THE EFFECTIVENESS OF A COMPUTER AND INTERNET-BASED SYSTEM IN A SHORT-TERM BEHAVIORAL WEIGHT LOSS INTERVENTION

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Computer and Internet-assisted weight loss interventions offer alternative delivery channels that might increase program appeal and potentially increase weight loss success. To date research focused on these innovative techniques is limited. **PURPOSE:** To examine the effectiveness adding a technology-based intervention component to an in-person, 12-week clinically-based behavioral weight loss intervention. **METHODS:** Fifty-seven subjects (body mass index = 33.1±2.8 kg/m^2; age = 41.3±8.7 yrs) participated in a 12-week intervention with random assignment to Standard Behavioral Program (SBWP), Intermittent Technology-Based Program (INT-TECH), or Continuous Technology-Based Program (CON-TECH). SBWP received an individual weight loss session at weeks 1-4, 6, 8, and 10, prescribed a diet of 1200-1500 kcal/d, and exercise progressing from 20-40 min/d on 5 days/wk. INT-TECH and CON-TECH received the components of SBWP, however, these groups also used a SenseWear Pro Armband (BodyMedia, Inc.) to monitor energy expenditure and a web-based program to monitor eating behaviors. INT-TECH used these features during weeks 1, 5, and 9, with CON-TECH using these features throughout the 12-week intervention. Outcomes included body weight, percent body fat, and cardiorespiratory fitness. **RESULTS:** Fifty subjects completed the investigation (88%). Intent-to-treat analysis revealed weight loss of 4.1±2.8 kg (4.6 ±2.8%), 3.4±3.4 kg (3.8±3.8%), and 6.2±4.0 kg (7.1±4.6%), for the SBWP,

INT-TECH, and CON-TECH groups, respectively (CON-TECH > INT-TECH, $p \leq 0.05$). Percent body fat was significantly decreased in CON-TECH (-4.1±2.9%) when compared to both SBWP (-1.6±1.5%) and INT-TECH (-1.6±1.7%) ($p \leq 0.05$). Cardiorespiratory fitness significantly increased in all groups by 14%, 3%, and 5% in SBWP, INT-TECH, and CON-TECH, respectively; $p<0.01$), with no significant group differences. **CONCLUSIONS:** Results indicate that a technology-based program that is used continuous over a 12-week intervention and is complimentary to a clinically-based in-person intervention improves weight loss by approximately 3% compared to a SBWP that does not use these technology features or by approximately 3.7% compare to INT-TECH uses the technology features only intermittently during the intervention. Considering these short-term results, future studies should examine the impact of adding these technology features to a SBWP on long-term weight loss outcomes, and for whom technology-based programs are most effective.

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I. INTRODUCTION

Obesity is a major public health concern in the United States ("The surgeon general's call to action to prevent and decrease overweight and obesity", 2001) as it is associated with increased mortality (Ajani et al., 2004) and also associated with an increased risk of other health disorders such as type 2 diabetes mellitus (Ford, Williamson, & Liu, 1997; Weinstein et al., 2004); coronary heart disease (Klein et al., 2004); certain cancers, including breast, prostate, endometrial, colon and gallbladder (Bray, 2002); respiratory complications (Jubber, 2004); and osteoarthritis (Powell, Teichtahl, Wluka, & Cicuttini, 2005). Overweight and obesity are classified by body mass index (BMI); overweight is defined as a BMI of 25-29.9 kg/m^2 and obesity is defined as a BMI of $\geq$30 kg/m^2. The most recent data indicate that the prevalence of overweight or obesity exceeds 65% and the prevalence of obesity is estimated to be 31% among the US adult population (Hedley et al., 2004). It is clear that effective interventions aimed at attenuating the growing obesity epidemic are vital.

Behavioral weight loss interventions have been shown to be effective in the treatment of overweight and obesity, typically producing weight losses between 8% to 10% of initial body weight within 4 to 6 months of treatment (Wing, 2002). These interventions incorporate a variety of strategies aimed at behavioral modification necessary for weight loss (Brownell, 2000; Wadden & Foster, 2000; Wing, 2002). It is imperative to continue to examine the effectiveness of behavioral weight loss interventions and explore means to enhance weight loss success within these interventions.

Recently, interest has been raised related to alternative channels through which weight loss interventions can be supported and delivered. Alternative methods, such as computerized and Internet-mediated programs have been shown to be feasible means to support and deliver weight loss and weight maintenance treatment (Agras, Taylor, Feldman, Losch, & Burnett, 1990; Burnett, Taylor, & Agras, 1985; Harvey-Berino et al., 2002; Harvey-Berino, Pintauro, Buzzell, & Gold, 2004; Harvey-Berino, Pintauro, & Gold, 2002; Tate, Jackvony, & Wing, 2003; Tate, Wing, & Winett, 2001; Taylor, Argras, Losch, Plante, & Burnett, 1991; Womble et al., 2004; Wylie-Rosett et al., 2001). Computer-based programs have been examined primarily as a method to help enhance the self-monitoring process, while Internet-based interventions have been investigated as a method to increase treatment dissemination and provide a potentially more appealing stand-alone weight loss treatment option. As a result, commercially available products that utilize computer and Internet technology have been developed to support and deliver weight loss programs. However, these commercially available products have not been tested within randomized behavioral weight loss trials.

The technology based system utilized in the conducted investigation was developed by BODYMEDIA® and Roche Diagnostics™. This system is a commercially available technology-based product designed for implementation in a clinical setting. The system was designed to support weight loss by providing users with more detailed information related to physical activity and dietary behaviors. The system includes an Internet application and a software application that allows users to track daily energy balance reflecting data obtained from an energy expenditure monitor and logged self-reported energy intake. The system was specifically designed so that weight loss behavior information can be shared between

clinicians and their patients through the system's Internet application (Roche Diagnostics, 2004). Currently, it is not known if this technology-based system results in improved outcomes in a short-term weight loss intervention. Therefore, the purpose of this study was to examine the effectiveness a technology based-system, when used in addition to an in-person standard 12-week behavioral weight loss intervention.

Rationale

The National Heart Lung and Blood Institute (NHLBI) has published the Clinical Guidelines for the Identification, Evaluation and Treatment of Overweight, this document presents evidence that weight control interventions combining a low-calorie diet, physical activity, and behavior therapy are most effective for weight loss and maintenance (National Heart Lung and Blood Institute, 1998). These interventions integrate a variety of behavioral techniques including self-monitoring, stimulus control, problem solving, cognitive restructuring, social support, nutrition education, physical activity, and the use of reinforcement contingencies (Brownell, 2000; Wadden & Foster, 2000; Wing, 2002). While these interventions have been shown to be effective in producing weight loss, this type of intervention delivery may not be practical for everyone. Alternative methods such as computer and Internet-mediated weight loss programs are needed to meet the demands for diversity and flexibility in weight loss program support and delivery, yet research supporting these alternative delivery channels is limited (Bessell et al., 2002).

The technology-based system analyzed in this study is an innovative product that might be an effective and appealing intervention tool for both participants and clinicians when utilized within a clinical weight management treatment environment. This system may be effective from the participant's perspective for two primary reasons, the system allows for

enhanced self-monitoring through objective daily energy expenditure measurement and it provides users with detailed energy balance data and related feedback. Both of these factors might promote participants to make more effective changes in dietary and exercise behaviors leading to greater weight loss success. From the clinician's perspective, the enhanced self-monitoring data has the potential to augment assessments, improve treatment plans and support education. Therefore, use of this technology-based system may also foster more engaging and effective treatment interactions when it is utilized within a clinical weight management program.

Self-monitoring is a critical component in behavioral weight loss interventions; it has been called the "cornerstone" and most effective component of weight control (Wadden, 1993; Wadden & Letiza, 1992). Self-monitoring involves the systematic observation and documentation of target behaviors (Boutelle & Kirschenbaum, 1998). Self- regulatory theories suggest that self-monitoring leads to sustained efforts to match behaviors to goals (Baumeister, Heatherton, & Tice, 1994; Carver & Schier, 1990). In the context of behavioral weight loss interventions, participants are encouraged to observe and record their eating and physical activity related behaviors. A strong association between self-monitoring and weight loss has been demonstrated by several research studies (Wadden & Letiza, 1992). The technology-based system analyzed in this study might provide an enhancement in the self-monitoring process by allowing the user to view and track daily energy balance. This system tracks number of steps, minutes of physical activity, daily energy balance, weight trends and food breakdown by fat, protein and carbohydrates (Roche Diagnostics, 2004). The utilization of this system may stimulate individuals to increase their behavioral awareness

and follow recommended physical activity and dietary intake guidelines, ultimately resulting in enhanced weight loss.

In addition to self-monitoring, the behavioral treatment of obesity relies heavily on the provision of feedback as a means to address and reinforce the adoption of weight loss behaviors (Burnett et al., 1985). In behavioral weight loss interventions, feedback on goal attainment for target behaviors is often delayed until interventionists review an individual's record of their weekly eating and exercise behaviors. The technology-based system analyzed in this study allows the user to receive feedback related to their daily energy balance. Individuals will receive messages that focus on energy intake and energy expenditure goals. Provision of feedback might help to reinforce behavioral changes and encourage individuals to maintain a consistent effort to modify their eating and exercise behaviors.

Behavioral weight loss treatment visits are usually conducted following a structured curriculum involving interactive discussions related to adherence to eating and exercise goals, tactics for overcoming behavior-specific barriers, and strategies for coping with general life stressors (Wadden & Butryn, 2003). The technology-based system analyzed in this study could be a valuable tool for the interventionist, potentially enhancing counseling session efficiency and effectiveness. The interventionist can review an individual's daily energy balance data and utilize this information to provide behavior-specific feedback, identify problem-solving strategies, and help the individual develop manageable goals.

To date, no randomized studies have been conducted to determine if the technology-based system used in this study is an effective tool to enhance short-term weight loss. Therefore, this study addressed the potential added value of this system when utilized in a clinical setting. The findings of this intervention may lead to the recommendation to

incorporate the use of this technology-based system in future clinical weight loss interventions, ultimately resulting in enhanced weight loss among participants of these programs.

Specific Aims

The specific aims of this study included:

1. Examine whether weight loss was greater when the technology-based system was utilized in conjunction with an in-person weight loss intervention, used intermittently (INT-TECH) or continuously (CON-TECH), compared to an in-person standard behavioral weight loss intervention (SBWP).
2. Examine whether reductions in body composition and regional adiposity were greater when the technology-based system was utilized in conjunction with an in-person weight loss intervention, INT-TECH or CON-TECH, compared to an in-person SBWP.
3. Examine whether cardiorespiratory fitness was increased when the technology-based system was utilized in conjunction with an in-person weight loss intervention, INT-TECH or CON-TECH, compared to an in-person SBWP.
4. Examine whether self-reported physical activity was increased when the technology-based system was utilized in conjunction with an in-person weight loss intervention, INT-TECH or CON-TECH, compared to an in-person SBWP.
5. Examine whether dietary intake was reduced when the technology-based system was utilized in conjunction with an in-person weight loss intervention, INT-TECH or CON-TECH, compared to an in-person SBWP.

Research Hypotheses

The following primary hypotheses were used to answer the stated primary aims:

1. The use of the technology-based system, both INT-TECH and CON-TECH groups, will result in greater weight loss compared to the SBWP group. In addition, the CON-TECH group will achieve greater weight loss compared to the INT-TECH group.
2. The use of the technology based-system, both INT-TECH and CON-TECH groups, will result in greater reductions in body composition and regional adiposity compared to the SBWP group. In addition, the CON-TECH group will achieve greater reductions in body composition and regional adiposity compared to the INT-TECH group.
3. The use of the technology-based system, both INT-TECH and CON-TECH groups, will result in a larger increase in cardiorespiratory fitness compared to the SBWP group. In addition, the CON-TECH group will achieve a larger increase in cardiorespiratory fitness compared to the INT-TECH group.
4. The use of the technology-based system, both INT-TECH and CON-TECH groups, will result in a larger increase in self-reported physical activity compared to the SBWP group. In addition, the CON-TECH group will achieve more significant increases in self-reported physical activity compared to the INT-TECH group.
5. The use of the technology-based system, both INT-TECH and CON-TECH groups, will result in a larger reduction in dietary intake compared to the SBWP group. In addition, the CON-TECH group will achieve a significantly larger reduction in dietary intake compared to the INT-TECH group.

Significance

Obesity has reached epidemic proportions in the United States, with over 65% of the adult population classified as overweight or obese (Hedley et al., 2004). Obesity has been independently associated with an increase in morbidity and mortality from several chronic diseases (National Heart Lung and Blood Institute, 1998). As a result obesity has become a critical public health concern; furthermore, the treatment of obesity places tremendous strain on economic resources. Therefore, a call to action has been declared for the effective management of the obesity epidemic (Pronk, 2003). The NHLBI has presented evidence that weight control interventions combining a low-calorie diet, physical activity, and behavior therapy are most effective for weight loss and maintenance (National Heart Lung and Blood Institute, 1998). However, continued examination and improvement of these weight loss interventions is necessary.

One potential avenue for the enhancement of weight loss interventions is through technology-based devices such as the technology-based system used in this study that help to improve self-monitoring and lead to more successful behavioral change. The demand for diversity and flexibility in weight loss treatment support and delivery deserves attention considering research supporting these alternative delivery channels is limited (Bessell et al., 2002). Therefore, the current study offers an original investigation of the effectiveness of a technology-based product that utilizes computer and Internet applications aimed at enhancing self-monitoring, feedback and clinical weight loss treatment interactions. Thus, if it is determined that utilization of the technology-based system used in this study leads to enhanced weight loss, implementation of such devices might be recommended in future weight loss treatment programs.

II. REVIEW OF LITERATURE

Introduction

The purpose of this study was to examine the effectiveness a technology-based system, when used in addition to an in-person standard 12-week behavioral intervention on weight loss in adults. The technology-based system used in this study is an innovative product that might be an effective and appealing supplement for both participants and clinicians when utilized within a clinical weight management treatment environment. This system may be effective from the participant's perspective for two primary reasons, the system allows for enhanced self-monitoring through objective daily energy expenditure measurement and it provides users with detailed energy balance data and related feedback. Both of these factors might promote participants to make greater changes in dietary and exercise behaviors leading to greater weight loss success. From the clinician's perspective, the enhanced self-monitoring data has the potential to augment assessments, improve treatment plans and support education. Therefore, use of the technology-based system may also foster more engaging and effective treatment interactions when it is utilized within a clinical weight management program.

The technology-based system used in this study is a commercially available technology-based product that offers support to clinical weight loss intervention delivery. This delivery format might be an appealing enhancement to standard clinical behavioral

weight loss interventions. Delivery of weight control interventions through alternative channels such as computer and Internet-mediated methods has been reviewed with some favor (Agras et al., 1990; Burnett et al., 1985; Tate et al., 2003; Tate et al., 2001; Taylor et al., 1991; Wylie-Rosett et al., 2001). This literature review provides the results and limitations of these published studies and initiated support for the conducted investigation as a potential enhancement to future weight loss interventions.

Obesity Prevalence

Obesity prevalence has reached epidemic proportions in the United States. Current data indicates that 65% of U.S. adults are classified as overweight or obese, 31% are classified obese, and approximately 5% of adults are considered extremely obese (Hedley et al., 2004). Over the past two decades, the prevalence of overweight (BMI $\geq$ 25 kg/m^2) has increased 40% (from 46.0% to 64.5%) and the prevalence of obesity (BMI $\geq$ 30 kg/m^2) has risen an alarming 110% (from 14.5% to 30.5%) (Flegal, Carroll, Ogden, & Johnson, 2002). In the year 2000, the U.S. Department of Health and Human Services issued Healthy People 2010. In this document a target level for adults at a healthy weight was set at 60%; in 1999-2002, the percentage of adults at a healthy weight was approximately half of this goal ("Healthy People 2010", 2000). It is clear that substantial effort must be focused on effective strategies to attenuate the obesity epidemic.

Research has shown that overweight and obesity are the consequence of many interacting factors, including genetic, metabolic, behavioral, and environmental influences (Stein & Colditz, 2004). However, the rapid increase in overweight and obesity prevalence tends to support behavioral and environmental changes over biological alterations as the primary influences on the obesity epidemic (Stein & Colditz, 2004). A shift in lifestyle

behavior demonstrated by increased energy consumption and decreased energy expenditure through physical activity creates a positive energy balance and resultant weight gain. The specific effects of changes in eating and exercise behaviors on the rising obesity epidemic provide a source of continued debate. However, it is understood that modifications in eating and exercise behaviors along with alterations in environmental cues are essential components of obesity management (Wing, 2002).

Behavioral Obesity Management

Behavioral obesity management aims to identify and modify eating, physical activity, and cognitive habits that contribute to an individual's body weight problem (Wadden & Butryn, 2003). Obesity management interventions often utilize conceptual and behavioral theories or models as important foundations to construct a structured curriculum aimed to promote effective behavioral change. Commonly used theories and models include the Social Cognitive Theory, Theory of Reasoned Action or Planned Behavior and the Transtheoretical Model and Stages of Change (Baranowski, Cullen, Nicklas, Thompson, & Baranowski, 2003). The conducted investigation relied on the relevant constructs of these models for curriculum development. Behavioral intervention curriculum commonly includes several related components such as nutrition and physical activity education and modification, self-monitoring, behavioral reinforcement or feedback, and problem solving (Wadden & Butryn, 2003). The conducted investigation focused on these components to guide weight loss related behavior change. The research-based evidence presented in the following sections provided more specific guidelines for the components and structure used in the conducted investigation.

Dietary Modification

Dietary modification is an essential component of behavioral weight loss interventions. Early research examined the effectiveness of very-low-calorie diets (VLCDs) on weight loss. VLCDs provide 400-800 kcal/day and are typically consumed as a liquid formula or as lean meat, fish, and fowl (Wing, 2002). It was shown that subjects were initially able to lose an average of 20 kg over a 12 week period when utilizing VLCDs (Wadden & Stunkard, 1983). However, VLCDs were expensive, unbalanced and often unsustainable (Wing, 2002). Currently behavioral weight loss interventions advocate a more balanced and less restricted diet consisting of 1,000 to 1,500 kcal/day, depending on initial body weight (Wing, 2002). In addition, research has shown that macronutrient composition is important; a diet that consists of 20-25% dietary fat intake, 55% carbohydrate intake, and 10-25% protein intake aids successful weight control (Jakicic, Marcus, Gallagher, Napolitano, & Lang, 2003; Klem, Wing, McGuire, Seagle, & Hill, 1997) Dietary modifications are often encouraged through the utilization of structured, portion-controlled meal plans (Wing et al., 1996). To accommodate personal preferences and scheduling barriers, the use of meal replacements in combination with whole foods have been shown to assist dietary adherence (Wadden et al., 1997; Wadden, Vogt, Foster, & Anderson, 1998). Therefore, the conducted investigation utilized this established research as a guide to develop dietary modification recommendations.

Physical Activity

Weight loss interventions promote adoption of regular physical activity. To improve health related outcomes, it is recommended that individuals engage in at least 30 minutes of moderate-intense physical activity, on most, preferably all days of the week, commonly

interpreted as striving for 150 minutes of moderate-intense physical activity per week (Pate et al., 1995). Currently there is limited evidence to support the goal of 150 minutes per week for maximizing weight loss and preventing weight regain. It appears that much higher levels of activity are necessary to offer individuals maximum weight loss and weight maintenance (Jakicic & Otto, 2005).

Recently, leading health organizations have produced guidelines that promote engaging in daily physical activity for greater than 30 minutes per day to help manage body weight. The 2005 Dietary Guidelines for Americans recommended that adults achieve 60 minutes of activity on most days of the week, while not exceeding caloric intake requirements, to manage body weight (US Department of Health and Human Services, 2005). The Institute of Medicine (IOM) has recommended 45 to 60 minutes of physical activity per day (Institute of Medicine, 2002) and the International Association for the Study of Obesity (IASO) has recommended 60 to 90 minutes per day (Saris et al., 2003) for successful weight management. Weight loss interventions must also consider the impact the intensity of physical activity on weight loss outcomes and aim to maximize energy expenditure while minimizing musculoskeletal risk (Jakicic & Otto, 2005). In the 2005 Dietary Guidelines it was specified that physical activity be performed at a moderate to vigorous intensity (US Department of Health and Human Services, 2005). Recent behavioral research in overweight women has shown that subjects were able to achieve significant weight loss and improved cardiorespiratory fitness when prescribed dietary modifications similar to the conducted investigation in combination with physical activity that was at least moderate in intensity (rating of perceived exertion of 11-15; 55-70% HR_{max}) and gradually progressed from 20 minutes per day to 40 to 60 minutes per day, 5 times per week (Jakicic et

al., 2003). Thus, the conducted investigation utilized this established research to create exercise adoption guidelines.

Self-Monitoring

Self-monitoring is a vital component of behavioral weight loss interventions (Wadden, 1993; Wadden & Letiza, 1992). Subjects are recommended to keep detailed daily records of their dietary intake, physical activity and body weight. Self-monitoring records can reveal patterns of excess energy intake and periods of reduced energy expenditure. Raising awareness of adverse eating and exercise behavior patterns permits the development of focused intervention strategies. Moreover, consistency of self-monitoring often correlates substantially with weight loss (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998; Wadden & Letiza, 1992). One study has even revealed a causal link between self-monitoring and effective weight control (Sperduto, Thompson, & O'Brein, 1986). Thus, all subjects in the conducted investigation were instructed to monitor their daily energy intake and physical activity.

While self-monitoring appears to be a necessary component of behavior change, research suggests that overweight individuals commonly under-report their energy intake and over-report their energy expenditure (Buchowski, Townsend, Chen, Acra, & Sun, 1999; Buhl, Gallagher, Hoy, Matthews, & Heymsfield, 1995; Irwin, Ainsworth, & Conway, 2001). Therefore, it is critical to continue to develop new and more effective methods to improve the accuracy and consistency of self-monitoring. The conducted investigation explored the self-monitoring process with the use of the technology-based system.

Behavioral Reinforcement and Feedback

Behavioral weight loss interventions are both goal and process-oriented (Wadden & Butryn, 2003). In the conducted investigation subjects were provided with target goals for dietary, physical activity, and self-monitoring behaviors. However, it is well understood that behavioral change is more than guiding individuals to achieve specific dietary and physical activity goals (Wadden & Butryn, 2003). Guidance focused on identifying barriers to change and the development of strategies to overcome these barriers is the foundation of successful behavioral modification. In the conducted investigation, interventionists used strategies such as stimulus control and cognitive restructuring to help subjects overcome personal weight loss barriers.

Treatment Contact

Structured behavioral interventions are typically delivered in group-based, in-person formats with an initial treatment period of 16 to 26 weeks (Wing, 2002). Treatment is usually provided to groups of 10 to 20 individuals during 60 to 90 minute session; these sessions are usually conducted by registered dietitians, behavioral psychologists, or related health professionals (Wadden & Butryn, 2003). Contact with interventionists as well as group members helps to facilitate patient motivation and support the weight loss process. On average, subjects in behavioral weight loss programs are able to achieve a 9 kg weight loss, equivalent to approximately a 10% reduction in initial body weight (Wing, 2002).

Weight loss interventions delivered in an in-person format have been shown to be the most effective treatments available for weight loss (Tate et al., 2001). However, alternative treatment delivery methods including mail (Cameron et al., 1990; Jeffery, Hellerstedt, & Schmid, 1990; O'Loughlin, Paradis, Meshefedjian, & Kishchuk, 1998) telephone (Hellerstedt

& Jeffery, 1997), and television (Meyers, Graves, Whelan, & Barclay, 1996) have produced successful, yet smaller weight loss and related behavior change. Thus, these types of programs offer an important alternative to face-to-face treatment worthy of continued development and investigation (Tate et al., 2001).

Computer and Internet-mediated weight loss interventions are additional alternative and innovative delivery channels that might increase program appeal and potentially increase weight loss success. Computer-based programs have been examined primarily as a method to help enhance the self-monitoring process, while Internet-based interventions have been investigated as a method to increase treatment dissemination and provide a potentially more appealing stand-alone weight loss treatment option. To date research focused on these innovative techniques is limited; yet, existing studies have shown that computer (Agras et al., 1990; Burnett et al., 1985; Taylor et al., 1991; Wylie-Rosett et al., 2001) and Internet-mediated programs (Harvey-Berino et al., 2004; Harvey-Berino et al., 2002; Tate et al., 2003; Tate et al., 2001) are acceptable and can be successful if applied in a structured format similar to in-person treatment programs. Computer and Internet-mediated programs have yet to produce the degree of weight loss achieved by in-person treatment programs. While computer and Internet-mediated programs have aimed to reduce the burden of face-to-face contact, a degree of in-person contact may be necessary to enhance weight loss success in these programs. Therefore, the conducted investigation aimed to draw on the gaps in the existing literature by examining the effectiveness of an innovative technology based-program in addition to an in-person, clinically based behavioral weight loss intervention.

Computer-Mediated Behavioral Weight Loss Interventions

Computer-mediated behavioral weight loss intervention research was initially pursued to examine novel strategies for improving the self-monitoring and feedback processes. Burnett et al. (1985) argued that traditional behavioral weight loss programs utilizing pencil and paper monitoring might delay valuable feedback on goal attainment level for target behaviors. Research has indicated that self-monitoring and related feedback are critical principles of behavioral change (Bandura, 1969). The development of portable hand-held computers presented an opportunity for researchers to examine the potential for these devices to enhance the self-report and feedback processes within a behavioral weight loss intervention. Specifically, it was suggested that portable hand-held computers would allow for more systematic self-report data collection in a natural environment and provide participants with immediate feedback, instructions, and reinforcement (Burnett et al., 1985). In summary, it was implied that computers might enhance "therapeutic interactions" missing from print material (Taylor et al., 1991). Four studies (Agras et al., 1990; Burnett et al., 1985; Taylor et al., 1991; Wylie-Rosett et al., 2001) examining computer-mediated weight loss interventions provide support for implementing similar technology to enhance future interventions. A summary of the results of these studies is presented in Table 2.1.

Table 2.1. Summary of Results for CAT Weight Loss Interventions

Study (treatment duration)	Intervention Groups	In-person contact	Weight loss (kg)	Physical Activity Change	Dietary Change	Self-monitoring frequency
Burnett et al. (1985) (8 wk)	CAT SBT	Yes Yes	3.7*† 1.5*	Yes* Yes*	Yes* Yes*	N/A
Agras et al. (1990) (12 wk)	CAT + support CAT no support SBT	Yes No Yes	2.3* 2.6* 1.8*	N/A	Yes* Yes* Yes*	70%† 29% 29%
Taylor et al. (1991) (12 wk)	CAT WL+CAT	Yes Yes	3.1* 5.3*†	Yes* Yes*	Yes* Yes*	50% 50%
Wylie-Rosett et al. (2001) (12 mo)	W W+C W+C+S	No No Yes	2.2* 4.7* 7.4*† (vs.W)	Yes*‡ Yes*‡ Yes*‡	Yes*‡ Yes*‡ Yes*‡	 ‡ ‡

CAT= Computer assisted therapy group.
SBT= Standard behavioral treatment group.
WL+CAT=Weight loss followed by CAT.
W= workbook only; W+C= workbook + computer.
W+C+S= workbook + computer + staff.
* Significant difference from baseline.
† Significant difference between groups; ‡ Significant correlation with weight loss.

Computer-Based versus Paper-Based Self-Monitoring

Burnett et al. (1985) aimed to examine the feasibility of using a portable microcomputer system within an 8-week weight loss program. Six female subjects (89±13.1 kg; 43.2±8.8 years of age) were assigned to an experimental group and six matched (on estimated body fat) female subjects (84.1±10.9 kg; 39.8±5.5 years of age) were assigned to a control treatment.

Subjects in the experimental group utilized an ambulatory computer-assisted therapy (CAT) program to make self-reports on 1) consumption of food between meals, 2) consumption of food at meals, and 3) exercise. The apparatus was a portable, lap-sized computer system developed specifically for the research study. Subjects received feedback following self-reports of caloric intake and physical activity. Subjects were prompted to log their data every four hours by an auditory beep. In addition, the computer provided

contingent praise and instructions. Based on goal attainment, the computer also prompted subjects to set higher goals for the following day.

Subjects in the control group used paper-and-pencil methods for self-monitoring, goal setting, and feedback. Control subjects had to determine values of caloric intake using a provided reference guide, these subjects were not cued to log data nor did they receive contingent praise or instructions.

Subjects in both groups monitored target behaviors four days per week. At set time points subjects were encouraged to set more ambitious goals for decreasing caloric intake ($\geq$1000 kcal/day) and increasing physical activity. To supplement the monitoring process, subjects in both groups met individually with a therapist for weekly 15-minute sessions to discuss progress.

Weight loss was significantly greater in the experimental group compared to the control group, (3.7 ± 1.2 kg and 1.5 ± 1.5 kg, respectively; $p<0.05$). When considered separately, caloric intake and physical activity change were not significantly different between groups. However, a significant difference ($p<0.05$) between groups was found when caloric and physical activity change scores were combined (using standardized Z scores) as an index of change in weight-related behaviors. Subjects in the experimental group showed a greater change in the index of weight related behaviors compared to the control group.

Interpretation of the results was cautioned due to the small sample size and the short intervention duration; however, investigators concluded that computer assisted weight loss treatment might function to aid individuals in learning to control their weight-related behavior more effectively and expeditiously through enhanced self-monitoring and feedback

of dietary and exercise behavior change. In the conducted investigation subjects utilized the technology-based system as a dietary and exercise self-monitoring tool.

Computer Assisted versus Standard Behavioral Weight Loss Therapy

Agras et al. (1990) aimed to examine the utility of CAT with or without group support versus group based standard behavioral therapy. Active treatment was 12 weeks in duration and subjects participated in follow-up assessments after one year. Ninety overweight women (BMI=29.7$\pm$4.3 kg/m^2; 45.2$\pm$12.4 years of age) were randomly assigned to one of three treatment conditions: 1) CAT with one introductory session and four follow-up group sessions (CAT with group support), 2) CAT with one introductory session (CAT without group support), or 3) behavior therapy conducted in 10 in-person sessions over the intervention.

Investigators aimed to examine the differences in body weight and the differential cost in treatment delivery. The portable computer was similar to the apparatus used by Burnett et al. (1985); however, updated features allowed for meal planning and various cognitive behavioral cues were added to motivate improvements in eating behavior control. The group assigned to the behavior therapy condition did not utilize CAT but they were encouraged to self-monitor and their treatment sessions focused on strategies to modify eating and exercise behaviors. All subjects were encouraged to consume a minimum of 1200 kcal/day and exercise from 20-45 minutes three or more times per week.

Weight loss from pre to post-treatment for all three groups was significant (2.19 kg; $p<0.001$), yet weight loss was not significantly different between groups. Eating patterns and eating behaviors were significantly improved in all groups; however, no differences were found between groups. At the one-year follow-up no significant differences in weight loss

were detected between groups. Despite the relatively low weight losses in all three groups the authors indicated that computer assisted therapy has merit as a tool to support behavioral weight loss. Self-monitoring frequency tended to be higher in the group assigned to CAT with group support suggesting that adherence to treatment goals might be facilitated through a combination of computer-based technology and in-person support. In the conducted investigation the technology-based system was used to supplement an in-person weight loss intervention.

Weight Loss Initiated Computer Assisted Therapy

Taylor et al. (1991) aimed to investigate factors that might produce greater weight loss using computer-assisted therapy. The computers used for this intervention had greater memory and a larger screen. These features permitted the development of a program with enhanced feedback and monitoring compared to the previously reviewed studies. In addition, the introduction of portion-controlled frozen foods was seen as a potentially beneficial strategy to promote a structured 1200-calorie guided weight loss program.

Fifty-seven overweight women (BMI=25-35 kg/m^2; 43.7$\pm$11.1 years of age) were randomized to one of two experimental groups: 1) Computer assisted therapy only (CAT only), or 2) Weight loss through a prescribed 1200 calorie diet (guided weight loss program) followed by CAT (WL+CAT). Active treatment lasted 12 weeks and a six-month follow-up was performed. The CAT only group received 4 group sessions to supplement computer use. The CAT only group received feedback and weight loss reinforcement and was encouraged to implement the guided weight loss program only if weight loss was not within goal range. The WL+CAT subjects were instructed to first use the guided weight loss program until they lost 8-10 pounds or until reaching week 5 of treatment, then they were instructed to

implement the computer program. All subjects were prescribed a gradually progressing exercise program.

At the completion of active treatment attrition was 14% in the CAT group and 4% in the WL+CAT group; it was not determined whether attrition was significantly different between groups. Weight loss was significantly greater in the WL+CAT group compared to the CAT group, (5.3$\pm$2.2 kg and 3.1$\pm$2.2, respectively; $p<0.001$); these differences remained significant at follow-up. Daily caloric intake and weekly exercise duration was not significantly different between groups. However, follow-up data showed that the WL+CAT group was performing significantly more exercise compared to the CAT only group ($p<0.002$). Adherence to self-monitoring began at approximately 90% of the recommended amount and decreased to 50% by the 12th week; self-monitoring adherence did not differ between groups.

The results of this study suggest that computer assisted therapy might not be necessary to enhance weight loss; however, the investigators gave merit to the potential utility of computer assisted therapy as a support to weight loss processes. In addition to supporting dietary and physical activity changes, investigators suggested that the computer could make therapist contact more efficient and effective. Self-report data retrieved from the computer might help to facilitate discussion related to barriers impeding dietary and physical activity behavior change. In the conducted investigation, interventionists utilized the energy balance data retrieved from the technology-based system during discussions with patients in intervention sessions.

Computer Assisted Therapy and Intervention Intensity

Wylie-Rosett et al. (2001) aimed to evaluate weight-loss outcomes, the effect on CVD risk factors, and the costs associated with a 12-month cognitive behavioral weight loss intervention delivered at three varying intensity levels. This study was conducted within a freestanding Health Maintenance Organization (HMO); thus, subjects were members of the HMO's patient population.

At baseline, 588 subjects were randomized to one of three treatment groups: 1) Workbook only (least intensity) (n= 116; BMI=36.5±6.0; 52.5±11.50 years of age), 2) Workbook + computer (intermediate intensity) (n= 236; BMI=35.7±6.7; 52.7±11.27 years of age), or 3) Workbook + computer + staff (most intense) (n= 236; BMI=35.16±6.5; 51.6±12.14 years of age). The three groups were designed to imitate self-help, non-clinical and clinical treatment approaches to weight management. The least intensive intervention group was provided with a workbook developed for the study (Wylie-Rosett, Swencionis, Caban, Friedler, & Schaffer, 1997). The intermediate and most intensive intervention groups utilized an on-site computer software program that was developed to guide subjects in using "The Complete Weight-loss Workbook", aid them in the development of tailored behavioral goals, and identify individual problems and potential strategies to overcome behavioral change barriers. Specifically, the software program addressed nutrition, fitness, and psychobehavioral attributes of weight loss. Recommendations for behavior change were made based on previous computer use and individual responses to the related validated questionnaires. Subjects were required to login weekly for the first 3 months and monthly thereafter. The most intensive intervention group also received staff support which included 6 closed-group sessions and up to 18 telephone or face-to-face consultations with a registered

dietitian and/or cognitive behavioral therapist. This additional staff support was aimed to reinforce behavior change, computer and workbook use.

Subjects were assessed at 0 and 12 months. During this time all groups achieved a significant reduction in body weight with the most intense group achieving a significantly larger weight loss compared to the least intense group (7.4$\pm$1.15 kg and 2.2$\pm$1.26 kg, respectively; $p<0.02$). All groups reported a significant reduction in energy intake, percent of energy intake from fat ($p<0.01$), and a mean increase in physical activity ($p\leq0.01$). Eating and physical activity behavior changes were correlated with weight loss; however, these behavioral changes were not significantly different between groups. Subjects utilizing the computer were more likely find value in keeping diet and physical activity records and these self-monitoring processes were associated with greater weight loss. Subjects in the most intensive group reported that the addition of staff support was a valuable resource for success. The conducted investigation utilized in-person support in addition to the technology-based system to mimic a clinical treatment environment, aiming to maximize treatment contact and enhance weight loss.

Summary of Computer-Mediated Weight Loss Interventions

In summary, the results of these computer-mediated interventions do not provide conclusive evidence that computer assisted therapy enhances weight loss. However, the utilization of computer assisted therapy within a structured behavioral weight loss intervention might serve as a valuable tool. The conducted investigation aimed to advance upon the existing computer assisted therapy research findings by using the technology-based system to facilitate the self-monitoring process. This system allows participants to track energy intake and it objectively monitors energy expenditure. Energy balance data provided

by the system is seen as enhanced feedback compared to the feedback format provided by the reviewed computer-mediated studies. This enhanced feedback might prompt subjects to be more persistent to behavior change processes that might ultimately improve weight loss. The energy balance data may also serve as a tool to enhance treatment interaction. In the conducted investigation interventionists received access to subject's energy intake and expenditure data prior to in-person visits. This information was used as a tool to discuss strategies to improve subject compliance to dietary and exercise treatment goals.

Computer-assisted therapy might also help participants adhere to treatment goals. It is essential to consistently examine process related measures that represent treatment adherence including self-monitoring and program attendance. Moreover, research studies must determine the relationship of these variables with weight loss. The conducted investigation measured the duration of armband use, number meals logged using the technology-based system (total, full entry, and user estimated), number of BALANCE diaries submitted with dietary and exercise data logged, and attendance at in-person sessions to determine if any correlations existed between these process measures and weight loss.

While computer-mediated weight loss interventions appear promising, these interventions might be more effective on weight loss outcome when used as a supplement to an in-person treatment program. Wylie-Rosette et al. (2001) showed that weight loss outcome was most successful in the group receiving staff support in addition to computer support. In the conducted investigation the technology-based system was used to supplement an in-person weight loss intervention.

Internet-Mediated Weight Loss Interventions

The studies reviewed in the previous section served as the first phase in examining the potential benefits of technology-assisted weight loss treatment programs. In line with advancing technology, it has been suggested that computer based programs can be adapted for use via the Internet (Tate et al., 2001). Thus, Internet-mediated interventions have become the next logical phase in exploring the effectiveness of technology-based weight loss interventions. An astounding 69% of U.S. adults report accessing the Internet regularly from home, work, school or another location (Taylor, 2004). With this statistic in mind, it is reasonable to consider the Internet as a valuable way to increase dissemination of weight loss treatment programs. Furthermore, some individuals might prefer the Internet over face-to-face treatment as it might be seen as a more convenient and less intimidating treatment mode (Harvey-Berino et al., 2002).

The Internet might have several additional advantages for enhancing weight loss interventions such as, permitting individuals with enhanced monitoring strategies, providing individuals with more detailed feedback regarding weight loss behaviors, and allowing interventionists to download an individual's logged energy intake and expenditure serving to enhance future treatment interactions. Few research studies have explored the potential utility of Internet-mediated weight loss interventions (Tate et al., 2003; Tate et al., 2001; Womble et al., 2004). The results from these studies are summarized in Table 2.2.

Table 2.2. Summary of Results for Internet-Mediated Weight Loss and Maintenance Interventions

Study (treatment duration)	Intervention Groups	In-person contact	Weight loss (kg)	Physical Activity Change	Dietary Change	Self-monitoring frequency	Login frequency/ attendance
Tate et al. (2001) (6mo.)	IE IBT	Initial visit + 2 check-ins both groups	1.3 2.9*†	Yes* Yes*	Yes* Yes*	N/A 13.65‡ (total)	9.5‡ 25.8†‡ (total)
Tate et al. (2003) (12 mo)	BI IBEC	Initial visit only	2.0 4.4*†	Yes* Yes*	Yes* Yes*	N/A N/A	3‡ 6†‡ (mean/mo)
Womble et al. (2004) (12 mo)	manual eDiets.com	6 visits, both groups	3.3† 0.8	N/A	Yes* Yes*	29‡ 18.3‡ (16 wk total)	17.7 (16 wk total)
Harvey-Berino et al. (2002) (22 wk)	Control In-person Internet	No Yes No	1.6 1.6 1.6	N/A No No	N/A No No	N/A 45% 38%	N/A 58%† 33%
Harvey-Berino et al. (2002) (12 mo)	Internet F-IPS M-IPS	No Yes Yes	+2.2† 0 0 (6 mo)	No No No	No No No	19% 22% N/A	39% 54%† N/A
Harvey-Berino et al. (2004) (12 mo)	Internet F-IPS M-IPS	No Yes Yes	0 0 0	No No No	No No No	18.6† 11.6 N/A	7.7 10† N/A

IE= Internet education group.
IBT= Internet behavioral therapy group.
BI= Basic Internet.
IBEC= Internet plus behavioral e-counseling.
F-IPS= frequent in-person support.
M-IPS= minimal frequent in-person support.
*Significant difference from baseline.
†Significant difference between groups.
‡Significant correlation with weight loss.

Short-term Internet-Mediated Weight Loss Intervention

Tate et al. (2001) published one of the first studies examining Internet technology to deliver a weight loss intervention. The aim of this study was to test the feasibility and initial efficacy of a structured Internet-mediated behavioral weight loss intervention compared with an educational Web site designed to represent weight loss resources available on the Internet. It was hypothesized that a 6-month Internet-mediated intervention would result in greater

weight loss compared to an education Web site, as the Internet-mediated behavioral intervention was designed to mimic the programmatic nature, structure, and professional contact provided in face-to-face clinical programs.

A total of 91 overweight adult hospital employees (81 women, 10 men; BMI=29.0±3.0 kg/m^2; 40.9±10.6 years of age) were randomized into one of two treatment groups: 1) Internet education (education; n=45) or 2) Internet behavior therapy (behavior therapy; n=46). Subjects in the education group were given access to the study Web site that provided a review of weight loss information and a directory of selected Internet resources related to diet, exercise, self-monitoring, and behavioral topics such as social support, stimulus control and stress management. Subjects in the education group also received an initial face-to-face group lesson during which they were recommended to consume an energy restricted diet consisting of 1200-1500 kcal/day and a daily fat intake of less than 20% of total energy intake and to increase their physical activity to expend a minimum of 1000 kcals/wk.

Subjects in the behavior therapy group received all of the resources provided to the education group; however, these subjects were also instructed to submit self-monitored dietary intake and physical activity along with any questions to the study Web site. Subjects in this group also received a weekly e-mail message from a therapist that included a behavior lesson, feedback and reinforcement based on their progress. To promote social support among subjects in the behavior therapy group, these subjects were encouraged to post comments and concerns to fellow subjects on an electronic bulletin board. All subjects met with a clinical psychologist at 3 and 6 months for a brief check-in.

Subjects in both groups were assessed at 0, 3 and 6 months. Attrition was 15% at 3 months and 22% at 6 months. Repeated-measures analysis of variance (ANOVA) on the pattern of weight loss showed a significant treatment by time interaction ($p<0.001$). Weight loss was significantly greater in the behavior therapy group compared to the education group at 3 (3.2 ± 2.9 kg vs. 1.0 ± 2.4 kg; $p<0.001$) and 6 months (2.9 ± 4.4 kg vs. 1.3 ± 3.0 kg; $p=0.04$). In addition, repeated-measures ANOVA on the pattern of change in waist circumference showed a significant treatment-by-time interaction ($p<0.001$) ($p=0.004$), with the behavior therapy group achieving greater reductions at 3 (5.3 ± 4.9 cm vs. 2.1 ± 3.9 cm; $p=0.001$) and 6 months (4.6 ± 5.5 cm vs. 2.3 ± 3.9 cm; $p=0.02$). During the study both groups significantly reduced their caloric intake ($p<0.001$) and increased their physical activity ($p=0.03$); however, these changes were not significantly different between groups.

The behavior therapy group logged on to the Web site more frequently than the education group at 3 and 6 months ($p<0.001$ at both time points). Login frequency was significantly correlated with weight change in both the behavior therapy group ($r_s=-0.43$; $p=0.003$) and in the education group ($r_s=-0.33$; $p=0.03$). Finally, within the behavior therapy group, total number of diaries submitted was significantly correlated with weight loss ($r_s=-0.50$; $p=0.001$)

Based on these results, investigators concluded that the Internet appears to be a viable delivery channel for structured behavioral weight loss programs. Since self-report diary submissions correlated with weight loss, it was stated that the Internet might serve as a resource to promote consistent behavioral self-monitoring. These findings provided support for the conducted investigation to utilize the Internet to promote dietary and physical activity self-monitoring. In addition, it appears that it is important to promote exposure to

intervention resources (suggested by login frequency). Therefore, the conducted investigation aimed to follow these established research findings by encouraging subjects to attend all intervention meetings and to consistently follow group specific treatment guidelines.

Extended Internet-Mediated Weight Loss Intervention

Tate et al. (2003) conducted a 12-month randomized trial examining the effects of an Internet-mediated weight loss intervention in adults at risk for Type 2 diabetes. Eligible subjects had to be overweight or obese and have 1 or more other risk factors for type 2 diabetes. Ninety-two subjects (82 women, 10 men) were randomly assigned to one of two treatment groups: 1) basic Internet weight loss program (basic internet; n= 46; BMI=33.7$\pm$3.7 kg/m^2; 47.3$\pm$9.5 years of age), or 2) Internet weight loss program plus behavioral electronic counseling (behavioral e-counseling; n= 46; BMI=32.5$\pm$3.8 kg/m^2; 49.8$\pm$9.3 years of age). All subjects attended an introductory group session during which they were recommended to follow specific dietary (1200-1500 kcal/day; fat intake $\leq$20% of energy intake) and exercise (minimum energy expenditure of 1000 kcal/wk) guidelines. In addition, all subjects were encouraged to self-monitor dietary and exercise behaviors, yet only the behavioral e-counseling group was required to submit this data.

The protocol for the two experimental groups in this study differed slightly from the study reviewed previously by in by Tate et al. (2001). Subjects in the basic Internet group were given access to a study Web site that was similar in content to the study reviewed previously by in by Tate et al. (2001). However, in this study subjects in both groups were also instructed to submit a weekly body weight measurement and in turn received weight loss information. In addition, subjects in the behavioral e-counseling group were required to

report calorie and fat intake, exercise energy expenditure and any comments daily for the first month and daily or weekly thereafter. Behavioral e-counseling subjects received e-mail from therapists 5 times per week for the first month and then 1 time per week, thereafter. The e-mail message included a behavior lesson, feedback and reinforcement based on their progress.

Subjects in both groups were assessed at 0, 3, 6, and 12 months. Adherence was 84% at 12 months of participation. Weight loss at 12 months was significantly greater in the behavioral e-counseling group compared to the basic Internet group (4.4±6.2 vs. 2.0±5.7; p=0.04); this pattern of weight change for subjects who completed the 12-month assessment was similar at 3 and 6 months. Subjects in the behavioral e-counseling group also had a greater reduction in percentage of initial body weight (4.8% vs. 2.2%; p=0.03), BMI (1.6±2.2 kg/m^2 vs. 0.8±2.1 kg/m^2; p=0.03) and waist circumference (7.2±7.5 cm vs. 4.4±5.7 cm; p=0.05) compared to the basic Internet group.

Both groups reported a significant reduction in caloric intake ($p<0.001$) between 0 and 12 months; however, these variables were not significantly different between groups. Mean increase in exercise energy expenditure did not differ from 0 to 12 months; however, between group differences were found from 0 to 3 months (behavioral e-counseling > basic internet; p=0.02). Finally, Web site login frequency was significantly higher in behavioral e-counseling subjects ($p<0.05$) and login frequency was significantly correlated with weight change between 0 and 12 months in both groups (behavioral e-counseling, r=-0.47, p=0.003; basic internet r=-0.61, $p<0.001$).

Investigators concluded that the addition of therapist contact in the form of e-counseling improves the efficacy of a basic Internet weight loss intervention. It was

suggested that Internet-mediated weight loss programs offer an alternative delivery channel that is worthy of future investigation. The weight-loss produced in this study was less than group face-to-face treatment; therefore, it was recommended that future studies aim to determine the optimal combination of Internet and face-to-face interventions. A degree of treatment contact may be an important factor in weight loss success. In the conducted investigation the technology-based system was used to supplement an in-person weight loss intervention.

Commercialized Internet-Mediated Weight Loss Program

Womble et al. (2004) examined 12-month weight loss in subjects randomly assigned to a commercialized Internet weight loss program or a weight loss manual. It was hypothesized that the Internet weight loss program would result in greater weight loss compared to the group receiving the weight loss manual due to the social support promoted by on-line meeting and bulletin board.

At baseline, 47 overweight women (BMI=33.5$\pm$3.1 kg/m^2; 43.7$\pm$10.2 years of age) were randomly assigned to one of two groups 1) commercialized Internet weight loss program (eDiets.com; n=23), or 2) a weight loss manual (manual; n=24). Subjects in the eDiets.com group were given access to the Web site, which provided a virtual visit with a dietitian. The dietitian prescribed a restricted calorie diet based on BMI (1200-1400 kcal/day). In addition, subjects were given tailored physical activity recommendations based on baseline self-described activity levels. Subjects in the eDiets.com group also received access to on-line professionally-led meetings, support groups, a virtual fitness trainer, e-mail reminders about the program goals, and bi-weekly diet and fitness e-newsletters. Subjects in

the eDiets.com group met with a psychologist on-site at 0, 8, 16, 26, and 52 weeks for 20 minutes to review treatment goals, methods, progress and satisfaction.

Subjects in the weight loss manual group received a copy of the *LEARN Program for Weight Management* (Brownell, 2000). This manual promotes a step-by-step process for modifying eating, exercise, and cognitions. Specifically, the manual encourages subjects to consume a restricted diet (1200-1500 kcal/day), increase physical activity (walking up to 30min/day), keep a record of food intake (for 16 weeks, similar to eDiet.com), and practice weight control behaviors. After 16 weeks, subjects in this group were provided the *Weight Maintenance Survival Guide* (Brownell & Rodin, 1990) which reinforced concepts presented in the *LEARN Program*. Subjects in the manual group also met with a psychologist on the same schedule as eDiets.com subjects.

Outcome measures were reported at 0, 16, and 52 weeks. Attrition was 34% at both 16 and 52 weeks; this rate did not differ between groups. A repeated measured ANOVA using last observation carried forward (LOCF) analysis, revealed a significant treatment-by-time interaction for weight loss ($p=0.02$). Subjects in the eDiets.com group lost significantly less weight at week 16 (0.7 ± 2.7 kg vs. 3.0 ± 3.1 kg; $p=0.01$) and 52 (0.8 ± 3.6 kg vs. 3.3 ± 4.1 kg; $p=0.04$). A similar pattern of results for weight loss was shown with baseline carried forward (BCF) analysis; however, the group differences were not significant with this analysis.

In terms of behavioral adherence, attendance at scheduled visits with the study psychologist did not differ between groups; however, a significant decrease was detected after 16 weeks ($p<0.001$). Total meeting attendance ($r=0.41$; $p=0.004$) and the number of food records kept at week 16 ($r=0.65$; $p<0.001$) and 52 ($r=0.40$; $p<0.006$) were correlated

with weight loss. While login frequency was not correlated with weight loss, a median split analysis revealed that subjects in the high login group lost significantly more weight at weeks 16 and 52 ($p<0.02$).

Investigators offered two potential reasons for why the results differed from their hypothesis. First, analysis indicated that subjects in the eDiets.com group made minimal use of their provided resources. Second, it was suggested that eDiets.com appeared to be less structured compared to the LEARN approach; for example, self-monitoring was not emphasized with eDiets.com. On site visits were held to promote retention; however attrition rates in this study were high, investigators assumed that this was influenced by the minimal weight loss associated with each program. In conclusion, it was recommended that future Internet-mediated interventions include practices found to enhance weight loss in more traditional weight loss programs such as, self-monitoring, personalized feedback and accountability.

The results from this study encourage adherence to essential components of behavioral weight management including self-monitoring frequency and dietary and physical activity change within Internet-mediated programs. In addition, a degree of in-person contact might be necessary to enhance weight loss outcome in these programs. Together, these essential components reinforce weight loss related behavior modification; therefore, the conducted investigation utilized these established research findings to recommend adherence to treatment goals through consistent in-person meeting attendance and self-monitoring. In addition, it is apparent that weight loss programs must be delivered in a structured manner to efficiently guide participants through behavior change processes. The conducted investigation intended to use relevant constructs from behavioral theories and models such as

the Social Cognitive Theory, Theory of Reasoned Action or Planned Behavior and the Transtheoretical Model and Stages of Change to guide the development of program curriculum and treatment interaction.

Summary of Internet-Mediated Weight Loss Interventions

The Internet appears to be capable for the delivery of structured weight loss interventions. Internet-mediated interventions might be useful in targeting certain individuals that prefer this delivery mode over face-to-face interventions. However, some individuals may need a certain degree of in-person contact and might respond better to an intervention that uses the Internet as a supplement to a standard behavioral weight loss intervention. Further exploration must be performed to understand for whom Internet-mediated treatment is most appropriate and to what degree the Internet can be utilized to deliver weight loss treatment. Within these studies it is important to describe the treatment approval and participant characteristics among responders and non-responders. To evaluate the effect of the technology-based system on weight loss, the conducted investigation employed a standard behavioral weight loss group (SBWP) and examined descriptive statistics for program approval and demographics across treatment groups.

The Internet might also serve to promote behavior change processes within weight loss interventions, including self-monitoring, and dietary and physical activity modification. To further understand the benefits of Internet-mediated interventions future investigations need to examine more objective measures of behavioral change. The studies by Tate et al. (2001, 2003) were not able to detect a difference in self-reported eating and exercise behaviors; however, weight loss was significantly different between treatment groups. Objective outcome measures such as change in cardiorespiratory fitness might help to

understand the discrepancies between self-reported behavior change and weight loss outcome. The conducted investigation included objective measures of body weight and fitness at baseline and at the end of treatment to enhance the evaluation of the technology-based system as an effective tool for use in structured weight loss interventions.

Internet-Mediated Weight Maint+enance Interventions

The potential benefit Internet-mediated interventions to support weight loss maintenance has been examined in three similar studies (Harvey-Berino et al., 2002; Harvey-Berino et al., 2004; Harvey-Berino et al., 2002). In all three studies the effect of Internet support on weight loss maintenance was compared to in-person support. Subjects attended weekly 1-hour meetings for 15-24 weeks; these meetings were conducted in-person or over interactive television (ITV). During weight loss treatment, all subjects were instructed to restrict and monitor their energy intake (1000-2500 kcal/day, based on body weight) and were given graded goals for programmed physical activity. A summary of the results from these studies is presented in Table 2.2.

Short-term Internet-Mediated Weight Loss Maintenance Program

Harvey-Berino et al. (2002) aimed to assess the feasibility and acceptability of conducting an Internet-mediated weight maintenance program. Forty-six participants (BMI=33.7$\pm$4.6 kg/m^2; 46.3$\pm$7.4 years of age; 80.4% female) began the initial weight loss program. Following 15 weeks of in-person weight loss treatment, average weight loss was 6.4$\pm$5.6 kg. Only 2 subjects dropped out after initial treatment; the remaining subjects were randomly assigned to one of three maintenance conditions: 1) no treatment control (C), 2) in-person therapist-led (TL), or 3) Internet.

Over the 22-week maintenance program, the TL group (n=14) met in-person on a bi-weekly basis and received telephone calls on alternate weeks. TL subjects were required to submit self-monitoring diaries and took part in a social-influence peer-support program. The Internet group (n=15) attended bi-weekly meetings in the form of an Internet chat session that was facilitated by a group therapist, during alternate weeks subjects in this group received an e-mail from the group therapist. Internet group subjects submitted self-monitoring data on the study's Web site and also took part in an Internet-mediated social-influence peer-support program.

During the maintenance condition, change in body weight from baseline was not significantly different between groups; on average, subjects lost 1.6 kg during the 22-week maintenance phase. Changes in BMI, diet and exercise were also not significant between groups. TL subjects attended more meetings compared to the Internet group ($p<0.005$). Subjects in both groups submitted a similar percentage of self-monitoring diaries and peer support contact was similar between groups. Overall subjects in the TL group were satisfied with their group assignment, only 9% would have preferred the Internet group. On the other hand, Internet group subjects were undecided about group preferences and overall group success. Moreover, approximately half of Internet group subjects felt they would have personally done better if they had met in-person.

Feasibility of using an Internet-mediated behavioral intervention was evaluated by tracking recruitment numbers; 64% of the usual patient pool was determined to be eligible for this study. In combination with the results presented above, investigators concluded that the Internet is a feasible delivery channel for a weight maintenance program though it is viewed as less acceptable compared to in-person treatment. It was speculated that the

acceptability of the Internet was affected by the quality of interpersonal interactions; however, the Internet did provide an opportunity for participants to keep in touch with one another.

The investigators propose that the decrease in satisfaction might have been because subjects in the Internet group were accustomed to in-person interaction and also that their expectations related to success decreased following the removal of this interaction format. The conducted investigation examined the effectiveness of an Internet-assisted weight loss intervention in conjunction with in-person support to evaluate the combined influence of both delivery channels.

Long-term Internet-Mediated Weight Maintenance Program

Harvey-Berino et al. (2002) examined maintenance of weight loss between an Internet group and 2 differing in-person support groups. It was hypothesized that Internet use would better support long-term contact; thus, resulting in more successful weight maintenance. The design of this study was similar to the previously reviewed study, such that all subjects participated in an in-person 24-week weight loss intervention, followed by a 12-month weight maintenance program. One hundred and twenty-two (104 women, 18 men) overweight adults (BMI=32.2$\pm$4.5 kg/m^2) began the initial weight loss intervention. Components and recommendations of the weight loss intervention were similar to the previously reviewed study Harvey-Berino et al. (2002). Following initial treatment subjects were randomized to one of three treatment groups: 1) Internet support (IS; n=40), 2) in-person support (F-IPS; n=41), or 3) minimal in-person support (M-IPS; n=41).

Details of the F-IPS and IS maintenance groups were similar to the respective TL and Internet conditions described in the previously reviewed study by Harvey-Berino et al.

(2002). The M-IPS maintenance group met in-person, monthly, for the first 6 months of the 12-month maintenance program; no contact was made with this group from months 7-12. The M-IPS group was encouraged to keep self-monitoring diaries, although the investigators did not collect diaries.

Over the initial 24-week weight loss intervention, subjects lost a significant amount of weight (9.5±5.9 kg); when analyzed by maintenance condition weight loss was similar across groups. Following initial weight loss intervention attrition was 18% and 24% over the 18-month study. During the first 6 months of the maintenance program, subjects in the IS group gained significantly more weight than the F-IPS group (+2.2±3.8 kg vs. 0±4 kg; $p=0.05$). IS group subjects sustained a significantly smaller weight loss than both the M-IPS and F-IPS groups at the end of the program (-5.7±5.9 kg vs. -10.4±9.3 kg vs. -10.4±6.3 kg; $p<0.05$ for IS, M-IPS and F-IPS groups, respectively). Weight loss was not significantly different between the M-IPS and F-IPS groups at any point. All groups significantly decreased energy intake during the initial 24-week treatment ($p<0.001$) and this value remained below baseline and at the end of the study ($p<0.001$). Likewise, all groups increased physical activity during the initial 24-week treatment ($p<0.001$), with physical activity level remaining above baseline and at the conclusion of the study ($p=0.008$). Differences in energy intake and physical activity were not significantly different between groups.

In relation to adherence to program goals, the F-IPS group attended more meetings ($p=0.04$) and reported more peer support contacts ($p=0.02$) than the IS group over the maintenance program. There was no difference in percentage of self-monitoring data between the F-IPS and M-IPS groups. Group acceptability was assessed in the IS and F-IPS

groups following initial weight loss treatment and 6 months of the weight maintenance program. Initial acceptability assessment revealed that slightly over one-third of subjects in both groups would have preferred to be assigned to the opposing group. Yet, after 6 months of maintenance twice as many IS subjects reported preference for in-person meetings, where as subjects in the in-person condition did not change their preference.

Investigators offered two potential explanations for their results. First, attendance was lower in the IS vs. F-IPS groups. Second, treatment satisfaction and expectations decreased in the IS group with removal of face-to-face contact. It was originally proposed that on-line meetings would be more convenient compared to the burden of traveling to the study site; however, this assumption did not appear to benefit meeting attendance. As stated previously, the conducted investigation will aim to maximize the benefits from Internet and in-person delivery channels by combining these treatment modes. In addition, investigators suggested that the Internet would offer a less anxiety-provoking environment; yet, it did not appear that the Internet was able to offer the quality interpersonal interactions attained with in-person group meetings. Weight loss success has been the most effective when delivered in an in-person format most likely due to the value of interpersonal interactions; therefore, the conducted investigation aimed to follow this established research by examining the effectiveness of a technology-based system when utilized within and in-person behavioral weigh loss treatment environment.

Expanded Delivery of an Internet-Mediated Weight Maintenance Program

Harvey-Berino et al. (2004) aimed to expand on the previously reviewed studies by examining the effectiveness an Internet-mediated weight maintenance program among a larger sample of overweight and obese adults. Two hundred fifty-five overweight or obese

(BMI=31.8±4.1kg/m^2; 45.8±8.9 years of age) men and women (n=46 and 209, respectively) initially participated in a 6-month weight loss intervention. Details of the weight loss intervention were similar to the previously reviewed study by Harvey-Berino et al. (2002), with the exception that this intervention was delivered over ITV. Following the weight loss intervention, subjects were randomly assigned to one of three weight maintenance groups: 1) IS (n=77), 2) F-IPS (n=77), or 3) M-IPS (n=78). Details of the maintenance program were identical to the previously reviewed study by Harvey-Berino et al. (2002); however the F-IPS and M-IPS conditions were delivered over ITV. Despite the results from the previously reviewed study by Harvey-Berino et al. (2002), it was hypothesized that the IS group would be more successful during the weight maintenance phase.

Over the initial 24-week weight loss intervention, subjects lost a significant amount of weight (7.8±5.3 kg); when analyzed by maintenance condition, weight loss was similar between groups. Following initial weight loss intervention, attrition was 9% and 24% over the 18-month study. Attrition was higher, although not statistically different, in the IS group compared to the F-IPS or M-IPS groups. All subjects were able to maintain a significant reduction in body weight from baseline ($p<0.001$), but no significant difference in maintenance of weight loss by condition was detected.

Examination of adherence to treatment goals showed subjects in the in the F-IPS group attended significantly more maintenance group meetings ($p=0.02$). Subjects in the IS group submitted more self-monitoring diaries ($p<0.01$) and reported significantly more peer support contacts ($p<0.01$) compared to the F-IPS group. All groups achieved a significant reduction in energy intake ($p<0.01$) and an increase in physical activity ($p<0.001$), these values were not significantly different between groups.

Investigators acknowledged that the results from this study directly contrast the findings of the previously reviewed study by Harvey-Berino et al. (2002). Following additional analysis, it was suggested that this contrast was primarily due to the lower performance of the in-person groups in this study compared with a better performance of the IS group. Investigators speculated that the effectiveness of an ITV-mediated intervention, although previously shown to be successful (Harvey-Berino, 1998), might have diminished the achievement of the in-person groups in this study. The conducted investigation held behavioral in-person sessions to create valuable inter-personal relationships between the subject and the interventionist. It was believed that this interaction would help subjects gain confidence and address personal barriers related to behavior change.

In addition, the investigators point to the high attrition rate as a probable influence on the results. It was suggested that the overall attrition rate was driven by the IS group which might indicate that Internet-mediated interventions are not unanimously appealing. Investigators recommended that future research explore the types of individuals for whom an Internet-mediated intervention is best suited and for what specific strategies (e.g. electronic self-monitoring) the Internet might be advantageous. The conducted investigation examined the acceptability of the technology-based system as a delivery channel for weight loss and descriptive characteristics of the subject sample were analyzed in an effort to generalize the findings to individuals with a similar demographic background.

Summary of Internet-Mediated Weight Maintenance Interventions

The results of these Internet-mediated weight maintenance interventions raise some questions as to the effectiveness of the Internet as an alternative delivery channel. First, two of the studies (Harvey-Berino et al., 2004; Harvey-Berino et al., 2002) failed to show a

difference in maintenance of weight loss between the Internet-mediated and in-person groups; whereas one study (Harvey-Berino et al., 2002) showed that maintenance of weight loss was inferior in the Internet-mediated group. The investigators speculated that these conflicting results might be related to mode of in-person delivery (in-person vs. ITV) and high attrition rate.

Second, all three studies implemented an Internet-mediated intervention after an initial in-person treatment program. While the investigators intended to examine the effectiveness of the Internet in the weight maintenance phase, they stated that this transfer of intervention modes might have led to poorer results in the Internet-mediated groups. It was suggested that future interventions avoid mixing intervention modes and recommended examining the effectiveness of the Internet as a sole means of weight loss treatment and maintenance (Harvey-Berino et al., 2002). However, based on the positive response of the Internet groups to some process measures (self-report), it might be valuable to examine the effectiveness of Internet-mediated weight loss and weight-maintenance interventions in conjunction with in-person support. It appears that both in-person and Internet-mediated programs can offer unique benefits; by combining these intervention modes future interventions may be more successful. Therefore, the conducted investigation explored the benefits received from a combined Internet-supported and in-person treatment program. If the technology-based system is shown to enhance short-term weight loss, it may be recommended that future studies examine the effectiveness of this system in longer-term weight management interventions.

Technology-Based System Research

The technology-based system used in this study was developed by BODYMEDIA® and Roche Diagnostics™. This system was designed to be a monitoring system that utilizes a wearable body monitor (armband), proprietary algorithms, and an Internet application (Roche Diagnostics, 2004) . The armband is worn on the back of the upper right arm and it evaluates daily energy expenditure based on a proprietary algorithm (Roche Diagnostics, 2004). Specifically, it uses a collection of sensors to obtain information such as movement, heat flow, skin temperature, near-body temperature, and galvanic skin response in conjunction with body measurements such as sex, age, height and weight to calculate energy expenditure (Roche Diagnostics, 2004). Data gathered from the armband is downloaded to a Web site where the proprietary algorithms are used to calculate a user's caloric expenditure, number of steps, and duration of physical activity.

The technology-based system software utilizes an Internet application that allows armband users to retrieve, save and view colleted data. In addition, the Internet application permits users to enter food intake and calculate daily caloric intake. In combination with energy expenditure data collected from the armband, the energy intake data further allows for a daily calculation of caloric balance and regular body weight tracking. The system employed in the current investigation was developed for the use in a clinical setting. This system allows professionals to track patient's energy balance data. Four studies (Fruin & Rankin, 2004; Jakicic et al., 2004; King, Torres, Potter, Brooks, & Coleman, 2004; Mignault, St.-Onge, Karelis, Allison, & Rabasa-Lhoret, 2005) have examined the validity and reliability of the armband; however, no studies have examined the entire technology-based system within a weight loss intervention.

Studies that reviewed the armband examined the validity of this device during specific exercise bouts (Fruin & Rankin, 2004; Jakicic et al., 2004; King et al., 2004). Jakicic et al. (2004) examined validity of the armband during four different modes of exercise and across various exercise intensities in a laboratory setting. When exercise-specific algorithms were used in combination with the armband, total energy expenditure measured with indirect calorimetry and the armband were not significantly different for treadmill walking, cycle ergometry, stair stepping, and arm ergometry.

Fuin et al. (2004) examined the reliability and validity of the armband during rest and two modes of exercise compared with indirect calorimetry. Mean resting energy expenditure estimated by the armband and indirect calorimetry did not differ. In addition, the armband produced highly reliable estimates of resting energy expenditure. No significant differences were found in energy expenditure between the armband and indirect calorimetry during cycle ergometry; however, the measures were poorly correlated. Although not directly compared, investigators stated the energy expenditure determined by the armband was more accurate compared to a triaxial accelerometer, which is a commonly used device to measure energy expenditure.

During treadmill walking, the armband overestimated energy expenditure of walking on a flat surface and underestimated energy expenditure of walking on an incline. However, it was stated that the armband was comparable to the triaxial accelerometer in estimating energy expenditure during exercise but better at estimating energy expenditure post exercise. Similar to the study performed by Jakicic et al.(2004), investigators recommended the use of contextual algorithms to increase the accuracy of the armband in estimating exercise energy expenditure.

King et al. (2004) compared the validity of five physical activity monitors during treadmill walking and running. Compared to the other physical activity monitors, the armband was shown to be the best estimate of total exercise energy expenditure at most speeds except slow walking. It was suggested due to the incorporation of heat production measurements and placement on the upper arm, the armband may be more effective in detecting arm movements, locomotion on a grade, and/or external work performed by pushing, lifting, or carrying objects.

None of the previous studies examined the use of the armband in free-living subjects. Mignault et al. (2005) measured total daily energy expenditure in type 2 diabetic subjects who wore the armband simultaneously with the determination of doubly labeled water (DLW) during a 10-day period. While the study was only performed in six subjects, no significant differences in mean daily energy expenditure was detected between the armband and DLW ($r=0.97$; $p=0.0014$). In addition the range of under- and over-estimation of the armband versus DLW was within an acceptable level of concordance between the two methods (-243 to 176 kcal/day, respectively).

Evaluation of the effectiveness of weight loss interventions is somewhat limited by subjective recall of physical activity which has been shown to be consistently over-reported in obese subjects (Buchowski et al., 1999; Irwin et al., 2001); the lack of an objective energy expenditure measure might complicate interpretation of weight loss results. Accurate assessment of energy expenditure is critical to the determination of energy balance, which in turn is important to determine in effective weight loss programs. In effort to offer improved accuracy in energy expenditure measurement among free-living subjects research has been performed using techniques such as doubly labeled water, accelerometers and pedometers

(Basset et al., 1996; Jakicic et al., 1999; Schoeller, 1999; Welk et al., 2000) Although these techniques have been shown to be feasible measures of energy expenditure, each is met with certain limitations. The findings of the previous studies indicate that use of the armband might allow for enhanced estimation of energy expenditure during rest, exercise and in free-living environments among subjects participating in a clinical behavioral weight loss intervention.

Summary

Obesity prevalence has reached epidemic proportions in the United States. The rapid increase in overweight and obesity prevalence tends to support behavioral and environmental changes as the primary influences on the obesity epidemic (Stein & Colditz, 2004). A shift in lifestyle behavior demonstrated by increased energy consumption and decreased energy expenditure through physical activity creates a positive energy balance and resultant weight gain. Behavioral obesity management aims to identify and modify eating, physical activity, and cognitive habits that contribute to an individual's body weight problem (Wadden & Butryn, 2003). In general, behavioral weight loss interventions have been shown to be effective in the treatment of overweight and obesity, typically producing weight losses between 8% and 10% of initial body weight within 4 to 6 months of treatment (Wing, 2002).

While interventions are typically delivered in group-based, in-person format, this program format might not appeal to everyone. Innovative intervention formats that incorporate advancing technology must be examined to increase program appeal and potentially increase weight loss success. One potential avenue for enhancement of weight loss interventions is through computer and Internet-mediated program support and/or delivery. Computer and Internet-mediated programs have been reviewed with some favor;

however, few studies have been performed on these alternative delivery channels and these studies have limitations that need to be addressed in future research.

Designed to assist clinical treatment, the technology-based system is an innovative tool that may enhance weight loss success among individuals seeking weight management treatment. The technology-based system may be effective for two primary reasons, the system allows for enhanced self-monitoring through objective daily energy expenditure measurement and it provides users with detailed energy balance data and related feedback. Both of these factors might promote greater changes in dietary and exercise behaviors leading to more successful weight loss. In addition, the enhanced self-monitoring data might foster more engaging and effective treatment interactions when the technology-based system is utilized within a clinical weight management program.

At this point, no behavioral weight loss interventions have examined the effectiveness of the technology-based system used in the conducted investigation. Therefore, this study investigated the technology based-system's clinical effectiveness to enhance short-term weight loss. The findings of this intervention may lead to the recommendation to incorporate use of this and similar technology-based systems in future clinical weight loss interventions, potentially improving weight loss outcomes.

III. METHODS

A. Introduction

Alternative methods, such as computerized and Internet based programs have been shown to be feasible means to support and deliver weight loss and weight management treatment (Agras et al., 1990; Burnett et al., 1985; Harvey-Berino et al., 2002; Harvey-Berino et al., 2004; Harvey-Berino et al., 2002; Tate et al., 2003; Tate et al., 2001; Taylor et al., 1991; Womble et al., 2004; Wylie-Rosett et al., 2001). However, evidence that computer-based methods can effectively produce weight loss and related behavior change is severely limited (Bessell et al., 2002). The technology-based system used in the conducted investigation is an innovative tool that may enhance weight loss success among individuals seeking weight management treatment. This system may be effective for two primary reasons, the system allows for enhanced self-monitoring through objective daily energy expenditure measurement and it provides users with detailed energy balance data and related feedback. Both of these factors might promote greater changes in dietary and exercise behaviors leading to more successful weight loss. In addition, the enhanced self-monitoring data might foster more engaging and effective treatment interactions when the technology-based system is utilized within a clinical weight management program. Therefore, the purpose of this study was to examine the effectiveness of technology-based system, when used in addition to an in-person standard 12-week behavioral weight loss intervention.

B. Subjects

B.1. Subject Demographics

A total of 60 overweight adults were recruited to participate in this study; 58 subjects were randomized to one of the three treatment groups (See Figure 4.1 for participant flow). Attempt was made to recruit both men and women; however, only one man participated. Randomization was performed, blocking on gender (male and female) and BMI (25-29.9, 30-34.9, and 35-39.9 kg/m^2). Therefore, gender and BMI were equally divided among the intervention groups. Individuals were considered eligible if they were 18-55 years old with a BMI of 25 to 39.9 kg/m^2. Individuals meeting the following criteria were considered ineligible for participation in the conducted investigation.

B.2. Exclusion Criteria:

1. Reported weight loss of >5% of current body weight in the previous 6 months.
2. Reported participating in a research project involving weight loss or physical activity in the previous 6 months.
3. Reported participating in a current research study that might influence outcomes of the current investigation.
4. Reported participation in regular exercise, defined as aerobic exercise for $\geq$ 20 minutes per day on $\geq$ 3 days per week over the previous 6 months.
5. Females that reported current pregnancy, pregnancy during the previous 6 months, or planned pregnancy during the study period.
6. Reported current treatment for a medical condition that might influence body weight (i.e., diabetes mellitus, cancer, etc).

7. Reported history of myocardial infarction or a previous history of heart surgery (e.g., coronary bypass, etc).
8. Reported taking medication that would affect heart rate or blood pressure responses to exercise (e.g., beta blockers).
9. Reported taking medication that could affect metabolism and/or influence body weight (e.g., synthroid).
10. Reported receiving treatment by a therapist for psychological issues or problems, currently taking psychotropic medications, or undergoing treatment with psychotropic medications within the previous 6 months.
11. Reported not having access to a computer and the Internet.
12. Reported inability to attach peripheral device or load necessary software to computer intended for use in this study.

B.3. Recruitment

Subjects were recruited using various media resources including newspaper advertisements, television, radio advertisements and mass mailings. Potential subjects were informed to contact the investigators at the University of Pittsburgh Physical Activity and Weight Management Research Center. Individuals were asked to participate in a brief telephone interview to determine initial eligibility. Eligible individuals were invited to attend a group orientation. At this orientation session, the individuals received a detailed description of the study; individuals were encouraged to ask all questions regarding their potential participation in the study. Research study orientation was conducted in 60-90 minutes sessions. Eligible, interested subjects were provided a written informed consent (See Appendix A for an example of this consent form). Preceding baseline assessments and study

participation, subjects completed a physical activity readiness questionnaire (PAR-Q) (Thomas, Reading, & Shephard, 1992) and a detailed medical history (See Appendix B for an example of these questionnaires). In order to minimize potential risk to the subject, all subjects provided written consent from their personal physician preceding participation in the study (see Appendix C for an example of this consent form).

C. Experimental Design

This study was a 12-week pretest-posttest randomized clinical weight loss intervention with assessments performed at 0 and 12 weeks of participation. The intervention included both dietary and exercise behavior modifications. A total of 58 subjects were randomized to one of following three intervention groups.

1. Standard In-Person Behavioral Weight Control Program (SBWP): Subjects (n= 19) in this intervention group received an in-person standard behavioral weight control program following a clinical treatment model.
2. Intermittent Technology-Based Behavioral Weight Control Program (INT-TECH): Subjects (n=19; Note: one subject randomized to this group did not participate in the intervention due to relocation prior to intervention initiation) in this group received all of the components included in the SBWP; however, individuals in this intervention group also utilized the technology-based system during weeks 1, 5, and 9 of the intervention period (See Table 3.3).
3. Continuous Technology-Based Behavioral Weight Control Program (CON-TECH): Subjects (n=19) in this group received all of the components included in the SBWP; however, individuals in this intervention group also utilized the technology-based system daily throughout the intervention period (See Table 3.3).

Specific details of each intervention group and the intervention components are described in section D.

D. Intervention Details

D.1. Intervention Schedule

The timeline for this study is illustrated in Table 3.1.

Table 3.1. Study Timeline

	12 Week Intervention																			
Recruit and Baseline Assessments ↓	↓	↓	↓											12-week Assessment ↓		Data Entry, Data Cleaning, Data Analysis ↓	↓	↓	↓	↓
Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15	Wk 16	Wk 17	Wk 18	Wk 19	Wk 20
Month 01				Month 02				Month 03				Month 04				Month 05			

Subjects participated in a series of assessments at baseline including body weight height, and fitness; these assessments were conducted for the following reasons: 1) to determine eligibility, 2) to minimize risk to subjects during the intervention phase of the study, and 3) for the purpose of collecting research data. The specific assessment details, including questionnaire descriptions are provided below (Section E). All assessments were conducted at baseline and following 12 weeks of treatment to determine the effect of the intervention on the stated outcomes.

D.2. Intervention Components

All groups received a 12-week weight control intervention that included both dietary and exercise modifications. The specific dietary and exercise goal are described in Section D.3.

D.2.a. Intervention Contact

Subjects in all groups (SBWP, INT-TECH, CON-TECH) received an in-person standard behavioral weight control program that followed a clinical treatment model. As justified in Chapter I, the technology-based system was designed to be implemented in a clinical setting; thus the treatment design, schedule and contact followed this model. The in-person visits were conducted in an individual session by a trained interventionist. All interventionists were assigned an equal number of subjects across the three treatment groups to minimize any interventionist to group treatment bias. In-person visits took place at weeks 1-4 during month 1, weeks 6 and 8 during month 2, and week 10 during month 3. See Table 3.3 for an illustration of the intervention contact. The individual sessions lasted approximately 45-60 minutes. During the in-person sessions the interventionist integrated behavioral strategies to assist with weight control; sessions followed a pre-specified content schedule (See section D.2.c). Body weight was measured at each in-person session; subjects were encouraged to monitor their body weight on their own during weeks when no in-person visits were scheduled. All sessions were conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh.

Table 3.2. Intervention Contact

	Month 1				Month 2				Month 3			
	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12
SBWP Components												
In-Person Visit	X	X	X	X		X		X		X		
HealthWear™ System												
INT-TECH Components												
In-Person Visit	X	X	X	X		X		X		X		
HealthWear™ System	X				X				X			
CON-TECH Components												
In-Person Visit	X	X	X	X		X		X		X		
HealthWear™ System	X	X	X	X	X	X	X	X	X	X	X	X

"X" indicates receiving the intervention component at the specified time period

D.2.b. Interventionist Training and Intervention Quality Control

Interventionists had training in nutrition, exercise physiology or behavioral sciences with health and weight-related counseling experience. To provide quality control of intervention sessions, all interventionists received training related to the structured session delivery format and the technology-based system. Interventionists were provided with a progression guide that gave structural and content assistance for each in-person visit. Weekly meetings were held to discuss the upcoming week's lesson and any problem solving strategies.

D.2.c. Behavioral Lesson Content

All in-person visits focused on a specific behavioral topic related to weight loss, eating behaviors, or exercise behaviors (See Table 3.3). The interventionist facilitated interactive discussion related to the specified topic. At each visit, participants were provided

written material as a supplement. During weeks that subjects did not attend an in-person session, they were mailed a behavioral lesson to offer a form of consistent weekly contact and support (See Table 3.3).

Table 3.3. Behavioral Lesson Titles

Week Number	Delivery format	Lesson Titles
1	IP	Behavioral approach to changing eating and exercise habits
2	IP	Healthy food choices
3	IP	Developing and implementing an exercise program
4	IP	Motivation
5	M	Energy balance
6	IP	Food guide pyramid/portion control
7	M	Stimulus control /Urge management
8	IP	Exercise barriers
9	M	Eating out
10	IP	Evaluating progress/Looking ahead
11	M	Problem solving
12	M	My time, my values

IP= in-person lesson; M= mailed lesson

Subjects in the INT-TECH and CON-TECH received brief additional counseling focused on their use and data retrieved from the technology-based system. Moreover, the counselor reviewed and provided feedback to the subject related to their compliance in using the technology-based system. Subjects were given an opportunity to discuss any questions or concerns related to use of the technology-based system. Prior to each counseling session the interventionist reviewed the subject's individual dietary and physical activity data, this information was used as an additional tool to facilitate discussion related to dietary and exercise behavior modification.

D.2.d. Technology-Based System

Subjects in the INT-TECH and CON-TECH groups utilized the technology-based system in addition to the standard behavioral program; the frequency of utilization varied between groups (see Table 3.2). Subjects were provided access to the technology-based system which included the armband and the Internet-based software application. During the orientation session, subjects were informed that they must have access to an IBM-compatible computer equipped with Internet-access, preferably with a high-speed connection. Subjects completed a questionnaire related to their computer and Internet access and experience (See Appendix G). This questionnaire also assessed the subject's ability to attach external devices and load software to their computer. Prior to randomization, all subjects were required to demonstrate their ability to access and respond to a Web site. The Web site was set up solely for the purpose of verifying Internet access needed for study participation. The Web site prompted subjects to complete a double entry of their initials and a temporary identification number. Failure to comply with this requirement prevented subjects from randomization and study participation.

At the initial in-person visit subjects in the INT-TECH and CON-TECH groups were oriented to the use of the technology-based system. Subjects in the INT-TECH and CON-TECH groups were provided with a secure login alias and user identification to protect their identity and confidential information. Subjects were required to demonstrate the ability to operate the armband and upload data to the technology-based system prior to completion of the first visit. At the end of this session, the primary investigator conducted a preliminary proficiency evaluation of technology-based system use. Verification of Web site access and data entry was performed within the first week of the intervention period. During weeks

when the technology-based system was used, subjects followed the specific instructions provided in Table 3.4.

Table 3.4. Instructions for the Technology-Based System Use

1. Install the technology-based system software on personal computer.
2. Initiate energy expenditure data collection each morning by placing armband on back of upper right arm.
3. Remove armband before going to bed.
4. Do not wear armband in the shower or bath.
5. Log daily dietary intake on the technology-based system's Web Site.
6. Download energy expenditure data from the armband daily.
7. Use self-monitoring diary to keep track of dietary intake and exercise, when access to the technology-based system's Web site is not available.

Subjects were encouraged to contact the technology-based system's on-line or telephone-based helpline if operational questions or problems arose. If technical problems were not resolved or responded to within 48 hours subjects were instructed to contact the primary investigator. During in-person visits the interventionists queried subjects regarding their use of technical support.

D.3. Standard Dietary and Exercise Recommendations

D.3.a. Dietary Recommendations

All subjects were prescribed an energy restricted dietary intervention. Subjects were encouraged to restrict energy intake to 1200-1800 kilocalories (kcal) per day based on initial body weight (<200 pounds = 1200 kcal/day; 200-250 pounds = 1500 kcal/day; > 250 pounds = 1800 kcal/day). Previous research studies have shown that participants achieving successful weight control consume a balanced diet with a macronutrient composition that

consists of 20-25% dietary fat intake, 55% carbohydrate intake, and 10-25% protein intake (Jakicic et al., 2003; Klem et al., 1997). Thus, subjects participating in the conducted investigation were recommended to consume a similar dietary composition.

Subjects were provided meal plans to facilitate the adoption of an energy-restricted diet (See Appendix E for a sample of these meal plans). Three to four plans per meal were provided to allow for variety and to accommodate different food preferences. Subjects were provided access to a calorie counting resource, either in book ("The Complete and Up to Date Fat Book", 2001) form (SBWP and INT-TECH groups) or in electronic form on the technology-based system site (INT-TECH and CON-TECH groups).

All subjects were encouraged to monitor their energy intake daily using the BALANCE diary (See Appendix F for an example) or the technology-based system's Internet application. When using the BALANCE diary, SBWP and INT-TECH subjects were instructed to record their eating intake patterns that included the time of day the food was consumed, the type of food consumed, and the caloric value of the food eaten. INT-TECH (weeks 1, 5, and 9) and CON-TECH subjects were encouraged to log their food intake regularly, performing full-entry, versus estimated entry of each meal. All subjects were encouraged to weigh and measure all of their food consumption; in addition, subjects were encouraged to use nutrition labels and to assist them in reporting their calorie and fat intake. To allow for dietary intake review, subjects utilizing the BALANCE diary returned completed diaries to the intervention staff at each in-person visit. Interventionists provided specific feedback focused on appropriate food choices, meal preparation and eating behaviors. The food diaries, when used appropriately, have been shown to promote effective behavioral change.

Subjects in the INT-TECH and CON-TECH groups logged their daily energy intake on the technology-based system Web site. The technology-based system was used to calculate nutrient values for each food item. Subjects in both groups were instructed to use the paper diary as a supplemental record of food intake during the day when access to the technology-based system was not readily available. As subjects in the INT-TECH groups did not utilize the technology-based system continuously, BALANCE diaries served as a support for sustained self-monitoring.

D.3.b. Exercise Recommendations

All subjects received similar instructions focused on improving their exercise behaviors. Subjects were prescribed an exercise intervention that was similar to research studies that indicate that higher levels of exercise may be necessary for preventing weight regain (Jakicic et al., 2003; Jakicic, Winters, Lang, & Wing, 1999; Klem et al., 1997). In particular, subjects were recommended to engage in aerobic exercise that was at least moderately intense on 5 days per week. Initially subjects were instructed to exercise 20 minutes per day, this duration was gradually progressed to at least 40 minutes per day (See Table 3.4). The exercise progression was 10 minutes per day in 4-week intervals. This progression has been shown to result is minimal injury that would limit exercise participation.

Subjects were encouraged to participate in activity that was at minimum moderate in intensity, with an RPE set at 11-13 on the 15-point RPE scale and/or heart rate range between 55-70% of maximal heart rate (Jakicic, Donnelly, NP, Jawad, & Jacobsen, 1995) (See Table 3.4). Activities that are consistent with this intensity level are similar to brisk walking.

Following the initial 6 weeks of treatment, subjects were permitted to exercise at an intensity of 11-15 on the RPE scale (55-80% of maximal heat rate) if desired.

Table 3.4. Description of Exercise Duration and Intensity Progression

Weeks 1-12	Days per week 5
	Minutes per week (Minutes per day)
Weeks 1-4	100 (20)
Weeks 5-8	150 (30)
Weeks 9-12	200 (40)
Exercise Intensity	RPE %HR_{max}
Weeks 1-6	11-13 55-70%
Weeks 7-12	11-15 55-80%

Subjects were instructed to monitor and record their exercise in an exercise log that was part of the BALANCE diary used to record dietary intake (see Appendix F). The self-monitoring of exercise included the type of exercise, the duration of the exercise session, and the intensity of the exercise session. Subjects returned the completed diaries to the intervention staff at each in-person visit for review. Interventionists reviewed and provided subjects with feedback focused on achievement of weekly exercise goals, daily exercise consistency, mode of exercise, etc.

Subjects in the INT-TECH and CON-TECH groups monitored their exercise on the technology-based system Web site by uploading data stored from the armband to their personal information page. As subjects in the INT-TECH groups did not utilize the technology-based system continuously, the BALANCE diaries served as a support for sustained self-monitoring.

E. Assessments

E.1. Weight

Body weight was assessed at 0 and 12 weeks. Subjects were clothed in a lightweight hospital gown, with weight being measured four hours post-prandial. Body weight was measured using a calibrated medical balance-beam scale (Health-O-Meter Inc., Bridgeview, IL). This measurement was assessed to the nearest 0.25 kg.

E.2. Height

Height was measured using a calibrated, wall mounted stadiometer (Perspective Enterprises, Inc., Kalamazoo, MI). Subjects were instructed to remove their shoes and stand with their back and heels of their feet against the wall for this measurement. Height was assessed to the nearest 0.1 cm. This measurement was completed at baseline only.

E.3. Body Composition

Body composition was estimated using a RJL BIA-01A (RJL Systems, Inc., Clinton Twp., MI) four terminal impedance analyzer. Resistance and reactance were measured to a maximum constant current of 500 microamps at a frequency of 50kHz. This instrument was calibrated according to the procedures recommended by the manufacturer using a 500-Ω resistor. Unitrac electrodes were placed at the following four sites on the right site of the body: 1) distal end of the second and third metacarpal, 2) between the ulnar and radial styloid processes, 3) distal end of the second and third metatarsal, 4) between the lateral and medial malleoli. Prior to electrode placement, the anatomical site was cleaned using rubbing alcohol. Lean body mass (LBM) was estimated using a published prediction equation (Segal, Loan, Fitzgerald, Hodgdon, & Itallie, 1985).

E.4. Regional Adiposity (Body Fat Distribution)

Abdominal adiposity was assessed using anthropometry. Anthropometry was performed at 0 and 12 weeks and involved the circumference measures of the waist and hips; the waist to hip ratio was computed. Subjects were clothed in a light-weight hospital gown for these assessments. These measurements were made using a Gulick tape measure. Two measurements were taken at each site, and the mean value was used for analysis. The difference between the two measurements taken at each site was not to exceed 1.0 cm; if this criteria was not met, additional measurements were taken until this was achieved.

E.5. Cardiorespiratory Fitness

Cardiorespiratory fitness was assessed at 0 and 12 weeks. The baseline assessment provided a screening tool to identify individuals who might have had existing contraindications to exercise participation. This initial assessment also provided data on baseline cardiorespiratory fitness. The assessment of cardiorespiratory fitness required the participant to be monitored by an electrocardiogram (ECG), which was further evaluated by a physician. The American College of Sports Medicine (ACSM) criteria were used as exclusionary criteria to determine if exercise participation was contraindicated. A modified Stanford treadmill protocol was used for exercise testing (American College of Sports Medicine, 2000). The speed of the treadmill was held constant at 3.0 mph (80.4 m/min) with the initial grade of the treadmill being 0% and increasing 2.5% increments at 3-minute intervals. Expired gas volumes and concentrations were measured continuously using a SensorMedics Vmax Metabolic Measuring Cart (SensorMedics, Yorba Linda CA); prior to each test the metabolic cart was calibrated according to the manufacturer recommended test procedures. Gas analyses were obtained at 20-second intervals during the test and

immediately upon termination of the exercise test. Heart rate during exercise testing was obtained at one-minute intervals using a 12-lead ECG (G.E. Medical) and immediately upon termination of exercise. Blood pressure (American Heart Association, 1972) and rating of perceived exertion (Borg, 1982) were assessed during the last minute of each stage and at the point of test termination. The test was terminated at 85% of age-predicted maximal heart rate. In addition, the ACSM criteria were followed for test termination (American College of Sports Medicine, 2000). Cardiorespiratory fitness level at 0 and 12 weeks is reported as oxygen uptake (VO_2) at 85% of age-predicted maximal heart rate and time (minutes) to reach termination. Following termination, subjects were monitored over a 5-10 minute recovery period to ensure that heart rate and blood pressure returned to pre-test levels. A submaximal test to assess fitness was selected for the following reasons: 1) studies have shown that few overweight adults achieve true physiological criteria for the attainment of maximal oxygen consumption (Donnelly, Jakicic, Roscoe, Jacobsen, & Israel, 1990) and 2) it has been shown that submaximal tests are sensitive to changes in fitness in populations similar to the subjects recruited for the conducted investigation (Jakicic et al., 2003; Jakicic et al., 2000; Jakicic et al., 1999).

E.6. Exercise Participation

The Paffenbarger Leisure-Time Activity Questionnaire was utilized at 0 and 12 weeks to assess total self-reported physical activity behavior (Paffenbarger, Wing, & Hyde, 1978). Studies have shown this questionnaire to be a valid and reliable assessment of physical activity (Ainsworth, Leon, Richardson, Jacobs, & Paffenbarger, 1993; Strath, Bassett, & Swartz, 2004) One study examined men and women with a broad range of physical activity habits; in this study correlation coefficients between total and heavy

physical activities on this questionnaire and physical activity records ranged from 0.34 and 0.69 (Ainsworth et al., 1993). This same study demonstrated test-retest reproducibility was 0.72 and 0.34-0.43 at 1 and 8 to 9 months, respectively (Ainsworth et al., 1993).

E.7. Dietary Intake

Dietary intake was assessed at 0 and 12 weeks using the 1998 version of the Block Food Frequency Questionnaire. This Food Frequency Questionnaire has been shown to be valid in comparison to 4-day food records, with correlations ranging from 0.5-0.6 (Block, Woods, Potosky, & Clifford, 1990)

E.8. Technology-Based System Use

At the 12-week assessment, subjects in the INT-TECH and CON-TECH groups completed a likert-scaled questionnaire related to their past and future use and evaluation of the technology-based system (See Appendix H). Questionnaire content areas included support of self-monitoring, understanding behavior change process, value of provided feedback, interaction with interventionists, motivation, and ease of use.

F. Statistical Analysis

Statistical analyses were performed using SPSS software, with statistical significance defined as $p \leq 0.05$. Data was analyzed initially to provide descriptive information on subject characteristics (age, body weight, BMI, etc.), fitness level, and energy intake. Analyses were conducted to determine if the data were normally distributed before conducting additional analyses.

Repeated measures analysis of variance (ANOVA) (group by time) with two time points 0 and 12 weeks, was used to test the differences in outcome measures between the

three intervention groups. One-way ANOVA was used to assess differences in absolute and relative weight loss across treatment groups. Appropriate transformations (non-parametric ANOVA for change score) were performed on outcome measures that were not normally distributed.

Intention to treat (ITT) analysis using repeated measures ANOVA (group by time) was fitted to test for differences in outcome measures between the three intervention groups. All randomized subjects were included in the analysis regardless of their follow-up status. ITT analysis was performed with baseline weight carried forward for those participants missing 12-week weight measures.

Additional descriptive statistics were performed to examine specific process (adherence) measures. These process measures included duration of armband use, number meals logged using the technology-based system [total, full entry (the number of meals in which the subject provided full entry of their meal), and user estimated (the number of meals in which the subject relied on an estimated value for food intake)], number of BALANCE diaries submitted with dietary and exercise data logged, and attendance at in-person sessions. One-way analysis of variance (ANOVA) was used to examine differences in process measures between groups. In addition, correlation analyses were performed to examine relationships between process measures and weight loss. Post- hoc analyses were performed using paired sample t-tests to examine differences in monitoring adherence across three 4-week treatment periods (weeks 1-4, 5-8, and 9-12). Adjustments were made for multiple comparisons; analyses with a significance value of $p \leq 0.016$ were considered to be significant.

G. Power Analysis

There are currently no published studies on the effectiveness of the technology-based system for improving weight loss or other study outcomes. Thus, the conducted investigation provides the initial data to allow for variance estimates to power a larger clinical trial. If we were to assume that our variance estimates from other weight loss studies is representative of what we would observe in this study (standard deviation= 7.2 kg), we would need to observe that the technology-based system improved weight loss by 3.6 kg (7.9 pounds) compared to the SBWP to achieve an effect size of 0.50 in this study. Based on a two-sample t-test with the type I error rate at 0.05 and 80% power, 63 subjects per group (189 total subjects) would be necessary to detect an effect size of 0.5 between the groups.

However, because this is the first clinical trial in this area and the magnitude of the impact that the technology-based system would have on the outcomes in this study was unknown. It was proposed that this study randomize 25 subjects to each group; after the recruitment and orientation phases we were able to randomize 19 subjects to each treatment group. We believe this provides a reasonable sample size to obtain variance estimates on the effectiveness of the technology-based system to enhance weight loss and the other outcomes proposed in this study. Moreover, the conducted investigation provides important descriptive data regarding the participant's perception of the benefits of using the technology-based system to compliment a standard in-person weight loss program.

IV. RESULTS

The purpose of this study was to examine the effectiveness a technology-based system when used in addition to an in-person standard 12-week behavioral weight loss intervention. This study was a pretest-posttest randomized clinical weight loss intervention with assessments performed at 0 and 12 weeks of participation. The independent variable was treatment group, Standard In-Person Behavioral Weight Control Program (SBWP), Intermittent Technology-Based Behavioral Weight Control Program (INT-TECH), and Continuous Technology-Based Behavioral Weight Control Program (CON-TECH). The primary dependent variables were body weight, body composition and regional adiposity, cardiorespiratory fitness, self-report physical activity, and dietary intake.

A. Subject Characteristics

Table 4.1 Characteristics of Subjects at Baseline§

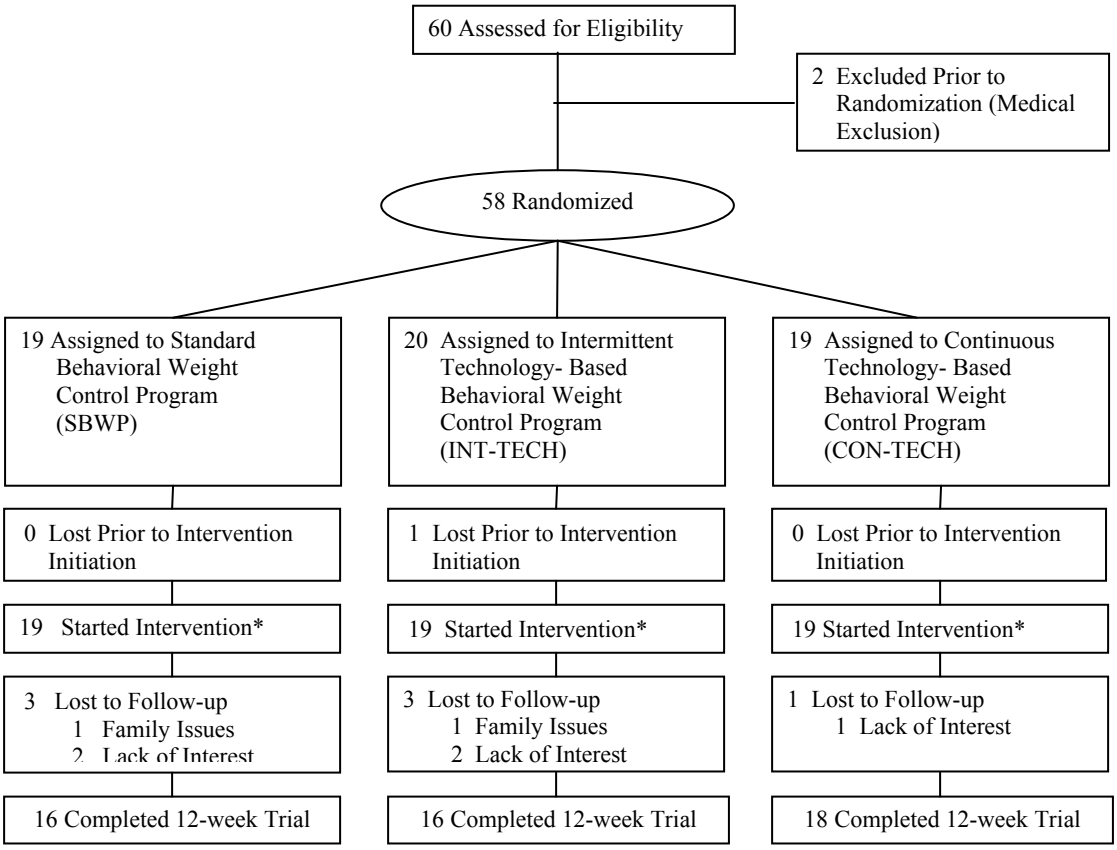
Variable	Total (n=57)	SBWP (n=19)	INT-TECH (n=19)	CON-TECH (n=19)	P-value
Age (years)	41.3±8.7	40.2±8.0	41.1±8.3	42.6±10.0	0.71
Height (cm)	163.7±5.5	162.7±4.6	165.2±6.2	162.9±5.1	0.29
Body Weight (kg)	88.8±9.1	89.1±9.0	91.0±8.8	86.6±9.5	0.34
% Minority Representation	38.6 (n=22)	36.8 (n=7)	36.8 (n=7)	42.1 (n=8)	χ^2=0.15
BMI (kg/m^2)	33.1±2.8	33.6±2.7	33.4±2.8	32.6±2.7	0.51
Body Composition (% fat)	42.4±3.8	42.7±4.2	42.3±3.1	42.1±4.2	0.89
Waist Circumference (cm)	104.6±9.7	105.6± 9.9	105.0±10.3	104.0±8.9	0.89
Treadmill Time to Reach 85% APMHR (min)	10.4±3.4	9.6±3.7	10.3±3.4	11.2±3.1	0.35
VO_2 at 85% APMHR (ml/kg/min)	21.4±3.2	20.7±2.9	21.2±2.3	22.1±4.1	0.37
Self-report Physical Activity (kcal/wk)	831.7±851.4	986.4±1292.6	862.5±603.9	681.3±430.3	0.45
Dietary Intake (kcal/d)	1837.0±809.4	1880.8±902.0	1840.6±831.1	1789.4±727.7	0.94

§Values expressed as means±standard deviation.
P-value= differences in variables across treatment groups.
APMHR= Age predicted maximum heart rate.

The subjects in this investigation were 57 adults (1 male, 56 females). Subjects were between 21 and 55 years of age, with a body mass index (BMI) ranging from 25 to 39 kg/m^2. Descriptive statistics are presented in Table 4.1. One-way analysis of variance (ANOVA) revealed no significant baseline differences between intervention groups for age, height, weight, body composition, waist circumference, fitness, physical activity, or dietary intake. Chi-square analysis revealed no significant baseline differences in percent minority representation between intervention groups. Primary outcome analyses were performed with all subjects included. Analyses were repeated with the male subject removed, comparison of these results showed no differences; thus, all results are presented including the male subject.

B. Retention Rates

Figure 4.1 Participant Flow



***** Number of participants evaluated in intent-to-treat analysis.

A total of 58 subjects were randomized to one of three treatment groups. One subject randomized to the INT-TECH group did not begin treatment due to relocation prior to intervention initiation; thus, data on this subject has been removed from analyses. A total of 50 subjects (88%) provided objective data at baseline and 12 weeks; these subjects are referred to as "completers". See Figure 4.1 for participant flow details. Differences in baseline characteristics between completers and non-completers regardless of group

assignment are presented in Table 4.2. As shown, non-completers were significantly younger (32.6±8.4 vs. 42.5±8.1, p=0.004) and more non-completers were minorities (85.7% vs. 14.3%, χ^2=7.5, p=0.006).

In the SBWP, INT-TECH, and CON-TECH groups, 16, 16, and 18 subjects, respectively, completed the intervention. Differences in baseline characteristics for completers and non-completers by group are presented and Table 4.3. There was no significant difference in intervention completion across groups (χ^2=0.52). Independent samples t-tests were performed to examine the differences in baseline differences between completers and non-completers for all subjects and within treatment groups. Within the SBWP group, significantly more non-completers were minorities. Outcome variables were analyzed using two methods, a completers analysis (only data from subjects competing the intervention) and an intent-to-treat (ITT) analysis (baseline observation carried forward for missing data).

Table 4.2 Differences in Baseline Characteristics between Completers and Non-Completers§

Variable	Completers (n=50)	Non-completers (n=7)
Age (years)	42.5±8.1	32.6±8.4*
Height (cm)	163.3±5.6	165.9±2.5
Weight (kg)	88.4±9.1	92.9±9.1
% Minority Representation	32.0 (n=16)	85.7 (n=6)*
BMI (kg/m^2)	33.1±2.7	33.7±2.8
Body Composition (% fat)	42.3±3.8	43.0±3.7
Waist Circumference (cm)	104.2±9.0	109.9±12.8
VO_2 at 85% APMHR (ml/kg/min)	21.4±3.3	20.7±2.9
Treadmill Time to Reach 85% APMHR (min)	10.4±3.3	10.4±4.2
Self-report Physical Activity (kcal/wk)	896.3±890.4	465.7±383.3
Dietary Intake (kcal/d)	1920.0±819.9	1244.1±396.3

§Values expressed as means±standard deviation.
APMHR= Age predicted maximum heart rate.
*p≤0.05 for difference between completers and non-completers.

Table 4.3 Differences in Baseline Characteristics between Completers and Non-Completers by Group§

Variable	SBWP		INT-TECH		CON-TECH	
	Completers (n=16)	Non-completers (n=3)	Completers (n=16)	Non-completers (n=3)	Completers (n=18)	Non-completers (n=1)
Age (years)	41.5±6.5	33.4±13.3	43.1±7.3	30.6±4.6	42.9±10.2	36.2
Height (cm)	162.1±4.8	165.9±0.7	165.0±6.6	165.8±4.3	162.7±5.2	166.0
Weight (kg)	89.8± 9.1	90.5±10.4	90.2±8.5	95.4±11.1	86.3±9.7	92.2
% Minority Representation	21.1 (n=4)	100 (n=3)†	26.3 (n=5)	66.7 (n=2)	36.8 (n=7)	100 (n=1)
BMI (kg/m^2)	33.8±2.7	32.9±3.6	33.1±2.8	34.6±3.0	32.6±2.8	33.5
Body Composition (% fat)	42.7±4.2	42.4±5.0	42.1±3.1	43.6±3.8	42.0±4.3	42.8
Waist Circumference (cm)	104.7±8.8	110.2±16.2	105.0±10.8	105.0±9.5	102.9±7.7	124.0
VO_2 at 85% APMHR (ml/kg/min)	20.9±2.9	19.8± 3.0	21.1± 2.1	21.6±3.7	22.2±4.2	20.7
Treadmill Time to Reach 85% APMHR (min)	9.8±3.6	8.3±4.7	10.1±3.3	11.7±4.4	11.1±3.21	12.7
Self-report Physical Activity (kcal/wk)	1110.1±1376.2	326.7±241.4	899.2±625.8	666.7±525.0	703.4±431.4	280.0
Dietary Intake (kcal/d)	2028.2±897.0	1094.9±436.4	1960.7±849.0	1200.2±283.4	1787.5±748.7	1823.1

§Values expressed as means±standard deviation.
†= χ^2 p-value=0.04 for difference between completers and non-completers within treatment group.
APMHR= Age predicted maximum heart rate.
GXT= Graded Exercise Test .

C. Change in Body Weight and BMI

C.1 Completers Analysis

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference in body weight between baseline and week 12 (SBWP: 88.8±9.1 vs. 84.0±9.5 kg; INT-TECH: 90.2±8.5 vs. 86.2±9.6 kg; CON-TECH: 86.3±9.7 vs.79.8±9.1 kg). These results are shown in Table 4.4. Figure 4.2 displays the treatment effect on weight loss. Absolute weight loss for participants who completed the intervention was 4.8±2.3,

4.0±3.6, and 6.5±3.9 kg, for the SBWP, INT-TECH, and CON-TECH groups ($p<0.01$), respectively ($p=0.08$, for group x time interaction effect). Relative weight loss for participants who completed the intervention was 5.5±2.6, 4.5±3.7, and 7.5±4.4% for the SBWP, INT-TECH, and CON-TECH groups ($p<0.01$), respectively ($p=0.06$, for group x time interaction effect). The prevalence of subjects achieving a 5% weight loss was 42% (n=8) in the SBWP group, 32% (n=6) in the INT-TECH group, and 63% (n=12) in the CON-TECH group. Chi-square analyses revealed no significant differences in the prevalence of 5% weight loss between groups ($\chi^2=3.96$, $p=0.14$).

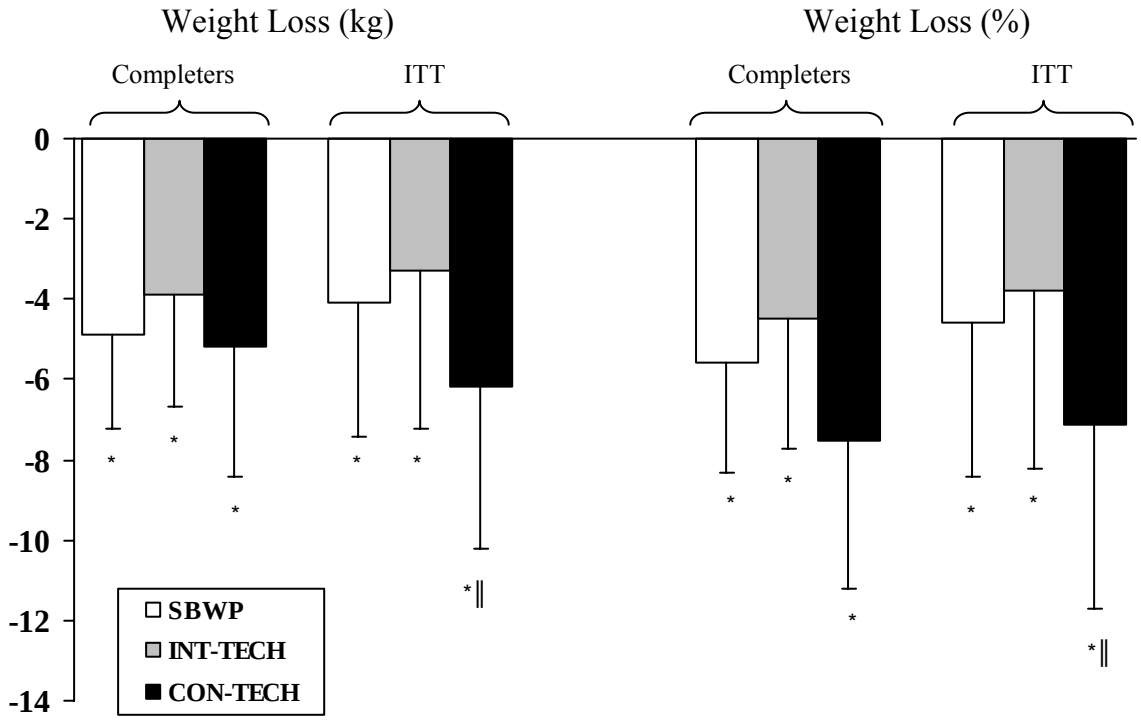
Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for BMI between baseline and week 12 (SBWP: 33.8±2.7 vs. 31.9±2.9 kg/m^2; INT-TECH: 33.1±2.8 vs. 31.7±3.4 kg/m^2; CON-TECH: 32.6±2.8 vs. 30.1±3.0 kg/m^2). The group x time interaction effect for BMI between baseline and 12 weeks was $p=0.06$. These results are shown in Table 4.4.

Table 4.4 Differences between Treatment Groups at 12 Weeks- Completers Analysis§

Outcome Variable	SBWP (n=16)	INT-TECH (n=16)	CON-TECH (n=18)	P-Value Time Effect	P-Value Group Effect	P-Value Group x Time
Body Weight (kg)						
0 wk	88.8±9.1	90.2±8.5	86.3±9.1			
12 wk	84.0±9.5	86.2±9.6	79.8±9.1	<0.01	0.25	0.08
BMI (kg/m^2)						
0 wk	33.8±2.7	33.1±2.8	32.6±2.8			
12 wk	31.9±2.9	31.7±3.4	30.1±3.0	<0.01	0.30	0.06
VO_2 at 85%APHMR (ml/kg/min)^						
0 wk	21.1±2.9	21.1±2.1	22.0±4.2			
12 wk	23.7±4.6	21.8±4.2	23.4±4.7	<0.01	0.60	0.43
Treadmill Time to reach 85% APMHR (min) ^						
0 wk	9.6±3.7	10.3±3.4	11.2±3.1			
12 wk	11.4±3.7	11.8±3.0	13.1±3.7	<0.01	0.41	0.75
Body Fat (%)						
0 wk	42.7±4.2	42.1±3.1	42.1±4.2			
12 wk	40.8±4.4	40.2±3.8	37.8±4.7	<0.01	0.38	<0.01‡
Waist Circumference (cm)						
0 wk	105.6± 9.9	105.0 ± 10.3	102.9 ± 7.7			
12 wk	100.2±10.5	101.5±12.6	96.5±6.8	<0.01	0.47	0.56
Self-report Physical Activity (kcal/wk)						
0 wk	1110.1±1376.2	899.2±625.9	703.6±431.4			
12 wk	1444.5±1026.0	2427.1±3383.3	1877.7±995.4	<0.01	0.58	0.28
Dietary Intake (kcal/d)+						
0 wk	2025.2±897.0	1932.7±871.1	1787.5±748.7			
12 wk	1331.6±571.5	1382.3±748.3	1273.3±467.9	<0.01	0.77	0.68

§Values expressed as means±standard deviation.
APMHR= Age predicted maximum heart rate.
GXT= Graded Exercise Test .
‡ Standard > Continuous and Intermittent > Continuous.
^ Two subjects (1 SBWP, 1 CON-TECH) did not complete 12 wk treadmill test due to injury/medical issues.
+ Two subjects (1 INT-TECH, 1 CON-TECH) did not complete 12 wk food frequency questionnaire.

Figure 4.2 Treatment Effect on Weight Loss



ITT= Intent-to-Treat Analysis
* Significant weight loss within treatment group, $p < 0.01$.
*‖ Significant weight loss between groups, Continuous > Intermittent, $p \leq 0.05$.

C.2 Intent-to-Treat Analysis

Intent-to-treat analysis was performed on all subjects; baseline weight was carried forward for subjects who failed to complete the 12-week assessment. Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) and group x time interaction effect ($p=0.04$) for difference in body weight between baseline and week 12 (SBWP: 89.1±9.0 vs. 85.9±8.3 kg; INT-TECH: 91.0±8.8 vs. 86.8±10.7 kg; CON-TECH: 86.6±9.5 vs. and 80.4±9.3 kg). These results are shown in Table 4.5. Figure 4.2 displays the weight loss results for the intent-to-treat analysis. Absolute weight loss was 4.1±2.8,

3.4±3.4, and 6.2±4.0 kg, for the SBWP, INT-TECH, and CON-TECH groups (p=0.04, for group x time interaction effect), respectively. Relative weight loss was 4.6±3.2, 3.8±3.8, and 7.1±4.6%, for the SBWP, INT-TECH, and CON-TECH groups, respectively (p=0.03, group x time interaction effect). Post-hoc analyses revealed that absolute and relative weight loss was significantly greater in the CON-TECH (6.2±4.0 kg and 7.1±4.6%) group compared to the INT-TECH group (3.3±3.3 kg and 3.8±3.8%) ($p \leq 0.05$, between group effect); no other significant differences in weight loss between groups were observed.

Repeated measures ANOVA (group x time) revealed a significant time ($p<0.01$) and group x time interaction effect (p=0.03) for the difference in BMI between baseline and week 12 (SBWP: 33.6±2.7 vs. 32.1±2.9 kg/m^2; INT-TECH: 33.4±2.8 vs. 32.2 ± 3.4 kg/m^2; CON-TECH: 32.6±2.8 vs. 30.3±3.0 kg/m^2). These results are shown in Table 4.5. Post-hoc analysis examining change in BMI, revealed that reduction in BMI was greater in the CON-TECH (-2.3±1.5 kg/m^2) and SBWP (-1.5±1.1 kg/m^2) groups compared to INT-TECH group (-1.2±1.1 kg/m^2) ($p \leq 0.05$ between group effect); no other significant differences in BMI between groups were observed.

Table 4.5 Differences between Treatment Groups at 12 Weeks- Intent-to-Treat Analysis§

Outcome Variable	SBWP (n=19)	INT-TECH (n=19)	CON-TECH (n=19)	P-Value: Time Effect	P-Value: Group Effect	P-Value: Group x Time
Body Weight (kg)						
0 wk	89.1±9.0	91.0±8.8	86.6±9.5			
12 wk	85.0±9.6	87.7±10.1	80.4±9.3	<0.01	0.16	0.04‖
BMI (kg/m^2)						
0 wk	33.6±2.7	33.4±2.8	32.6±2.7			
12 wk	32.1±2.9	32.2 ± 3.4	30.3 ± 3.0	<0.01	0.26	0.03‖
VO_2 at 85%APHMR (ml/kg/min)						
0 wk	20.7±2.9	21.2±2.3	22.1±4.1			
12 wk	22.5±4.5	21.2±4.1	23.4±4.5	<0.01	0.45	0.50
Treadmill Time to reach 85% APMHR (min)						
0 wk	9.6±3.7	10.3±3.4	11.2 ±3.1			
12 wk	11.0± 3.8	11.8±3.1	13.1±3.5	<0.01	0.23	0.62
Body Fat (%)						
0 wk	42.7±4.2	42.3±3.1	42.1±4.2			
12 wk	41.0±4.4	40.7±3.9	38.0±4.7	<0.01	0.33	<0.01‡
Waist Circumference						
0 wk	105.6± 9.9	105.0 ± 10.3	104.0±8.9			
12 wk	101.8±11.6	102.0±12.0	98.0±9.1	<0.01	0.48	0.43
Self-report Physical Activity (kcal/wk)						
0 wk	986.4±1292.6	862.5±603.9	681.3±430.3			
12 wk	1268.0±1029.1	2149.2±3163.0	1793.6±1034.4	<0.01	0.59	0.28
Dietary Intake (kcal/d)						
0 wk	1880.8±902.0	1840.6±831.1	1789.4±727.7			
12 wk	1294.3±548.4	1406.1±710.5	1302.3±471.8	<0.01	0.93	0.75

§Values expressed as means±standard deviation.
APMHR= Age predicted maximum heart rate.
GXT= Graded Exercise Test .
‖ Intermittent > Continuous.
‡ Standard > Continuous and Intermittent > Continuous.

D. Change in Body Composition and Regional Adiposity

D.1 Completers Analysis

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) and group x time interaction effect ($p<0.01$) for the difference between percent body fat at baseline and week 12 (SBWP: 42.7±4.2 vs. 40.8±4.4%; INT-TECH: 42.1±3.1 vs. 40.2±3.8%; CON-TECH: 42.0±4.3 vs. 37.8±4.7%). These results are shown in Table 4.4.

Post-hoc analysis examining change in percent body fat, revealed that reduction in percent body fat was greater in the CON-TECH (-4.3±2.9%) group compared to SBWP (-1.9±1.5%) and INT-TECH groups (-1.9±1.5%) ($p \leq 0.05$). Comparable to these results, analyses of change in absolute fat mass revealed that reduction in fat mass was greater in the CON-TECH (-6.1±3.5) group compared to SBWP (-3.7±2.1) and INT-TECH groups (-3.2±2.5) ($p \leq 0.05$). Change in absolute lean mass was not significantly different between the SBWP (-1.2±1.3kg), INT-TECH (-0.7±1.2kg), and CON-TECH (-0.4±2.2kg) groups ($p=0.45$).

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference in waist circumference between baseline and week 12 (SBWP: 105.6± 9.9 vs. 100.2±10.5 cm; INT-TECH: 105.0 ± 10.3 vs. 101.5±12.6 cm; CON-TECH: 102.9±7.7 vs. 96.5±6.8 cm). These results are shown in Table 4.4. The group x time effect for change in waist circumference was not significant ($p=0.56$).

D.2 Intent-to-Treat Analysis

Intent-to-treat analysis was performed on all subjects; baseline body fat percentage was carried forward for subjects who failed to complete the 12-week assessment. Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) and group x time interaction effect ($p<0.01$) for the difference between percent body fat at baseline and week 12 (SBWP: 42.7±4.2 vs. 41.0±4.4%; INT-TECH: 42.3±3.1 vs. 40.7±3.9%; CON-TECH: 42.1±4.2 vs. 38.0±4.7%). These results are shown in Table 4.5. Post-hoc analysis examining change in percent body fat, revealed that reduction in percent body fat was greater in the CON-TECH group (-4.1±2.9%) compared to SBWP (-1.6±1.5%) and INT-TECH groups (-1.6±1.7%) ($p \leq 0.05$). Comparable to these results, analyses of change in absolute fat mass revealed that reduction in fat mass was greater in the CON-TECH (-5.8±3.7) group

compared to SBWP (-3.1±2.3) and INT-TECH groups (-2.7±2.6) ($p \leq 0.05$). Change in absolute lean mass was not significantly different between the SBWP (-1.0±1.3kg), INT-TECH (-0.6±1.2kg), and CON-TECH (-0.4±2.1kg) groups ($p=0.54$).

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for change in waist circumference between baseline and week 12 (SBWP: 105.6±9.9 vs. 101.8±11.6 cm; INT-TECH: 105.0±10.3 vs. 102.0±12.0 cm; CON-TECH: 104.0±8.9 vs. 98.0±9.1 cm). These results are shown in Table 4.5. The group x time effect for change in waist circumference was not significant ($p=0.43$).

E. Change in Cardiorespiratory Fitness

E.1 Completers Analysis

Cardiorespiratory fitness was represented as relative VO_2 at 85% age-predicted maximal heart rate (APMHR) and time to reach 85% APMHR. Two subjects who completed the intervention were unable to complete the cardiorespiratory fitness assessment at 12-weeks due to injury; thus, they were not considered in this analysis. Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference between at baseline and week 12 cardiorespiratory fitness, expressed as relative VO_2 at 85% APMHR (SBWP: 21.1±2.9 vs. 23.7±4.6 ml/kg/min; INT-TECH: 21.1±2.1 vs. 21.8±4.2 ml/kg/min; CON-TECH: 22.0±4.2 vs. 23.4±4.7 ml/kg/min) and time to reach 85% APMHR (SBWP: 9.6±3.7 vs. 11.4±3.7 min; INT-TECH: 10.3±3.4 vs.11.8±3.0 min; CON-TECH: 10.9±3.2 vs. 13.1±3.7 min). These results are shown in Table 4.4. The group x time interaction effect for change in cardiorespiratory fitness was not significant ($p=0.16$ for relative VO_2 at 85% APMHR and, $p=0.75$ for time to reach 85% APMHR).

E.2 Intent-to-Treat Analysis

Intent-to-treat analysis was performed on all subjects; baseline cardiorespiratory fitness was carried forward for subjects who failed to complete the 12-week assessment. Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) in cardiorespiratory fitness from baseline to week 12, expressed as relative VO_2 at 85% APMHR (SBWP: 20.7±2.9 vs. 22.5±4.5 ml/kg/min; INT-TECH: 21.2±2.3 vs. 21.2±4.1 ml/kg/min; CON-TECH: 22.1±4.1 vs. 23.4±4.5 ml/kg/min) and time to reach 85% APMHR (SBWP: 9.6±3.7 vs. 11.0±3.8 min; INT-TECH: 10.3±3.4 vs. 11.8±3.1; CON-TECH: 11.2 ±3.1 vs. 13.1±3.5 min). These results are shown in Table 4.5. The group x time interaction effect for change in cardiorespiratory fitness was not significant ($p=0.50$ for relative VO_2 at 85% APMHR and, $p=0.62$ for time to reach 85% APMHR).

F. Change in Self-Reported Physical Activity

F.1 Completers Analysis

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference between self-report physical activity at baseline and week 12 (SBWP: 986.4±1292.6 vs. 1444.5±1026.0 kcal/wk; INT-TECH: 862.5±603.9 vs. 2427.1±3383.3 kcal/wk; CON-TECH: 703.4±431.4 vs. 1877.7±995.4 kcal/wk). These results are shown in Table 4.4. The group x time interaction effect for the difference in self-report physical activity was not significant ($p=0.28$).

F.2 Intent-to-Treat Analysis

Intent-to-treat analysis was performed on all subjects; baseline self-reported physical activity was carried forward for subjects who failed to complete the 12-week assessment.

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference between self-report physical activity at baseline and week 12 (SBWP: 986.4±1292.6 vs. 1268.0±1029.1 kcal/wk; INT-TECH: 862.5±603.9 vs. 2149.2±3613.0 kcal/wk; CON-TECH: 681.3±430.3 vs.1793.6±1034.4 kcal/wk). These results are shown in Table 4.5. The group x time interaction effect for the difference in self-report physical activity was not significant ($p=0.28$).

G. Change in Dietary Intake

G.1 Completers Analysis

Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference between dietary intake at baseline and week 12 (SBWP: 2025.2±897.0 vs. 1331.6±571.5 kcal/d; INT-TECH: 1932.7±871.1 vs. 1382.3±748.3 kcal/d; CON-TECH:1787.5±748.7 vs. 1273.3±467.9 kcal/d). These results are shown in Table 4.4. The group x time interaction effect for the difference in dietary intake was not significant ($p=0.68$). Analysis of change in dietary fat intake revealed that reduction in percent fat intake was significantly greater in the CON-TECH (-10.8±8.5%) vs. INT-TECH (-4.8±5.7%) and SBWP (-5.8±5.1%) groups ($p<0.05$).

G.2 Intent-to-Treat Analysis

Intent-to-treat analysis was performed on all subjects; baseline dietary intake was carried forward for subjects who failed to complete the 12-week assessment. Repeated measures ANOVA (group x time) revealed a significant time effect ($p<0.01$) for the difference between dietary intake at baseline and week 12 (SBWP: 1880.8±902.0 vs. 1294.3±548.4 kcal/d; INT-TECH: 1840.6±831.1 vs. 1406.1±710.5 kcal/d; CON-TECH:

1789.4±727.7 vs. 1302.3±471.8 kcal/d). These results are shown in Table 4.5. The group x time interaction effect for the difference in self-report physical activity was not significant (p=0.75). Analysis of change in dietary fat intake revealed that reduction percent fat intake was significantly greater in the CON-TECH (-10.2±8.6%) vs. INT-TECH (-3.8±5.4%) and SBWP (-4.9±5.1%) groups ($p<0.05$).

H. Process Measures

H.1. Descriptive Data on Process Measures

Descriptive analyses were used to examine several process measures, including: individual meeting attendance (all groups), armband use (INT-TECH and CON-TECH), dietary logging (INT-TECH and CON-TECH), BALANCE diary submission by caloric and exercise data logging (SBWP and INT-TECH). These data are presented by completers and intent-to-treat analyses in Table 4.6 and Table 4.7, respectively.

Table 4.6 Descriptive Analysis of Process Measures- Completers Analysis§

Variable	All Subjects (n=50)	SBWP (n=16)	INT-TECH (n=16)	CON-TECH (n=18)
Percent Attendance	91.4±18.7	94.6±10.3*	82.1±26.3	96.8±13.5*
Total Armband Time on Body (hrs)	-	-	191.3±119.5	852.0±368.8
wks 1-4	-	-	72.1±35.8	350.6±113.5 [a,b]
wks 5-8	-	-	70.4±49.9	289.1±142.9 [c]
wks 9-12	-	-	51.0±45.3	206.8±150.4
Total Meals Logged	-	-	61.8±37.7	275.9±115.2
wks 1-4	-	-	22.3±12.7	102.8±32.2
wks 5-8	-	-	21.4±14.1	95.7±43.1 [c]
wks 9-12	-	-	17.6±15.6	76.2±50.9
Meals Logged- Full Entry	-	-	60.6±36.5	239.1±117.2
wks 1-4	-	-	22.2±12.7	99.8±33.2 [a,b]
wks 5-8	-	-	21.3±14.1	78.5±44.6 [c]
wks 9-12	-	-	16.6±14.6	59.8±50.4
Meals Logged -User Estimate	-	-	1.2±2.8	36.8±69.6
wks 1-4	-	-	0.1± 0.5	2.9±6.0
wks 5-8	-	-	0.1±0.3	15.0±32.5
wks 9-12	-	-	1.1±2.8	16.5±32.3
Total Diaries with kcals logged	-	7.4±3.5	3.9±3.2	-
wks 1-4	-	3.6±0.8 [a,b]	1.9±1.1 [a,b]	-
wks 5-8	-	2.5±1.6 [c]	1.2±1.3 [c]	-
wks 9-12	-	1.4±1.7	0.9±1.3	-
Total Diaries with exercise logged	-	8.2±3.2	4.4±3.0	-
wks 1-4	-	3.6±0.8 [a,b]	2.1±1.0 [a,b]	-
wks 5-8	-	2.8±1.4 [c]	1.2±1.3	-
wks 9-12	-	1.8±1.6	1.2±1.3	-

§Values expressed as means±standard deviation unless otherwise specified.
* Significantly different between groups, SBWP and CON-TECH > INT-TECH ($p \leq 0.05$)
[a] value for wks 1-4 significantly greater than value for wks 5-8 ($p \leq 0.05$).
[b] value for wks 1-4 significantly greater than value for wks 9-12 ($p \leq 0.05$).
[c] value for wks 5-8 significantly greater than value for wks 9-12 ($p \leq 0.05$).

H.1a. Attendance

The process data for completers analysis is presented in Table 4.6. Percent attendance was 91.4±18.7% for all subjects. Percent attendance was significantly different between groups (p=0.05). Post-hoc analysis revealed that percent attendance was significantly higher in the SBWP and CON-TECH groups vs. the INT-TECH group (94.6±10.3% and 96.8±13.5% vs. 82.1±26.3%, $p \leq 0.05$).

The process data for intent-to-treat analysis is presented in Table 4.7. Percent attendance was 85.5±25.1% for all subjects and 87.2±20.7%, 76.7±29.4%, and 92.5±23.0%

for the SBWP, INT-TECH, and CON-TECH groups, respectively. Percent attendance was not significantly different between groups (p=0.14).

H.1b. Armband Use

Data for the completers analyses are shown in Table 4.6 and the distribution of total armband time on body TOB is shown in Appendix J. These results show that TOB was 191.3±119.5 and 852.0±368.8 hours for the INT-TECH and CON-TECH groups, respectively. TOB was analyzed across four-week treatment periods (weeks 1-4, 5-8 and 9-12). Repeated-measures ANOVA revealed that TOB significantly decreased over time within the INT-TECH group (p=0.04) and the CON-TECH group (p=0.001). Paired samples t-tests were performed adjusting for multiple comparisons; analyses with a significance value of $p \leq 0.016$ were considered to be significant. Within the INT-TECH group, difference in TOB was not statistically significant across the 3 treatment periods [1-4 vs. 5-8 (72.1.5±35.8 vs. 70.4±50.0 hrs, p=0.84; weeks 1-4 vs. 9-12 (72.1±35.8 vs. 51.0±45.3 hrs, p=0.02; weeks 5-8 vs. 9-12 (70.4±50.0 vs. 51.0±45.3 hrs, p=0.02)]. Within the CON-TECH group, TOB was significantly greater during weeks 1-4 vs. 5-8 (350.6±113.5 vs. 289.1±142.9, p=0.007), weeks 1-4 vs. 9-12 (350.6±113.5 vs. 206.8±150.4 hrs, $p \leq 0.01$), and weeks 5-8 vs. 9-12 (289.1±142.9 vs. 206.8±150.4 hrs, p=0.002). The data for intent-to-treat analyses are shown in Table 4.7, results were similar to the findings for treatment completers.

H.1c. Meal Logging- Technology-based Groups

The data for treatment completers are shown in Table 4.6. The data for intent-to-treat analyses are shown in Table 4.7, results were similar to the findings for treatment completers. The results for treatment completers are presented below.

Total number of meals logged was 61.8±37.7 and 275.9±115.2 for the INT-TECH and CON-TECH groups, respectively. These data are shown in Table 4.6. Total number of meals logged was analyzed across four-week treatment periods. Repeated-measures ANOVA revealed that total number of meals logged was significantly different across treatment periods for the CON-TECH group only ($p \leq 0.01$). Paired samples t-tests were performed adjusting for multiple comparisons; analyses with a significance value of $p \leq 0.016$ were considered to be significant. Total number of meals logged was significantly greater during weeks 5-8 vs. 9-12 only (95.7±43.1 vs. 76.2±50.9, $p=0.004$). Total number of meals logged was not significantly different during weeks 1-4 vs. 5-8 (102.8±32.2 vs. 95.7±43.1, $p=0.40$) or during weeks 1-4 vs. 9-12 (102.8±32.2 vs. 76.2±50.9, $p=0.019$).

The number of meals logged with full entry (user logs intake vs. estimated intake) was 60.6±36.5 and 239.1±117.2 for the INT-TECH and CON-TECH groups, respectively. These data are shown in Table 4.6. The number of meals logged with full entry was analyzed across four-week treatment periods. Repeated-measures ANOVA revealed that the number of meals logged with full entry was significantly different across treatment periods for the CON-TECH group only ($p=0.003$). Paired sample t-tests were performed adjusting for multiple comparisons; analyses with a significance value of $p \leq 0.016$ were considered to be significant. The number of meals logged with full entry was significantly greater during weeks 1-4 vs. 5-8 (99.8±33.2 vs. 78.5±44.6, $p=0.003$), weeks 1-4 vs. 9-12 (99.8±33.2 vs. 59.8±50.4, $p \leq 0.01$), and weeks 5-8 vs. 9-12 (78.5±44.6 vs. 59.8±50.4, $p=0.011$).

The number of meals logged with user estimate was 1.2±2.8 and 36.8±69.6 for the INT-TECH and CON-TECH groups, respectively. These data are shown in Table 4.6. The number of meals logged with user estimate was analyzed across four-week treatment periods.

Repeated-measures ANOVA revealed that the number of meals logged with user estimate was not significantly different across treatment periods for the CON-TECH (p=0.20) or INT-TECH group (p=0.38).

H.1d. BALANCE Diary Process Data

The data for treatment completers are shown in Table 4.6. The data for intent-to-treat analyses are shown in Table 4.7, results were similar to the findings for treatment completers. The results for treatment completers are presented below.

The total number of diaries submitted with caloric intake logged (diary back had any calorie and/or fat data logged) was 7.4±3.5 for the SBWP (potential number= 12) and 3.9±3.2 (potential number= 9) for the INT-TECH group. These data are shown in Table 4.6. Repeated-measures ANOVA revealed that the total number of diaries submitted with caloric intake was significantly different across four-week treatment periods (weeks 1-4, 5-8 and 9-12) for the SBWP group (potential number/4 week period = 4) ($p \leq 0.01$) and the INT-TECH group (potential number/4 week period = 3) (p=0.004). Paired samples t-tests were performed adjusting for multiple comparisons; analyses with a significance value of $p \leq 0.016$ were considered to be significant. Within the SBWP group, the total number of diaries submitted with caloric intake was significantly greater during weeks 1-4 vs. 5-8 (3.6±0.8 vs. 2.5±1.6, p=0.005), weeks 1-4 vs. 9-12 (3.6±0.8 vs. 1.4±1.7, $p \leq 0.01$), and weeks 5-8 vs. 9-12 (2.5±1.6 vs. 1.4±1.7, p=0.012). Within the INT-TECH group, the total number of diaries submitted with caloric intake was significantly greater during weeks between weeks 1-4 and 5-8 (1.9±1.1 vs. 1.2±1.3, p=0.016), and between weeks 1-4 and 9-12 (1.9±1.1 vs. 0.9±1.3, p=0.005), with no significant difference between weeks 5-8 and 9-12 (1.2±1.3 vs. 0.9±1.3, p=0.26).

The total number of diaries submitted with exercise logged (diary inside had any information related to exercise recorded) was 8.2±3.2 for the SBWP group (potential number= 12) and 4.4±3.0 for the INT-TECH groups (potential number = 9). These data are shown in Table 4.6. Repeated-measures ANOVA revealed that the total number of diaries submitted with exercise was significantly different across treatment periods for the SBWP group ($p \leq 0.01$) and INT-TECH group ($p=0.009$). Paired samples t-tests were performed adjusting for multiple comparisons; analyses with a significance value of $p \leq 0.016$ were considered to be significant. Within the SBWP group the total number of diaries submitted with exercise was significantly greater during weeks 1-4 vs. 5-8 (3.6±0.8 vs. 2.8±1.4, $p=0.009$), weeks 1-4 vs. 9-12 (3.6±0.8 vs. 1.8±1.6, $p \leq 0.01$), and weeks 5-8 vs. 9-12 (2.8±1.4 vs. 1.8±1.6, $p=0.015$). Within the INT-TECH group, the total number of diaries submitted with exercise was significantly greater during weeks 1-4 vs. 5-8 (2.1±1.0 vs. 1.2±1.3, $p=0.006$), and weeks 1-4 vs. 9-12 (1.9±1.1 vs. 1.2±1.3, $p=0.006$). Within the INT-TECH group the total number of diaries submitted with exercise was not significantly different between weeks 5-8 and 9-12 (1.2±0.3 vs. 1.2±0.3 $p=1.0$).

Table 4.7 Descriptive Analysis of Process Measures- Intent-to-Treat Analysis§

Variable	All Subjects (n=57)	SBWP (n=19)	INT-TECH (n=29)	CON-TECH (n=19)
Percent Attendance	85.5±25.1	87.2±20.7	76.7±29.4	92.5±23.0
Total Armband Time on Body (hrs)	-	-	165.9±125.8	807.2±408.3
wks 1-4	-	-	65.5±40.3 [b]	332.1±136.5 [a,b]
wks 5-8	-	-	59.3±52.6 [c]	273.8±153.9 [c]
wks 9-12	-	-	42.9±45.6	195.9±153.7
Total Meals Logged	-	-	53.9±39.8	261.4±128.6
wks 1-4	-	-	20.7±13.9	97.4±39.2
wks 5-8	-	-	18.0±15.2	90.7±47.3 [c]
wks 9-12	-	-	14.8±15.7	72.3±52.5
Meals Logged- Full Entry	-	-	52.9±38.6	226.5±126.4
wks 1-4	-	-	20.6±13.9	94.5±39.5 [a,b]
wks 5-8	-	-	17.9±15.1	74.4±46.9 [c]
wks 9-12	-	-	13.9±14.7	56.6±50.8
Meals Logged -User Estimate	-	-	1.0±2.6	34.9±68.1
wks 1-4	-	-	0.1± 0.5	2.7±5.9
wks 5-8	-	-	0.1±0.2	14.2±31.7
wks 9-12	-	-	0.9±2.6	15.6±31.6
Total Diaries with kcals logged	-	6.5±3.8	3.5±3.1	-
wks 1-4	-	3.3±1.0 [a,b]	1.7±1.1 [a,b]	-
wks 5-8	-	2.1±1.8 [c]	1.0±1.3 [c]	-
wks 9-12	-	1.2±1.6	0.7±1.2	-
Total Diaries with exercise logged	-	7.2±3.7	3.9±3.1	-
wks 1-4	-	3.3±1.0 [a,b]	1.9±1.0 [a,b]	-
wks 5-8	-	2.3±1.6 [c]	1.0±1.3	-
wks 9-12	-	1.5±1.6	1.0±1.3	-

§Values expressed as means±standard deviation unless otherwise specified.
[a] value for wks 1-4 significantly greater than value for wks 5-8 ($p<0.05$).
[b] value for wks 1-4 significantly greater than value for wks 9-12 ($p<0.05$).
[c] value for wks 5-8 significantly greater than value for wks 9-12 ($p<0.05$).

H.2. Treatment Group Comparison

Table 4.8 presents the data comparing process measures between treatment groups for intervention completers. Group comparisons were made between the INT-TECH and CON-TECH groups for the technology-based process measures (i.e. armband time on body and meal logging). The data are presented as weekly means for each variable. Weekly means were calculated for each variable by taking the variable mean total presented in Table 4.6 and dividing by the potential number of weeks that the technology-based system was used. The CON-TECH group the utilized the technology based system every week during the 12-week

study. The INT-TECH group utilized the system 3 weeks (once during each 4 week period, i.e. week 1, 5, and 9). As shown in Table 4.8 the data observed for armband time on body and meal logging variables were not significantly different between the INT-TECH and CON-TECH groups when a weekly average comparison was made ($p>0.05$ for all comparisons).

Group comparisons were made between the SBWP and INT-TECH groups for the diary process measures (diaries submitted with caloric intake and exercise) as percentages of potential diary submission. The SBWP group utilized the BALANCE diaries every week during the 12-week study; thus there was potential for 12 diaries, including caloric and exercise information, to be submitted. The INT-TECH group utilized the BALANCE diaries during weeks 2-4, 6-8, and 10-12; thus there was potential for 9 diaries, including caloric and exercise information, to be submitted.

As shown in Table 4.8 compared to the INT-TECH, the SBWP group submitted a significantly higher percentages of diaries with calories and exercise logged during the first treatment period (weeks 1-4), 87.5 ± 20.4 vs. 62.5 ± 32.3 ($p=0.02$) and 89.1 ± 20.3 and 68.8 ± 33.3 ($p=0.05$). Also, compared to the INT-TECH, the SBWP group submitted a significantly higher percentages of diaries with exercise logged during the second treatment period (weeks 5-8) 89.1 ± 20.3 and 68.8 ± 33.3 ($p=0.04$). All other comparisons were not statistically significant.

Table 4.8 Process Measure Comparison by Group – Completers Analysis§

Variable	SBWP (n=16)	INT-TECH (n=16)	CON-TECH (n=18)
Armband Time on Body (hrs/wk)	-	63.8±39.8	71.0±30.7
wks 1-4	-	72.1±35.8	87.6±28.4
wks 5-8	-	70.4±49.9	72.3±35.7
wks 9-12	-	51.0±45.3	51.7±37.6
Total Meals Logged (meals/wk)	-	18.0±13.2	24.3±10.7
wks 1-4	-	20.7±13.9	24.3±9.8
wks 5-8	-	18.0±15.2	22.7±11.8
wks 9-12	-	14.8±15.7	18.0±13.1
Meals Logged- Full Entry (meals/wk)	-	17.6±12.8	18.9±10.5
wks 1-4	-	20.6±13.9	23.6±9.9
wks 5-8	-	17.9±15.1	18.6±11.7
wks 9-12	-	13.9±14.7	14.2±12.7
Meals Logged -User Estimate (meals/wk)	-	0.3±0.9	2.9±5.7
wks 1-4	-	0.1± 0.5	0.7±1.5
wks 5-8	-	0.1±0.2	3.6±7.9
wks 9-12	-	0.9±2.6	3.9±7.9
Total Diaries with kcals logged (% of potential)	68.2±26.6	49.3±36.7	-
wks 1-4 (% of potential)	87.5±20.4*	62.5±32.3	-
wks 5-8 (% of potential)	62.5±40.8	39.6±44.3	-
wks 9-12 (% of potential)	35.9±41.8	29.2±41.9	-
Total Diaries with exercise logged (% of potential)	62.0±29.5	43.8±35.0	-
wks 1-4 (% of potential)	89.1±20.3*	68.8±33.3	-
wks 5-8 (% of potential)	70.3±34.4*	39.6±44.3	-
wks 9-12 (% of potential)	45.3±41.0	39.6±44.3	-

§Values expressed as weekly mean±standard deviation unless otherwise specified.

* Significant difference between groups, SBWP > INT-TECH, $p \leq 0.05$.

H.3. Correlations between Process Measures and Change in Body Weight

Table 4.9 Correlates of Absolute Change in Body Weight- Completers Analysis[+]

Variable	All Subjects (n=50)	SBWP (n=16)	INT-TECH (n=16)	CON-TECH (n=18)
Percent Attendance	-0.32*	0.25	-0.44	-0.30
Change in Self-report Physical Activity (week 12 – baseline)	-0.35*	-0.52*	-0.45	-0.30
Change in Dietary Intake[+] (week 12 – baseline)	0.11	0.07	-0.19	0.29
Total Armband Time on Body (hrs)	-	-	-0.68**	-0.71**
wks 1-4	-	-	-0.57*	-0.58*
wks 5-8	-	-	-0.60*	-0.64**
wks 9-12	-	-	-0.53*	-0.81**
Total Meals Logged	-	-	-0.44	-0.56*
wks 1-4	-	-	-0.38	-0.38
wks 5-8	-	-	-0.34	-0.38
wks 9-12	-	-	-0.34	-0.55*
Meals Logged- Full Entry	-	-	-0.45	-0.59*
wks 1-4	-	-	-0.37	-0.45
wks 5-8	-	-	-0.34	-0.47*
wks 9-12	-	-	-0.33	-0.59**
Meals Logged -User Estimate	-	-	-0.17	-0.03
wks 1-4	-	-	-0.36	0.11
wks 5-8	-	-	0.03	0.01
wks 9-12	-	-	0.03	0.01
Total Diaries with kcals logged	-	0.10	-0.50*	-
wks 1-4	-	-0.24	-0.45	-
wks 5-8	-	0.04	-0.38	-
wks 9-12	-	0.25	-0.33	-
Total Diaries with exercise logged	-	0.03	-0.47	-
wks 1-4	-	-0.35	-0.29	-
wks 5-8	-	-0.22	-0.38	-
wks 9-12	-	0.31	-0.33	-

[+]Absolute change in body weight = weight at baseline – weight at week 12.
*Significantly correlated with change in body weight, $p \leq 0.05$.
** Significantly correlated with change in body weight, $p \leq 0.01$.
[+] Two subjects (1 INT-TECH, 1 CON-TECH) did not complete 12 wk food frequency questionnaire.

Correlation analyses were performed between all process measures and change in body weight (calculated as body weight at week 12 minus baseline body weight) for subjects who completed the intervention. The results from the completers analysis are displayed in Table 4.9. The results from the intent-to-treat analysis are displayed in Table 4.11.

H.3a. Attendance

Completers analysis (Table 4.9) revealed a significant correlation between change in body weight and percent attendance when all subjects were combined ($r=-0.32$, $p=0.025$). No significant correlations were found between change in body weight and percent attendance within treatment groups. Intent-to-treat analysis (Table 4.11) showed significant correlations between change in body weight and percent attendance in all subjects ($r=-0.5$, $p<0.01$), INT-TECH ($r=-0.63$, $p<0.01$), and CON-TECH ($r=-0.47$, $p=0.04$) groups.

H.3b. Change in Self-Report Physical Activity

Completers analysis (Table 4.9) revealed a significant correlation between change in body weight and change in self-report physical activity in all subjects ($r=-0.35$, $p=0.014$) and in the SBWP group ($r=-0.52$, $p=0.04$). Intent-to-treat analysis (Table 4.11) showed significant correlations between change in body weight and change in self-report physical activity in all subjects ($r=-0.49$, $p<0.01$), SBWP ($r=-0.62$, $p<0.01$), and INT-TECH ($r=-0.65$, $p<0.01$) groups.

H.3c. Armband Use

Completers analysis (Table 4.9) revealed a significant correlation between change in body weight and total armband TOB among subjects in the INT-TECH ($r=-0.68$, $p=0.004$) and CON-TECH ($r= -0.71$, $p=0.001$) groups. Table 4.9 also displays the correlations between change in body weight and armband TOB during the three, four-week treatment periods. Similar results were found using the intent-to-treat analysis (Table 4.11). Physical activity data obtained from the armband were also analyzed; these data were strongly correlated with armband TOB in the INT-TECH ($r=0.93$, $p<0.01$) and CON-TECH ($r=0.87$,

p<0.01) groups. Thus, results from correlation analyses performed between physical activity and weight loss outcomes were similar to results of TOB analyses (data not presented). Change in body weight was further analyzed for TOB by median-split and across tertiles for the INT-TECH and CON-TECH groups. These data are presented in Table 4.10. Further analyses were performed to examine differences in baseline demographic variables and change in other primary outcome variables by median-split and across tertiles for the technology-based groups. These data are presented in Appendix K.

Table 4.10 Change in Body Weight for Total Time on Body Median Split and Tertiles §[+]

		INT-TECH			CON-TECH		
		Time on Body (hrs)	n	Change in Body Weight	Time on Body (hrs)	n	Change in Body Weight
Median Split	1	≤222	7	-2.1 ± 2.2	≤977	9	-4.0 ± 2.9
	2	≥223	9	-5.5± 3.3 [a]	≥978	9	-9.0 ± 3.0 [a]
Tertiles	1	≤75	4	-1.9 ± 3.1	≤692	5	-3.7 ± 3.0
	2	76-266	6	-3.6 ± 2.4	693-1039	6	-5.4 ± 2.9[a]
	3	≥267	6	-5.7 ± 3.7	≥1040	7	-10.2 ± 2.7[b,c]

§Values expressed as means ± standard deviation.
[+]Absolute change in body weight = weight at baseline – weight at week 12.
[a] value for split 2 is significantly greater than value for split 1 (p≤0.05).
[b] value for split 3 is significantly greater than value for split 2 (p≤0.05).
[c] value for split 3 is significantly greater than value for split 1 (p≤0.05).

H.3d. Meal logging: Technology-Based groups

Completers analysis (Table 4.9) revealed a significant correlation between change in body weight and total meals logged and meals logged with full entry among subjects in the CON-TECH group (r=-0.56, p=0.001 and r= -0.59, p=0.01, respectively). Table 4.9 also displays the correlations between change in body weight and meal logging during the three, four-week treatment periods. Intent-to-treat analysis (Table 4.11) showed similar results for

CON-TECH group subjects. Also, significant correlations were found between change in body weight and total meals logged and meals logged with full entry among subjects in the INT-TECH group (r=-0.62, p=0.005 and r=-0.63, p=0.004, respectively).

H.3e. BALANCE Diary Process Data

Completers analysis (Table 4.9) revealed a significant correlation between change in body weight and total diaries with kilocalorie intake recorded among subjects in the INT-TECH group (r= -0.50, p=0.05). Intent-to-treat analysis (Table 4.11) showed similar results for INT-TECH group subjects. Table 4.11 also displays the correlations between change in body weight and meal logging during the three, four-week treatment periods. Table 4.11 also shows a significant correlation between change in body weight and total diaries with exercise recorded among subjects in the INT-TECH group (r=-0.65, p=0.003).

Table 4.11 Correlates of Absolute Change in Body Weight- Intent-to-Treat Analysis[+]

Variable	All Subjects (n=57)	SBWP (n=19)	INT-TECH (n=19)	CON-TECH (n=18)
Percent Attendance	-0.54**	-0.30	-0.63**	-0.47*
Change in Self-report Physical Activity (week 12 – baseline)	-0.49**	-0.62*	-0.65**	-0.36
Change in Dietary Intake (week 12 – baseline)	0.11	0.34	0.07	0.32
Total Armband Time on Body (hrs)	-	-	-0.75**	-0.76**
wks 1-4	-	-	-0.59**	-0.64**
wks 5-8	-	-	-0.69**	-0.69**
wks 9-12	-	-	-0.63**	-0.83**
Total Meals Logged	-	-	-0.62*	-0.64**
wks 1-4	-	-	-0.42	-0.47*
wks 5-8	-	-	-0.56*	-0.47*
wks 9-12	-	-	-0.52*	-0.61**
Meals Logged- Full Entry	-	-	-0.63**	-0.65**
wks 1-4	-	-	-0.42	-0.53*
wks 5-8	-	-	-0.56*	-0.54*
wks 9-12	-	-	-0.51*	-0.64**
Meals Logged -User Estimate	-	-	-0.27	-0.05
wks 1-4	-	-	-0.35	0.05
wks 5-8	-	-	-0.04	-0.05
wks 9-12	-	-	-0.10	-0.05
Total Diaries with kcals logged	-	-0.30	-0.60**	-
wks 1-4	-	-0.50*	-0.54*	-
wks 5-8	-	-0.29	-0.51*	-
wks 9-12	-	-0.08	-0.49*	-
Total Diaries with exercise logged	-	-0.38	-0.65**	-
wks 1-4	-	-0.59**	-0.45*	-
wks 5-8	-	-0.45	-0.51*	-
wks 9-12	-	-0.11	-0.49*	-

[+]Absolute change in body weight = baseline - weight at week 12.
*Significantly correlated with change in body weight, $p \leq 0.05$.
** Significantly correlated with change in body weight, $p \leq 0.01$.

H.4. Inter-Process Correlations

Tables 4.12 and 4.13 display the correlations between the process measures for completers and ITT analyses, respectively. Among completers within the INT-TECH group, percent attendance was significantly correlated with armband TOB ($r=0.79$, $p<0.01$), total meals logged ($r=0.74$, $p<0.01$), meals logged with full-entry ($r=0.72$, $p<0.01$), diaries with kilocalories logged ($r=0.70$, $p<0.01$), and diaries with exercise logged ($r=0.71$, $p<0.01$).

Among CON-TECH group subjects, the completers analysis revealed no significant correlations between percent attendance and the other process measures. ITT analysis of the correlations percent attendance and other process measures revealed similar results for the INT-TECH group, except the correlations were slightly stronger. Also, within the CON-TECH group, ITT analysis revealed significant correlations between percent attendance and armband TOB ($r=0.53$, $p\leq0.05$), total meals logged ($r=0.53$, $p\leq0.05$), and meals logged with full entry ($r=0.53$, $p\leq0.05$). Within the SBWP group, ITT analysis revealed significant correlations between percent attendance and diaries with kilocalories logged ($r=0.46$, $p\leq0.05$).

Among completers within the INT-TECH group, armband TOB was significantly correlated with total meals logged ($r=0.83$, $p<0.01$), meals logged with full entry ($r=0.83$, $p<0.01$), diaries with kilocalories logged ($r=0.56$, $p<0.05$), and diaries with exercise logged ($r=0.66$, $p<0.01$). Among completers within the CON-TECH group, TOB was significantly correlated with total meals logged ($r=0.67$, $p<0.01$), meals logged with full entry ($r=0.76$, $p<0.01$). ITT analysis of the relationship between armband TOB and other process measures revealed similar findings for the INT-TECH and CON-TECH group

Table 4.12 Inter-Process Correlations- Completers Analysis

Variable	Percent Attendance			Armband TOB			Meals Logged			Meals Logged FE			Meals Logged UE			Food Diaries^			Exercise Diaries^^		
	S	I	C	S	I	C	S	I	C	S	I	C	S	I	C	S	I	C	S	I	C
Percent Attendance		-	-		0.79**	0.40		0.74**	0.40		0.72**	0.40		0.37	0.21	0.06	0.70**		-0.43	0.71**	
Armband TOB		0.79**	0.40		-	-		0.83**	0.67**		0.83**	0.76**		0.42	-0.36		0.56*			0.66**	
Meals Logged		0.74**	0.40		0.83**	0.67**		-	-		0.99**	0.82**		0.55*	0.00		0.69**			0.86**	
Meals Logged FE		0.72**	0.40		0.83**	0.76**		0.99**	0.82**		-	-		0.49*	-0.49*		0.68**			0.85**	
Meals Logged UE		0.37	0.21		0.42	-0.36		0.55*	0.00		0.49*	-0.49*		-	-		0.30			0.42	
Food Diaries^	0.06	0.70**			0.56*			0.69**			0.68**			0.30		-	-		0.85**	0.92**	
Exercise Diaries^^	-0.43	0.71**			0.66**			0.86**			0.85**			0.42		0.85**	0.92**		-	-	

S= SBWP group, I= INT-TECH group, C= CON-TECH group.
FE= Full Entry, UE= User Estimate.
^= Total BALANCE diaries submitted with caloric data recorded.
^^= Total BALANCE diaries submitted with exercise data recorded.
*Significantly correlation between process measures, $p \leq 0.05$.
** Significantly correlation between process measures, $p \leq 0.01$.

Table 4.13 Inter-Process Correlations- Intent-to-Treat Analysis

Variable	Percent Attendance			Armband TOB			Meals Logged			Meals Logged FE			Meals Logged UE			Food Diaries^			Exercise Diaries^^		
	S	I	C	S	I	C	S	I	C	S	I	C	S	I	C	S	I	C	S	I	C
Percent Attendance		-	-		0.86**	0.53*		0.82**	0.53*		0.81**	0.53*		0.41	0.28	0.46*	0.75**		0.43	0.79**	
Armband TOB		0.86**	0.53*		-	-		0.88**	0.75**		0.88**	0.81**		0.46*	-0.25		0.64**			0.76**	
Meals Logged		0.82**	0.53*		0.88**	0.75**		-	-		1.00 **	0.86**		0.55*	0.07		0.73**			0.88**	
Meals Logged FE		0.81**	0.53*		0.88**	0.81**		1.00 **	0.86**		-	-		0.51*	-0.37		0.72**			0.88**	
Meals Logged UE		0.41	0.28		0.46*	-0.25		0.55*	0.07		0.51*	-0.37		-	-		0.31			0.45*	
Food Diaries^	0.46*	0.75**			0.64**			0.73**			0.72**			0.31		-	-		0.90**	0.67**	
Exercise Diaries^^	0.43	0.79**			0.76**			0.88**			0.88**			0.45*		0.90**	0.91**		-	-	

S= SBWP group, I= INT-TECH group, C= CON-TECH group.
FE= Full Entry, UE= User Estimate.
^= Total BALANCE diaries submitted with caloric data recorded.
^^= Total BALANCE diaries submitted with exercise data recorded.
*Significantly correlation between process measures, $p \leq 0.05$.
** Significantly correlation between process measures, $p \leq 0.01$.

H.5. Qualitative Evaluation of the Technology-Based System

Two questionnaires, past and future use, were used to assess the subjective value of the technology based system. The response frequencies for all items are presented in two forms, as a combination of the INT-TECH and CON-TECH group responses and separately for each group. These results are located in Appendix I.

V. DISCUSSION

A. Introduction

Computer and Internet-based technology offer both supportive and alternative delivery channels for weight management interventions. To date research focused on these innovative techniques has been limited; yet, existing studies have shown that computer (Agras et al., 1990; Burnett et al., 1985; Taylor et al., 1991; Wylie-Rosett et al., 2001) and Internet-mediated programs (Harvey-Berino et al., 2004; Harvey-Berino et al., 2002; Tate et al., 2003; Tate et al., 2001) are acceptable and can result in successful weight loss outcomes. Computer and Internet-mediated programs have yet to produce the degree of weight loss achieved by in-person treatment programs. Therefore, the current investigation aimed to draw on the gaps in the existing literature by examining the effectiveness of an innovative technology based-program, in addition to an in-person, clinically-based behavioral weight loss intervention.

The primary aims of the current investigation were to evaluate the effect of the technology-based system on body weight, BMI, body composition, cardiorespiratory fitness, physical activity, and dietary intake. In comparing the effectiveness of this system, three treatment groups were employed: Standard Behavioral Weight Control Program (SBWP), Intermittent Technology-Based Behavioral Weight Control Program (INT-TECH), and Continuous Technology-Based Behavioral Weight Control Program (CON-TECH).

Previous research has yet to examine the comprehensive application of a computer and Internet-based system similar to the system utilized in the current investigation. It was hypothesized that application of the technology-based system within a structured in-person behavioral weight control program would result in a significantly greater effect on the study outcomes for two primary reasons. First the technology-based system includes a portable system worn as an armband, which allows for objective measurement of daily energy expenditure. Second, the system provides users with detailed energy balance data and related feedback, with this information based on energy expenditure data collected from the armband and dietary intake logged using the system's Internet-based nutritional database. The combination of these strategies would appear to represent an enhancement of behavioral monitoring procedures (i.e. dietary and exercise monitoring) compared to paper-and-pencil standard monitoring procedures. Moreover, it was hypothesized that continuous compared to intermittent use (CON-TECH vs. INT-TECH groups) of the technology-based system would result in a significantly greater effect on the study outcomes.

B. Summary and Conclusions

The attrition rate in the current investigation was 12%; 50 of the 57 randomized subjects completed this investigation. Overall, subjects completing the intervention were significantly younger and more non-completers were minorities. Attrition rate did not differ between the treatment groups, SBWP (n=3), INT-TECH (n=3), CON-TECH (n=1). Furthermore, there were no significant differences observed between completers and non-completers across treatment group. Thus, it appears in terms of program completion the treatment was equally well-received across treatment groups. Moreover, the attrition in this

study was similar to the 15% attrition reported by Tate et al. (2001) following the initial 3-months of an Internet-based weight loss intervention.

B1. Body Weight

Results of this study demonstrated significant ($p<0.05$) weight loss across all treatment conditions (SBWP= 4.8±2.3 kg, INT-TECH= 4.0±3.6 kg, and CON-TECH= 6.5±3.9 kg). Post-hoc analyses of intervention completers indicating a trend ($p=0.08$) toward significance with the CON-TECH and SBWP groups showing greater weight loss compared to the INT-TECH group ($p = 0.08$) (see Table 4.4 and Figure 4.2). Thus, based on completers analysis, the results from this study do not support the primary hypothesis that both INT-TECH and CON-TECH groups would result in greater weight loss compared to the SBWP group or that subjects in the CON-TECH group would achieve greater weight loss compared to the INT-TECH group. Results from the intent-to-treat analysis revealed a significant difference in weight loss between intervention groups and these results support the hypothesis that the CON-TECH group would achieve greater weight loss compared to the INT-TECH group.

The weight losses achieved in the current investigation were somewhat greater than the weight loss reported in published studies of comparable duration that examined the effect of computer or Internet supported/mediated programs on weight loss. For example, Burnett et al. (1985) observed weight loss of 3.7 kg following 8-weeks of computer-assisted therapy (CAT), with Agras et al. (1990) reporting weight loss of 2.3 kg following 12-weeks of an intervention involving CAT. The somewhat better weight loss observed in the current study may be due to enhanced intervention strategies and intervention intensity.

More current interventions have examined the use of the Internet as an alternative channel for delivering a weight loss intervention. In 2001, Tate et al. observed weight losses of approximately 3 kg following 3 and 6 months of treatment in the more structure intervention group. Tate et al. (2003) implemented a behavioral e-counseling intervention that resulted in weight loss of 4.4 kg following 12-months of treatment. The combination of the computer technology with in-person contact may explain the greater weight loss (6.5±3.9 kg) observed in the CON-TECH group in this current study. Moreover, compared to previous Internet-based studies, the current investigation might have resulted in greater weight losses due to differences in intervention protocol. For example, studies conducted by Tate et al. (2001 and 2003) involved minimal in-person treatment contact, whereas the current study included seven individual in-person visits across the 12-week intervention. Therefore, future studies should continue to examine the contribution of combining a technology-based intervention with in-person session for weight loss to determine if this is more effective that either delivery channel when used alone.

The weight losses observed in the SBWP group in the current investigation are comparable to weight losses observed in standard behavioral interventions conducted at the Physical Activity and Weight Management Research Center (PAWMRC) at the University of Pittsburgh. These group-based interventions have observed a mean weight loss of 5.9 kg within the initial 12 weeks, with participants attending structured weekly meetings. The current investigation observed a mean weight loss of 4.7 kg in the SBWP group over the same duration, with participants attending only seven meetings.

Currently, there are not published studies on the effectiveness of the technology-based system for improving weight loss. Thus, the conducted investigation provides the

initial data to allow for variance estimates to power a larger clinical trial. The sample size used in the current investigation allowed for the detection of statistically significant differences in weight loss between the INT-TECH and CON-TECH groups; however, the weight loss difference observed between the SBWP and CON-TECH groups was not statistically significant. Power analyses were conducted to determine the necessary sample size to detect statistically significant differences between the SBWP and CON-TECH groups. The results from the completers analysis indicated an effect size of 0.57 (weight loss difference = 1.7±3.0 kg). Assuming this effect size and an error rate of 0.05, 54 and 71 subjects per group would be required to detect this effect size with 80% and 90% power, respectively. The ITT analyses indicated an effect size of 0.62 (weight loss difference = 2.1±3.4 kg) which could be detected with 80% or 90% power with samples of 40 and 53 subjects, respectively.

B.2. Change in Body Composition

This study also examined the effect of SBWP, INT-TECH, and CON-TECH on changes in body composition and regional adiposity. Results presented in Tables 4.4 and 4.5 indicate that the reduction in percent body fat in CON-TECH (4.1±2.9%) was significantly greater than the changes observed in SBWP (1.6±1.5%) and INT-TECH (1.6±1.7%). These findings support the hypothesis that CON-TECH enhanced changes in body composition compared to INT-TECH and SBWP, suggesting that continuous use of the technology-based system might lead to improvements in the reduction of body fatness. However, these results should be interpreted with caution. The BIA method of measuring body composition has been shown to potentially have a margin of error that could explain these observed

differences (Jakicic and Wing, 1998). Thus, future research should employ other measures of body composition that may overcome the limitations of BIA.

B.3. Change in Regional Adiposity

This study demonstrated significant reductions in regional adiposity as measured by waist circumference in SBWP, INT-TECH, and CON-TECH (see Tables 4.4 and 4.5). However, these reductions in waist circumference were not significantly different between the intervention groups, which does not support the hypothesis related to this outcome variable. This finding may be a result of the difference in the magnitude of weight loss observed between the treatment conditions in this study not being sufficient to result in differences in waist circumference. While waist circumference is an indicator or abdominal adiposity, there are limitations to this technique. For example, Ross et al. (1996) reported modest correlations of r=0.69 and r=0.47 (males and females, respectively) between waist circumference and visceral adiposity using magnetic resonance imaging, which provides a more accurate assessment of regional adiposity. Consequently, the use of anthropometry (waist circumference) rather than more detailed measures of regional adiposity may have limited the ability to detect differences between the groups.

B.4. Change in Cardiorespiratory Fitness and Physical Activity

There were observed increases in cardiorespiratory fitness in all conditions (SBWP, INT-TECH, CON-TECH) across the 12-week intervention period (see Tables 4.4 and 4.5). However, no significant difference between the intervention groups was detected, which does not support the hypothesis related to the expected difference in cardiorespiratory fitness. It has been demonstrated that there is a dose-response effect of physical activity on changes in

cardiorespiratory fitness ("Physical Activity and Health: A Report of the Surgeon General", 1996). In the current study; however, change in physical activity was not significantly different between intervention groups (SBWP, INT-TECH, CON-TECH) (see Tables 4.4 and 4.5), which may explain the lack of a significant difference between the intervention groups for cardiorespiratory fitness. Moreover, it is of concern that neither CON-TECH nor INT-TECH resulted in greater increases in physical activity compared to SBWP, as more intensive internet-based weight loss interventions have demonstrated a similar result (Tate et al. 2001 and 2003). Future weight loss intervention research needs to examine how to use the Internet in conjunction with objective energy expenditure monitoring to lead to greater improvements in cardiorespiratory fitness and physical activity in overweight and obese adults. This may be of benefit because of the independent effects of both fitness and physical activity on health-related outcomes in overweight and obese adults (Farrell et al. 2002).

B.5 Change in Dietary Intake

There were significant reductions in dietary intake in all treatment conditions, with no significant difference observed between SBWP, INT-TECH, and CON-TECH groups (see Table 4.4 and 4.5). The results observed for change in dietary intake in the current investigation were similar to the reported results from the reviewed computer and Internet-based studies (Burnett, Taylor, & Agras, 1985; Agras, Taylor, Feldman, Losch, & Burnett, 1990; Taylor, Argras, Losch, Plante, & Burnett, 1991; Tate, Wing, & Winett, 2001; Wylie-Rosett et al., 2001; Tate, Jackvony, & Wing, 2003; and Womble et al., 2004) that have reported no significant differences between intervention conditions. Overweight individuals commonly under-report their energy intake (Buchowski, Townsend, Chen, Acra, & Sun, 1999; Buhl, Gallagher, Hoy, Matthews, & Heymsfield, 1995; Irwin, Ainsworth, & Conway,

2001), and this may partially explain the lack of a significant difference between the intervention groups in this study. In addition, the food frequency questionnaire that was used in this study may not have allowed for the detection of modest differences in daily dietary intake necessary to result in the observed differences in body weight between the groups.

B.6. Self-Monitoring of Process Measures

Self-monitoring appears to be a behavioral strategy vital to weight loss success (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998; Wadden & Letiza, 1992; Sperduto, Thompson, & O'Brein, 1986). In the current study, self-monitoring in the SBWP group, based on total diaries with calories or exercise logged, was not significantly correlated with weight loss (see Tables 4.9 and 4.10). However, self-monitoring of energy expenditure using the armband and presented as armband time on body (TOB) was significantly correlated with weight loss for both the INT-TECH and CON-TECH groups (see Tables 4.9 and 4.11). These results suggest that TOB might serve as a vital indicator for weight loss success within the technology-based groups (i.e. greater TOB was associated with greater weight loss). This may be a result of the armband providing a simple and effective method of objectively monitoring energy expenditure, which may influence energy balance. Alternatively, TOB could be an indicator of compliance to other important self-monitoring strategies that results in improved weight loss. For example, TOB was significantly correlated with self-monitoring of eating behaviors, which were also correlated with weight loss in this study. Thus, the combination of these compliance measures may have lead to more exposure to energy balance feedback using the computerized system, which may have contributed to improved weight loss in the CON-TECH group. These factors should be

examined more extensively in future research related to the use of computerized technology for weight loss interventions.

B.7. Qualitative Analysis of the Technology-Based System

Results from the subjective evaluation of the technology-based system are provided in Appendix I. Combined results of past use of the technology-based system, showed that the INT-TECH and CON-TECH groups reported the system was easy to use and it helped to raise awareness and promoted change in weight loss related behaviors. Approximately 21% of the subjects disagreed that the technology-based system was comfortable to wear and did not interfere with their social lives. This result indicates that wearing the armband might have been seen as a barrier to program compliance. In fact, 18% of subjects reported that they did not wear the armband because it was uncomfortable, whereas 30% of subjects reported they would not use the armband in the future for this reason. Significantly more subjects in the CON-TECH vs. INT-TECH group agreed that the technology-based system helped to overcome barriers to adopting a health diet and exercise, and the system helped with interaction with personal weight loss counselors regarding diet and exercise. These subjective results suggest that it may be possible that consistent use of the technology-based system within the CON-TECH group helped to enhance treatment interactions and thus potentially influencing weight loss outcomes compared to the INT-TECH group.

Subjects were queried on the future use of the technology-based system to assist with weight loss and no differences in response frequency for any item were found between groups. Overall, about 42% of subjects reported that, if given the opportunity, they would use the technology-based system daily in the future to assist with tracking both eating and exercise behaviors; 46% reported the would use the system periodically; and 12% reported

that they would not use the system in the future. In addition, about 42% of subjects reported that they would wear the armband component of the system on a daily basis in the future, 12% reporting that they would not wear the armband, and 46% reported that they would wear the armband periodically.

While these questions on past and future use of the technology-based system have not been tested for reliability and validity, these results provide some insight related to the benefits and potential compliance issues of using the technology-based system for weight loss. First, it appears that subjects randomized to either technology-based group reported that the system was helpful in raising awareness and promoting change in weight loss-related behaviors. The differences in response frequency reported between groups might indicate that during a short-term intervention, continuous versus intermittent use of the technology-based system might help subjects better to overcome barriers to adopting a health diet and exercise and interact with weight loss counselors. However, there may be barriers to continuous use of the armband that may impact compliance to using the entire system, which may impact weight loss.

C. Limitations and Future Research

This study was the first to examine the effectiveness of the technology based system on the specified outcomes. This investigation is not with out limitations which could impact the application of the observed results. The following limitations and recommendations should be considered for future research:

1. The generalizability of the findings is limited to individuals with similar demographics to the subjects who participated in this investigation. Future studies must aim to evaluate the technology-based system in a more diverse

background in an attempt to develop an improved understanding of for whom the system will work.

2. The study examined pre-specified treatment groups in a clinical-based protocol (i.e. study design). Future studies should examine the effectiveness of the system in several different ways and also measure the cost-effectiveness of these programs. A few different treatment options include: use of the system without in-person support, use of the system in a group-based treatment environment, use of the system in a more portable or convenient manner (i.e. hand-held computer), and evaluate dose response and variable treatment intensity (i.e. continuous use for 1 month followed by intermittent use or goal-based technology system application).

3. The sample size used in the study may not have provided sufficient power to detect differences in study outcomes between treatment groups (weight loss was not significantly different between the SBWP and CON-TECH groups). In addition the sample size might have limited the ability to detect significant behaviorally-based correlations with weight loss (correlations between dietary self-monitoring and weight loss were not observed within the SBWP group). Future studies should examine the effectiveness of the system in a larger sample.

4. The study was 12-weeks in duration, which limits the ability to know how the technology-based system would influence study outcomes long term. Future studies should examine the effectiveness of this system on weight loss and behavioral outcomes longer than 12 weeks.

5. The feedback provided to the technology-based group was very general, primarily based on energy balance data. Future studies should examine the impact of a more tailored feedback approach, potentially directed through the weight loss counselor.

6. This investigation examined changes in physical activity and dietary intake through self-report. While the measurement instruments utilized have been shown to be reliable and valid, these tools have potential for high self-report related error. Future studies should attempt to examine the effectiveness of the technology based system on physical activity and dietary changes with more objective assessment tools.

7. The subjects in the technology-based groups evaluated the subjective value of system. The questionnaire used to assess this value was not assessed for reliability and validity. Therefore, future studies should determine the most important characteristics associated with the potential effectiveness of the system and develop a questionnaire with established psychometric properties.

D. Summary

In summary, this study examined the use of computer and Internet-based technology in conjunction with a behavioral weight loss intervention. It was found that continuous use of this system resulted in greater weight loss compared to intermittent use of the system. In addition, difference in weight loss between the continuous and standard group was approximately 2 kg. Results also showed that TOB was a vital indicator of weight loss in both technology-based groups. Thus, it appears that the differential weight losses observed

between the technology-based groups may be related to the differential exposure to this system. These findings suggest that weight loss outcomes may be improved when technology-based devices are employed with continuous, consistent exposure within a structured treatment environment. Clinically, these devices offer alternative and supportive delivery channels which may enhance treatment interactions. Due to the limitations of this short term study; however, additional research needs to be conducted before concluding that technology-based devices are beneficial in the context of weight loss interventions with structure similar to this investigation.

APPENDIX A

INFORMED CONSENT

Approval Date:
Renewal Date:
University of Pittsburgh
IRB #

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: The Effect of HealthWear on Short-Term Weight Loss

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SOURCE OF SUPPORT: Roche Diagnostics

DESCRIPTION:

The number of overweight and obese adults in the United States has been increasing at a rapid rate. Being overweight is associated with increased risk of many medical conditions including heart disease and diabetes. Developing treatment programs to treat obesity can significantly improve health. This study will examine whether adding HealthWear, which is a computer-based system developed by Roche Diagnostics, to an intervention conducted by a weight loss coach improves weight loss in adults. In addition, this study will investigate the effect of this intervention on body composition, fitness, other behavioral factors, and perceived benefits and barriers to using this technology.

You are being invited to take part in this research study because you are within the body weight range for this study, and do not have any medical conditions that would prohibit you from participating in moderate to vigorous activity. People invited into this study have to be men or women between 18-55 years of age. Women participants cannot be pregnant, and if you are a woman you will be required to accurately report whether you are pregnant to the investigators prior to beginning this study and during the study if your status should change. This study is being performed on a total of 75 individuals at the University of Pittsburgh. To be eligible to participate in this study, you need to have access to a computer and the internet.

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

Screening Procedures:

Procedures to determine if you are eligible to take part in a research study are called "screening procedures." For this research study, the screening procedures include:

A. You will complete a physical activity readiness questionnaire (PAR-Q), and this will take approximately 5 minutes to complete. You will also complete a detailed medical history, and this will take approximately 20 minutes to complete. These questionnaires will allow the investigators to determine if you have any significant medical condition that would indicate exercise is unsafe for you. You will also be required to provide medical clearance from your personal physician before starting this study.

Experimental Procedures:

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

You will first be asked to complete a series of questionnaires, and it is estimated that you will be able to complete these questionnaires in approximately 60 minutes. These questionnaires will provide information about your health, exercise and diet habits. You will also be required to provide written clearance from you personal physician approving your participation in this study. Your body weight, body composition, physical fitness, blood pressure, level of physical activity, and food

intake will be measured. These assessments will take place at the Physical Activity and Weight Management Research Center in Birmingham Towers at the University of Pittsburgh, and these assessments will be completed in approximately 90 minutes. A brief description of these assessments follows.

A. Body Weight and Height: Your body weight will be measured using a standard medical scale. Your height will be measured with a ruler that is attached to a flat wall. These will be measured at 0, 4, 8, and 12 weeks during this study.

B. Body Composition: Your body composition is the amount of fat weight and lean weight (muscle and bone) that you have on your body. Your body composition will also be measured using a technique known as Bioelectrical Impedance Analysis (BIA). This procedure requires that a small electrode be placed on your hand, wrist, ankle, and foot. A low-level signal that is not harmful to you and that you will not feel is transmitted between the electrodes. There is no harm or risk associated with this procedure. Measurements of your waist and hip areas will also be made using a measuring tape. These measures will be made at 0 and 12 weeks during this study.

C. Cardiorespiratory Fitness: Measurement of your cardiorespiratory fitness will provide information about how fit your heart and lungs are to perform exercise. Your fitness will be estimated by having you walking on a treadmill. The speed of the treadmill will be kept at 3.0 mph (a brisk pace), however the grade of the treadmill will increase 2.5% every 3 minutes so that it feels like you are walking up a hill. As you are walking, your heart rate, blood pressure, and perception of physical exertion will be measured. Your heart rate will be measured using an electrocardiogram, which is also known as an ECG. The ECG will require that electrodes be placed on the chest and abdomen areas of your body. You will continue to walk on this treadmill until you reach a heart rate that is 85 percent of your maximal capacity, and then the test will be stopped. During this test you will breathe in and out through a sterilized mouthpiece and will wear a set of nose clips so that no air flows through your nose. The air that you breathe will be measured by a machine known as a metabolic cart. This will provide information about the amount of oxygen that you need when you are exercising. Fitness will be measured at 0 and 12 weeks during this study.

D. Muscular Strength: Muscular strength refers to the maximum amount of weight you can lift and is specific to each muscle group. Your muscular strength will be estimated for upper and lower body by having you perform one weight lifting exercise that uses the chest muscles and one that uses the leg muscles. You will be asked to lift the maximum amount of weight you can lift one (1) time when performing a seated chest press (which uses the chest muscles) and single leg extension (which uses the leg muscles) on an exercise machine.

E. Physical Function: You will participate in a test to measure your physical function, and this is known as the sit-to-stand test. You will be instructed to sit in

the middle of a chair with your back straight, feet flat on the floor, and arms crossed at the wrists and held against the chest. You will then rise to a full stand and then return to a fully seated position as many times as you can in 30 seconds. You are not permitted to swing your arms or push off the chair using your hands to assist yourself to either the seated or standing position. You will also perform a test of grip strength that will require you to squeeze on a machine similar to you making a tight fist.

F. Blood Pressure: Your blood pressure will be measured using a standard blood pressure cuff and will follow standard measurement procedures. Blood pressure will be measured at 0 and 12 weeks during this study.

G. Exercise, Dietary Patterns, Function, Factors that Influence Behavior Change, and Use of the HealthWear System: You will complete questionnaires about the amount of exercise that you do, the amount and types of foods that you eat, and your ability to perform common tasks. You will also complete questionnaires about factors such as your mood, general health, and other things that may affect your exercise and eating behaviors. These questionnaires will be completed at 0 and 12 weeks during this study. However, the questionnaires specific to exercise, dietary patterns, and use of the HealthWear System will be completed at 0, 4, 8, and 12 weeks. It is estimated that you will be able to complete these questionnaires in approximately 60 minutes.

Weight Control and Exercise Procedures

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

A. Standard Behavioral Weight Control Intervention:

1.) Intervention Sessions and Contacts: You will attend sessions with a weight loss coach. You will meet with your weight loss counselor during weeks 1, 2, 3, 4, 6, 8, 10, and 12. Each session will last 30 to 45 minutes. These sessions will be scheduled at a time that is convenient for both you and your weight loss coach.

2.) Diet: You will be placed on a diet that encourages you to decrease the amount of total calories and fat that you eat. If you are less than 200 pounds, you will be placed on a 1200 calorie per day diet, if you are 200 to 250 pounds you will be placed on a 1500 calorie per day diet, and if you are greater than 250 pounds you will be placed on an 1800 calorie per day diet. You will also be taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this will be returned to the weight loss coach at each session.

3.) Exercise: You will be given a home-based walking program for exercise. You will be instructed to exercise 5 days per week, with the duration on each day increasing from 20 to 40 minutes during the first 12-weeks of the program, and you will maintain this level of exercise throughout the remainder of the program. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. You will record your exercise in a diary that is returned to the weight loss coach at each session.

B. Standard Behavioral Weight Control plus Periodic HealthWear Use:

1.) Intervention Sessions and Contacts: You will attend sessions with a weight loss coach. You will meet with your weight loss counselor during weeks 1, 2, 3, 4, 6, 8, 10, and 12. Each session will last 30 to 45 minutes. These sessions will be scheduled at a time that is convenient for both you and your weight loss coach.

2.) Diet: You will be placed on a diet that encourages you to decrease the amount of total calories and fat that you eat. If you are less than 200 pounds, you will be placed on a 1200 calorie per day diet, if you are 200 to 250 pounds you will be placed on a 1500 calorie per day diet, and if you are greater than 250 pounds you will be placed on an 1800 calorie per day diet. You will also be taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this will be returned to the weight loss coach at each session.

3.) Exercise: You will be given a home-based walking program for exercise. You will be instructed to exercise 5 days per week, with the duration on each day increasing from 20 to 40 minutes during the first 12-weeks of the program, and you will maintain this level of exercise throughout the remainder of the program. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. You will record your exercise in a diary that is returned to the weight loss coach at each session.

4.) Use of HealthWear: You will be provided with and instructed to use HealthWear at weeks 1, 5, and 9 during the intervention phase of this study. HealthWear includes a monitor that is worn on your upper right arm that will track the amount of energy your burn and the amount of physical activity that you perform. You will wear this monitor during all of your waking hours and will remove the monitor when you sleep or

participate in water activities such as showering, bathing, or swimming. HealthWear also involves the use of computer software that you will use to track your eating behaviors each day. The information from the activity monitor and the computer software will be sent to your weight loss counselor using the internet. HealthWear will also provide you feedback regarding your ability to achieve the eating and physical activity goals for this study. You will be assigned a user name and a password to maintain your confidentiality when using this system. You will be responsible for providing the computer and the internet service that you will use during this study.

C. Standard Behavioral Weight Control plus Continuous HealthWear Use:

1.) Intervention Sessions and Contacts: You will attend sessions with a weight loss coach. You will meet with your weight loss counselor during weeks 1, 2, 3, 4, 6, 8, 10, and 12. Each session will last 30 to 45 minutes. These sessions will be scheduled at a time that is convenient for both you and your weight loss coach.

2.) Diet: You will be placed on a diet that encourages you to decrease the amount of total calories and fat that you eat. If you are less than 200 pounds, you will be placed on a 1200 calorie per day diet, if you are 200 to 250 pounds you will be placed on a 1500 calorie per day diet, and if you are greater than 250 pounds you will be placed on an 1800 calorie per day diet. You will also be taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this will be returned to the weight loss coach at each session.

3.) Exercise: You will be given a home-based walking program for exercise. You will be instructed to exercise 5 days per week, with the duration on each day increasing from 20 to 40 minutes during the first 12-weeks of the program, and you will maintain this level of exercise throughout the remainder of the program. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. You will record your exercise in a diary that is returned to the weight loss coach at each session.

4.) Use of HealthWear: You will be provided with and instructed to use HealthWear during the entire intervention phase (weeks 1-12) of this study. HealthWear includes a monitor that is worn on your upper right arm that will track the amount of energy your burn and the amount of physical activity that you perform. You will wear this monitor during all of your waking hours and will remove the monitor when you sleep or

participate in water activities such as showering, bathing, or swimming. HealthWear also involves the use of computer software that you will use to track your eating behaviors each day. The information from the activity monitor and the computer software will be sent to your weight loss counselor using the internet. HealthWear will also provide you feedback regarding your ability to achieve the eating and physical activity goals for this study. You will be assigned a user name and a password to maintain your confidentiality when using this system. You will be responsible for providing the computer and the internet service that you will use during this study.

RISKS and BENEFITS:

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

A. Risks of Exercise: There are moderate risks associated with participating in an exercise test and a regular exercise program. During exercise, you may experience a serious cardiac event, an arrhythmia, or chest pain. An example of a cardiac event would be a heart attack or another medical condition that causes damage to your heart or cardiovascular system. The possibility of experiencing a serious cardiac event has been estimated to be less than 1 per 20,000 in exercising adults, with the risk of death during a maximal exercise test being less than 0.5 per 10,000 tests. Therefore, the risk is of this happening to you is rare, because it occurs in less than 1% of people (less than 1 out of 100 people). In addition, during exercise, you may experience an increase in heart rate, an increase in blood pressure, shortness of breath, or general fatigue. The risk of this happening to you is likely because these occur in more that 25% of people (more than 25 out of 100 people). In the event that you experience a serious medical condition during your exercise testing session or during a supervised exercise session, the session will be stopped and appropriate emergency medical care will be provided. This may include providing CPR until Paramedics or other appropriate medical personnel arrive. Because some of the exercise sessions that you will be ask to do will not be supervised by the staff, the staff cannot provide medical assistance to you in the event of an emergency during these exercise sessions.

B. Risk of having the air that you breath in and out measured by a metabolic cart: When measuring the air that you breath in and out during exercise, you may experience a dry mouth. This risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

C. Risk of Electrocardiogram (ECG): You may experience skin irritation or skin redness from electrodes being placed on your skin. The risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

D. Risk of Assessing Muscular Strength and Physical Function: You may experience muscle fatigue or soreness from completing these assessments. The risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people). You may also experience a muscle sprain or strain resulting from these assessments. The risk of this happening to you is rare because this occurs in less than 25% of people (less than 25 out of 100 people).

E. HealthWear Activity Monitor: Some people may experience mild skin irritation at the site where the activity monitor is worn. One cause of skin irritation has already been identified in people who wear the armband for extensive periods of time (i.e., more than 24 hours). Specifically, the build-up of sweat that can be trapped between the skin and the armband can cause pink pustules or pimples to appear. This condition is named miliaria, or prickly heat. This condition is common and occurs in 1% to 25% of people (1 to 25 out of 100 people) that wear the armband. To help to prevent this condition you should clean your arm using rubbing alcohol before putting on the activity monitor. Also, you should use soap and water to clean the elastic strap that attaches the monitor to your arm before each use. You should also wipe off the monitor using rubbing alcohol and allow this to dry before putting it on your arm.

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

G. Risks of Reducing Your Calorie and Fat Intake: Consuming a moderately low fat and low calorie diet appears to be safe and effective for weight loss. However, if you reduce your calorie or fat intake below recommended levels you may experience dry skin and thinning of your hair. This is common and occurs in 1% to 25% of people (1 to 25 out of 100 people). You may also experience problems with your gall bladder. This is infrequent and occurs in less than 1% of people (less than 1 out of 100 people).

H. Risk Associated with Participating in the Intervention: Attending sessions has been shown to be effective for weight loss. However, attendance at these sessions may involve you sharing information about yourself and your weight loss efforts to your weight loss coach. You can elect not to share this private information about yourself to your weight loss coach. Your weight loss coach will be instructed to keep all information shared in the sessions confidential. In addition, if you are assigned to use HealthWear you will transfer information to your weight loss coach using the internet. There is the risk that this information could be viewed by others who use the internet; however, the risk is of this happening to you is rare, because it occurs in less than 1% of people (less than 1 out of 100 people).

To avoid risk to the fetus, it is important that women not become pregnant while participating in this research study. Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you are a woman and choose to be sexually active, you should use the appropriate "double barrier" method of birth control (such as female use of a diaphragm, intrauterine device (IUD), or contraceptive sponge, in addition to male use of a condom), or the female should be using prescribed "birth control" pills, injections, or implants. Such birth control methods should be used for 30 days prior to beginning your participation in this study and continue throughout the study period. If you choose to be sexually active during this study, you understand that even with the use of these birth control measures pregnancy could still result. The risks of participating in this study while pregnant include potential loss of pregnancy or possible birth defects. Therefore, if you become pregnant you are to inform the investigators immediately and discontinue your participation in the diet and exercise components of this study.

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

Benefits

A. Benefits of Exercise: The benefits of participation in an exercise program have been shown to include improvements in physical fitness, weight loss, improvements in blood pressure, and improvements in blood cholesterol levels. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study.

B. Benefits of Reducing your Calorie and Fat Intake: Consuming a low fat and low calorie diet appears to be safe and effective for weight loss. Additional benefits of eating this type of diet can be improvements in blood pressure and improvements in blood cholesterol levels. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study.

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

NEW INFORMATION

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

COSTS and PAYMENTS

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study (i.e., the Screening Procedures, Experimental Procedures, or Weight Control and Exercise Procedures described above).

You will be paid $50 for completing the assessments following the 12 week intervention. These will include body weight, height, body composition, cardiorespiratory fitness, muscular strength, blood pressure, and questionnaire to assess exercise, dietary patterns, and factors that influence behavior change. If you do not complete all of these assessments you will not be compensated for your participation.

COMPENSATION FOR INJURY

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

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of the University of Pittsburgh Medical Center. It is possible that the University of Pittsburgh Medical Center may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. You will not receive any monetary payment for, or associated with, any injury that you suffer in relation to this research.

CONFIDENTIALITY

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

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (e.g., physician office) records. The information that will be recorded will be limited to information concerning medical clearance from your physician to participate in this research study. This may include information related to coronary heart disease risk factors such as blood pressure, blood cholesterol, or other medical conditions that may increase the risk of heart disease and/or indicate that exercise participation may be unsafe for you. This information will be used to determine whether it is safe for you to participate in this research study. The results collected from this research study (e.g. diagnosis of new disease or condition) will be sent to

your primary care physician upon your written approval according to procedures approved by the University of Pittsburgh Institutional Review Board.

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

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, your research records may be required to release identifiable information (which may include your identifiable medical record information) related to your participation in this research study in response to an order from a court of law. If the researchers learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of the sponsor of this research study, the National Institutes of Health, will review and/or obtain identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical record information, the University of Pittsburgh Medical Center and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical record information related to your participation in the study.

Authorized representatives of the University of Pittsburgh Medical Center hospitals, or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e., quality assurance).

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical record information) related to your participation in this research study for 5 years following the completion of

this study, as per University policy, or when such is approved by the sponsor of this study, whichever should occur last.

RIGHT TO PARTICIPATE or WITHDRAW FROM PARTICIPATION

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no affect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no affect on your current or future medical care at a University of Pittsburgh Medical Center hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

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

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

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

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

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-

212-2668). By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature	Date

CERTIFICATION OF INFORMED CONSENT

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

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date

APPENDIX B

PRE-PARTICIPATION SCREENING FORMS

Physical Activity Readiness Questionnaire (PAR-Q)

Subject ID: _____ Date: _____

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

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

   □ yes □ no

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

   □ yes □ no

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

   □ yes □ no

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

   □ yes □ no

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

   □ yes □ no

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

   □ yes □ no

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

   □ yes □ no

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

GENERAL HEALTH HISTORY

Subject ID:_____

DATE: _____

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

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

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

   If yes, please describe the problem:_____

   _____

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

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

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

MEDICATION	REASON FOR TAKING
_____	_____
_____	_____
_____	_____
_____	_____

6. Over the last 6 months, on how many weekdays (Monday through Friday) do you usually drink wine, beer, or liquor on average?
   (0) □ Never
   (1) □ Less than once/month
   (2) □1-2 times/month
   (3) □1 day/week
   (4) □ 2 days/week
   (5) □ 3 days/week
   (6) □ 4 days/week
   (7) □ 5 days/week

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

8. Over the last 6 months, on how many weekend days (Saturday and Sunday) do you usually drink wine, beer, or liquor?
   (0) □ Never
   (1) □ Less than once/month
   (2) □ 1-2 times/month
   (4) □ 1 weekend day/week
   (5) □ 2 weekend days/week

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

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

			Please describe daily habit
Cigarettes	□yes	□no	_____
Pipe	□yes	□no	_____
Cigars	□yes	□no	_____
Chewing Tobacco	□yes	□no	_____

11. Do you plan to spend frequent time out of town on business or vacation during the next 18 months? □yes □no Please describe:_____
_____

12. Is it possible that you will relocate in the next 18 months? □yes □no Please describe: _____

WOMEN ONLY ANSWER THE FOLLOWING QUESTIONS

13. Are you currently pregnant? □yes □no

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

15. Do you plan to become pregnant in the next 18 months? □yes □no

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

17. Have you had a hysterectomy? □yes □no

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

19. Do you take :

Birth Control Pills?	□yes	□no
Estrogens (ie. Premarin)?	□yes	□no
Progesterone (ie. Provera)?	□yes	□no

APPENDIX C

PHYSICIAN CONSENT

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

TO:

Physician's Name

Address

City **State** **Zip**

( )

Telephone Number

RETURN TO: (envelope provided)
John M. Jakicic, Ph.D.
University of Pittsburgh
Department of Health and Physical Activity
Physical Activity and Weight Management Research Center
2100 Wharton Street, Suite 600
Pittsburgh, PA 15203
Telephone: (412) 488-4184
FAX: (412) 488-4174

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

1. A walking program that will be primarily home-based. The exercise will gradually be progressed from 20 minutes per day to as much as 40 minutes per day, 5 days per week. Exercise intensity will be set at 60-70% of the patient's maximal heart rate.

2. A diet program that will reduce energy intake to 1200-1500 calories per day, with dietary fat reduced to 20-30% of total energy intake.

3. A graded exercise test which involves walking on a motorized treadmill, with the workload gradually increasing every 3 minutes. The test will be terminated when the patient achieves 85% of their age-predicted maximal heart rate, or prior to this level if the individual experiences signs or symptoms that would indicate that exercise is contraindicated. Both blood pressure and heart rate will be monitored continuously. The ACSM Guidelines for Exercise Testing will be followed.

4. Behavioral modification techniques for changing exercise behaviors.

5. A list of additional factors that are exclusionary criteria for this study that you should consider are listed on the attached sheet.

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

☐ I know of no contraindications to this patient participating in any of the above components of the program.

☐ I feel that this program would not be appropriate for this patient for the following reason(s):

_____

_____

_____ _____

Signature of Physician Date

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

Inclusion Criteria

1. 18-55 years of age.
2. Body mass index (BMI) between 25.0-39.9 kg/m^2.
3. Male or Female.

Exclusion Criteria

1. Report losing >5% of current body weight in the previous 6 months.
2. Report participating in a research project involving weight loss or physical activity in the previous 6 months.
3. For women, report being pregnant during the previous 6 months, or planning on becoming pregnant over the following 3 months of the intervention. (Pregnancy during initial screening will be based on self-report and will be included on the detailed medical history that is completed by subjects.)
4. Currently being treated for any medical condition that could impact body weight (i.e., diabetes mellitus, cancer, etc.).
5. History of myocardial infarction, or a history of undergoing heart surgery such as bypass or angioplasty.
6. Taking medication that would affect heart rate or blood pressure responses to exercise (e.g., beta blockers).
7. Taking medication that could affect metabolism and/or contribute to a change in body weight (e.g., synthroid).
8. Being treated by a therapist for psychological issues or problems, taking pyschotropic medications, or receiving treatment with psychotropic medications within the previous 6 months.

APPENDIX D

EQUIPMENT COMPETENCY CHECK LIST

Subject ID:_____

Equipment Competency Checklist

1. Subject placed armband in correct position.

_____

2. Subject initiated armband for data collection.

_____

3. Subject removed armband for data retrieval.

_____

4. Subject accessed HealthWear Web Site (www.healthwear.com).

_____

5. Subject accessed personal information page with user ID and password.

_____

6. Subject entered sample data into HealthWear interface.

_____

7. Subject connected cable to USB port for armband attachment.

_____

8. Subject attached armband to cable.

_____

9. Subject downloaded sample data to personal information page.

_____

10. Subject was able to interpret data feedback.

_____

Signature of staff member: _____

APPENDIX E

MEAL PLANS

1200 Calorie Eating Plan Guidelines

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

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

   Breakfast: 200-300 calories

   Lunch: 300-350 calories

   Dinner: 500-550 calories

   Snack: 0-200 calories

2. During the initial 12 weeks of the program, meals and snacks should be limited to the foods on the lists that are provided for you.
3. Average calorie and fat gram information is provided for all the foods you will be eating. If a particular brand differs from this average, use the calorie and fat gram information on the nutritional label or refer to the Fat Book. Transfer the calorie and fat information to your self-monitoring book.
4. Your eating plan is designed to provide no more than 20% of your calories from fat. For your 1200 calorie eating plan, this breaks down to 26 grams of fat.
5. We recommend that you weigh and measure your food portions, especially your portions of meat. Purchase a food scale if you do not already have one and use it and the labels on the food to help you select appropriate portions.
6. To help ensure adequate intake of vitamins and minerals, a daily multi-vitamin is recommended.

1200 Calorie Breakfast

(200-300 kcal)

Selection 1

- 1 serving of Cold or Hot cereal
- 4 oz. Milk or 1 serving of Milk
- 4 oz. Fruit Juice or 1 serving of Fruit

Selection 2

- 2 servings of Bread
- 2 servings of Jam/Jelly/Fat-Free Cream Cheese
- 4 oz. Fruit Juice or 1 serving of Fruit

Selection 3

- Egg Substitute
- 1 serving of Bread
- 1 serving of Jam/Jelly/Fat-Free Cream Cheese
- 4 oz. Fruit Juice or 1 serving of Fruit

Selection 4

- 1 serving Non-Fat or Lite Yogurt
- 1 serving of Bread
- 1 serving of Jam/Jelly/Fat-Free Cream Cheese
- 4 oz. Fruit Juice or 1 serving of Fruit

Breakfast Foods

Calorie and Fat Content

Cereal Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
* Bran Flakes	2/3 cup	90	0
Cheerios (plain)	1 cup	110	2
Corn Flakes	1 cup	110	0
* Oatmeal, cooked	1 cup cooked or 1 package of instant	145 130-150	2.0 2.0-2.5
* Raisin Bran	3/4 cup	130	0
*Shredded Wheat, Spoon Size	2/3 cup	110	0
*Kashi (e.g., GoLean / Good Friends)	3/4 cup	90-120	1.0

Milk/ Yogurt Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Skim Milk or Super Skim Milk	4 oz.	45	0
1% Milk	4 oz.	50	1.5
Soymilk (Nonfat or Lite)	4oz.	40-55	0-0.75
Non-Fat, Lite, or PlainYogurt	6-8 oz.	100-130	0

Bread Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
* 100% Whole Wheat Toast	1 slice	90	1
White Toast	1 slice	80	1
English Muffin	1/2	70	0.5
Bagel (any flavor) *(this is a standard Lender's Bagel – Panera bagel has approx. 290 cal, Panera Cin. Crunch: 510 cal)*	1/2	100	1
Diet Bread	2 slices	80	0

***These foods are recommended to increase the fiber in your diet.**

Egg Substitute Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Fleischmann's Egg Beaters	1/2 cup	50	0
Healthy Choice Cholesterol-Free Egg Product	1/2 cup	50	0
Egg Whites	3 large	50	0

Fruit Juice Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
100% Orange Juice	4 oz.	60	0
100% Grapefruit Juice	4 oz.	50	0
100% Apple Juice	4 oz.	60	0

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Banana	1/2	55	0
* Orange	1	65	0
* Grapefruit	1/2	45	0
* Strawberries	1 cup, whole	45	0
*Raisins	2 Tbs.	60	0
*Grapes	1 cup	60	0
*Blueberries	1 cup	80	0

Jam/Jelly/Cream Cheese/Margarine Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Regular Jam/Jelly (any flavor)	2 tsp.	30 (average)	0
Diet Jam/Jelly (any flavor)	2 tsp.	15 (average)	0
Fat-Free Cream Cheese	2 Tbs.	25 (average)	0
Reduced Fat Margarine	2 tsp.	35 (average)	4
Plant Sterol Margarine (e.g., Light Benecol)	1 Tbs.	30 (average)	3

***These foods are recommended to increase the fiber in your diet.**

1200 Calorie Lunch

300-350 kcal

Selection 1

- 1 serving of Chicken, Turkey, Salmon, Tuna, or Ham
- 2 servings of Bread
- 1 serving of a Condiment
- 1 Fruit serving

Selection 2

- *Salad
- 1 serving of Chicken, Turkey, Tuna, Salmon, or Ham
- 1 serving of a Condiment
- 1 serving of Bread
- 1 Fruit serving
- 4 oz. of Milk or 6-8 oz. of Non-Fat Yogurt

Selection 3

- 1 serving of Cottage Cheese
- 1 serving of Fruit
- 1 serving of Bread

Selection 4

- Low-Calorie Frozen Entree ($\leq$300 calories and $\leq$10 grams of fat)
- *Salad
- 1 serving of Fat-Free or Reduced Fat Dressing
- 1 Fruit serving

Selection 5 (Vegetarian Option)

- *Salad
- 1 serving of Beans, Tofu, Hummus, or Cheese
- 1 serving of Bread
- 1 serving of Fruit
- 1 serving of Milk

***Limited to items from the Free Foods List**

Lunch Foods
Calorie and Fat Content

Protein Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Tuna, white, in water	3 oz.	110	3
Pink Salmon, in water	3 oz.	125	5
*Turkey Breast, oven roasted	3 oz.	90	3
*Chicken Breast, oven roasted	3 oz.	90	3
*Ham, sliced or chipped	3 oz.	90	4.5
Cottage Cheese, 1% milk-fat	1/2 cup	90	1
Hummus	2 Tbs.	60	2
Tofu (Lite)	3 oz.	35	1.0
Beans	1/2 cup	100	0
Chickpeas	1/4 cup	75	0
Peanut Butter	1 Tbs.	80	6.0
Soy Burger (e.g., Boca Burger)	1 patty	90	1.0

*Oscar Meyer, Hillshire Farms, Healthy Choice, Eckrich and others make healthier versions of luncheon meats.

Bread Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Pita Bread	1/2	75	0
Bagel (any flavor-store bought-not bakery)	1/2	100	1
* 100% Whole Wheat Bread	1 slice	80	2
White Bread	1 slice	80	2
Crackers, Reduced or Fat-Free	6	100	0-3
Diet Bread	2 slices	80	0
Melba Toast	5 each	84	0
Breadsticks (Store bought, plain)	1	80	1.0
Rice (cooked)	1/2 cup	130	0

***These foods are recommended to increase the fiber in your diet.**

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Apple	1	80	0
* Orange	1	65	0
* Peaches, fresh	1	40	0
* Peaches, canned in water	1 cup	60	0
* Pear, fresh	1 medium	100	0
* Pear, canned in water	1 cup	70	0
* Pineapple, canned in water	1/2 cup	70	0
* Banana	1/2	55	0

***These foods are recommended to increase the fiber in your diet.**

Milk/Yogurt Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Skim Milk or Super Skim Milk	4 oz.	45	0
1% Milk	4 oz.	50	1.5
Non-Fat, Lite, or Plain Yogurt	6-8 oz.	100-130	0
Soymilk (Nonfat or Lite)	4 oz.	40-55	0 – 0.75
Fat-Free / Veggie Cheese Slice	1 slice	30-40	0-2

Salad Dressing/Condiment	Serving Size	Calories/Serving	Fat(gm)/Serving
Mayonnaise	1 Tbs.	100	11
Reduced Fat Mayonnaise	1 Tbs.	50	5
Fat-Free Mayonnaise	1 Tbs.	12	0
Fat-Free Dressing	1 Tbs.	18	0
Reduced-Fat Dressing	1 Tbs.	30	2
#Mustard	2 Tbs.	15	0

#Honey mustards are acceptable as well, but check the label for fat grams.

Frozen Low-Calorie Entrees or Dinners
Choose from Healthy Choice, Lean Cuisine, Weight Watchers or Budget Gourmet Light/Healthy which have: $\leq$ 300 kcal, $\leq$ 10 grams of fat

1200 Calorie Dinner
(500-550 kcal)

Selection 1

- 1 serving of Fish or Poultry (baked or broiled)
- 1 serving of Pasta, Potato, or Rice
- 1 serving of Vegetable
- 1 serving of Reduced Fat Margarine
- 1 Fruit serving

Selection 2

- Low-Calorie Frozen Entree (<400 calories, ≤12 grams of fat)
- 1 Vegetable serving
- 1 serving of Reduced Fat Margarine
- *Salad
- 1 serving of Fat-Free or Reduced Fat Dressing
- 1 Fruit serving

Selection 3

- 1 serving of Pasta with Marinara Sauce (see recipe)
- *Salad
- 1 serving of Fat-Free or Reduced Fat Dressing
- 1 Fruit serving

Selection 4

- Chinese Stir Fry (see recipe)
- 1½ servings of Rice
- 1 serving of Fruit

Selection 5 (Vegetarian Option)

- 1 serving of Beans, Cheese, Tofu, or Hummus
- 2 servings of Rice or 1 serving Pasta/Potato
- 1 serving of Vegetables
- 1 serving Reduced Fat Margarine
- 1 serving of Fruit

***Limited to items from the Free Foods List**

Dinner Foods

Calorie and Fat Content

Protein Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Fish - Fresh or Frozen (unbreaded)	5 oz.	150	2
Turkey, ground, lean, no skin (e.g., ground turkey *breast*)	3 oz.	115-160	1-8
Turkey, white meat, no skin	4 oz.	175	4
Chicken, white meat, no skin	4 oz.	190	4
Tofu (Lite)	3 oz.	35	1.0
Soy Burger (e.g., Boca Burger)	1 patty	90	1.0

Starch Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Pasta (cooked)			
• White, *Whole Wheat	1 cup	200	1.0
Rice (cooked)			
• White, Wild, *Brown	1/2 cup	130	0
Potato			
• Mashed, skim milk, reduced fat margarine	1 cup	160	3
• *Baked in skin	Medium	220	0
• Boiled w/o skin	Medium	145	0
• *Sweet (Yam) baked with skin	Medium	135	0
Rolls (any type with approx. 80 calories and 2 grams of fat)	1	80	2

Vegetable Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
*Asparagus	8 spears	30	0
*Broccoli, cooked	1 cup	45	0
*Brussel Sprouts, cooked	1 cup	65	0
*Cabbage, cooked, green/red	1 cup	30	0
*Carrots, cooked	1 cup	70	0
*Cauliflower, cooked	1 cup	30	0
*Corn, cooked	1/2 cup	90	0
*Green Beans, cooked	1 cup	45	0
*Peas, cooked			
• Green	1/2 cup	65	0
• Snow	1 cup	70	0
Peppers, chopped	1 cup	40	0
*Spinach, cooked	1 cup	40	0
*Squash, cooked			
• Summer	1 cup	35	0
• Winter	1/2 cup	50	0
Marinara Sauce (recipe)	1 cup	115	5
Marinara Sauce (jar) (e.g., Healthy Choice/Ragu)	1 cup	100	2
*Zucchini	1 cup	28	0

Fat Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Fat-Free Dressing	1 Tbs.	18	0
Reduced-Fat Dressing	1 Tbs.	30	0
Reduced-Fat Margarine	2 Tsp.	35	4
Plant Sterol Margarine (e.g., Light Benecol)	1 Tbs.	30 (average)	3

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Apple	1	80	0
* Orange	1	65	0
* Peaches, canned in water	1 cup	60	0
* Pear, canned in water	1 cup	70	0
* Pineapple, fresh or canned	1/2 cup	70	0
* Banana	1/2	55	0

Frozen Low-Calorie Entrees or Dinners

Choose from Healthy Choice, Lean Cuisine, Weight Watchers or Budget Gourmet Light/Healthy which have:

- $\leq$ 400 kcal
- $\leq$ 12 grams of fat

***These foods are recommended to increase the fiber in your diet.**

Recipe: Marinara Sauce

1 Tbs. Canola oil	8 oz. Water
1 clove of Garlic, finely chopped	1 tsp. Basil
1/2 cup of Diced onions	1/2 tsp. Oregano
16 oz. Crushed tomatoes, canned	1/4 tsp. Fresh ground black pepper
6 oz. Tomato paste, canned	1/4 tsp. Thyme
	2 tsp per serving Parmesan cheese, grated

1. Add canola oil to medium-size cooking pot. Heat over medium heat.
2. Saute garlic and onions in oil until transparent.
3. Add crushed tomatoes, tomato paste and water. Allow mixture to come to a boil, then reduce heat to allow mixture to simmer.
4. Add spices. Adjust amounts as desired.
5. Simmer sauce for 1/2 hour.
6. Serve over pasta with 2 tsp. of grated Parmesan cheese per serving.

Yield: 4 - 1 cup servings
Per Serving: 115 calories and 5.0 grams of fat

Recipe: Chinese Stir-Fry

2 Tbs. Soy sauce	1 Tbs. Canola oil
2 Tbs. Water	1 Clove garlic, finely chopped
1 tsp. Firmly packed brown sugar	3/4 pound Boneless, skinless chicken breast, cut into 1" cubes
1 Tbs. Fresh ginger, grated (optional)	3 cups Mixed vegetables, cut into bite-sized pieces (broccoli, carrots, cauliflower, snowpeas, etc.)
2 Green onions, diced	

1. Mix soy sauce, water, brown sugar, ginger, and diced onions. Stir until blended. Set aside.
2. Add canola oil to wok or large non-stick skillet. Heat over medium heat.
3. Add garlic and cubed chicken to wok or skillet. Stir-fry 5 minutes.
4. Add mixed vegetables to chicken. Stir-fry 3 minutes or until vegetables are tender crisp.
5. Add soy sauce mixture to chicken and vegetables. Stir-fry until thoroughly heated.
6. Serve over a bed of rice.

Yield: 3 - 1 cup servings
Per Serving: 180 calories and approximately 9.0 grams of fat

1200 Calorie Snack List

(50-200 kcal, depending on caloric content of breakfast, lunch and dinner)

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Apple	1	80	0
* Orange	1	65	0
* Peaches, fresh	1	40	0
* Peaches, canned in water	1 cup	60	0
*Pear, fresh	1 medium	100	0
* Pear, canned in water	1 cup	70	0
* Pineapple, fresh or canned	1/2 cup	70	0
* Banana	1/2	55	0

Protein Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Cottage Cheese, 1% milkfat	1/2 cup	90	1
Non-Fat, Lite, or Plain Yogurt	6-8 oz.	100-130	0

Milk Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Skim Milk or Super Skim Milk	4 oz.	45	0
1% Milk	4 oz.	50	1.5
Soymilk (Nonfat or Lite)	4 oz.	40-55	0 – 0.75
Nonfat Pudding	3.5 oz	90	0

Fruit Juice Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
100% Apple Juice	4 oz.	60	0
Cranberry Juice, low calorie	8 oz.	50	0
100% Grapefruit Juice	4 oz.	50	0
100% Orange Juice	4 oz.	60	0
100% Pineapple Juice	4 oz.	60	0

Snack Foods	Serving Size	Calories/Serving	Fat(gm)/Serving
*Air Popped Popcorn	2 cups	55	0
*Light Microwave Popcorn	3 cups	60	1
Pretzels	3/4 cup	110	1
Rice Cake, Standard Size	2	100	0
Low-fat Quaker Granola Bar	1	110	2
Crackers: Reduced-Fat or Fat-Free	6	100	0-3
Cookies: Reduced-Fat or Fat-Free	2-4	150-200	0-6
Graham Crackers	2 squares	60	1.3

Hot Chocolate Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Carnation Sugar-free Hot Cocoa, Mocha & Rich Chocolate	1 envelope	50	<1

***These foods are recommended to increase the fiber in your diet.**

Free Foods List

Salad Greens and Raw Vegetables

Cabbage	Onion
Celery	Radishes
Chinese cabbage	Romaine
Cucumber	Spinach
Endive	Sprouts
Escarole	Peppers
Lettuce	Mushrooms

Drinks

Bouillon or broth without fat	Coffee/Tea
Bouillon (low sodium)	Drink mixes (sugar-free)
Carbonated drinks (sugar-free)	Tonic water (sugar-free)
Carbonated water (sugar-free)	

- Use only low-fat/non-fat dairy creamers (such as Fat-Free Coffee Mate or Carnation Coffee-Mate Lite Non-Dairy Creamer), skim milk, soy milk, or 1% milk in coffee/tea. Adjust milk/yogurt servings accordingly.

Condiments

Artificial butter flavors (Butter Buds)	Mustard
Catsup (1 TBS)	Picante Sauce
Horseradish	Pickles (dill, unsweetened)
Hot Sauce	Taco Sauce
	Vinegar

Sweet Substitutes

Candy (hard, sugar-free)	Gum (sugar-free)
Gelatin (sugar-free)	Sugar substitutes (aspartame, Splenda)

Miscellaneous

Herbs	Soy Sauce
Lemon Juice	Spices
Non-Stick Pan Spray	Worcestershire Sauce
Nonfat Butter Spray (6 sprays)	

1500 Calorie Eating Plan Guidelines

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

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

   Breakfast: 200-350 calories

   Lunch: 400-450 calories

   Dinner: 600-650 calories

   Snack: 0-250 calories

2. During the initial 12 weeks of the program, meals and snacks should be limited to the foods on the lists that are provided for you.
3. Average calorie and fat gram information is provided for all the foods you will be eating. If a particular brand differs from this average, use the calorie and fat gram information on the nutritional label or refer to the Fat Book. Transfer the calorie and fat information to your self-monitoring book.
4. Your eating plan is designed to provide no more than 20% of your calories from fat. For your 1500 calorie eating plan, this breaks down to 33 grams of fat.
5. We recommend that you weigh and measure your food portions, especially your portions of meat. Purchase a food scale if you do not already have one and use it and the labels on the food to help you select appropriate portions.
6. To help ensure adequate intake of vitamins and minerals, a daily multi-vitamin is recommended.

1500 Calorie Breakfast

(200-350 kcal)

Selection 1

- 1 ½ servings of Cold or Hot cereal
- 8 oz. Milk or 1 serving of Milk
- 4 oz. Fruit Juice or 1 serving of Fruit

Selection 2

- 2 servings of Bread
- 2 servings of Jam/Jelly/Fat-Free Cream Cheese
- 4 oz. Fruit Juice or 1 serving of Fruit

Selection 3

- Egg Substitute
- 2 servings of Bread
- 2 servings of Jam/Jelly/Fat-Free Cream Cheese
- 4 oz. Fruit Juice or 1 serving of Fruit

Selection 4

- 1 serving Non-Fat or Lite Yogurt
- 1 serving of Bread
- 1 serving of Jam/Jelly/Fat-Free Cream Cheese
- 4 oz. Fruit Juice or 1 serving of Fruit

Breakfast Foods

Calorie and Fat Content

Cereal Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
* Bran Flakes	2/3 cup	90	0
Cheerios (plain)	1 cup	110	2
Corn Flakes	1 cup	110	0
* Oatmeal, cooked	1 cup cooked or 1 package of instant	145 130-150	2.0 2.0-2.5
* Raisin Bran	3/4 cup	130	0
*Shredded Wheat, Spoon Size	2/3 cup	110	0
*Kashi (e.g., GoLean / Good Friends)	3/4 cup	90-120	1.0

Milk/ Yogurt Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Skim Milk or Super Skim Milk	4 oz.	45	0
1% Milk	4 oz.	50	1.5
Soymilk (Nonfat or Lite)	4oz.	40-55	0-0.75
Non-Fat, Lite, or PlainYogurt	6-8 oz.	100-130	0

Bread Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
* 100% Whole Wheat Toast	1 slice	80	1
White Toast	1 slice	80	1
English Muffin	1/2	70	0.5
Bagel (any flavor) *(this is a standard Lender's Bagel – Panera bagel has approx. 290 cal, Panera Cin. Crunch: 510 cal)*	1/2	100	1
Diet Bread	2 slices	80	0

Egg Substitute Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Fleischmann's Egg Beaters	1/2 cup	50	0
Healthy Choice Cholesterol-Free Egg Product	1/2 cup	50	0
Egg Whites	3 large	50	0

Fruit Juice Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
100% Orange Juice	4 oz.	60	0
100% Grapefruit Juice	4 oz.	50	0
100% Apple Juice	4 oz.	60	0

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Banana	1/2	55	0
* Orange	1	65	0
* Grapefruit	1/2	45	0
* Strawberries	1 cup, whole	45	0
*Raisins	2 Tbs.	60	0
*Grapes	1 cup	60	0
*Blueberries	1 cup	80	0

Jam/Jelly/Cream Cheese/Margarine Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Regular Jam/Jelly (any flavor)	2 tsp.	30 (average)	0
Diet Jam/Jelly (any flavor)	2 tsp.	15 (average)	0
Fat-Free Cream Cheese	2 Tbs.	25 (average)	0
Reduced Fat Margarine	2 tsp.	35 (average)	4
Plant Sterol Margarine (e.g., Light Benecol)	1 Tbs.	30 (average)	3

***These foods are recommended to increase the fiber in your diet.**

1500 Calorie Lunch

400-450 kcal

Selection 1

- 1 serving of Chicken, Turkey, Salmon, Tuna, or Ham
- 2 servings of Bread
- 1 serving of a Condiment
- 1 Fruit serving

Selection 2

- *Salad
- 1 serving of Chicken, Turkey, Tuna, Salmon, or Ham
- 1 serving of a Condiment
- 2 servings of Bread
- 1 Fruit serving
- 8 oz. of Milk or 6-8 oz. Non-Fat Yogurt

Selection 3

- 1 serving of Cottage Cheese
- 1 serving of Fruit
- 2 servings of Bread

Selection 4

- Low-Calorie Frozen Entree ($\leq$300 calories and $\leq$10 grams of fat)
- *Salad
- 1 serving of Fat-Free or Reduced Fat dressing
- 1 Fruit serving

Selection 5 (Vegetarian Option)

- *Salad
- 1 serving of Beans, Tofu, Hummus, or Cheese
- 2 servings of Bread
- 1 serving of Fruit
- 1 serving of Milk

***Limited to items from the Free Foods List**

Lunch Foods
Calorie and Fat Content

Protein Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Tuna, white, in water	3 oz.	110	3
Pink Salmon, in water	3 oz.	125	5
*Turkey breast, oven roasted	3 oz.	90	3
*Chicken breast, oven roasted	3 oz.	90	3
*Ham, sliced or chipped	3 oz.	90	4.5
Cottage Cheese, 1% milk-fat	½ cup	90	1
Hummus	2 Tbs.	60	2
Tofu (Lite)	3 oz.	35	1.0
Beans	½ cup	100	0
Chickpeas	¼ cup.	75	0
Peanut Butter	1 Tbs.	80	6.0
Soy Burger (e.g., Boca Burger)	1 patty	90	1.0

*Oscar Meyer, Hillshire Farms, Healthy Choice, Eckrich and others make healthier versions of luncheon meats.

Bread Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Pita bread	1/2	75	0
Bagel (any flavor store bought, not bakery)	1/2	100	1
* 100% Whole Wheat Bread	1 slice	80	2
White Bread	1 slice	80	2
Crackers, Reduced or Fat-Free	6	100	0-3
Diet Bread	2 slices	80	0
Melba Toast	5 each	84	0
Breadsticks (store bought, plain)	1	80	1.0
Rice (cooked)	1/2 cup	130	0

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Apple	1	80	0
* Orange	1	65	0
* Peaches, fresh	1	40	0
* Peaches, canned in water	1 cup	60	0
*Pear, fresh	1 medium	100	0
* Pear, canned in water	1 cup	70	0
* Pineapple, canned in water	1/2 cup	70	0
* Banana	1/2	55	0

***These foods are recommended to increase the fiber in your diet.**

Milk/Yogurt Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Skim Milk or Super Skim Milk	4 oz.	45	0
1% Milk	4 oz.	50	1.5
Soymilk (Nonfat or Lite)	4 oz.	40-55	0 – 0.75
Fat-Free / Veggie Cheese Slice	1 slice	30-40	0-2
Non-Fat, Lite, or Plain Yogurt	6-8 oz.	100-130	0

Salad Dressing/Condiment	Serving Size	Calories/Serving	Fat(gm)/Serving
Mayonnaise	1 Tbs.	100	11
Reduced Fat Mayonnaise	1 Tbs.	50	5
Fat-Free Mayonnaise	1 Tbs.	12	0
Fat-Free Dressing	1 Tbs.	18	0
Reduced-Fat Dressing	1 Tbs.	30	2
#Mustard	2 Tbs.	15	0

#Honey mustards are acceptable as well, but check the label for fat grams.

Frozen Low-Calorie Entrees or Dinners
Choose from Healthy Choice, Lean Cuisine, Weight Watchers or Budget Gourmet Light/Healthy which have: $\leq$ 300 kcal, $\leq$ 10 grams of fat

1500 Calorie Dinner
(600-650 kcal)

Selection 1

- 1 serving of Fish or Poultry (baked or broiled)
- 1 serving of Pasta, Potato, or Rice
- 1 serving of Vegetable
- 2 servings of Reduced Fat Margarine
- 1 Dinner Roll
- 1 Fruit serving

Selection 2

- Low-Calorie Frozen Entree (<400 calories, ≤12 grams of fat)
- 1 Vegetable serving
- 1 serving of Reduced Fat Margarine
- *Salad
- 1 serving of Fat-Free or Reduced Fat Dressing
- 1 Dinner Roll
- 1 Fruit serving

Selection 3

- 1 serving of Pasta with Marinara Sauce (see recipe)
- *Salad
- 1 serving of Fat-Free or Reduced Fat Dressing
- 1 Fruit serving

Selection 4

- Chinese Stir Fry (see recipe)
- 1½ servings of Rice
- 1 serving of Fruit

Selection 5 (Vegetarian Option)

- 1 serving of Beans, Cheese, Tofu, or Hummus
- 2 servings of Rice or 1 serving Pasta/Potato
- 1 serving of Vegetables
- 1 serving Reduced Fat Margarine
- 1 serving of Fruit

***Limited to items from the Free Foods List**

Dinner Foods

Calorie and Fat Content

Protein Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Fish - Fresh or Frozen (unbreaded)	5 oz.	150	2
Turkey, ground, lean, no skin (e.g., ground turkey *breast*)	3 oz.	115-160	1-8
Turkey, white meat, no skin	4 oz.	175	4
Chicken, white meat, no skin	4 oz.	190	4
Tofu (Lite)	3 oz.	35	1.0
Soy Burger (e.g., Boca Burger)	1 patty	90	1.0

Starch Servings	**Serving Size**	**Calories/Serving**	**Fat(gm)/Serving**
Pasta (cooked)			
• White, *Whole Wheat	1 cup	200	1.0
Rice (cooked)			
• White, Wild, *Brown	1/2 cup	130	0
Potato			
• Mashed, skim milk, reduced fat margarine	1 cup	160	3
• *Baked in skin	Medium	220	0
• *Boiled w/o skin	Medium	145	0
• *Sweet (Yam) baked with skin	Medium	135	0
Rolls (any type with approx. 80 calories and 2 grams of fat)	1	80	2

Vegetable Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
*Asparagus	8 spears	30	0
*Broccoli, cooked	1 cup	45	0
*Brussel Sprouts, cooked	1 cup	65	0
*Cabbage, cooked, green/red	1 cup	30	0
*Carrots, cooked	1 cup	70	0
*Cauliflower, cooked	1 cup	30	0
*Corn, cooked	1/2 cup	90	0
*Green Beans, cooked	1 cup	45	0
*Peas, cooked			
• Green	1/2 cup	65	0
• Snow	1 cup	70	0
Peppers, chopped	1 cup	40	0
*Spinach, cooked	1 cup	40	0
*Squash, cooked			
• Summer	1 cup	35	0
• Winter	1/2 cup	50	0
Marinara Sauce (recipe)	1 cup	115	5
Marinara Sauce (jar) (Healthy Choice/Ragu)	1 cup	100	2
*Zucchini	1 cup	28	0

Fat Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Fat-Free Dressing	1 Tbs.	18	0
Reduced-Fat Dressing	1 Tbs.	30	0
Reduced-Fat Margarine	2 Tsp.	35	4
Plant Sterol Margarine (e.g., Light Benecol)	1 Tbs.	30 (average)	3

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Apple	1	80	0
* Orange	1	65	0
* Peaches, canned in water	1 cup	60	0
* Pear, canned in water	1 cup	70	0
* Pineapple, canned in water	1/2 cup	70	0
* Banana	1/2	55	0

Frozen Low-Calorie Entrees or Dinners
Choose from Healthy Choice, Lean Cuisine, Weight Watchers or Budget Gourmet Light/Healthy which have: • $\leq$ 400 kcal • $\leq$ 12 grams of fat

***These foods are recommended to increase the fiber in your diet.**

Recipe: Marinara Sauce

1 Tbs. Canola oil	8 oz. Water
1 clove of Garlic, finely chopped	1 tsp. Basil
1/2 cup of Diced onions	1/2 tsp. Oregano
16 oz. Crushed tomatoes, canned	1/4 tsp. Fresh ground black pepper
6 oz. Tomato paste, canned	1/4 tsp. Thyme
	2 tsp per serving Parmesan cheese, grated

1. Add canola oil to medium-size cooking pot. Heat over medium heat.
2. Saute garlic and onions in oil until transparent.
3. Add crushed tomatoes, tomato paste and water. Allow mixture to come to a boil, then reduce heat to allow mixture to simmer.
4. Add spices. Adjust amounts as desired.
5. Simmer sauce for 1/2 hour.
6. Serve over pasta with 2 tsp. of grated Parmesan cheese per serving.

Yield: 4 - 1 cup servings
Per Serving: 115 calories and 5.0 grams of fat

Recipe: Chinese Stir-Fry

2 Tbs. Soy sauce	1 Tbs. Canola oil
2 Tbs. Water	1 Clove garlic, finely chopped
1 tsp. Firmly packed brown sugar	3/4 pound Boneless, skinless chicken breast, cut into 1" cubes
1 Tbs. Fresh ginger, grated (optional)	3 cups Mixed vegetables, cut into bite-sized pieces (broccoli, carrots, cauliflower, snowpeas, etc.)
2 Green onions, diced	

1. Mix soy sauce, water, brown sugar, ginger, and diced onions. Stir until blended. Set aside.
2. Add canola oil to wok or large non-stick skillet. Heat over medium heat.
3. Add garlic and cubed chicken to wok or skillet. Stir-fry 5 minutes.
4. Add mixed vegetables to chicken. Stir-fry 3 minutes or until vegetables are tender crisp.
5. Add soy sauce mixture to chicken and vegetables. Stir-fry until thoroughly heated.
6. Serve over a bed of rice.

Yield: 3 - 1 cup servings
Per Serving: 180 calories and approximately 9.0 grams of fat

1500 Calorie Snack List

(50-200 kcal, depending on caloric content of breakfast, lunch and dinner)

Fruit Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
* Apple	1	80	0
* Orange	1	65	0
* Peaches, fresh	1	40	0
* Peaches, canned in water	1 cup	60	0
*Pear, fresh	1 medium	100	0
* Pear, canned in water	1 cup	70	0
* Pineapple, canned in water	1/2 cup	60	0
* Banana	1/2	55	0

Protein Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Cottage Cheese, 1% milkfat	1/2 cup	90	1
Non-Fat, Lite, or Plain Yogurt	6-8 oz.	100-130	0

Milk Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Skim Milk or Super Skim Milk	4 oz.	45	0
1% Milk	4 oz.	50	1.5
Soymilk (Nonfat or Lite)	4 oz.	40-55	0 – 0.75
Nonfat Pudding	3.5 oz	90	0

Fruit Juice Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
100% Apple Juice	4 oz.	60	0
Cranberry Juice, low calorie	8 oz.	50	0
100% Grapefruit Juice	4 oz.	50	0
100% Orange Juice	4 oz.	60	0
100% Pineapple Juice	4 oz.	60	0

Snack Foods	Serving Size	Calories/Serving	Fat(gm)/Serving
*Air Popped Popcorn	2 cups	55	0
*Light Microwave Popcorn	3 cups	60	1
Pretzels	3/4 cup	110	1
Rice Cake, standard size	2	100	0
Low-fat Quaker Granola Bar	1	110	2
Crackers: Reduced-Fat or Fat-Free	6	100	0-3
Graham Crackers	2 squares	60	1.3
Cookies: Reduced-Fat or Fat-Free	2-4	150-200	0-6

Hot Chocolate Servings	Serving Size	Calories/Serving	Fat(gm)/Serving
Carnation Sugar-free Hot Cocoa, Mocha & Rich Chocolate	1 envelope	50	<1

***These foods are recommended to increase the fiber in your diet.**

Free Foods List

Salad Greens and Raw Vegetables

Cabbage
Carrot
Celery
Chinese cabbage
Cucumber
Endive
Escarole
Lettuce
Onion
Peppers
Radishes
Romaine
Spinach
Sprouts
Mushrooms

Drinks

Bouillon or broth without fat
Bouillon (low sodium)
Carbonated drinks (sugar-free)
Carbonated water (sugar-free)
Coffee/Tea
Drink mixes (sugar-free)
Tonic water (sugar-free)

- Use only low-fat/non-fat dairy creamers (such as Fat-Free Coffee Mate or Carnation Coffee-Mate Lite Non-Dairy Creamer), skim milk, soy milk, or 1% milk in coffee/tea. Adjust milk/yogurt servings accordingly.

Condiments

Artificial butter flavors (Butter Buds)
Catsup (1 TBS)
Horseradish
Hot Sauce
Mustard
Picante Sauce
Pickles (dill, unsweetened)
Taco Sauce
Vinegar

Sweet Substitutes

Candy (hard, sugar-free)
Gelatin (sugar-free)
Gum (sugar-free)
Sugar substitutes (aspartame, Splenda)

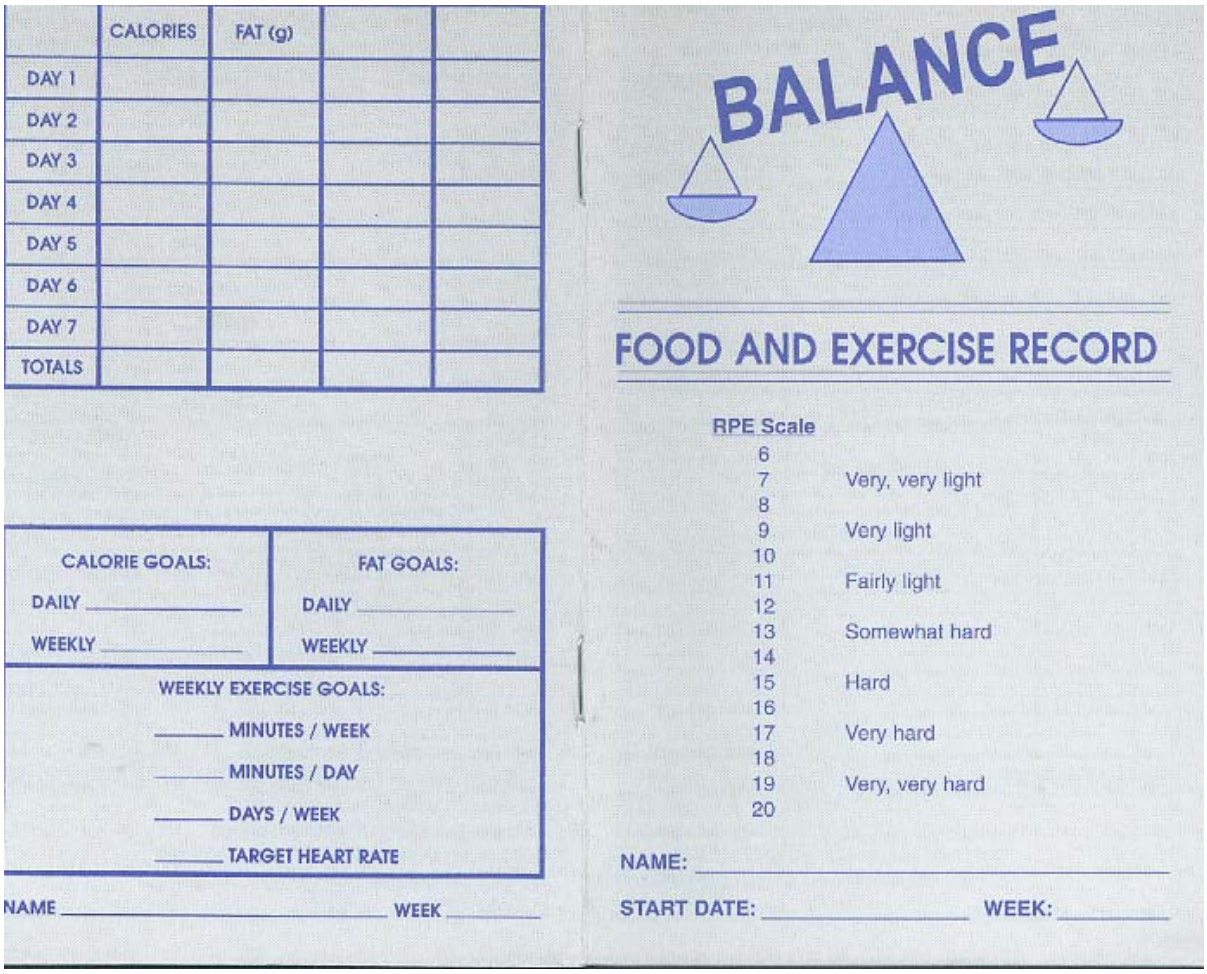
Miscellaneous

Herbs
Lemon Juice
Non-stick pan spray
Soy Sauce
Spices
Worcestershire Sauce

APPENDIX F

FOOD AND EXERCISE DIARY

Food and Exercise Record Front and Back



	CALORIES	FAT (g)		
DAY 1				
DAY 2				
DAY 3				
DAY 4				
DAY 5				
DAY 6				
DAY 7				
TOTALS				

CALORIE GOALS:
DAILY _____
WEEKLY _____

FAT GOALS:
DAILY _____
WEEKLY _____

WEEKLY EXERCISE GOALS:
_____ MINUTES / WEEK
_____ MINUTES / DAY
_____ DAYS / WEEK
_____ TARGET HEART RATE

NAME _____ WEEK _____

BALANCE

FOOD AND EXERCISE RECORD

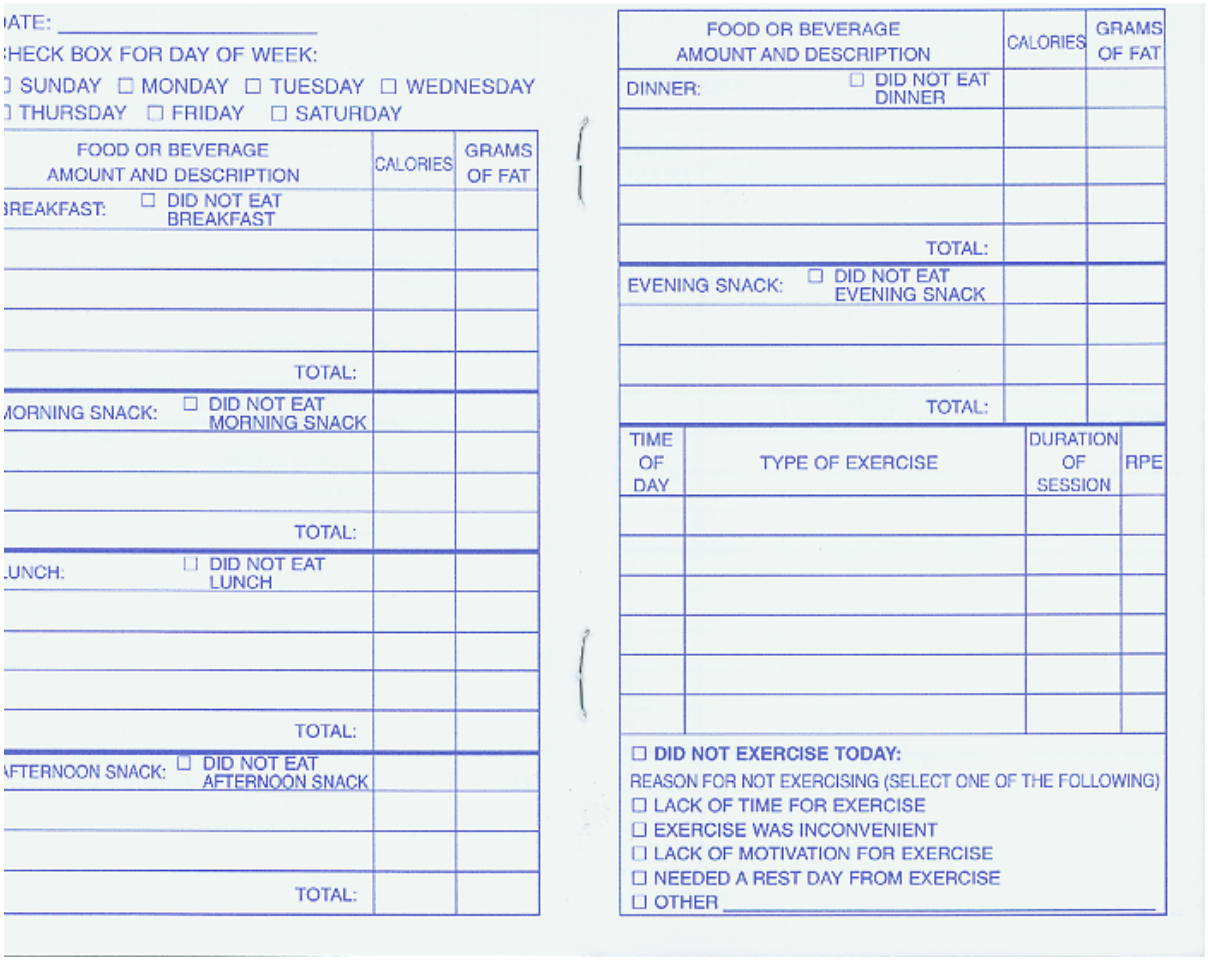
RPE Scale

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

NAME: _____

START DATE: _____ WEEK: _____

Food and Exercise Record Inside



ATE: _____

HECK BOX FOR DAY OF WEEK:

SUNDAY ☐ MONDAY ☐ TUESDAY ☐ WEDNESDAY
THURSDAY ☐ FRIDAY ☐ SATURDAY

FOOD OR BEVERAGE AMOUNT AND DESCRIPTION	CALORIES	GRAMS OF FAT
REAKFAST: ☐ DID NOT EAT BREAKFAST		
TOTAL:		
ORNING SNACK: ☐ DID NOT EAT MORNING SNACK		
TOTAL:		
UNCH: ☐ DID NOT EAT LUNCH		
TOTAL:		
FTERNOON SNACK: ☐ DID NOT EAT AFTERNOON SNACK		
TOTAL:		

FOOD OR BEVERAGE AMOUNT AND DESCRIPTION	CALORIES	GRAMS OF FAT
DINNER: ☐ DID NOT EAT DINNER		
TOTAL:		
EVENING SNACK: ☐ DID NOT EAT EVENING SNACK		
TOTAL:		

TIME OF DAY	TYPE OF EXERCISE	DURATION OF SESSION	RPE

☐ **DID NOT EXERCISE TODAY:**
REASON FOR NOT EXERCISING (SELECT ONE OF THE FOLLOWING)
☐ LACK OF TIME FOR EXERCISE
☐ EXERCISE WAS INCONVENIENT
☐ LACK OF MOTIVATION FOR EXERCISE
☐ NEEDED A REST DAY FROM EXERCISE
☐ OTHER _____

APPENDIX G

COMPUTER EXPERIENCE AND REQUIREMENTS

Computer Experience and Requirements

Date: _____

Subject ID: _____

1. Select one of the following categories that best represents your competency in using computers and the Internet to perform the following skills:
   - Data entry using programs such as Word and Excel
   - Accessing and retrieving information from a Web site
   - Sending e-mail

   _____ Very confident

   _____ I am confident that given minimal support I could perform the skills listed above.

   _____ I am not at all confident in my ability to perform these skills.

2. Identify the location of the computer that you intend to use for this study:

   _____ Home

   _____ Work

   _____ Other, please indicate: _____

3. Do you have the capability to attach external devices to a USB port on this computer?

   _____ Yes

   _____ No

   _____ I do not know

4. Do you have the capability to load software on this computer?

   _____ Yes

   _____ No

   _____ I do not know

APPENDEX H

TECHNOLOGY-BASED SYSTEM SURVEY

Past Use of the BODYMEDIA System

ID: _____ Date: _____

Please indicate your level of agreement or disagreement with each of the following statements relative to your past use of the BODYMEDIA system using the scale provided. If the statement does not apply to your experience, please select "Not Applicable".

Statements Regarding Past Use of the BODYMEDIA System	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**
1. The BODYMEDIA system made it easier to monitor my dietary intake.	O_1	O_2	O_3	O_4	O_5	O_0
2. The BODYMEDIA system made it easier to monitor my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
3. The BODYMEDIA system made it easier to understand how I needed to change my eating behaviors to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
4. The BODYMEDIA system made it easier to understand how I needed to change my exercise behaviors to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
5. The BODYMEDIA system provided valuable feedback and information to help me modify my eating patterns to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
6. The BODYMEDIA system provided valuable feedback and information to help me to modify my exercise to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
7. The BODYMEDIA system helped me to overcome the barriers that I typically experience to eating a healthy diet.	O_1	O_2	O_3	O_4	O_5	O_0
8. The BODYMEDIA system helped me to overcome the barriers that I typically experience to exercising.	O_1	O_2	O_3	O_4	O_5	O_0
9. The BODYMEDIA system helped me to interact with my weight loss counselor regarding my diet.	O_1	O_2	O_3	O_4	O_5	O_0
10. The BODYMEDIA system helped me to interact with my weight loss counselor regarding my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
11. The BODYMEDIA system made me more aware of my eating behaviors compared to if I did not use the BODYMEDIA system.	O_1	O_2	O_3	O_4	O_5	O_0
	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**

Statements Regarding Past Use of the BODYMEDIA System	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
12. The BODYMEDIA system made me more aware of my exercise compared to if I did not use THE BODYMEDIA SYSTEM.	O_1	O_2	O_3	O_4	O_5	O_0
13. The BODYMEDIA system made me more aware of my weight loss efforts compared to if I did not use THE BODYMEDIA SYSTEM.	O_1	O_2	O_3	O_4	O_5	O_0
14. The BODYMEDIA system motivated me to be adherent with my eating behaviors.	O_1	O_2	O_3	O_4	O_5	O_0
15. The BODYMEDIA system motivated me to be adherent with my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
16. The BODYMEDIA system motivated me to be adherent with my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
17. The BODYMEDIA system made me more accountable for their weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
18. It was easy to setup the BODYMEDIA system software on my computer.	O_1	O_2	O_3	O_4	O_5	O_0
19. The BODYMEDIA system software was easy to use to track my eating behaviors.	O_1	O_2	O_3	O_4	O_5	O_0
20. The BODYMEDIA system software was easy to use to track my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
21. The BODYMEDIA system software was easy to use to track my weight loss progress.	O_1	O_2	O_3	O_4	O_5	O_0
22. The armband was easy to setup.	O_1	O_2	O_3	O_4	O_5	O_0
23. The armband was comfortable to wear.	O_1	O_2	O_3	O_4	O_5	O_0
24. Wearing the armband did not interfere with my job.	O_1	O_2	O_3	O_4	O_5	O_0
25. Wearing the armband did not interfere with my social life.	O_1	O_2	O_3	O_4	O_5	O_0
26. Wearing the armband did not make me feel uncomfortable around others.	O_1	O_2	O_3	O_4	O_5	O_0
27. The information obtained by wearing the armband was helpful in increasing my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**

Statements Regarding Past Use of THE BODYMEDIA System	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
28. The information obtained by wearing the armband was helpful in my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
29. The feedback related to my step counts obtained by wearing the armband was helpful in increasing my exercise and weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
30. The feedback related to my minutes of physical activity obtained by wearing the armband was helpful in increasing my exercise and weigh loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
31. The feedback related to my daily caloric intake obtained from The BODYMEDIA system was helpful in my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
32. The feedback related to my daily energy balance obtained from the BODYMEDIA system was helpful in my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
33. The feedback related to my body weight trends obtained from the BODYMEDIA system was helpful in my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0
34. The feedback related to my food breakdown (fat, protein, and carbohydrates) obtained from the BODYMEDIA system was helpful in my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0

35. On average, I used the BODYMEDIA system to assist me with tracking my eating behaviors
    a. every day
    b. at least 3 days per week
    c. at least once per week
    d. at least one week per month
    e. less than one week per month
    f. only when I am struggling with my weight control efforts
    g. I do not plan on using the BODYMEDIA SYSTEM.

36. On average, I used the software component of the BODYMEDIA system to assist me with tracking my exercise behaviors
    a. every day
    b. at least 3 days per week
    c. at least once per week
    d. at least one week per month
    e. less than one week per month
    f. only when I am struggling with my weight control efforts
    g. I do not plan on using the BODYMEDIA system.

37. On average, I wore the armband from the BODYMEDIA system to assist me with tracking my exercise
    a. every day
    b. at least 3 days per week
    c. at least once per week
    d. at least one week per month
    e. less than one week per month
    f. only when I am struggling with my weight control efforts
    g. I do not plan on using the armband

38. When I did not wear the armband, the main reason that I did not wear the armband was
    a. The armband was uncomfortable.
    b. I did not find the armband to provide helpful information.
    c. Family, friends, or coworkers questioned me about the armband.
    d. The armband was visible and I could not conceal it under my clothing.
    e. Wearing the armband made me feel uncomfortable in public situations.

    Other (please specify): _____

Future Use of the BODYMEDIA System

ID: _____ Date: _____

Please indicate your level of agreement or disagreement with each of the following statements relative to your future use of the BODYMEDIA system using the scale provided. If the statement does not apply to your experience, please select "Not Applicable".

Statements Regarding Future Use of the BODYMEDIA System	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**
1. I would use the BODYMEDIA system in the future to monitor my dietary intake.	O_1	O_2	O_3	O_4	O_5	O_0
2. I would use the BODYMEDIA system in the future to monitor my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
3. I would use the BODYMEDIA system in the future to help me to understand how I needed to change my eating behaviors to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
4. I would use the BODYMEDIA system in the future to help me to understand how I needed to change my exercise behaviors to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
5. I would use the BODYMEDIA system in the future because of the valuable feedback and information it provides to help me modify my eating patterns to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
6. I would use the BODYMEDIA system in the future because of the valuable feedback and information it provides to help me to modify my exercise to control my weight.	O_1	O_2	O_3	O_4	O_5	O_0
7. I would use the BODYMEDIA system in the future because it helps me to overcome the barriers that I typically experience to eating a healthy diet.	O_1	O_2	O_3	O_4	O_5	O_0
8. I would use the BODYMEDIA system in the future because it helps me to overcome the barriers that I typically experience to exercising.	O_1	O_2	O_3	O_4	O_5	O_0
	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**

Statements Regarding Future Use of the BODYMEDIA System	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
9. I would use the BODYMEDIA system in the future because it helps me to interact with my weight loss counselor regarding my diet.	O1	O2	O3	O4	O5	O0
10. I would use the BODYMEDIA system in the future because it helps me to interact with my weight loss counselor regarding my exercise.	O1	O2	O3	O4	O5	O0
11. I would use the BODYMEDIA system in the future because it is easy to use to track my eating behaviors.	O1	O2	O3	O4	O5	O0
12. I would use the BODYMEDIA system in the future because it is easy to use to track my exercise.	O1	O2	O3	O4	O5	O0
13. I would use the BODYMEDIA system in the future because it is easy to use to track my weight loss progress.	O1	O2	O3	O4	O5	O0
14. I would use the BODYMEDIA system in the future because it made me more aware of my eating behaviors compared to if I did not use THE BODYMEDIA SYSTEM.	O1	O2	O3	O4	O5	O0
15. I would use the BODYMEDIA system in the future because it made me more aware of my exercise compared to if I did not use THE BODYMEDIA SYSTEM.	O1	O2	O3	O4	O5	O0
16. I would use the BODYMEDIA system in the future because it made me more aware of my weight loss efforts compared to if I did not use THE BODYMEDIA SYSTEM.	O1	O2	O3	O4	O5	O0
17. I would use the BODYMEDIA system in the future because it motivated me to be adherent with my eating behaviors.	O1	O2	O3	O4	O5	O0
18. I would use the BODYMEDIA system in the future because it motivated me to be adherent with my exercise.	O1	O2	O3	O4	O5	O0
19. I would use the BODYMEDIA system in the future because it motivated me to be adherent with my weight loss efforts.	O1	O2	O3	O4	O5	O0
20. I would use the BODYMEDIA system in the future because it made me more accountable for their weight loss efforts.	O1	O2	O3	O4	O5	O0
	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**

Statements Regarding Future Use of the BODYMEDIA System	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
21. I would use the armband in the future.	O_1	O_2	O_3	O_4	O_5	O_0
22. I would use the armband because it is comfortable to wear.	O_1	O_2	O_3	O_4	O_5	O_0
23. I would use the armband in the future because it did not interfere with my job.	O_1	O_2	O_3	O_4	O_5	O_0
24. I would use the armband in the future because it did not interfere with my social life.	O_1	O_2	O_3	O_4	O_5	O_0
25. I would use the armband in the future because it did not make me feel uncomfortable around others.	O_1	O_2	O_3	O_4	O_5	O_0
26. I would use the armband in the future because it was helpful in increasing my exercise.	O_1	O_2	O_3	O_4	O_5	O_0
27. I would use the armband in the future because it was helpful in my weight loss efforts.	O_1	O_2	O_3	O_4	O_5	O_0

28. If given the opportunity to use the BODYMEDIA system in the future to assist me with tracking my eating behaviors, I would do this
    a. every day
    b. at least 3 days per week
    c. at least once per week
    d. at least one week per month
    e. less than one week per month
    f. only when I am struggling with my weight control efforts
    g. I do not plan on using the BODYMEDIA system

29. If given the opportunity to use the BODYMEDIA system (both software and armband) in the future to assist me with tracking my exercise behaviors, I would do this
    a. every day
    b. at least 3 days per week
    c. at least once per week
    d. at least one week per month
    e. less than one week per month
    f. only when I am struggling with my weight control efforts
    g. I would not use the BODYMEDIA system to track my exercise behaviors in the future

30. If given the opportunity to wear the armband component of the BODYMEDIA system in the future, it helpful to wear the armband
    a. every day
    b. at least 3 days per week
    c. at least once per week
    d. at least one week per month
    e. less than one week per month
    f. only when I am struggling with my weight control efforts
    g. I would not use the armband component of the BODYMEDIA system.

31. If you do not have a desire to use the armband feature of the BODYMEDIA system in the future, the main reason would be
    a. The armband is uncomfortable.
    b. The armband does not provide helpful information.
    c. Family, friends, or coworkers will question me about the armband.
    d. The armband is visible and I can not conceal it under my clothing.
    e. Wearing the armband will make me feel uncomfortable in public situations.
    f. Other (please specify): _____

APPENDEX I

TECHNOLOGY-BASED SYSTEM SURVEY RESULTS

Past Use of the BODYMEDIA System

Statements Regarding Past Use of the BODYMEDIA System§	Strongly Disagree/ Disagree		Neutral/ NA		Agree/ Strongly Agree	
§Data Presented as:	Total n=33		Total n=33		Total n=33	
	CON-TECH n=18	INT-TECH n=15	CON-TECH n=18	INT-TECH n=15	CON-TECH n=18	INT-TECH n=15
37. The BODYMEDIA system made it easier to monitor my dietary intake.	12.1		9.1		78.8	
	5.6	20.0	5.6	13.3	88.9	66.7
38. The BODYMEDIA system made it easier to monitor my exercise.	6.1		9.1		84.8	
	0.0	13.3	5.6	13.3	94.4	73.3
39. The BODYMEDIA system made it easier to understand how I needed to change my eating behaviors to control my weight.	9.1		6.1		84.8	
	5.6	13.3	5.6	13.3	88.9	73.3
40. The BODYMEDIA system made it easier to understand how I needed to change my exercise behaviors to control my weight.	6.1		9.1		84.8	
	0.0	13.3	5.6	13.3	94.4	73.3
41. The BODYMEDIA system provided valuable feedback and information to help me modify my eating patterns to control my weight.	9.1		15.2		75.8	
	5.6	13.3	11.1	20.0	83.3	66.7
42. The BODYMEDIA system provided valuable feedback and information to help me to modify my exercise to control my weight.	6.1		9.1		84.8	
	0.0	13.3	11.1	6.7	89.9	80.0
43. The BODYMEDIA system helped me to overcome the barriers that I typically experience to eating a healthy diet.	12.1		24.2		63.6	
	0.0*	26.7*	22.2*	26.7*	77.8*	46.7*
44. The BODYMEDIA system helped me to overcome the barriers that I typically experience to exercising.	12.1		18.2		69.7	
	0.0*	26.7*	16.7*	20.0*	83.3*	53.3*
45. The BODYMEDIA system helped me to interact with my weight loss counselor regarding my diet.	18.2		24.5		57.6	
	5.6**	33.3**	11.1**	40.0**	83.3**	26.7**
46. The BODYMEDIA system helped me to interact with my weight loss counselor regarding my exercise.	15.2		30.3		54.5	
	5.6*	26.7*	16.7*	46.7*	77.8*	26.7*
47. The BODYMEDIA system made me more aware of my eating behaviors compared to if I did not use the BODYMEDIA system.	12.1		12.1		75.8	
	5.6	20.0	0.0	26.7	94.4	53.3

* χ^2 p-value ≤ 0.05, ** χ^2 p-value ≤ 0.01

	Total		Total		Total	
	CON-TECH	INT-TECH	CON-TECH	INT-TECH	CON-TECH	INT-TECH
48. The BODYMEDIA system made me more aware of my exercise compared to if I did not use THE BODYMEDIA SYSTEM.	3.0		9.1		87.9	
	0.0	6.7	5.6	13.3	94.4	80.0
49. The BODYMEDIA system made me more aware of my weight loss efforts compared to if I did not use THE BODYMEDIA SYSTEM.	9.0		15.2		81.8	
	0.0	6.7	5.6	26.7	94.4	66.7
50. The BODYMEDIA system motivated me to be adherent with my eating behaviors.	6.1		9.1		84.8	
	0.0	13.3	11.1	6.7	88.9	80.0
51. The BODYMEDIA system motivated me to be adherent with my exercise.	6.1		9.1		87.9	
	0.0	13.3	5.6	6.7	94.4	80.0
52. The BODYMEDIA system motivated me to be adherent with my weight loss efforts.	3.0		9.1		87.9	
	0.0	6.7	5.6	13.3	94.4	80.0
53. The BODYMEDIA system made me more accountable for their weight loss efforts.	9.1		15.2		75.8	
	0.0	20.0	5.6	13.3	83.3	66.7
54. It was easy to setup the BODYMEDIA system software on my computer.	15.2		12.1		72.7	
	5.6	26.7	5.6	20.0	88.9	53.3
55. The BODYMEDIA system software was easy to use to track my eating behaviors.	21.2		6.1		72.7	
	11.1	33.3	0.0	13.3	88.9	53.3
56. The BODYMEDIA system software was easy to use to track my exercise.	12.1		6.1		81.8	
	0.0	26.7	0.0	6.7	94.4	66.7
57. The BODYMEDIA system software was easy to use to track my weight loss progress.	12.1		21.2		66.7	
	5.6	20.0	5.6	26.7	83.3	46.7
58. The armband was easy to setup.	3.0		9.1		87.9	
	0.0	6.7	6.7	0.0	93.3	93.3
59. The armband was comfortable to wear.	21.2		24.2		54.5	
	16.7	26.7	27.8	20.0	55.6	53.3
60. Wearing the armband did not interfere with my job.	12.1		18.2		69.7	
	5.6	20.0	16.7	13.3	72.2	66.7
61. Wearing the armband did not interfere with my social life.	21.2		21.2		57.6	
	27.8	13.3	16.7	26.7	55.6	60.0

$^{*}\chi^2$ p-value ≤ 0.05, $^{**}\chi^2$ p-value ≤ 0.01

	Total		Total		Total	
	CON-TECH	INT-TECH	CON-TECH	INT-TECH	CON-TECH	INT-TECH
62. Wearing the armband did not make me feel uncomfortable around others.	21.2		18.2		60.6	
	16.7	26.7	16.7	13.3	66.7	53.3
63. The information obtained by wearing the armband was helpful in increasing my exercise.	9.1		6.1		84.8	
	5.6	20.0	0.0	6.7	94.4	73.3
64. The information obtained by wearing the armband was helpful in my weight loss efforts.	9.1		15.2		75.8	
	0.0	20.0	5.6	20.0	88.9	60.0
65. The feedback related to my step counts obtained by wearing the armband was helpful in increasing my exercise and weight loss efforts.	12.1		9.1		78.8	
	0.0	26.7	5.6	6.7	88.9	66.7
66. The feedback related to my minutes of physical activity obtained by wearing the armband was helpful in increasing my exercise and weigh loss efforts.	15.2		9.1		75.8	
	5.6	26.7	5.6	6.7	83.3	66.7
67. The feedback related to my daily caloric intake obtained from the BODYMEDIA system was helpful in my weight loss efforts.	12.1		12.1		75.8	
	5.6	20.0	0.0	20.0	88.9	60.0
68. The feedback related to my daily energy balance obtained from the BODYMEDIA system was helpful in my weight loss efforts.	9.1		18.2		72.7	
	5.6	13.3	5.6	26.7	83.3	60.0
69. The feedback related to my body weight trends obtained from the BODYMEDIA system was helpful in my weight loss efforts.	18.2		18.2		69.7	
	5.6	20.0	11.1	20.0	77.8	60.0
70. The feedback related to my food breakdown (fat, protein, and carbohydrates) obtained from the BODYMEDIA system was helpful in my weight loss efforts.	21.2		30.3		48.5	
	16.7	26.7	16.7	40.0	61.1	33.3

$^{*}\chi^2$ p-value ≤ 0.05, $^{**}\chi^2$ p-value ≤ 0.01

	Total	
	CON-TECH	INT-TECH
71. On average, I used the BODYMEDIA system to assist me with tracking my eating behaviors		
h. every day	45.5	
	73.3**	26.7**
i. at least 3 days per week	21.2	
	38.9**	0.0**
j. at least once per week	0.0	
	0.0**	0.0**
k. at least one week per month	18.2	
	0.0**	40.0**
l. less than one week per month	9.1	
	0.0**	20.0**
m. only when I am struggling with my weight control efforts	3.0	
	0.0**	6.7**
n. I do not plan on using the BODYMEDIA SYSTEM.	3.0	
	0.0**	6.7**
72. On average, I used the software component of the BODYMEDIA system to assist me with tracking my exercise behaviors		
a. every day	39.4	
	58.8**	23.1**
b. at least 3 days per week	21.2	
	41.2**	0.0**
c. at least once per week	3.0	
	0.0**	6.7**
d. at least one week per month	18.2	
	0.0**	40.0**
e. less than one week per month	9.1	
	0.0**	20.0**
f. only when I am struggling with my weight control efforts	3.0	
	0.0**	6.7**
g. I do not plan on using the BODYMEDIA SYSTEM.	3.0	
	0.0**	6.7**

* χ^2 p-value ≤ 0.05, ** χ^2 p-value ≤ 0.01

	Total	
	CON-TECH	INT-TECH

38. On average, I wore the armband from the BODYMEDIA system to assist me with tracking my exercise

	Total	
a. every day	51.5	
	82.4**	20.0**
b. at least 3 days per week	9.1	
	17.6**	0.0**
c. at least once per week	0.0	
	0.0**	0.0**
d. at least one week per month	24.2	
	0.0**	53.3**
e. less than one week per month	9.1	
	0.0**	20.0**
f. only when I am struggling with my weight control efforts	0.0	
	0.0**	0.0**
g. I do not plan on using the BODYMEDIA SYSTEM.	3.0	
	0.0**	6.7**

39. When I did not wear the armband, the main reason that I did not wear the armband was

	Total	
f. The armband was uncomfortable.	18.2	
	16.7	20.0
g. I did not find the armband to provide helpful information.	0.0	
	0.0	0.0
h. Family, friends, or coworkers questioned me about the armband.	0.0	
	0.0	0.0
i. The armband was visible and I could not conceal it under my clothing.	15.2	
	11.1	20.0
j. Wearing the armband made me feel uncomfortable in public situations.	6.1	
	11.1	0.0
k. Other ^	60.6	
	54.5	45.5

* χ^2 p-value ≤ 0.05, ** χ^2 p-value ≤ 0.01

^ Responses provided for option f "Other":

a. Forgot to wear.
2. Part of intermittent group.
3. Always wore armband.
4. Was Resting.
5. Armband was defective, waited for replacement.
6. Armband caused rash.

Future Use of the BODYMEDIA System

Statements Regarding Past Use of the BODYMEDIA System§	Strongly Disagree/ Disagree		Neutral/ NA		Agree/ Strongly Agree	
§Data Presented as:	Total n=33		Total n=33		Total n=33	
	CON-TECH n=18	INT-TECH n=15	CON-TECH n=18	INT-TECH n=15	CON-TECH n=18	INT-TECH n=15
32. I would use the BODYMEDIA system in the future to monitor my dietary intake.	18.2		9.1		72.7	
	22.2	13.3	13.3	5.6	72.2	73.3
33. I would use the BODYMEDIA system in the future to monitor my exercise.	12.1		0		87.9	
	11.1	13.3	0.0	0.0	88.9	86.7
34. I would use the BODYMEDIA system in the future to help me to understand how I needed to change my eating behaviors to control my weight.	15.2		3.0		81.8	
	16.7	13.3	5.6	0.0	77.8	86.7
35. I would use the BODYMEDIA system in the future to help me to understand how I needed to change my exercise behaviors to control my weight.	15.2		3.0		81.8	
	16.7	13.3	5.6	0.0	77.8	86.7
36. I would use the BODYMEDIA system in the future because of the valuable feedback and information it provides to help me modify my eating patterns to control my weight.	15.2		3.0		81.8	
	16.7	13.3	0.0	6.7	83.3	80.0
37. I would use the BODYMEDIA system in the future because of the valuable feedback and information it provides to help me to modify my exercise to control my weight.	12.1		6.1		81.8	
	11.1	13.3	5.6	0.0	83.3	80.0
38. I would use the BODYMEDIA system in the future because it helps me to overcome the barriers that I typically experience to eating a healthy diet.	18.2		18.2		63.6	
	22.2	13.3	11.1	20.0	66.7	60.0
39. I would use the BODYMEDIA system in the future because it helps me to overcome the barriers that I typically experience to exercising.	18.2		9.1		72.7	
	22.2	13.3	5.6	6.7	72.2	73.3
40. I would use the BODYMEDIA system in the future because it helps me to interact with my weight loss counselor regarding my diet.	24.2		30.3		45.5	
	33.3	13.3	27.8	26.7	38.9	53.3
41. I would use the BODYMEDIA system in the future because it helps me to interact with my weight loss counselor regarding my exercise.	27.3		27.3		45.5	
	33.3	20.0	27.8	20.0	38.9	53.3
42. I would use the BODYMEDIA system in the future because it is easy to use to track my eating behaviors.	15.2		3.0		81.8	
	16.7	13.3	0.0	6.7	83.3	80.0
43. I would use the BODYMEDIA system in the future because it is easy to use to track my exercise.	9.1		0		91.9	
	5.6	13.3	0.0	0.0	94.4	86.7
44. I would use the BODYMEDIA system in the future because it is easy to use to track my weight loss progress.	12.1		9.1		78.8	
	11.1	13.3	11.1	6.7	77.8	80.0

	Total		Total		Total	
	CON-TECH	INT-TECH	CON-TECH	CON-TECH	INT-TECH	CON-TECH
45. I would use the BODYMEDIA system in the future because it made me more aware of my eating behaviors compared to if I did not use THE BODYMEDIA SYSTEM.	9.1		6.1		84.8	
	11.1	6.7	11.1	0.0	77.8	93.3
46. I would use the BODYMEDIA system in the future because it made me more aware of my exercise compared to if I did not use THE BODYMEDIA SYSTEM.	9.1		3.0		87.9	
	11.1	6.7	5.6	0.0	83.3	93.3
47. I would use the BODYMEDIA system in the future because it made me more aware of my weight loss efforts compared to if I did not use THE BODYMEDIA SYSTEM.	15.2		15.2		69.7	
	16.7	13.3	16.7	13.3	66.7	73.3
48. I would use the BODYMEDIA system in the future because it motivated me to be adherent with my eating behaviors.	15.2		3.0		81.8	
	22.2	6.7	0.0	6.7	77.8	86.7
49. I would use the BODYMEDIA system in the future because it motivated me to be adherent with my exercise.	9.1		9.1		81.8	
	11.1	6.7	11.1	6.7	77.8	86.7
50. I would use the BODYMEDIA system in the future because it motivated me to be adherent with my weight loss efforts.	15.2		9.1		75.8	
	16.7	13.3	11.1	6.7	72.2	80.0
51. I would use the BODYMEDIA system in the future because it made me more accountable for their weight loss efforts.	18.2		6.1		75.8	
	5.6	13.3	22.2	6.7	72.2	80.0
52. I would use the armband in the future.	18.2		12.1		69.7	
	22.2	6.7	5.6	13.3	72.2	66.7
53. I would use the armband because it is comfortable to wear.	30.3		27.3		42.4	
	33.3	26.7	33.3	13.3	33.3	53.3
54. I would use the armband in the future because it did not interfere with my job.	15.2		27.3		57.6	
	22.2	6.7	22.2	20.0	50.0	66.7
55. I would use the armband in the future because it did not interfere with my social life.	33.3		21.2		45.5	
	44.4	20.0	22.2	13.3	33.3	60.0
56. I would use the armband in the future because it did not make me feel uncomfortable around others.	27.3		27.3		45.5	
	33.3	20.0	22.2	26.7	44.4	46.7
57. I would use the armband in the future because it was helpful in increasing my exercise.	15.2		12.1		72.7	
	16.7	13.3	11.1	6.7	72.2	73.3
58. I would use the armband in the future because it was helpful in my weight loss efforts.	18.2		12.1		69.7	
	22.2	13.3	11.1	6.7	66.7	73.3

	Total	
	CON-TECH	INT-TECH

59. If given the opportunity to use the BODYMEDIA system in the future to assist me with tracking my eating behaviors, I would do this

a. every day	39.4	
	33.3	46.7
b. at least 3 days per week	30.3	
	33.3	26.7
c. at least once per week	3.0	
	0.0	6.7
d. at least one week per month	6.1	
	5.6	6.7
e. less than one week per month	6.1	
	11.1	0.0
f. only when I am struggling with my weight control efforts	3.0	
	5.6	0.0
g. I do not plan on using the BODYMEDIA SYSTEM.	12.1	
	11.1	13.3

60. If given the opportunity to use the BODYMEDIA system (both software and armband) in the future to assist me with tracking my exercise behaviors, I would do this

a. every day	39.4	
	33.3	46.7
b. at least 3 days per week	27.3	
	27.8	26.7
c. at least once per week	3.0	
	0.0	6.7
d. at least one week per month	9.1	
	11.1	6.7
e. less than one week per month	9.1	
	11.1	0.0
f. only when I am struggling with my weight control efforts	3.0	
	5.6	0.0
g. I do not plan on using the BODYMEDIA SYSTEM.	12.0	
	11.1	13.3

	Total	
	CON-TECH	INT-TECH

61. If given the opportunity to wear the armband component of the BODYMEDIA system in the future, it helpful to wear the armband

a. every day	42.4	
	33.3	53.3
b. at least 3 days per week	18.2	
	22.2	13.3
c. at least once per week	6.1	
	0.0	13.3
d. at least one week per month	12.1	
	16.7	6.7
e. less than one week per month	6.1	
	11.1	0.0
f. only when I am struggling with my weight control efforts	3.0	
	5.6	0.0
g. I do not plan on using the BODYMEDIA SYSTEM.	12.1	
	11.1	13.3

62. If you do not have a desire to use the armband feature of the BODYMEDIA system in the future, the main reason would be

a. The armband was uncomfortable.	30.3	
	27.8	33.3
b. I did not find the armband to provide helpful information.	0.0	
	0.0	0.0
c. Family, friends, or coworkers questioned me about the armband.	9.1	
	5.6	13.3
d. The armband was visible and I could not conceal it under my clothing.	12.1	
	5.6	20.0
e. Wearing the armband made me feel uncomfortable in public situations.	6.1	
	11.1	0.0
f. Other	33.3	
	44.4	20.0

APPENDIX J

DISTRIBUTION OF TOTAL ARMBAND TIME ON BODY

Figure J.1 Distribution of Armband Total Time on Body for INT-TECH group

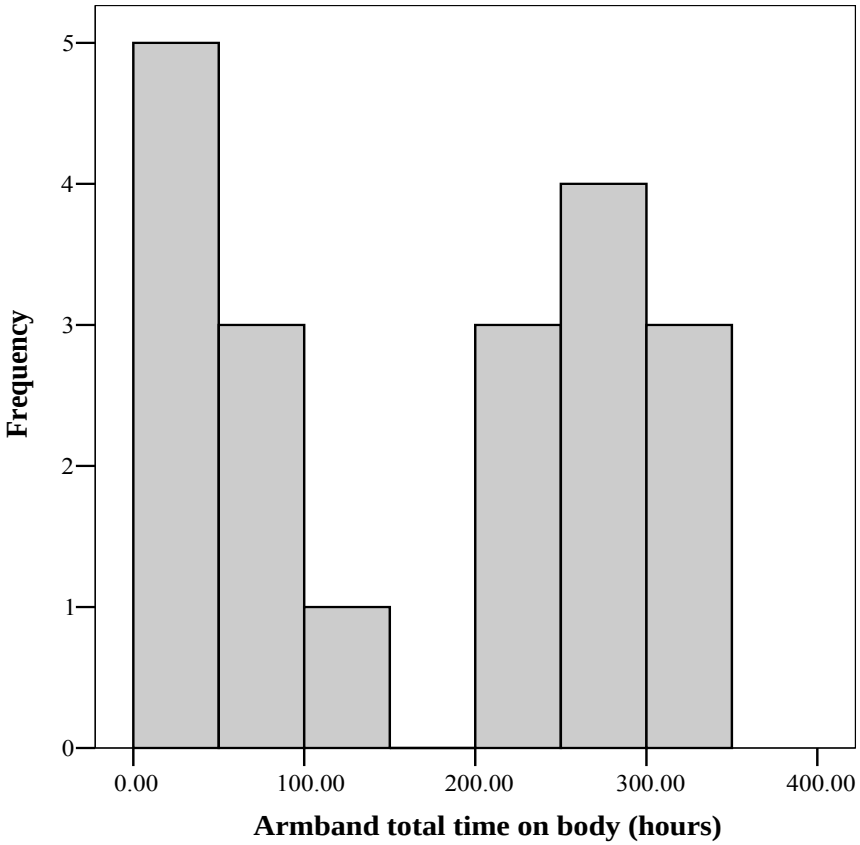
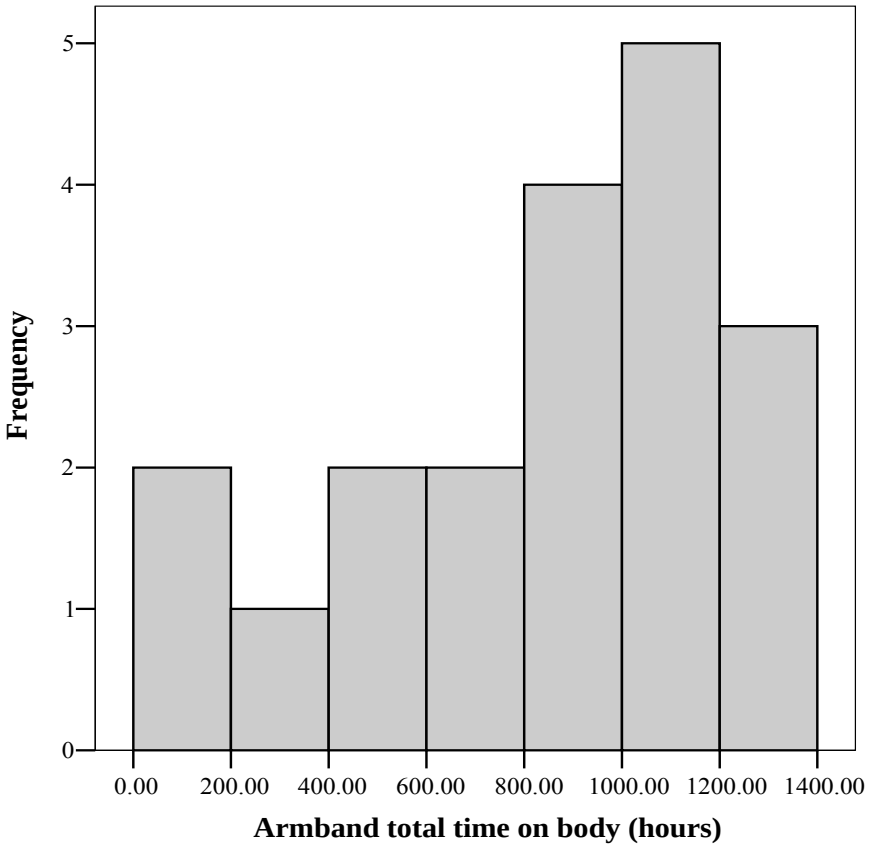


Figure J.2 Distribution of Armband Total Time on Body for CON-TECH group



APPENDEX K

ADDITIONAL TIME ON BODY ANALYSES

Table K.1 Differences in Demographic Variables between Total Time on Body Median Split §

	INT-TECH		CON-TECH	
Time on Body (hrs)	Split 1 ≤222 (n=10)	Split 2 ≥223 (n=9)	Split 1 ≤977 (n=10)	Split 2 ≥978 (n=9)
Variable				
Age (years)	37.8±9.3	44.8±5.3	39.7±9.9	45.8±9.7
Height (cm)	163.7±7.1	166.8±4.8	161.8±5.0	164.1±5.2
Weight (kg)	94.4±10.7	87.2±3.9	87.6±8.4	85.5±11.0
% Minority Representation	60.0 [a]	11.1	50.0	33.3
BMI (kg/m^2)	35.4±2.4 [a]	31.4±1.6	33.5±2.7	31.7±2.6
Body Composition (% fat)	43.8±2.5 [a]	40.7±2.9	43.8±2.2 [a]	40.1±5.0
Waist Circumference (cm)	108.8±10.7	100.9±8.6	104.5±8.6	103.5±9.7
VO_2 at 85% APMHR (ml/kg/min)	21.2±2.7	21.1±1.9	22.1±4.6	22.1±3.8
Treadmill Time to Reach 85% APMHR (min)	10.4±3.8	10.2±3.1	11.9±2.6	10.4±3.7
Self-report Physical Activity (kcal/wk)	656.2±465.7	1091.7±681.3	646.2±540.3	720.3±291.5
Dietary Intake (kcal/d)	2075.4±970.0	1579.8±591.8	1600.8±559.8	1999.0±863.1

§Values expressed as means ± standard deviation.
[a] value for split 1 is significantly greater than value for split 2 ($p \leq 0.05$).

Table K.2 Change in Primary Outcome Variables between Total Time on Body Median Split §

	INT-TECH		CON-TECH	
Time on Body (hrs)	Split 1 ≤222 (n=10)	Split 2 ≥223 (n=9)	Split 1 ≤977 (n=10)	Split 2 ≥978 (n=9)
Variable				
Weight (kg)	-1.4±2.1	-5.5±3.3 [a]	-3.6±3.0	-9.0±3.0
BMI (kg/m^2)	-0.6±0.8	-1.9±1.1 [a]	-1.3±1.2	-3.3±1.0
Body Composition (% fat)	-0.8±0.9	-2.5±2.1 [a]	-2.8±3.3	-5.4±1.9
Waist Circumference (cm)	0.3±3.7	-6.7±7.4 [a]	-5.1±6.6	-7.2±11.0
VO_2 at 85% APMHR (ml/kg/min)	0.4±1.9	0.8±4.0	0.3±3.3	2.2±2.2
Treadmill Time to Reach 85% APMHR (min)	0.9±1.0	2.0±2.1	1.4±1.9	2.6±2.2
Self-report Physical Activity (kcal/wk)	304.3±554.4	2378.2±4409.3	689.6±850.5	1582.1±1076.6
Dietary Intake (kcal/d)	-535.3±535.9	-322.5±710.1	-499.3±597.9	-473.7±605.4

§Values expressed as means ± standard deviation.
[a] value for split 2 is significantly greater than value for split 1 ($p \leq 0.05$).

Table K.3 Differences in Demographic Variables across Total Time on Body Tertiles §

	INT-TECH			CON-TECH		
Time on Body (hrs)	Tertile 1 ≤75 (n=6)	Tertile 2 76-266 (n=7)	Tertile 3 ≥267 (n=6)	Tertile 1 ≤692 (n=6)	Tertile 2 693-1039 (n=7)	Tertile 3 ≥1040 (n=6)
Variable						
Age (years)	37.8±9.2	42.0±8.4	44.9±5.7	41.2±8.2	39.2±11.9	47.9±8.6
Height (cm)	165.1±7.8	163.1±5.2	167.7±5.5	161.6±5.7	161.9±4.6	165.3±5.0
Weight (kg)	95.7±10.0	90.2±9.5	87.2±4.9	87.1±6.2	85.6±12.0	87.3±10.6
% Minority Representation	66.7	28.6	16.7	66.7	28.6	33.3
BMI (kg/m^2)	35.1±2.0 [a]	33.9±2.9 [b]	31.0±1.9	33.4±2.1	32.6±3.6	31.9±2.5
Body Composition (% fat)	43.8±2.6	42.9±3.0	40.2±3.1	44.4±2.7	41.8±2.0	40.0±6.2
Waist Circumference (cm)	106.3±7.7[a]	110.8±11.1	97.1±7.3	105.8±10.0	99.3±7.4	107.9±8.2
VO_2 at 85% APMHR (ml/kg/min)	21.4±3.0	20.8±1.9	21.3±2.3	22.3±5.5	21.7±2.7	22.7±4.7
Treadmill Time to Reach 85% APMHR (min)	11.7±3.9	8.5±2.9	11.1±3.1	12.3±2.8	10.4±2.8	11.0±4.0
Self-report Physical Activity (kcal/wk)	752.3±442.9	743.7±520.1	1111.2±826.7	531.0±548.8	769.7±433.8	728.4±314.6
Dietary Intake (kcal/d)	1812.0±652.6	2010.9±1194.0	1670.7±523.1	1439.4±554.4	1825.5±658.0	2097.0±903.8

§Values expressed as means ± standard deviation.

[a] value for tertile 1 is significantly greater than value for tertile 3 ($p \leq 0.05$).

[b] value for tertile 2 is significantly greater than value for tertile 3 ($p \leq 0.05$).

Table K.4 Change in Primary Outcome Variables across Total Time on Body Tertiles§

	INT-TECH			CON-TECH		
Time on Body (hrs)	Tertile 1 ≤75 (n=6)	Tertile 2 76-266 (n=7)	Tertile 3 ≥267 (n=6)	Tertile 1 ≤692 (n=6)	Tertile 2 693-1039 (n=7)	Tertile 3 ≥1040 (n=6)
Variable						
Weight (kg)	-1.3±2.6	-3.1±2.6	-5.7±3.7	-3.1±3.1	-5.4±2.9	-10.2±2.3 [ab]
BMI (kg/m^2)	-0.5±1.1	-1.2±1.0	-2.0±1.2	-1.2±1.2	-2.0±1.1	-3.7±0.9 [ab]
Body Composition (% fat)	-0.7±0.7	-1.4±1.0	-2.9±2.5	-3.6±4.1	-2.8±1.8	-6.0±1.8
Waist Circumference (cm)	1.0±4.1	-5.2±6.5	-4.5±7.9	-4.2±8.4	-1.2±7.2	-13.7±5.8 [ab]
VO_2 at 85% APMHR (ml/kg/min)	0.5±2.5	1.2±1.7	-0.1±4.7	0.2±2.0	2.0±4.3	1.4±1.6
Treadmill Time to Reach 85% APMHR (min)	0.8±1.1	2.1±1.9	1.3±1.8	0.9±1.4	2.4±2.4	2.4±2.2
Self-report Physical Activity (kcal/wk)	365.7±714.1	2135.7±5249.5	1217.2±352.3	813.0±951.2	979.8±976.7	1566.3±1217.4
Dietary Intake (kcal/d)	-547.2±642.9	-397.3±426.6	-365.3±843.7	-379.9±653.3	-560.9±517.1	-508.5±678.8

§Values expressed as means ± standard deviation.

[a] value for tertile 3 is significantly greater than value for tertile 1 ($p \leq 0.05$).

[b] value for tertile 3 is significantly greater than value for tertile 2 ($p \leq 0.05$).

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