitor physical activity and energy expenditure within the context of a weight loss intervention.

5.4 EATING BEHAVIORS AND PHYSICAL ACTIVITY

A key focus of the interventions implemented in this study was to improve the engagement in eating behaviors that have been shown to be important for weight loss. In fact, all of the interventions (SBWL, TECH, TECH-BT) resulted in similar improvements in eating behavior (Table 5 and 6). The mean improvement on the Eating Behavior Inventory (EBI) scale over this 3 month intervention is slightly less than the improvement reported for studies that were 6 months in duration[35, 109]. An important finding in this study is that eating behavior improved in both TECH and TECH-BT, with this improvement being similar to the change that occurred in

SBWL. Moreover, there were comparable reductions in energy intake and dietary fat intake as measured by a food frequency questionnaire. Thus, these results suggest that a technology-based intervention combined with a once per month brief telephone contact with an interventionist can be effective in improving eating behaviors, reducing energy intake, and reducing fat intake in severely obese adults.

Hours of self-reported moderate-to-vigorous physical activity (MVPA) significantly increased across all groups. However, the lack of a difference between the treatment groups rejects the original hypothesis suggesting that TECH-BT would have greater improvements in physical activity compared to TECH or SBWL. These results do demonstrate however that the technology is able to elicit similar improvements in physical activity as in-person interventions within Class II and III obese adults. Others have also reported on the ability for a SBWL program to increase physical activity in severely obese adults[61], yet data are lacking on the effectiveness of non-in-person and technology-based intervention to improve physical activity in this population group. It should also be noted that there were no serious adverse events in the current study resulting from engaging in physical activity. This may suggest that when appropriately screen for contraindications for moderate-to-vigorous physical activity it is relatively safe to engage severely obese adults in interventions that promote engagement in this important weight loss behavior. It is also important to highlight that all of the interventions were equally effective at reducing sedentary behavior in these severely obese adults. This is an important finding as sedentary behavior has been implicated to increase health risk[111].

5.5 CLINICAL IMPLICATIONS

Obesity is a major health issue in the United States with approximately 33% of the population classified as obese[1]. It has also been shown that the treatment of obesity-related co-morbidities escalates health care costs[22-24]. However, even modest reductions in body weight have demonstrated improvements in health consequences related to obesity[23-24]. Thus, it is important to focus on intervention techniques for not only reducing body weight, but increasing the appeal of overweight and obese patients to participate in a weight loss interventions, which may require effective non-in-person interventions.

The results of this study have demonstrated that short-term technology-based interventions combined with brief monthly telephone calls are as effective for weight loss as an in-person group based intervention. In addition, the reductions in body weight were accompanied by reductions in BMI, blood pressure, heart rate, anthropometric measures and sedentary time, and increases in physical activity and improved eating behaviors when compared to the in-person intervention. While it is recognized that this study was relatively short in duration (3 months), these findings provide optimism that may expand the portfolio of lifestyle intervention options available to effectively treat obesity.

While this study does not allow for the intervention to be dismantled to determine the components of TECH or TECH-BT that were most important for weight loss success, one could speculate on how various components of the intervention may have contributed to weight loss success. For example, using the technology to set intervention goals (physical activity, energy intake, weight loss) that can be viewed by the participant, using the technology to provide feedback on goal achievement, and having the interventionist use this information during the brief telephone contact each month to personalize this interaction may have collectively contributed to the success of the TECH and TECH-BT to achieve weight loss in this study. Unfortunately, resources were not available to conduct a cost-effective analysis for this study to compare SBWL, TECH, and TECH-BT. However, if shown to be more cost-effective, either the TECH or TECH-BT may provide a cost-effective weight loss option that may be appealing to a segment of overweight and obese adults seeking treatment. A cost-effective option for weight loss in severely obese adults may also have appeal to clinical programs implemented in hospitals, through health insurance companies, or through community-based interventions, which may allow for broader dissemination of effective weight loss interventions.

5.6 LIMITATIONS AND FUTURE DIRECTIONS

This was the first study to specifically examine the effectiveness of TECH and TECH-BT compared to SBWL in severely obese adults. Thus, this study was intended as a pilot study to inform a larger intervention trial to examine these interventions further. However, it is recognized that there are limitations to this study as outlined below that may limit the interpretation of the findings reported, and these limitations should be considered in future research undertaken on this topic.

1. This study randomized 39 subjects to start the interventions implemented in this study. However, the differences in weight loss between the groups were approximately 1-1.5 kg. While this information is valuable for adequately powering a larger clinical trial, this sample size was not sufficient to detect differences between groups for weight loss of this magnitude. Thus, it cannot be determined definitively if these interventions result in similar magnitudes of weight loss or if differences between groups is not able to be

detected based on the sample size included in this study. With the sample size presented in this study, there was power to detect a 3.7 kg difference between groups.

2. This study included 31 women and 8 men spread across the 3 intervention conditions. This is not sufficient to test for gender differences either within or between the intervention conditions, and therefore conclusions based on gender would be purely speculative. Thus, future studies should consider samples sizes that would allow for gender comparisons.
3. This study included 28 Caucasians and 11 non-Caucasians spread across the 3 intervention conditions. This is not sufficient to test for racial/ethnic differences either within or between the intervention conditions, and therefore conclusions based on race/ethnicity would be purely speculative. Thus, future studies should consider samples sizes that would allow for racial/ethnic group comparisons.
4. The current study was 3 months in duration. This is similar in duration to the study conducted by Polzien et al.[74] yet somewhat less that the 6 month duration of the study conducted by Pellegrini et al[35]. Unique to the current study is the focus specifically on the effectiveness of these interventions in adults with severe obesity (Class II and III obesity). Thus, conclusion regarding the effectiveness of these interventions, specifically TECH and TECH-BT for weight loss in severely obese adults cannot be determined beyond the 3 months examined in this study. Future studies should be conducted that are longer in duration to allow for the long-term effectiveness of these interventions to be examined.
5. The current study examined the effectiveness of technology when combined with a brief monthly intervention telephone contact. Thus, the current study is not able to determine

the extent that combination of the technology and telephone calls had on weight loss compared to either of these intervention strategies if implemented alone in a group of severely obese adults. Future studies should be conducted to determine the contribution of each of these intervention strategies when used alone on weight loss in severely obese adults, as this may inform dissemination of these findings within clinical intervention programs.

6. While this study examined severely obese adults, these individuals did not necessarily present with significant risk factors (e.g., hypertension, hyperlipidemia, hyperglycemia, hyperinsulinemia) for other chronic diseases, which limits the ability of this study to determine if the interventions would have resulted in differential effects on these outcomes. Future studies should consider recruiting severely obese adults who also present with additional risk factors or metabolic conditions (e.g., diabetes mellitus, etc.) to determine if the interventions can influence these outcomes.

5.7 SUMMARY

In summary, this study demonstrated that short-term technology-based interventions combined with brief monthly telephone calls are as effective for weight loss as an in-person group based intervention in adults with severe obesity (BMI: 35 to 45 kg/m^2). The observed weight loss was also accompanied by reductions in BMI, blood pressure, heart rate, anthropometric measures and sedentary time, and increases in physical activity and improved eating behaviors. These findings were observed regardless of the intervention condition (SBWL, TECH, TECH-BT). Thus, these findings provide initial evidence that short-term weight loss interventions can be successfully implemented in a variety of ways with similar effectiveness in adults with severe obesity, which suggests that there are options for how to deliver weight loss interventions in this population group. Whether these interventions can be equally effective across a longer intervention period or within subgroups (men vs. women, different race/ethnic groups, etc.), or if there are differences in cost-effectiveness of these interventions, warrants further investigation. However, these results provide promise for implementing non-surgical or non-pharmacological interventions that focus solely on lifestyle modification for weight loss in adults with severe obesity.

APPENDIX A

RECRUITMENT FORM

Thank you for your interest in our program. My name is **___________** and I would briefly like to tell you about this research program.

Procedure for Describing the Study and Obtaining Verbal Consent to Conduct the Phone Screen: A description of the study will be read to participants, and this description includes important components of the informed consent process (see attached script). Individuals who express an interest in participating in this study will be told the following to obtain verbal consent:

- ***Investigators Component of Informed Consent:*** *This study is being conducted by Renee J. Rogers and Dr. John M. Jakicic at the University of Pittsburgh.*

- ***Description Component of Informed Consent****: We are interested in recruiting 84 men and women to participate in this study. This study will examine the influence of a technology-based system during a behavioral weight loss intervention on weight loss and exercise participation. To do this, eligible individuals will participate in a 6-month program that will assist you with changing your dietary habits and increasing your exercise. You will be randomly assigned to receive one of three weight loss interventions, which means that you cannot select the intervention that you receive, but it will be determined by a method similar to flipping a coin. All groups will receive a weight loss program that includes changes in your diet and exercise. The first group will attend group and individual meetings regularly across the 6 months. The other two groups will be given a technology-based system to use over the 6 months that includes wearing an activity monitor that is worn on the upper arm which assesses the amount of energy you burn and logging into the Internet each day, and these groups will also receive periodic phone calls from the staff. The weight loss intervention will be held at a University of Pittsburgh facility located on the South Side of Pittsburgh, and meetings will start between 5:30 and 6:00 in the evening, and these will be held on (Day of*

<u>Week to be determined)</u>. Individuals who are eligible to participate in this study will undergo assessments of body weight, body composition which assesses the amount of fat and lean weight on their body, and fitness. These assessments will be completed before you start the study and at 3 and 6 months. If you complete this study you can earn up to $50.00.

- *If you are interested in participating in this study, I will need to ask you a few questions about your demographic background, physical health, and medical history to determine if you appear to be eligible to participate in this study. It will take approximately 5 minutes to ask you all of the questions. If we complete the interview, I will ask you for some specific information (your complete name, date of birth, and mailing address) so that we can contact you regarding your participation in this study. I will then schedule you to attend an orientation session that will explain all of the procedures of this study in greater detail.*

- ***Confidentiality Component of Informed Consent:*** *If your answer to a particular question tells me clearly that you will not be eligible for this study, I will stop the interview, and not ask you any more personal questions.*

- ***Right to Participate or Withdraw from Participation Component of Informed Consent:*** *Your responses to these questions are confidential, and the information related to your health history or current behaviors that you are about to give me will be destroyed after this interview even if you are found to be eligible.*

- ***Do you have any questions related to any of the information that I have provided to you?*** Staff member will answer any questions or will defer these questions to the Principal Investigator or Co-Investigator when appropriate prior to proceeding. If the individual would like to think about their participation prior to proceeding with the Phone Screen, they will be provided with the telephone number that they can call if they decide to participate in the future.

Voluntary Consent Component of Informed Consent:

- ***Do you agree that the procedures that will be used to conduct this Phone Screen have been described to you, all of your questions have been answered, and you give me permission to ask you questions now as part of the initial Phone Screen?*** If "YES" indicate the participant's agreement with this statement on the top of the next page, and sign your name and date the form, and then complete the Phone Screen. If "NO", thank the individual for calling and <u>do not</u> complete the Phone Screen.

Phone Screen Interview

The caller gives verbal permission to conduct the Phone Screen: _____ YES______ NO

Verbal Assent was given to: ____

Staff Member Signature: ___________________________________

Date Verbal Assent was given: ______________________________

Eligible based on telephone screening: ☐ Yes ☐ No

If "No", list reason for ineligibility: _____________________________________

1. Gender: ☐ Male ☐ Female

2.a. Age: ☐☐ **(21-55)**

2.b.Date of Birth: ☐☐/☐☐/☐☐

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

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

4. Current Weight: ☐☐☐ pounds ***Office Use: BMI = _______(25-40 kg/m^2)***

5. Current Height: ☐ feet ☐☐ inches

6. Are you able to walk for exercise? ☐ **YES** ☐ No

If "no", specify reason: ____

7. Do you currently exercise regularly at least once per week at a moderate intensity for at least 20 minutes? ☐Yes ☐ **NO**

If "yes", How many days per week? ________

If "yes", How long have you been exercising this way?____________

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

a. Heart Disease	☐ Yes ☐ **NO**	________________________
b. Angina	☐ Yes ☐ **NO**	________________________
c. Hypertension	☐ Yes ☐ **NO**	________________________
d. Heart Attack	☐ Yes ☐ **NO**	________________________
e. Stroke	☐ Yes ☐ **NO**	________________________
f. Diabetes (sugar)	☐ Yes ☐ **NO**	________________________
g. Cancer	☐Yes ☐ **NO**	________________________

9. Are you presently being treated by a doctor or other medical person for any other physical or psychological problems? ☐ Yes ☐ **NO**

If "yes", specify: ____

10. Do you take any prescription medications (includes psychotropics)? ☐ Yes ☐**NO**

If "yes", specify the following:

Medication Name	Used to Treat:

11. Are you taking any medications for the purpose of weight loss? ☐Yes ☐**NO**

If "yes", specify: ____

12. Are you currently a member of another organized exercise or are you participating in an organized weight reduction program? ☐ Yes ☐ **NO**

If "yes", specify: ____

13. Have you lost >5% or more pounds within the past 3 months? ☐ Yes ☐ **NO**

If "yes", specify number of pounds: ____Method used:______________________

14. Are you currently participating in other research studies? ☐ Yes ☐ **NO**

If "yes", specify: ____

15. Have you been a participant in a previous exercise or weight control study? ☐Yes ☐**NO**

If "yes", specify:____

15. Do you have daily access to a computer? ☐**YES** ☐No

If "yes", do you know how to use this computer? ☐**YES** ☐No

If "yes", where is this computer located?________________________________

16. Do you have daily access to the Internet? ☐**YES** ☐No

If "yes", do you know how to access the Internet? ☐**YES** ☐No

If "yes", what service do you use to access the Internet? ____________________

17. Do you a smartphone that is an iphone or a phone that is powered with the Android Operating System? ☐**YES** ☐No

If "yes", provide the type of smartphone? _____________________________

18. Do you plan to spend any time out of town on vacation or business in the next 6 months that may affect your ability to attend weekly group meetings? ☐ Yes ☐ **NO**

If "yes", specify: ____

19. Do you plan on relocating outside of the Greater Pittsburgh Area within the next 6 months? ☐ Yes ☐ **NO**

If "yes", specify: ____

WOMEN ONLY COMPLETE THE FOLLOWING QUESTIONS

20. a. Are you currently pregnant? ☐ Yes ☐ **NO**

b. Have you been pregnant in the last 6 months? ☐ Yes ☐ **NO**

c. Breast feeding in the last 3 months ☐ Yes ☐ **NO**

d. Do you plan on becoming pregnant in the next 3 months? ☐ Yes ☐ **NO**

Contact Tracking Form

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

Date: ____/____/____Staff Member Completing Form: ____________________

Name: ____

Street Address: ____

City: ______________________________ State: ___ Zip Code:________

Home Phone: ____________________ Work Phone: ____________________

OFFICE USE ONLY:

Eligible: ☐ Yes ☐ No

Invited to Orientation: ☐ Yes ☐ No

Date of Orientation:____/____/____

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

PAGE 1 WILL BE RETAINED FOR DEMOGRAPHIC STATISTICS

PAGES 2-3 <u>MUST BE SHREDDED</u> AT THE CONCLUSION OF THIS INTERVIEW

APPENDIX B

TELEPHONE CONTACT FORM

- **BEFORE THE PHONE CALL:**

☐ Review and Prepare for Phone Call: BodyMedia Dashboard / Report and Review previous phone call notes.

NOTE: Three (3) attempts should be made on the day of the scheduled call. If unsuccessful, 3 additional attempts should be made throughout the week and prior to the next scheduled in-person contact.

Attempt	Date	Time	No Answer	Number Busy	Left Message on Machine	Left Message with Person	Contacted	Coach Initials
1	__/__/__	__:__AM/PM	☐1	☐2	☐3	☐4	☐5	
2	__/__/__	__:__AM/PM	☐1	☐2	☐3	☐4	☐5	
3	__/__/__	__:__AM/PM	☐1	☐2	☐3	☐4	☐5	
4	__/__/__	__:__AM/PM	☐1	☐2	☐3	☐4	☐5	
5	__/__/__	__:__AM/PM	☐1	☐2	☐3	☐4	☐5	
6	__/__/__	__:__AM/PM	☐1	☐2	☐3	☐4	☐5	

INTRODUCTION	
"Hello, this is ________ calling from the NEW4Life Study for our scheduled telephone call. Do you have a few minutes to speak with me about how the program is going for you?"	If "Yes" then proceed with the call using the script below. If "No" reschedule a time with a participant to complete this call.

ASSESSING TECHNOLOGY "Before we talk about the progress that you are making with your weight loss efforts, I just want to ask you a few questions about the technology that we have recently implemented as part of your program."	
USE OF BODYMEDIA FIT SYSTEM	**NOTES**
A. Are you able to login to the www.bodymedia.com website? ☐ Yes ☐ No (investigate why this is occurring – indicate in notes) ☐ Participant has not tried (encourage the participant to login to the website)	
B. Are you experiencing any difficulty in wearing the armband? ☐ Yes–problem solve (indicate in notes) ☐ No–encourage continued use (check the website to make sure that the participant is wearing the armband and is uploading their data)	
C. Are you experiencing any difficulty in completing the daily food diary? ☐ Yes–problem solve (indicate in notes) ☐ No–encourage continued use (check the website to make sure that the participant is logging their food)	

ASSESSING WEIGHT LOSS BEHAVIOR "Let's spend a few minutes talking about your weight loss efforts."
A. What is your goal over the course of the next month? Are you attempting to: (make appropriate notes below) ☐ Lose additional weight ☐ Maintain current weight with no additional weight loss/gain. If maintain, Why?

B. Are you experiencing any barriers that are affecting your ability to eat in a manner that is consistent with weight loss or weight loss maintenance? ☐ If "Yes" then ask questions about barriers listed below and problem solve with the participant (Indicate in notes) ☐ Not enough time to cook ☐ Illness ☐ Not planning meals ☐ Holiday ☐ Eating out ☐ Vacation ☐ Not grocery shopping ☐ Lack of support ☐ Family/Work Demands ☐ Lack of motivation ☐ Other: ______________________________ ☐ If "No" then briefly highlight the importance of maintaining a healthy diet for weight control and encourage compliance with the recommended calorie and fat goals.	
C. Are you experiencing any barriers to achieving (100, 150, or 200) minutes per week of exercise? ☐ If "Yes" then ask questions about barriers listed below and problem solve with the participant (Indicate in notes) ☐ Not enough time ☐ Illness ☐ Inconvenience ☐ Holiday ☐ Weather ☐ Vacation ☐ Tired/Fatigued ☐ Lack of support ☐ Family/Work Demands ☐ Not Enjoyable ☐ Other: ______________________________ ☐ If "No" then briefly highlight the importance of continuing to exercise for weight control and encourage compliance with the recommended 250-300 minutes of moderate intensity exercise.	

List the SMART Goal(s) for the next month:

COMPLETING THE CALL
1. Schedule the next phone call with the participant. ☐ Yes – completed
2. Record the total duration of the call. ____________ minutes

- **AFTER THE PHONE CALL:**

☐ Update the Intervention Call Schedule

☐ Indicate that the call was completed with a "Y" on the Call List Tracking spreadsheet in the scheduled intervention week. (i.e. Phone call is scheduled for week 3 on the intervention calendar, but contact was not made until week 4 – put the "Y" under the week set for the phone call according to the intervention calendar, in this case, week 3.)
If applicable: Add any attendance/make-up notes to the appropriate intervention week.

☐ Log the phone call and time in Study Manager

Signature of Coach: ____ **Date:** _______________

APPENDIX C

INTERVENTION SCHEDULE – COHORT 1

Week	Week Start Date	Mail Date TECH TECH-BT	Exercise Minutes	Lesson	Supplement Materials SBWL	Supplement Materials TECH TECH-BT	TECH TECH-BT Phone Call	TECH TECH-BT Reports	Report Date
1	W-6/27	N/A group meeting	100	Introduction	Meal Plans Self-Monitoring Example	Meal Plans Self-Monitoring Example BodyMedia Guide Link Guide			
2	W-7/4 (no group holiday)	F-6/29 include SBWL	100	Healthy Food Choices & Food Label		Week 2 Letter		X	13-Jul
3	W-7/11	SU-7/8	100	Goal Setting	% Weight Loss Chart Weight Tracker	Week 3 Letter % Weight Loss Chart Weight Tracker	X		
4	W-7/18	S-7/14	100	Implementing Your Exercise Program	MONTH 1 Review	Week 4 Letter MONTH 1 Review		X	27-Jul
5	W-7/25	M-7/23	150	Motivation		Week 5 Letter			
6	W-8/1	M-7/30	150	Problem Solving/Behavior Chains		Week 6 Letter		X	10-Aug
7	W-8/8	M-8/6	150	My Time, My Values	Worksheet	Week 7 Letter	X		
8	W-8/15	M-8/13	150	Calorie Control	MONTH 2 REVIEW	Week 8 Letter MONTH 2 REVIEW		X	24-Aug
9	W-8/22	M-8/20	200	Role of Thoughts in Weight Management		Week 9 Letter			
10	W-8/29	M-8/27	200	Barriers to Exercise		Week 10 Letter		X	7-Sep
11	W-9/5	M-9/3	200	Stimulus Control		Week 11 Letter	X		
12	W-9/12	M-9/10	200	Evaluating your Progress (3 month) Motivation Revisited		Week 12 Letter		X	21-Sep

APPENDIX D

INTERVENTION SCHEDULE – COHORT 2

Week	Week Start Date	Mail Date TECH TECH-BT	Exercise Minutes	Lesson	Supplement Materials SBWL	Supplement Materials TECH TECH-BT	TECH TECH-BT Phone Call	TECH TECH-BT Reports	Report Date
1	W-9/5	N/A group meeting	100	Introduction	Meal Plans Self-Monitoring Example	Meal Plans Self-Monitoring Example BodyMedia Guide Link Guide			
2	W-9/12	M-9/10	100	Healthy Food Choices & Food Label		Week 2 Letter		X	21-Sep
3	W-9/19	M-9/17	100	Goal Setting	% Weight Loss Chart Weight Tracker	Week 3 Letter % Weight Loss Chart Weight Tracker	X		
4	W-9/26	M-9/24	100	Implementing Your Exercise Program	MONTH 1 Review	Week 4 Letter MONTH 1 Review		X	5-Oct
5	W-10/3	M-10/1	150	Motivation		Week 5 Letter			
6	W-10/10	M-10/8	150	Problem Solving/Behavior Chains		Week 6 Letter		X	19-Oct
7	W-10/17	M-10/15	150	My Time, My Values	Worksheet	Week 7 Letter	X		
8	W-10/24	M-10/22	150	Calorie Control	MONTH 2 REVIEW	Week 8 Letter MONTH 2 REVIEW		X	2-Nov
9	W-10/31	M-10/29	200	Role of Thoughts in Weight Management		Week 9 Letter			
10	W-11/7	M-11/5	200	Barriers to Exercise		Week 10 Letter		X	16-Nov
11	W-11/14	M-11/12	200	Stimulus Control		Week 11 Letter	X		
12	W-11/21	M-11/19	200	Evaluating your Progress (3 month) Motivation Revisited		Week 12 Letter		X	26-Nov

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