The Effect of Home-Based Resistance Exercise in Overweight and Obese Adults

by

Laura Ann Fonzi

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COMMITTEE MEMBERSHIP

UNIVERSITY OF PITTSBURGH
SCHOOL OF EDUCATION

This thesis was presented

by

Laura Ann Fonzi

It was defended on

June 25, 2008

And approved by

Kristie Abt, Ph.D.

Amy Otto, Ph.D., RD, LDD

Andrea Locke, PT

John M. Jakicic, Ph.D.
Thesis Director

ABSTRACT

THE EFFECT OF HOME-BASED RESISTANCE EXERCISE IN OVERWEIGHT AND OBESE ADULTS

Laura Ann Fonzi, B.S.

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PURPOSE: The purpose of this study was to examine the changes in muscular strength, physical function and health-related quality of life (HRQOL) with the addition of resistance training to a 12 week behavioral weight loss intervention in overweight and obese adults. **METHODS**: Forty-eight overweight adults (body mass index = 33.3±3.5 kg/m^2) participated in this study. Thirty-eight subjects completed the 12 week behavioral weight loss intervention consisting of weekly behavioral counseling and weekly exercise sessions. Twenty-two subjects completed the 12 week standard behavioral weight loss intervention (SBWI) and sixteen subjects completed the 12 week home-based resistance exercise program (HBRE). The following measurements were performed at baseline and again at week 12: body weight, body mass index, body composition, muscular strength (1 RM chest press and 1 RM leg extension), physical function and HRQOL. **RESULTS**: A repeated measures ANOVA showed that there were significant decreases from baseline to week 12 for body weight, body mass index, lean body mass, and percent body fat. Measures of physical function showed improvement in step-up time, walk test time, chair rise time, and single leg balance time. There was a significant reduction in absolute upper body muscular strength, with no significant change in absolute lower body muscular strength. There were significant improvements is subscales of HRQOL for role physical, vitality, and general health ($p<0.05$), with a trend towards improvement in

physical functioning (p=0.07). There were no significant differences in the pattern of change in any of the outcome measures between SBWI and HBRE. However, compliance to prescribed resistance exercise was approximately 40% of prescribed exercise days for HBRE**. CONCLUSION**: Overall, this investigation produced positive changes from baseline to week 12 in the outcome variables of weight, body composition, physical function, and HRQOL. Resistance exercise did not further improve these outcomes compared to what was achieved with a non-resistance exercise behavioral weight loss intervention. This may have been a result of less than optimal compliance to the resistance exercise training aspect of the intervention in HBRE. These results imply that the addition of resistance training to a standard behavioral weight loss program offers no increased benefit in the variables of interest, possibly resulting from low compliance, and future studies should examine strategies to improve the compliance to resistance exercise in overweight adults undertaking a behavioral weight loss intervention.

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1.0 INTRODUCTION

Current research in the United States indicated that 66.3% of the population is overweight (BMI $\geq$ 25.0 kg/m^2), 32.2% is obese (BMI $\geq$ 30.0 kg/m^2), and 4.8% is extremely obese (BMI $\geq$ 40.0 kg/m^2) (Ogden, 2006). This is a significant public health concern due to the increased morbidity and mortality associated with overweight and obesity (NIH, 1998). The health-related conditions associated with excess body weight may include cardiovascular disease, type II diabetes, gallbladder disease, stroke, gout, liver disease and others (NIH, 1998). These obesity related conditions result in a significant financial burden due to increased health-

(Finkelstein, 2003). In addition, obesity–attributable absenteeism cost employers $2.95 billion in 2003 (Finkelstein, 2005).

A major, and often overlooked, concern in overweight and obese individuals is the reduction in health related quality of life (HRQOL) (Kolotkin, 2001; Fontaine, 2000). One component of HRQOL is physical function, which has been shown to be reduced in obese individuals (Zoico, 2004; Apovian, 2002). Low physical function in obese individuals may be partially due to reduced muscular strength. Thus, focusing an intervention on increasing muscular strength in obese individuals may result in an increase in physical function, which may result in an improved HRQOL (see figure 1.0).

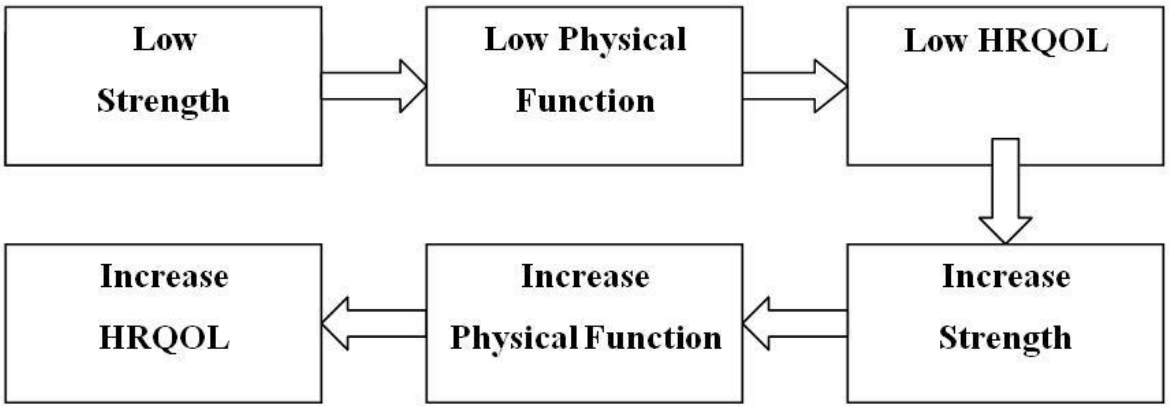

Figure 1. Conceptual Model for Increase in HRQOL

Exercise in the form of resistance training has been shown to increase muscular strength in obese individuals (Kraemer, 1997; Geliebter, 1997; Pronk, 1992; Jakicic, 2001). However, these resistance training programs have typically utilized traditional resistance training equipment such as free-weights and weight machines, and have been conducted primarily in supervised settings (Geliebter, 1997; Kraemer, 1997). The condition of a supervised setting for resistance training may not be easily accessible to most individuals. In addition, research has supported a greater adherence rate to home-based exercise when compared to supervised exercise sessions (Perri, 1997; King, 1991). Therefore, alternative resistance exercise interventions for overweight and obese individuals should be examined.

Evidence from research on older adults suggests that a program using equipment such as exercise bands, exercise balls and other forms of resistance exercise that can be performed at home will increase muscular strength (Mikesky, 1994; Skelton, 1995). However**,** the effects of these types of resistance exercises have not been systematically studied in an obese population. Therefore, the purpose of this study was to examine if this form of resistance exercise can improve strength, enhance physical function, and improve HRQOL in obese adults during a short-term period of weight loss.

1.1 RATIONALE AND SIGNIFICANCE

Overweight and obesity contribute to a reduced HRQOL, which may be partially due to reduced physical function. While this reduced physical function may be a result of excess body weight, it may also be a result of insufficient muscular strength of overweight and obese individuals to efficiently and comfortably support their own body weight. The reduced muscular strength may also contribute to decreased efficiency of activities of daily living (i.e., getting out of a chair, carrying groceries, etc.). This would suggest that an increase in muscular strength may increase physical function and result in an improved HRQOL in overweight and obese individuals (see figure 1.0)

The most effective behavioral weight loss interventions combine both reductions in energy intake and increases in energy expenditure through exercise to impact energy balance. However, to increase muscular strength, resistance exercise needs to be included in the weight loss intervention. It is well documented that exercise consisting of cardiovascular training alone will not result in a significant increase in muscular strength (Kraemer, 1997; Donnelly, 1993; Geliebter, 1997). This is supported by the American College of Sports Medicine Position Stand in which it was concluded that resistance exercise may be an important factor for increasing muscular strength, which in turn may increase physical function in overweight and obese individuals (Jakicic, 2001).

A close examination of weight loss literature appears to indicate that resistance exercise has primarily been examined in supervised settings, which have included the use of traditional weight training machines and free-weights. However, this form of resistance exercise may not translate to individuals who are unwilling or unable to attend sessions at facilities where this type of equipment is available, or can not afford to purchase this type of equipment for their home. Of interest is that alternative exercise programs using elastic bands for resistance training demonstrate a positive effect on muscular strength and physical function in elderly participants (Rogers, 2002; Zion, 2003; Skelton, 1995). Alternative forms of resistance exercise have not been systematically studied in overweight and obese individuals, and it is therefore unclear if similar effects would be demonstrated for muscular strength and physical function in the overweight and obese. This study examined this important research question, and if found to be

effective, alternative forms of resistance exercise would be used to provide a home-based program to improve muscular strength and physical function in the overweight and obese.

1.2 PRIMARY AIMS AND HYPOTHESES

1. To examine the effect of the addition of resistance exercise when added to a standard weight loss program on muscular strength.
   Hypothesis: It was hypothesized that the resistance exercise group will have improved muscular strength when compared to a standard weight loss group.
2. To examine the effect of the addition of resistance exercise when added to a standard weight loss program on physical function.
   Hypothesis: It was hypothesized that the resistance exercise group will have improved physical function when compared to a standard weight loss group.
3. To examine the effect of the addition of resistance exercise when added to a standard weight loss program on HRQOL.
   Hypothesis: It was hypothesized that the resistance exercise group will have improved HRQOL compared to a standard weight loss group.

1.3 SECONDARY AIMS AND HYPOTHESES

4. To examine the effect of the addition of resistance exercise when added to a standard weight loss program on body weight.
   Hypothesis: It was hypothesized that the resistance exercise group will have a greater reduction in body weight than the standard weight loss group.
5. To examine the effect of the addition of resistance exercise when added to a standard weight loss program on percent body fat.
   Hypothesis: It was hypothesized that the resistance exercise group will have a greater reduction in body fat percentage than the standard weight loss group.

6. In addition, a non-hypothesis driven aim will be to describe adherence to the resistance training exercises using the following components:
    a. Number of weekly in-person sessions attended
    b. Number of days per week the exercises were completed at home

2.0 LITERATURE REVIEW

2.1 OBESITY PREVALENCE

In the United States, obesity is increasing to epidemic levels. Recent statistical data shows that 66.3% of the population is overweight (BMI $\geq$ 25.0 kg/m^2), 32.2% is obese (BMI $\geq$ 30.0 kg/m^2), and 4.8% is extremely obese (BMI $\geq$ 40.0 kg/m^2) (Ogden, 2006). In spite of the implementation of new surgical, pharmacological and behavioral techniques and treatments, the prevalence of obesity has increased from 22.9% in 1988 to 30.5% in 2000 (Flegal, 2002).

2.2 RISKS ASSOCIATED WITH OBESITY

Obese and overweight individuals are at higher risk for many diseases and illnesses such as cardiovascular disease, which umbrellas various complications including, but not limited to, hypertension, hypercholesterolemia and hyperlipidemia. These individuals are also at risk for other serious illnesses such as type II diabetes mellitus and certain types of cancer (Wing, 1999; Rimm, 1995). Among all Americans diagnosed with type II diabetes, 67% have a BMI $\geq$ 27 kg/m^2, while 46% have a BMI $\geq$ 30 kg/m^2 (NIDDK, 2001). In addition, Calle et al (2003) reported that individuals with a BMI > 40 kg/m^2 had death rates from cancer that were 52% and 62% higher for men and women, respectively. Obesity is a disease that is not easily treated,

although it has been extensively researched. A great deal of literature exists on differing exercise, nutritional and behavioral weight loss strategies, with no definitive answer on the most effective interventions for overweight and obese individuals. The purpose of this literature review is to explore in greater detail the effectiveness of past and current weight loss interventions and to describe their effect on muscular strength, physical function and health related quality of life.

2.3 ASSOCIATION BETWEEN OBESITY, MUSCULAR STRENGTH, PHYSICAL FUNCTION, AND HRQOL.

Obese individuals appear to have greater absolute strength when compared to normal weight individuals; however, research has repeatedly documented decreased relative muscular strength in overweight and obese adults when adjusted for weight (Miyatake, 2000; Zoico, 2004; Hulens, 2001). For example, Miyatake et al (1999) studied 357 obese and 1683 nonobese Japanese men and women, examining weight bearing index [leg strength (kg)/body weight (kg)] within subjects. This investigation reported that across all ages, weight-bearing index was lower in obese (0.81 for men and 0.60 for women) than nonobese (0.92 for men and 0.74 for women) subjects.

Hulens et al (2001) studied peripheral muscle strength in 80 lean and 173 obese women using isometric handgrip and isokinetic strength measures including trunk flexion, extension and rotation as well as knee flexion and extension. Absolute isokinetic strength was significantly greater in the obese subjects; however relative measures of strength, correcting for fat-free mass, showed that all measures of strength were at least 6% lower in the obese than lean subjects, with the exception of trunk flexion strength.

Obesity also appears to correspond to a decreased physical function (Zoico, 2004; Apovian, 2002). Zoico et al (2004) examined associations between body composition and functional ability in 167 elderly women (67-78 yrs) and 120 young women (20-50 yrs). Results showed that subjects with a BMI > 30 kg/m^2 were at a 3-4 times greater risk for functional limitations. These results are further supported by Apovian et al (2002), who reported that

higher BMIs are associated with low function in both the upper and lower body. In addition, longitudinal research conducted by Ferraro et al (2002) reported that having a BMI > 30 kg/m^2 was associated with higher levels of disability 10 to 20 years later in life.

Several areas of physical function that may be affected by obesity include walking speed and efficiency (Hulens, 2003; Chen, 2004). Decreased walking speed has been found to be a predictor of functional decline and associated with decreased ability to perform activities of daily living (Judge, 1996). It has also been found to be associated with falls. (Corbeil, 2001). Hulens et al (2003) found that obese women walked significantly slower (5.9 km/hr) than lean women (7.2 km/hr). In addition, decreased walking efficiency at normal walking speed (0.9 to 1.2 m/s) was observed by Chen et al (2004) in obese persons when compared to their lean counterparts. Moreover, obesity can negatively affect performance on activities of daily living. For example, Han et al (1998) reported that large waist circumference and high BMI are associated with disabilities that impair activities of daily living. In addition, population studies in obese individuals have shown that impaired physical function may reduce HRQOL (Fontaine, 2000; Samsa, 2001).

HRQOL has also been shown to increase with weight loss interventions including physical activity (Fontaine, 2000, Kolotkin, 2001). Fontaine et al (2000) studied 38 moderately overweight individuals to assess the effects of weight loss on HRQOL using a diet and aerobic exercise program. HRQOL increased relative to baseline values on multiple components of the SF-36 including physical functioning where the score increased from 86.3 ± 7.1 to 95.7 ± 6.7. The increase in the subscale of physical functioning contributed to the overall increase in HRQOL.

2.4 TRADITIONAL BEHAVIORAL WEIGHT LOSS INTERVENTIONS

The components of a standard weight loss program typically include the following components: dietary intake restriction, physical activity in various forms, behavioral counseling and/or self-monitoring. Jakicic et al (2001) provided a guide for appropriate weight loss

strategies using past and current research within obesity literature. The recommendations for an effective weight loss intervention include an energy deficit of 500-1000 kcal/day, a decrease in dietary fat to <30% of total energy intake per day, at least 150 minutes of moderate physical activity per week, resistance training for the increase in function and strength, and when indicated, pharmacotherapy. Two components of the intervention recommendations that will be further explored in this literature review will be muscular strength and physical function.

Traditional weight loss interventions involving behavioral components have been conducted extensively over the past several decades. Miller et al (1997) conducted a meta-analysis of weight loss interventions over the past 25 years and concluded that in a standard 15-week diet or diet plus exercise program, weight loss averaged approximately 11 kg. After one year, the diet only groups and diet plus exercise groups maintained an average weight loss of 6.6 kg and 8.6 kg, respectively. The results from this meta-analysis indicate that physical activity is an important component for weight loss maintenance.

Hagan et al (1986) studied the effects of diet and exercise on weight loss through subject groups consisting of diet only and diet + exercise over a 12 week intervention. The diet consisted of 1,200 kcals while the exercise volume was 5 days per week of 30 minutes walking and/or running. The study reported that weight loss in the diet and exercise group for men and women (-11.8 kg and -10.4 kg) was significantly greater than in the diet only group for men and women (-9.1 kg and -7.8 kg).

Moreover, Wing et al (1998) assessed the long-term effects of lifestyle modification in overweight individuals on weight change during a two-year investigation. 154 participants were randomly placed into one of three intervention groups: diet, exercise, and diet + exercise. After 6 months, weight loss in the diet group (-9.1 ± 6.4 kg) and diet + exercise group (-10.3 ± 7.7 kg) was significantly greater than in the exercise group (-2.1 ± 4.2 kg). At the two year follow-up measurements, only the diet + exercise group maintained a significant weight loss (-2.5 kg) from baseline. These results suggest the importance of exercise in addition to diet for short-term weight loss.

2.5 EFFECTS OF WEIGHT LOSS INTERVENTIONS ON MUSCULAR STRENGTH

During periods of energy restriction and weight loss, it has been shown that an increase in muscular strength can be observed. For example, Kraemer et al (1997) conducted a study on 31 overweight women who were randomly placed into three intervention groups consisting of diet only (D), diet plus aerobic endurance training (DE) or diet plus aerobic endurance training plus strength training (DES). The strength training group followed a progressive resistance training program that included weight machines. Following 12 weeks of the intervention, all three groups, D, DES and DE reduced total body weight by 6.2 kg, 6.8 kg and 7.0 kg, respectively. This study found that the DES group showed increases in maximal strength where the D and DE group did not. The findings suggest that it is possible to increase strength while decreasing body weight in diet plus strength training groups, but not without strength training.

Geliebter et al (1997) studied the effects of strength and aerobic training during weight loss in obese subjects on physiological variables. 65 subjects (25 men) were placed into one of three groups; diet plus strength training, diet plus aerobic training and diet only. The strength training group participated in progressive resistance exercises for the upper and lower body using machines. After 8 weeks, mean weight loss of 9.0 kg did not significantly differ between groups. The diet plus strength training group showed significant increases in measured flexed arm muscle mass (+1.1 cm) as well as grip strength (+3.3 u) ($p<.05$). The diet only and diet plus aerobic training group did not show any improvement in strength.

Donnelly et al (2005) examined muscle hypertrophy during large-scale weight loss using a liquid diet. The study examined 14 obese females placed into two groups consisting of a diet only and a diet plus weight training group. Over a period of 90 days, subjects in both groups lost an average of 16 kg, with no significant difference in weight loss between groups ($p<.05$). The diet only group had a decline in strength of 13.3%, while the diet plus weight training group had an increase in strength of 17.6%. In addition, the cross-sectional area of slow twitch and fast twitch fibers did not change in diet only subjects, but significantly increased in the weight training subjects, showing muscle hypertrophy. The evidence supports that it is possible to increase strength during moderate weight loss in obese individuals, and it is plausible to elicit muscle hypertrophy during periods of weight loss.

2.6 EFFECTS OF HOME-BASED RESISTANCE TRAINING ON MUSCULAR STRENGTH

Many studies have been conducted on increasing muscular strength and physical functioning in the elderly, using alternative forms of resistance training in home-based programs. Mikesky et al (1994) and Zion et al (2003) conducted similar research studies that included the use of elastic tubing only in a home-based training program on 31 and 8 elderly subjects, respectively. Mikesky measured muscular strength using isokinetic testing while Zion measured both dynamic strength and physical function using testing such as the Timed Up & Go. Mikesky et al reported significant increases in isokinetic eccentric knee extension (12%) and flexion strength (10%). Zion et al showed significant increase in dynamic strength in the chest press, quadriceps extension and leg press as well as showing a functional mobility increase in all but one of the participants.

In addition, Skelton et al (1995) studied the effects of resistance training using rice bags and elastic tubing in 52 women aged 75 years and older placed into an exercise or a non-exercise control group. The intervention consisted of 2 home sessions in conjunction with 1 supervised session per week. Isometric knee extensor strength, elbow flexor strength, handgrip strength and leg extensor power were measured. Following a 12 week intervention period, all measures increased by a mean of 27%, 22%, 4% and 18%, respectively.

The effects of home-based resistance training exercises have been systematically studied in the elderly population. However, the effects have not been methodically examined in the overweight and obese. In addition, other gaps in obesity literature exist including the following areas: the ability to increase strength with alternative forms of resistance training, the effects of obesity on sub-components of HRQOL, and whether increases in strength cause specific increases in physical function which in turn increase HRQOL.

2.7 SUMMARY

Clear and concise evidence supports that a significant concern in obese individuals is a decreased HRQOL. One component of HRQOL is physical function, which seems to be related to muscular strength. Resistance training has repeatedly been shown to increase muscular strength in obese individuals during periods of moderate to severe weight loss. Thus, an increase in muscular strength may also result in increased physical function, which can improve HRQOL of overweight and obese individuals (see figure below).

However, most resistance exercise interventions have used either exercise machines or free-weights to elicit the desired improvements in muscular strength. There is some evidence that resistance exercise that uses exercise bands and other alternative forms of resistance can also improve muscular strength, but this has not been examined in overweight and obese individuals during periods of weight loss. Moreover, the effect of such an intervention on physical function and HRQOL has not been examined. This study examined these important research questions.

3.0 METHODS

This study examined the effect of home-based resistance training on muscular strength, physical function, and health-related quality of life (HRQOL) in overweight and obese adults, during a short-term behavioral weight loss intervention. Additional outcomes included fat-free mass (FFM) and body weight. To examine these research questions, the following methods and procedures were implemented. All intervention procedures were approved by the Institutional Review Board (IRB) at the University of Pittsburgh, and written informed consent was obtained from all participants prior to participation in the study.

3.1 SUBJECTS

48 subjects with a body mass index (BMI) between 25.0 and 39.9 kg/m^2 with ages between 18 and 55 years were recruited to participate in this study. Subjects were excluded from participation in the study using the following criteria:

3.2 EXCLUSION CRITERIA

1. Known metabolic disorder such as diabetes, hypothyroidism or others.
2. An orthopedic problem that would limit participation in exercise.
3. Currently participating in regular exercise of at least 20 minutes per day on 3 or more days of the week during the prior 6 months.

4. Currently participating in any level of resistance training during the prior 6 months.
5. Current pregnancy, pregnant within the prior 6 months, or planning to become pregnant within the next 6 months.
6. Taking medication that would have an effect on heart rate and/or blood pressure.
7. Having a non-medicated resting systolic blood pressure of > 160mmHg or diastolic > 100mmHg
8. History of myocardial infarction or valvular disease.
9. Weight loss of >5% of body weight within the prior 12 months.

3.3 RECRUITMENT

The subjects in this study were recruited through various media sources including television, radio, newspaper and mail announcements. Potential participants were directed to contact the investigators at the University of Pittsburgh Physical Activity and Weight Management Research Center at a number provided. A brief phone interview was conducted in order to determine initial eligibility. Eligible individuals were invited to attend an orientation session to understand further the specific details of this study. Interested participants who provided written informed consent completed a General Health History and Physical Activity Readiness Questionnaire (PAR-Q) (Appendices A and B). Additionally, all subjects provided documentation from their primary care physician to confirm that there were no contraindications to their participation in the weight loss or exercise program proposed for this study (Appendix C).

3.4 EXPERIMENTAL DESIGN

This research study used a randomized design and included two intervention groups. Subjects participated in a 3-month behavioral weight loss program with randomization to a

standard behavioral weight loss program (SBWI) or a standard behavioral weight loss program plus home-based resistance exercise training (HBRE). The specific components of these interventions are described in detail below. Subjects completed the outcome assessments described below at baseline and following the 3-month intervention period.

3.5 INTERVENTION COMPONENTS

3.5.1 Standard Behavioral Weight Loss Intervention (SBWI)

Intervention Contact

Subjects attended weekly, in-person, group-based weight control meetings for a period of 12 consecutive weeks. Each session lasted approximately 45-60 minutes. These sessions consisted of interventionist lead lesson plans that integrate behavioral strategies to assist with weight control. At the beginning of each in-person session, body weight was measured to determine weekly progress, and to allow for individual feedback to be provided to participants. All sessions were conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh.

Dietary Recommendations

All subjects were prescribed an energy restricted dietary intervention. Subjects were directed to restrict energy intake to 1200-1800 kilocalories (kcal) per day based on initial body weight measured (<200 pounds = 1200 kcal/day; 200-250 pounds = 1500 kcal/day; > 250 pounds = 1800 kcal/day). Prior research has shown that participants who achieved successful weight control consumed a balanced diet, with a macronutrient composition that consists of the following: 20-25% dietary fat intake, 55% carbohydrate intake, and 10-25% protein intake (Klem,1997). Therefore, a similar dietary macronutrient composition was recommended to participants in this study.

Subjects were provided meal plans to facilitate the implementation of an energy-restricted diet (See Appendix D for a sample meal plan). Approximately three to four plans per meal were provided to allow for variety and also to accommodate various food preferences.

Subjects were instructed to self-monitor daily energy intake utilizing a weekly diary (See Appendix E for example). Subjects were instructed to record their eating patterns including the time of day that the food was consumed, the type of food that was consumed, and the caloric value and fat content of the food that was consumed. In addition, subjects were instructed to weigh and measure all food that is being consumed and to use nutritional labels or a resource book that were provided to them ("The Complete and Up to Date Fat Book") to determine the calorie and fat content of the food that is consumed. Subjects returned each completed weekly diary to the intervention staff during each in-person visit. Interventionists provided specific written feedback on the diary, focusing on appropriate food choices, meal preparation and eating behaviors; these diaries were returned to participants.

Exercise Recommendations

Subjects were directed to engage in aerobic exercise that is considered at least moderately intense, on 5 days per week. Initially subjects were instructed to exercise 20 minutes per day, with the duration gradually progressing to at least 40 minutes per day (See Table 1.0). The exercise progression consisted of 10 minutes per day in 4-week intervals.

Subjects were encouraged to participate in activity that was at least moderate in intensity. This was defined as a rating of perceived exertion (RPE) of approximately 11-13 on the 15-point Borg scale and/or a target heart rate range between 55-70% of maximal heart rate (See Table 1.0). Activities that are consistent with this intensity level are similar to "brisk walking."

Table 3-1 Description of Aerobic Exercise Progression

	Days per week	
Weeks 1-12	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**
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 is part of the diary used to record dietary intake. 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 feedback to subjects that focused on achievement of weekly exercise goals, daily exercise consistency, mode of exercise, etc.

3.5.2 SBWI plus Home-Based Resistance Exercise (HBRE)

Subjects in the HBRE group received all of the components included in the SBWI described in detail above (Intervention Contact, Dietary Recommendations, and Exercise Recommendations). In addition, the HBRE group was prescribed a resistance exercise program that is described in detail below.

Resistance Exercise Program

Subjects were provided with the following equipment necessary for the resistance exercise program: elastic exercise bands, exercise ball (appropriate for height), and illustrations of the recommended exercises that were performed. Subjects were prescribed a resistance training intervention that was similar to prior research indicating the efficacy of elastic tubing for resistance training (Mikesky, 1994; Skelton, 1995). Resistance bands were available in 4 different resistance levels ranging from easy to difficult. Subjects were provided with bands appropriate for individual strength levels. In order to determine what bands are appropriate, a staff member conducted an exercise class including all prescribed exercises. Subjects were encouraged to use elastic bands that forced the specific muscle group being worked to be at a rating of perceived exertion (RPE) between 6 and 8 (OMNI 1-10 scale) upon completing all of the recommended sets and repetitions.

Subjects performed all resistance exercises during each in-person session and were directed to engage in the resistance training exercises on an additional 4 days per week, to total 5 days per week of resistance training exercises (See Appendix F for exercises and progressions).

The resistance training exercises were performed in addition to the aerobic component of the SBWI. Subjects were instructed to complete 2-3 sets of 8 to 12 repetitions, depending on the specific exercise, with the appropriate level of resistance.

Subjects were instructed to monitor and record their resistance exercise in their exercise diaries. The self-monitoring of resistance exercise included the exercises performed along with the number of repetitions and sets performed for each exercise. In addition, subjects recorded their rating of perceived exertion for the primary, active muscle in each exercise. Subjects returned the completed diaries to the intervention staff at each in-person visit for review. Interventionists reviewed the diaries and provided feedback to subjects that focused on achievement of weekly resistance training goals, daily resistance exercise consistency, etc. Additionally, the RPE ratings for each active muscle were examined in order to determine whether a higher-level resistance band should be used. Subjects progressed to the next highest resistance band when reporting an RPE of less than 6 for the active muscle involved on 2 separate occasions when completing the prescribed repetitions and sets. This progression minimized the risk of injury that may have prevented a subject from participating in exercise as well as ensuring that the specific muscle groups are being given the appropriate load for individual strength levels.

3.6 ASSESSMENT PROCEDURES

All assessments were performed at baseline and following 3 months of the intervention. These assessments included the following measures and procedures:

Weight: Individual body weight was assessed using a calibrated balance beam scale and measured to the nearest 0.25 pounds. Subjects were weighed without shoes and wearing a lightweight, cloth hospital gown.

Height: Individual height was measured using a wall mounted stadiometer without shoes. Height was measured to the nearest 0.1 centimeter.

Body Mass Index (BMI): BMI was calculated from the weight and height measurements in kg/m^2.

Body Composition: Body composition was assessed using a RJL bioelectrical impedance analyzer (BIA), which measured relative fat free and fat mass using the equation proposed by Segal et al (1988). All subjects were instructed to fast, except for water, for at least 4 hours prior to this assessment in order to minimize error in analysis due to over hydration. This was confirmed prior to testing via a verbal query.

Muscular Strength: Muscular strength was assessed using a 1 repetition maximal test (1-RM). Upper body strength was measured using the vertical chest press and lower body strength will be assessed using the leg extension. The 1-RM procedures were obtained through the American College of Sports Medicine's (ACSM) guidelines for the vertical chest press and leg extension. The specific procedures are described below in detail.

For the vertical chest press, the subject sat on the machine that was adjusted for height, with feet flat on the floor and back against the support pad. Hands were placed in a neutral grip position, gripping the handles that are located at the chest level. A perceived maximum weight was obtained from the subject and a warm-up was conducted for 5-10 repetitions of 40-60% of this perceived value. The subject then rested for one minute and performed 4-5 repetitions at 60-80% of the perceived maximum weight. Next, a small amount of weight was added (decided by the investigator and subject) and a 1-RM lift was attempted. If the lift was completed, the subject rested for 1-2 minutes before attempting a heavier lift. A repetition was considered complete when the subject's arms were almost fully extended in front of them with elbows approximately 5 degrees short of full extension followed by a complete return to starting position. If the lift was not fully completed, a small amount of weight was taken off and another, slightly lighter, lift was attempted. It was the goal of this procedure to determine the 1-RM within 3-5 maximal attempts. ACSM's Guidelines for Exercise Testing and Prescription describes the 1-RM as the weight of the last successfully completed lift (6^{th} edition, 2000).

For the leg extension, the subject sat on the machine that was previously adjusted for height, with back against the support pad as well as knees aligned with the pivoting point of the machine. The subject then extended the legs as completely as possible, going from 90 degrees of flexion to full extension, back to the starting position. A perceived maximum weight was obtained from the subject and a warm-up was conducted for 5-10 repetitions of 40-60% of this

perceived value. The subject then rested for one minute and performed 4-5 repetitions at 60-80% of the perceived maximum weight. Next, a small amount of weight was added (decided by the investigator and subject) and a 1-RM lift was attempted. If the lift was completed, the subject rested for 1-2 minutes before attempting a heavier lift. A repetition was considered complete when the subject's legs were extended to the full range of motion (as determined through a non-weighted position) followed by a complete return to starting position. If the lift was not fully completed, a small amount of weight was taken off and another, slightly lighter, lift was attempted. It was the goal of this procedure to determine the 1-RM within 3-5 maximal attempts. ACSM's Guidelines for Exercise Testing and Prescription describes the 1-RM as the weight of the last successfully completed lift (6^{th} edition, 2000).

Health Related Quality of Life (HRQOL): Health-related quality of life was assessed using the Short Form Medical Outcome Questionnaire (SF-36). The SF-36 includes measures of functional health and well being as well as physical and mental health summaries. It has been validated in numerous studies and satisfied rigorous psychometric criteria for validity and consistency (Garatt et al, 1993).

Cardiorespiratory Fitness: Cardiorespiratory fitness was assessed at 0 and 12 weeks. The baseline assessment served as a screening tool to identify individuals who may have existing contraindications to exercise participation as well as to provide data on baseline cardiorespiratory fitness. The participant was monitored by an electrocardiogram (ECG), which was monitored at the time of the exercise test by an American College of Sports Medicine (ACSM) certified Exercise Specialist. ACSM criteria was used to determine if exercise participation was contraindicated. The speed of the treadmill was held constant at 3.0 mph with the initial grade of the treadmill being 0% and increasing by 2.5% increments at 3-minute intervals. Heart rate during exercise testing was obtained at one-minute intervals using a 12-lead ECG and immediately upon termination of exercise. Blood pressure and rating of perceived exertion (Borg 6-20 Scale) 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 was followed for test termination. Cardiorespiratory fitness level at 0 and 12 weeks was reported as the time to achieve 85% of age-predicted maximal heart rate. Following termination, participants were monitored over a 5-10 minute recovery period to ensure that heart rate and blood pressure return to near pre-test levels.

Physical Activity: Physical activity was determined through a questionnaire that was developed by Paffenbarger et al, for the Harvard Alumni Study in 1983. The questions related information on energy expenditure per week from activities performed during leisure time, which will include structured exercise, walking, sports, stair climbing and/or other recreation.

Physical Function: Physical function was determined through the use of 5 timed tests incuding: walk, step up, chair rise, right leg balance and left leg balance tests. All staff were trained by a Physical Therapist to correctly use this test battery.

3.7 DATA ANALYSIS

Data were analyzed using commercially available statistical software (SPSS version 14.0) with statistical significance defined as $p<0.05$. Two-factor (Group X Time) repeated measures of analysis of variances will be performed to test the specific aims of the study. Separate analyses were conducted on the following outcome variables: 1) muscular strength (primary outcome), 2) physical function (primary outcome), 3) HRQOL (primary outcome), 4) body weight (secondary outcome), 5) body composition (secondary outcome). In addition, Pearson Product Moment correlations were computed to assess the association between measures of adherence to the resistance training protocol and changes in muscular strength.

3.8 POWER ANALYSIS

This was a pilot study to provide information that will further inform future studies in this area. Therefore, data related to HRQOL were used to conduct the power analysis for this study. Fontaine et al (2000) demonstrated that physical function measured by the SF-36 improved with weight loss from 86.3 ± 7.1 to 95.7 ± 6.7, for an effect size of approximately 1.36. Because of the nature of this proposed study, a more conservative effect size of 1.0 was used to conduct the power analysis to determine a reasonable sample size. Assuming a standard deviation similar to

that reported by Fontaine et al (2000) of approximately 6.9, alpha defined as 0.05, and statistical power set at 90%, a sample of 46 subjects (23 per group) would be required to detect an effect size of 1.0 in this study. Allowing for an attrition rate of <10% at 12 weeks, approximately 50 subjects (25 per group) were to be recruited and randomized into the two intervention groups proposed in this study. For this study, recruitment and randomization included 25 subjects to SBWI and 23 subjects to HBRE.

4.0 RESULTS

The purpose of this study was to examine the effectiveness of home-based resistance exercise when used in addition to an in-person standard 12-week behavioral weight loss intervention. This study was a randomized clinical weight loss intervention with pretest and posttest assessments performed at 0 and 12 weeks of participation. The independent variable was treatment group: Standard Behavioral Weight Loss Intervention (SBWI) or Home Based Resistance Exercise (HBRE). The primary dependent variables were muscular strength, physical function and health-related quality of life. Other, secondary variables included body weight and body composition.

4.1 SUBJECT CHARACTERISTICS

The subjects in this study included 48 adults (6 men, 42 women). The average age of the subjects was 44.9±8.8 years, with a mean body mass index (BMI) of 33.3±3.5 kg/m^2. Descriptive statistics are presented in Table 4.1. A one-way analysis of variance (ANOVA) revealed that there were no significant baseline differences between intervention groups for all variables measured, including: age, height, body weight, BMI, lean body mass and percent body fat. A chi-square analysis revealed that there were no significant differences at baseline for percent minority representation between intervention groups. There was also no significant difference in the percentage of males and females randomly assigned to each of the intervention conditions.

4.2 RETENTION RATES

A total of 38 subjects (79% of all subjects) provided objective data at baseline and again at 12 weeks. These subjects are referred to as "completers." Those 10 subjects (21% of all subjects) not providing objective data at both baseline and again at 12 weeks are referred to as "non-completers." The non-completers were 3 (12%) for SBWI and 7 (30%) for HBRE, with no significant difference between these groups based on a chi-square analysis (p=0.12). Study withdrawal resulted from various personal reasons including, but not limited to: work related issues, family problems and/or physical injuries or limitations. Baseline characteristics of subjects categorized as completers or non-completers are shown in Table 4.2.

Table 4-1 Characteristics of Subjects at Baseline

Variable	Total	SBWI	HBRE	P-value
	(n=48)	**(n=25)**	**(n=23)**	
Age (years)	45.0 ± 8.8	45.1 ± 9.0	44.9 ± 8.9	.95
Height (cm)	168.0 ± 6.3	167.7 ± 6.5	168.3 ± 6.3	.75
Body Weight (kg)	94.1 ± 12.6	92.8 ± 11.8	95.5 ± 13.5	.46
BMI (kg/m^2)	33.3 ± 3.5	33.0 ± 3.4	33.6 ± 3.6	.51
Lean Body Mass	55.0 ± 6.9	54.8 ± 7.3	55.1 ± 6.6	.86
Percent Body Fat	23.2 ± 6.2	40.7 ± 6.4	41.8 ± 6.0	.52
% Female Representation	87.5% (n=42)	84.0% (n=21)	91.3% (n=21)	.45
% Minority Representation	31.3% (n=15)	14.6% (n=7)	16.7 (n=8)	.55

4.3 ADHERENCE TO THE INTERVENTION PROTOCOL

Overall attendance at the weekly group intervention sessions was 67.9±28.7% (8.1±3.4 sessions). Comparison of the SBWI and HBRE showed that attendance at these intervention sessions was 72.8±24.9% (8.7±2.9 sessions) and 63.0±31.9% (7.5±3.8 sessions), respectively (p

= 0.25). In addition, HBRE was to attend 10 supervised resistance training sessions over the 12 week period, with the mean number of sessions attended being 57.3±35.7% (5.7±3.5 sessions). HBRE was prescribed to perform 60 days of resistance exercise according to the intervention protocol. Examination of self-reported diary information revealed that subjects reported participating in 19.9±20.7 days of resistance exercise, which was 40.3±33.9% of the prescribed days.

Table 4-2 Differences in Baseline Characteristics between Completers and Non-Completers by Group

Variable	SBWI		HBRE	
	Completers (n = 22)	Non-Completers (n = 3)	Completers (n = 16)	Non-Completers (n = 7)
Age (years)	44.2 ± 9.2*	51.3 ± 4.1*	45.2 ± 9.2	44.0 ± 8.7
Height (cm)	167.9 ± 6.8	166.4 ± 4.5	168.6 ± 6.3	167.5 ± 6.7
Body Weight (kg)	93.5 ± 12.2	87.5 ± 8.1	99.0 ± 13.1**	87.5 ± 11.5**
Body Mass Index (kg/m^2)	33.2 ± 3.6	31.6 ± 2.2	34.7 ± 3.5***	31.1 ± 2.9***
Lean Body Mass (kg)	55.3 ± 7.6	50.8 ± 1.8	56.1 ± 7.1	53.0 ± 5.0
Percent Body Fat	40.5 ± 6.8	41.7 ± 3.5	43.0 ± 6.6	39.1 ± 3.5
% Minority Representation	20.0 (n=5)	28.0 (n=2)	21.7 (n=5)	8.7 (n=3)

*indicates significantly different at p=0.07

**indicates significantly different at p=0.06

***indicates significantly different at p=0.02

4.4 CHANGE IN BODY WEIGHT AND BODY COMPOSITION

Body weight and BMI results are presented in Table 4.3. Results of a repeated measures ANOVA showed that there was a significant ($p<.001$) reduction in body weight from baseline to week 12 for both SBWI (93.5 ± 12.2 kg vs. 88.0 ± 12.4 kg) and HBRE (99.0 ± 13.1 kg vs. 92.8 ± 13.5 kg). The pattern of weight loss was similar between SBWI and HBRE as reflected in the non-significant group x time interaction ($p = .57$). Similar results were found for BMI, with a significant reduction from baseline to 12 weeks shown for SBWI (33.1 ± 3.6 kg/m^2 vs. 31.2 ± 3.6 kg/m^2) and HBRE (34.7 ± 3.5 kg/m^2 vs. 32.6 ± 4.0 kg/m^2). The pattern of change in BMI was not significantly different between SBWI and HBRE ($p = .66$).

Body composition is represented by lean body mass and percent body fat (see 4.3.). Results of a repeated measures ANOVA showed that there was a significant ($p<.001$) reduction in both lean body mass and percent body fat from baseline to week 12 for both SBWI (lean body mass: 54.6±6.9 vs. 53.7±6.9; % body fat: 41.2±6.1 vs. 38.3±6.6) and HBRE (lean body mass: 56.1±7.1 vs. 55.3±7.1; % body fat: 43.0±6.6 vs. 39.8±8.3). The non-significant group x time interaction for both lean body mass ($p=.87$) and percent body fat ($p=.66$) indicates that the pattern of loss of lean body mass and percent body fat were similar between both groups (SBWI and HBRE).

4.5 CHANGE IN CARDIORESPIRATORY FITNESS

Treadmill time to reach 85% of participants' age predicted maximal heart rate was significantly ($p=.003$) increased from baseline to week 12 in SBWI (9.3±5.0 min vs. 11.0±4.8 min) and HBRE (9.5±5.5 min vs. 11.1±5.0 min). The pattern of treadmill time increase was similar between SBWI and HBRE as indicated by the non-significant group x time interaction ($p=.90$).

Table 4-3 Differences between Treatment Groups at 12 Weeks - Completers

Outcome Variable	SBWI (n=22)	HBRE (n=16)	Time Effect	Group Effect	Group x Time Effect
Body Weight (kg)					
0 wk	93.5±12.2	99.0±13.1			
12 wk	88.0±12.4	92.8±13.5	<.001	.22	.57
BMI (kg/m^2)					
0 wk	33.1±3.6	34.7±3.5			
12 wk	31.2±3.6	32.6±4.0	<.001	.21	.66
Lean Body Mass (kg)					
0 wk	54.6±6.9	56.1±7.1			
12 wk	53.7±6.9	55.3±7.1	<.001	.52	.87
Percent Body Fat					
0 wk	41.2±6.1	43.0±6.6			
12 wk	38.3±6.6	39.8±8.3	<.001	.47	.66
Treadmill Time (min) to reach 85%APMHR					
0 wk	9.3±5.0	9.5±5.5			
12 wk	11.0±4.8	11.1±5.0	.003	.93	.90
Walk Test (sec)					
0 wk	36.5±4.7	35.4±3.4			
12 wk	34.0±4.5	33.1±4.0	<.001	.48	.78
Step Up (sec)					
0 wk	8.8±2.2	9.3±2.2			
12 wk	5.9±2.2	7.5±1.7	<.001	.10	.25
Left Leg Balance(sec)					
0 wk	33.1±25.2	26.3±23.3			
12 wk	48.4±19.8	38.7±22.5	.001	.24	.72
Right Leg Balance (sec)					
0 wk	33.5±22.1	29.6±24.9			
12 wk	44.2±22.7	41.9±21.1	.005	.66	.83
Chair Rise (sec)					
0 wk	15.7±3.1	15.5±2.7			
12 wk	12.4±2.1	13.3±2.5	<.001	.71	.12

Table 4-4 Differences between Treatment Groups at 12 Weeks Intent-to-Treat Analysis

Outcome Variable	SBWI (n=25)	HBRE (n=23)	Time Effect	Group Effect	Group x Time Effect
Body Weight (kg)					
0 wk	92.8±11.8	95.5±13.5			
12 wk	87.9±11.8	91.2±13.0	<.001	.40	.63
BMI (kg/m^2)					
0 wk	33.0±3.4	33.6±3.6			
12 wk	31.2±3.4	32.1±3.7	<.001	.43	.56
Lean Body Mass (kg)					
0 wk	54.8±7.3	55.1±6.6			
12 wk	54.0±7.3	54.6±6.5	<.001	.82	.56
Percent Body Fat					
0 wk	40.7±6.4	41.8±6.0			
12 wk	38.2±6.7	39.6±7.1	<.001	.50	.75
Treadmill Time (min) to reach 85%APMHR					
0 wk	9.5±5.0	9.7±5.0			
12 wk	10.8±4.8	10.9±4.5	.003	.90	.79
Leg Extension (kg)	(n=23)	(n=23)			
0 wk	29.4±7.2	31.4±10.9			
12 wk	30.2±8.7	30.8±10.3	.88	.62	.35
Chest Press (kg)					
0 wk	28.0±9.8	29.5±10.2			
12 wk	27.3±10.4	28.1±9.7	.01	.71	.40
Walk Test (sec)					
0 wk	37.1±4.5	35.6±34.1			
12 wk	35.2±4.8	34.1±4.0	<.001	.28	.53
Step Up (sec)					
0 wk	8.8±2.0	9.3±2.1			
12 wk	7.1±2.0	8.1±2.0	<.001	.15	.42

L.Leg Balance(sec)					
0 wk	31.2±24.3	30.4±23.2			
12 wk	42.9±22.3	38.5±22.1	.001	.67	.55
R.Leg Balance (sec)					
0 wk	31.3±23.0	29.1±25.3			
12 wk	39.4±25.0	37.1±24.0	.005	.73	.99
Chair Rise (sec)					
0 wk	15.8±3.1	15.4±2.7			
12 wk	13.3±2.8	14.0±2.8	<.001	.84	.08

4.6 CHANGE IN MUSCULAR STRENGTH

Muscular strength was measured using a chest press and leg extension. Results of a repeated measures ANOVA showed that there was a significant (p=.007) decrease in absolute muscular strength for the chest press from baseline to 12 weeks in SBWI (28.1±11.0 kg vs. 31.6±11.8 kg) and HBRE (27.2±11.6 kg vs. 29.5±11.3 kg). However, there was a non-significant (p=.82) increase in absolute muscular strength for leg extension between baseline and 12 weeks. There was also a non-significant group x time interaction for both the chest press (p=.49) and the leg extension (p=.65) indicating that the pattern of increase in muscular strength was similar between SBWI and HBRE for both the chest press and leg extension. These data as well as data for muscular strength measured relative to body weight as well as lean body mass are presented in Table 4.4.

4.7 CHANGE IN PHYSICAL FUNCTION

Physical function was assessed using multiple tests including the walk test, step up and chair rise. Results of a repeated measures ANOVA showed that there was a significant (p<.001) decrease in time for the walk test, step up test and chair rise between baseline and 12 weeks for SBWI (walk test: 36.5±4.7 vs. 34.0±4.5 seconds; step up: 8.8±2.2 vs. 5.9±2.2 seconds; chair rise: 15.7±3.1 vs. 12.4±2.1 seconds) and HBRE (walk test: 35.4±3.4 vs. 33.1±4.0 seconds; step up: 9.3±2.2 vs. 7.5±1.7 seconds; chair rise: 15.5±2.7 vs. 13.3±2.5 seconds). The non-significant group x time interaction for the walk test (p=0.78), step up (p=0.25) and chair rise (p=0.12) indicates a similar pattern of decrease in time to task completion for each both SBWI and HBRE.

The test for physical function using the single leg standing balance on both the left and right leg showed that there was a significant (p=.001) increase in balance time for the left leg between baseline and 12 weeks for SBWI (33.1±25.2 vs. 48.4±19.8 seconds) and HBRE

(26.3±23.3 vs. 38.7±22.5 seconds). Results also showed a significant (p =.005) increase in balance time for the right leg between baseline and 12 weeks for SBWI (33.5±22.1 vs. 44.2±22.7 seconds) and HBRE (29.6±24.9 vs.41.9±21.1 seconds). The non-significant group x time interaction for the left leg (p=.72) as well as for the right leg (p=.83) from baseline to week 12 suggest that there was no difference in the pattern of change between groups for this measure of physical function.

Table 4-5 Differences in Absolute and Relative Muscular Strength between Treatment Groups at 12 Weeks - Completers

Outcome Variable	SBWI	HBRE	Time Effect	Group Effect	Group x Time Effect
Absolute Chest Press (kg)*					
0 wk	28.1±11.0	31.5±11.7			
12 wk	27.1±11.6	29.5±11.3	.007	.47	.26
Absolute Leg Extension (kg)**					
0 wk	29.6±8.1	34.2±12.2			
12 wk	30.6±9.9	33.4±11.5	.96	.32	.36
Relative to Body Weight Chest Press (kg lifted/kg body weight)*					
0 wk	0.30±0.13	0.32±0.11			
12 wk	0.31±0.14	0.32±0.12	.35	.77	.71
Relative to Body Weight Leg Extension (kg lifted/kg body weight)**					
0 wk	0.33±0.08	0.34±0.11			
12 wk	0.36±0.10	0.36±0.11	.02	.85	.43
Relative to LBM Chest Press (kg lifted/kg lean body mass)*					
0 wk	0.51±0.15	0.55±0.13			
12 wk	0.50±0.17	0.52±0.13	.40	.58	.37

Relative to LBM Leg Extension (kg lifted/kg lean body mass)**					
0 wk	0.56±0.14	0.60±0.18			
12 wk	0.59±0.17	0.59±0.17	.52	.71	.34

*SBWI: n=18, HBRE: n=15

**SBWI: n=17, HBRE: n=14

4.8 CHANGE IN HEALTH-RELATED QUALITY OF LIFE

Health-Related Quality of Life (HRQOL) was assessed using the SF-36 questionnaire. The variables of interest were: physical functioning, role physical, social functioning, bodily pain, mental health, role emotional, vitality and general health. The results are presented in Table 4.5. Results of a repeated measure ANOVA showed that there was no significant difference in scores from baseline to 12 weeks in either group for the following variables: social functioning, bodily pain, mental health, role emotional. There was a significant increase in scores for role physical (p=.03), vitality (p=<.001) and general health (p<.001). Additionally, a trend was observed for increase in scores for physical functioning (p=.07). There were non-significant group x time interactions for all variables measured, indicating that the pattern of increase in HRQOL scores were similar between SBWI and HBRE for all variables.

Table 4-6 Differences in HRQOL between Treatment Groups at 12 Weeks - Completers - SF-36

Outcome Variable	SBWI (n=18)	HBRE (n=15)	Time Effect	Group Effect	Group x Time Effect
Physical Functioning					
0 wk	84.3±14.7	88.7±12.7			
12 wk	89.0±12.2	94.7±7.7	.07	.12	.83
Role Physical					
0 wk	76.2±34.9	78.3±33.9			

12 wk	88.1±26.9	98.3±6.5	.03	.36	.57
Social Functioning					
0 wk	88.1±16.5	91.4±17.5			
12 wk	93.5±13.5	87.5±21.9	.85	.76	.23
Bodily Pain					
0 wk	70.0±18.4	75.6±17.1			
12 wk	70.0±18.7	78.1±20.4	.67	.22	.67
Mental Health					
0 wk	72.4±16.7	79.7±14.1			
12 wk	79.2±14.9	79.2±16.5	.27	.42	.20
Role Emotional					
0 wk	82.5±30.9	79.2±36.3			
12 wk	85.7±32.6	93.8±25.0	.25	.75	.46
Vitality					
0 wk	43.8±22.9	50.9±22.6			
12 wk	61.9±17.4	63.8±20.4	<.001	.45	.47
General Health					
0 wk	65.7±17.6	70.0±21.9			
12 wk	76.2±16.3	79.1±12.5	<.001	.50	.78

4.9 INTENTION-TO-TREAT ANALYSES

Data were reanalyzed for all outcome variables using an intent-to-treat analysis. These results are presented in Table 4.4. For these analyses, missing data were replaced with baseline data, which resulted in no change from baseline being assumed for individuals with missing data at 12 weeks. Results of these analyses showed no change in the pattern of results presented for only those subjects with data at 12 weeks. The results of the intention-to-treat analyses are presented in Table 4.4.

4.10 ASSOCIATION BETWEEN SELF-REPORTED RESISTANCE TRAINING AND CHANGE IN MUSCULAR STRENGTH

Pearson correlations were computed to examine the association between self-reported strength training days and the outcome of muscular strength in the HBRE group. The number of days of self-reported days of resistance exercise training was not correlated with change in absolute strength of the upper ($r=-0.09$, $p=0.74$) or lower body ($r=-0.17$, $p=0.55$). When expressed as percentage of days of resistance exercise out of the number of days prescribed non-significant correlations were reported for upper ($r=-0.21$, $p=0.47$) and lower body strength ($r=-0.19$, $p=0.53$).

5.0 DISCUSSION

5.1 INTRODUCTION

The significant increase in overweight and obesity in the US has stimulated an interest in health-related problems that may occur as a result of the disease. More specifically, health-related quality of life (HRQOL) in obese individuals has been shown to be relatively low when compared to normal weight individuals (Kolotkin 2001). This decreased HRQOL may be due to a decrease in physical function which may be a function of decreased muscular strength. Therefore, the primary purpose of this investigation was to examine HRQOL, physical function, muscular strength and obesity across a 12 week weight loss and resistance training intervention. Additional outcomes included body weight, body mass index, and body composition.

5.2 DISCUSSION OF RESULTS

5.2.1 Effect of Intervention on Changes in Body Weight and Body Composition

Results of this study demonstrated significant ($p<0.05$) weight loss for both treatment conditions (SBWI = 5.5 kg, HBRE = 6.2 kg). This magnitude of weight loss is slightly more

than the weight loss of 4.3 ± 5.5 kg in response to a 12 week weight loss intervention reported by Jensen et al (2004). Other studies of similar duration have reported slightly greater weight loss. For example, Geliebter et al (1997) reported a weight loss of 7.8 ± 3.8 kg during an 8 week diet and strength training program. In addition, Kraemer et al (1997) reported a weight loss of 7.0 kg in a diet + aerobic training + strength training group during a 12 week intervention.

In the current investigation, percent body fat was significantly reduced from baseline to week 12 in SBWI (-2.9%) and HBRE (-3.2%). Again, these reductions in percent body fat are similar in magnitude to what others have reported in response to weight loss programs of similar duration. Ballor et al (1987) reported -3.9% body fat reduction during an 8 week diet and resistance exercise intervention. Similarly, Kraemer et al (1997) reported a -4.3% reduction in body fat during a 12 week study that included diet and exercise.

Despite significant reduction in both body weight and percent body fat in response to the intervention implemented in this study, post hoc analyses revealed that there was no significant difference between the groups for change in weight ($p=0.57$) and change in percent body fat ($p=0.66$). These data suggest no additional effect of resistance exercise on these outcome variables. Other studies of resistance exercise combined with a reduction in energy intake have also shown no significant effect of resistance exercise on change in body weight during a similar duration intervention (Ballor 1988; Kraemer 1997). Additionally, Wadden et al (1997) also reported no significant effect of resistance training on body weight change over a longer duration study of 48 weeks.

5.2.2 Effect of Intervention on Changes in Muscular Strength

Results of this study indicated that there was a significant decrease from baseline to week 12 in upper body muscular strength for both SBWI and HBRE, as measured using a chest press ($p=.004$). There results suggest that the inclusion of resistance exercise in this study was not sufficient to prevent the reduction in upper body strength. When expressed relative to body weight or lean body mass the resistance exercise continued to show no improvement compared to what was observed for SBWI.

These results are not consistent with what other investigators who have included resistance exercise as part of a comprehensive weight loss program have reported**.** For example, even with severe energy restriction (~520 kcal\d), Donnelly et al. (1993) showed improvements in absolute and relative upper body strength with the inclusion of resistance exercise. Geliebter et al. (1997) and Kraemer et al. (1997) have also shown improvements in upper body strength with the inclusion of resistance exercise to a program of energy restriction and weight loss. Of interest is that our current study used a home-based resistance exercise program that included the use of exercise bands rather than free-weight or resistance exercise equipment, which was the mode of training in studies that have shown an increase in strength in response to resistance exercise training (Geliebter 1997; Kraemer 1997; Donnelly 1993). This may explain the difference in findings from this current study when compared to other studies of resistance exercise combined with energy restriction and weight loss.

Examination of the data from this study also showed no change in absolute lower body muscular strength for either SBWI or HBRE as measured using a leg extension ($p=.82$) or for lower body muscular strength when expressed relative to lean body mass ($p=.40$). There was, however, a significant increase in lower body muscular strength when expressed relative to body weight ($p=.02$). These findings are of interest for two reasons. First, these results suggest that weight loss of the magnitude reported in this study will not result in a reduction in lower body strength. In addition, the inclusion of resistance exercise in this study did not improve lower body muscular strength beyond what was observed at baseline. This may be a result of the type of resistance exercise implemented in this study. In studies of resistance exercise combined with weight loss when a more aggressive resistance exercise program was implemented there were observed increases in lower body muscular strength (Kraemer 1997; Donnelly 1993). An additional explanation for these results was potentially the less than optimal compliance to the home-based protocol implemented in this study, with self-reported adherence to the resistance exercise protocol being 40.3% of prescribed days of resistance exercise.

5.2.3 Effect of Intervention on Changes in Physical Function

Results of this study indicated that there was a significant improvement in physical function as assessed by the walk, step up, chair rise and single leg balance tests across the 12

week intervention (see Table 4.3.) These results are of public health importance because of the finding that weight loss of approximately 5.5 to 6.2 kg over a 12-week period can result in improvements in objectively measured physical function. To our knowledge there is limited information available on the effects of weight loss on objectively measured parameters of physical function, which suggests that additional research should be conducted in this area. However, the addition of resistance exercise to weight loss (HBRE) did not improve physical function beyond what was observed in response to SBWI. This may be a result of the resistance exercise protocol also not producing improvements beyond what was observed for SBWI for either upper or lower body muscular strength (see Table 4.3.). Thus, additional research into the effect of resistance exercise in combination with weight loss should be conducted in which the resistance exercise protocol was sufficient to improve muscular strength.

5.2.4 Effect of Intervention on Changes in HRQOL

Results of this study indicated that there was a significant increase from baseline to week 12 in the following HRQOL variables: role physical, vitality and general health for both SBWI and HBRE as measured using the SF-36 questionnaire ($p=.03$, $<.001$, $<.001$, respectively). There was a trend of increase for physical functioning ($p=.07$) and no significant changes from baseline to week 12 for social functioning, bodily pain, mental health or role emotional. These results suggest that the weight loss intervention increased variables that contribute to overall HRQOL. This is of public health importance, as weight loss in overweight and obese individuals has been associated with improvements in HRQOL (Fine, 1999; Fontaine, 1999; Kolotkin, 2001).

These results are consistent with weight loss interventions of similar duration. For example, Fontaine et al (1998) reported significant increases in physical functioning, role-physical, general health, vitality and mental health following a after a 13-week diet and exercise program. In addition, Samsa et al (2001) reported increases in general health and physical function during a weight loss intervention from week 0 to week 8. Unfortunately, results from this current study showed no additional benefit of resistance exercise training on the observed improvements in HRQOL.

The specific pathway by which weight loss improves HRQOL is unclear. Overweight and obese individuals may have difficulty in activities of daily life including shortness of breath walking upstairs, low-back pain and other musculoskeletal disorders. Increased difficulty to perform activities of daily living may not only cause an individual to have a low level of physical functioning, but also a low perception of general health, mental health, role physical and vitality. Research has shown that overweight and obese individuals who have experienced weight reduction have had a higher perceived ability to accomplish activities of daily living which may be due to pain relief and increased spontaneous physical activity (Larsson, 2004). Interestingly, research has shown that the mode of physical activity utilized by participants in a weight reduction intervention did not have an influence on the increase in HRQOL (Fontaine, 1999). In addition, treatment-induced weight loss had a substantial effect on HRQOL in all individuals regardless of whether their weight was initially debilitating.

5.2.5 Effect of the Addition of Resistance Exercise to Retention and Attrition

The attrition rate in this study was 20.9% over the 12 weeks of the intervention. This attrition rate is slightly higher than those of similar weight loss studies. For example, Perri et al (1997) reported an 18.4% attrition rate for a 24 week weight loss intervention. The attrition rate for HBRE in this study was 30.4% and only 12.0% for SBWI, suggesting that the addition of the resistance exercise program resulted in a higher attrition rate. This is important because not only did the resistance exercise program not result in improvements in weight loss, muscular strength, or measures of physical function, resistance exercise may have also contributed to a higher attrition rate. Additionally, adherence to the supervised exercise sessions for the HBRE group was 57.3%. This adherence rate is significantly lower than other studies of similar duration including Wadden et al (1997) who reported a 92.0% attendance rate to exercise sessions during the first 8 weeks of an intervention including diet, strength training and aerobic exercise. Moreover, Ross et al (2000) reported a 98.0% attendance rate to exercise sessions during a 12 week investigation.

Thus, weighing the physiological benefits of resistance exercise against the behavioral implications should be considered for future studies. Moreover, it may be important to

considered additionally behavioral strategies to facilitate the adoption of resistance exercise that does not negatively impact retention within a weight management program.

5.3 LIMITATIONS AND FUTURE RESEARCH

The current study posed several limitations which should be addressed in future research:

1. This study examined the effects of a 12 week behavioral weight loss intervention with resistance training on weight loss, body composition, muscular strength, physical function and HRQOL. The intervention lasted only 3 months, thus it is unclear if a longer duration would have an effect on the outcome variables observed. Future investigations may benefit from a long-term behavioral weight loss intervention including resistance training (i.e. ≥12 months).
2. The current study used resistance bands for the strength training intervention. Although resistance bands have been shown to produce significant strength gains in the elderly population, little to no research has been conducted with this type of equipment in the obese population. Therefore, it is unclear if the bands elicit results in the overweight and obese population. Because obese individuals have greater absolute strength, the bands may not have generated enough resistance for this population. Future research should focus on higher resistance bands for this population.
3. In the current study, muscular strength was measured using a machine with a weight stack and a cable pulley system to assess chest press and leg extension. However, the resistance training exercises in this intervention were performed with exercise bands and may not have exactly simulated the chest press and leg extension exercises that were assessed. This may have limited the ability to detect changes in muscular strength in this study. This limitation may need to be considered in future research examining this topic.
4. For this study, the SF-36 questionnaire was used to measure HRQOL. This questionnaire was given to participants to complete before the muscular strength

and physical function tests were performed both a baseline and 12-weeks. Thus, this prevented the subjects from receiving objective feedback from the functional tests or muscular strength tests prior to completing this questionnaire. This may have affected the subjective evaluation of HRQOL as reported on the SF-36. Thus, future studies may consider how objective measures of HRQOL and muscular strength affect subjective ratings of HRQOL, and whether providing objective feedback influences perceptions of HRQOL.

5. Subjects in the current study self-reported participating in only 40.3% of the prescribed days of resistance exercises. This low adherence rate may have had an undesirable effect on muscular strength changes. In addition, statistical analyses did not show a significant correlation between change in absolute muscular strength (upper and lower) and number of self-reported days. This could be due to the specific exercises provided or to the mode of resistance, i.e. exercise bands. Future research should focus on investigating possible reasons for low adherence to exercise bands or the specific exercises provided.
6. The current study had a higher attrition rate (30.4%) in the HBRE group when compared to the SBWI (12.0%). This could have been due to a number of factors including, but not limited to: likeability of the resistance bands, volume of exercise was not manageable, inappropriate exercises and/or progressions, or there was not enough training with the bands. Future investigations should utilize a longer training period with the bands and vary the band progressions to decrease boredom and increase likeability of the bands. In addition, examination of enjoyment and satisfaction regarding the use of resistance bands instead of tradition weight machines or free weights may provide beneficial information regarding the efficacy of implementing this type of intervention.

5.4 SUMMARY

This study showed no additional effect of using resistance bands in conjunction with diet and cardiovascular exercise on any of the variables observed including: body weight, body fat percentage, muscular strength, physical function and HRQOL. This is of importance, as it may indicate that the addition of resistance training to a behavioral weight loss program does not offer increased changes of outcome variables of importance or that the mode of resistance training utilized in this study was ineffective. Additionally, adherence to prescribed resistance exercise was less than one-half of the days prescribed and the attrition rate was higher in the resistance training group than in the standard behavioral weight loss group. The low adherence to prescribed resistance exercise and high attrition rate make it difficult to discern why there were no additional benefits of resistance training on outcome variables.

Overall, this investigation produced results that showed a decrease in body weight, body fat percentage and an increase in muscular strength, physical function and HRQOL. This is of importance to the US population as obesity is rapidly increasing and HRQOL as well as other health-related problems are of great concern. This investigation may have implications for increasing HRQOL and function in overweight and obese individuals.

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APPENDIX A

GENERAL HEALTH HISTORY

Subject ID:_____

DATE: ___/____ / ____

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

Diagnosis		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 B

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?
   o yes o no

2. Do you feel pain in your chest when you do physical activity?
   o yes o no

3. In the past month, have you had chest pain when you were not doing physical activity?
   o yes o no

4. Do you lose your balance because of dizziness or do you ever lose consciousness?
   o yes o no

5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
   o yes o no

6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
   o yes o no

7. Do you know of any other reason why you should not do physical activity?
   o yes o no

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

APPENDIX C

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

O:

Physician's Name
Address
City State Zip
( )
Telephone Number

Your patient _____ has asked to participate in a diet and exercise program at the University of Pittsburgh. This is an 18month study that is designed to help patients to change their diet and exercise habits in order to reduce body weight and to maintain this weight loss long-term. This program will involve the following:

1. A calorie restricted (1200 - 1500 calories per day) and fat restricted (20-30% of total calories) diet.

2. A walking program that will be primarily home-based which involves gradually increasing duration from 20-40 minutes per day, 5 days per week. Exercise intensity will be set at 55-70% of the patient's maximal heart rate. In addition, a resistance exercise program consisting of exercise band and exercise balls performed at a moderate intensity.

3. Behavioral modification techniques for changing eating and exercise behaviors.

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

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

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

_____

_____

_____

Signature of Physician

APPENDIX D

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)	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 (≤300 calories and ≤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, and Eckrich 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

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

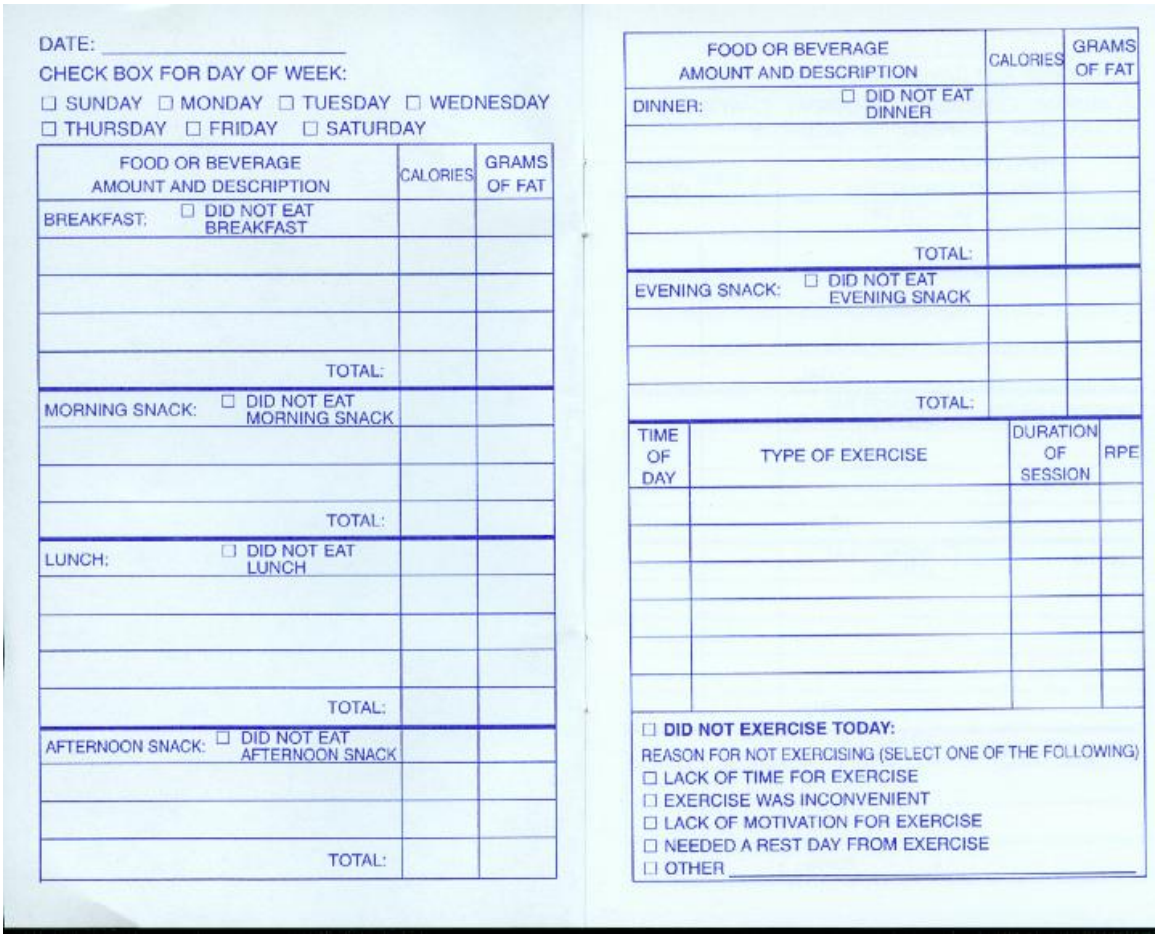
Candy (hard, sugar-free)
Gelatin (sugar-free)
Gum (sugar-free)
Sugar substitutes (aspartame, Splenda)

Miscellaneous

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

APPENDIX E

EXAMPLE PAGE FROM A WEEKLY DIARY



DATE: _____

CHECK BOX FOR DAY OF WEEK:

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

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

RESISTANCE EXERCISES

OVERHEAD SHOULDER RAISE

--Weeks 1-12--

-Stand with your right foot on an exercise band with the handle on the ground close to the inside of your right foot

-Grasp the other handle in your right hand and lift your right arm so that your shoulder and elbow are in a straight line and are perpendicular to your wrist

-Lift your right arm overhead so that your arm is fully extended with your biceps muscle close to your ear

-Return to starting position and repeat

-Switch arms and repeat on the left side

SEATED ROWS

- -Weeks 1-4- -

-Sit on a chair with both feet flat on an exercise band, bent at the waist

-Grasp one handle in each hand with equal distance between the floor and the handle for each

-With palms facing your body, row upward, keeping your elbows close to your sides

-Return to the starting position and repeat

- -Weeks 5-12- -

-Execute the movement exactly the same except seated on an exercise ball instead of a chair

CHEST PRESS

- -Weeks 1-4- -

-Lay on the floor with the band flat under your upper back

-Grasp one handle in each hand with equal distance between the floor and the handle for each

-With elbows bent and palms facing forward, press up until your arms are fully extended

-Return to the starting position and repeat

- -Weeks 5-12- -

-Execute the movement exactly the same except lay on an exercise ball in a bridge position instead of on the floor

BICEPS CURL

- -Weeks 1-4- -

-Stand with one foot flat on the band and grasp the handles in each hand

-Bend your elbows and curl your hands up toward your shoulders

-Lower to starting position and repeat

- -Weeks 5-12- -

-Execute the movement exactly the same except stand on the band with both feet instead of one

TRICEPS KICKBACK

- -Weeks 1-12- -

-Split your stance with one leg in front of the other

-Grasp the handles in each hand with the right arm higher than the left

-Bend at the waist with your abdominals contracted

-Bend your right arm with your elbow close to your ribcage

-Hold the left down by your side

-Extend the right arm as fully as possible

-Return to starting position and repeat

-Switch arm positions and repeat on the left arm

SQUATS

- -Weeks 1-4- -

-Standing with feet shoulder-width apart, place your back against a wall with your legs out in front of you

-Bend your knees until you reach a 90-degree angle

-Make sure your knees don't go past your toes

-Return to starting position and repeat

- -Weeks 5-12- -

-Execute the movement exactly the same except place a stability ball between your lower back and a wall

LUNGES

- -Weeks 1-4- -

-Standing with feet shoulder-width apart and right hand on a stable base for support

-Take a step forward with your right foot, and lower your body until both knees are at a right angle

-Return to starting position and repeat

-Repeat with left leg

-Always keep your upper body vertical and do not let your knees go past your toes

- -Weeks 5-12- -

-Execute the movement exactly the same except place a stability ball between your lower back and a wall

CALF RAISES

- -Weeks 1-4- -

-Stand with feet hip width apart with toes pointing forward

-Place your hands on the wall for support

-Contract calves by pushing off balls of feet to raise heels up in air (standing on toes)

-Lower heels and repeat

-Remember to keep knees slightly bent throughout movement to prevent any knee strain

- -Weeks 5-12- -

-Execute the movement exactly the same except place a stability ball between your chest and a wall and lean into it for support

FRONT CRUNCHES

- -Weeks 1-4- -

-Lay on the floor with your knees bent at a 90-degree angle

-Place your hands either across your chest or behind your head

-Leading with your abdominals, crunch your body upward as far as you can go

-Lower to starting position and repeat

- -Weeks 5-12- -

-Execute the movement exactly the same except sit on and exercise ball, walk your feet out and roll your body down the ball until it is pressed against the small of your back

-Complete the same movement as you did on the floor

TWISTING CRUNCHES

- -Weeks 1-4- -

-Lay on the floor with your knees bent at a 90-degree angle

-Place your hands either across your chest or behind your head

-Leading with your abdominals, crunch and twist your body upward as far as you can go to one side

-Lower to starting position and repeat to the other side

- -Weeks 5-12- -

-Execute the movement exactly the same except sit on and exercise ball, walk your feet out and roll your body down the ball until it is pressed against the small of your back

-Complete the same movement as you did on the floor

APPENDIX G

Test Protocol for Physical Performance Testing

Before each task, the tester demonstrates the task for the participant. The participant is free to omit the most straining actions if there is potential pain or risk. Time is noted from a stop-watch. Perceived exertion or perceived difficulty is obtained following each task.

1. Timed gait speed while carrying groceries

The participant's gait velocity is timed during a 50 meter (164 feet) walk while he or she is carrying two weighted grocery bags (~10 lbs each).) The subject is be brought to the start line of a 50 meter walk test course. The subject, on the command of "Ready, go" starts the walk. The time from the start command, "Ready, go" until the finish line is crossed is recorded. Perceived exertion is recorded after test completion.

2. Timed chair rise for five repetitions

The participant is timed in the performance of 5 repetitions of sit to stand from a seat height that is approximately 14 inches in height. The individual is instructed to cross their hands over their chest and maintain this position during the test. The test starts in the sitting position and end in the sitting position. The test begins with the tester saying, "Ready, stand" and the tester counts the number of trials aloud while the participant is performing the test. On the last repetition (trial 5), the tester cues the participant to end the test. The time to complete 5 repetitions is recorded. Perceived exertion is recorded after test completion.

3. One leg stance on each leg

Participants are asked to stand on each leg for up to 60 seconds. The timing for the test begins when the subject raises his or her foot off the ground. The test is terminated if the other foot touches the ground, if the other foot contacts the stance leg, if the ankle motion is excessive or if there is movement of the stance leg (hopping). Otherwise, the test is terminated when the 60 second time limit is achieved. Perceived difficulty is recorded after test completion.

4. Step up to a stool

Participants are asked to step up to a high stool or bench with each leg. The test begins with the subject standing in front of the stool. The subject is asked to step onto the stool leading with the right foot, place both feet on the stool, and then descend from the stool to return to starting position. The subject continues with the test by stepping onto the stool leading with the left foot, placing both feet on the stool, and then descending from the stool to return to starting position. Cueing is provided during the test. The time is recorded from the start of "Ready, go" until the subject has returned to the starting position. This test takes place close to a support surface with the tester in position to assist the subject as needed. Perceived difficulty is recorded at the end of the test.

APPENDIX H

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

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Alternative Behavioral and Physical Activity Approaches to Weight Loss

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

CO-INVESTIGATORS: Amy D. Otto, Ph.D.
Department of Health and Physical Activity

University of Pittsburgh
Birmingham Towers, Suite 600
2100 Wharton Street
Pittsburgh, PA 15203
Telephone: 412-488-4184

Laura Fonzi, BS
Department of Health and Physical Activity
University of Pittsburgh
Birmingham Towers, Suite 600
2100 Wharton Street
Pittsburgh, PA 15203
Telephone: 412-488-4184

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

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

DESCRIPTION:

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

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

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

You are being invited to take part in this research study because you are within the body weight range for this study, and do not have any medical conditions that would prohibit you from participating in moderate to vigorous activity. Moderate activity is defined as activity similar to brisk walking where you can also have a conversation, with vigorous activity defined as activity is walking at a faster pace and you can not have a conversation because you are breathing deeper

and faster. People invited into this study have to be men or women between 18-55 years of age. This study is being performed on a total of 120 individuals at the University of Pittsburgh.

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

Screening Procedures:

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

You will complete a physical activity readiness questionnaire (PAR-Q), and this will take approximately 5 minutes to complete. You will also complete a detailed medical history, and this will take approximately 20 minutes to complete. These questionnaires will allow the investigators to determine if you have any significant medical condition that would indicate that exercise is unsafe for you. You will also be required to provide medical clearance from your personal physician before starting this study. Women participants cannot be pregnant, and if you are a woman you will be required to accurately report whether you are pregnant to the investigators prior to beginning this study and during the study if your status should change.

Experimental Procedures:

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

You will first be asked to complete a series of questionnaires, and it is estimated that you will be able to complete these questionnaires in approximately **90 minutes**. These questionnaires will provide information about your health, exercise and diet habits. Your body weight, body composition, blood pressure, physical fitness, muscular strength, physical function, level of physical activity, and food intake will be measured. These assessments will take place at the Physical Activity and Weight Management Research Center in Birmingham Towers (South Side of Pittsburgh) at the University of Pittsburgh, and these assessments will be completed in approximately 90 minutes. A brief description of these assessments follows.

A. Body Weight and Height (10 minutes): Your body weight will be measured using a standard medical scale. Your height will be measured with a ruler that is attached to a flat wall. These will be measured at 0, 3, and 6 months during this study.

B. Body Composition (10 minutes): Your body composition is the amount of fat weight and lean weight (muscle and bone) that you have on your body. Your body composition will be measured using a technique known as Bioelectrical Impedance Analysis (BIA). This procedure requires that a small electrode be placed on your hand, wrist, ankle, and foot. A low-level signal that is not harmful to you and that you will not feel is transmitted between the electrodes. Measurements of your waist and hip areas will also be made using a measuring tape. These measures will be made at 0, 3, and 6 months during this study.

C. Blood Pressure (5 minutes): Your blood pressure will be measured using a standard blood pressure cuff and will follow standard measurement procedures. Blood pressure will be measured at 0, 3, and 6 months during this study.

D. Cardiorespiratory Fitness (30 minutes): Measurement of your cardiorespiratory fitness will provide information about how fit your heart and lungs are to perform exercise. Your fitness will be estimated by having you walk on a treadmill. The speed of the treadmill will be kept at 3.0 mph (a brisk pace), however the grade of the treadmill will increase 2.5% every 3 minutes so that it feels like you are walking up a hill. As you are walking, your heart rate, blood pressure, and perception of physical exertion will be measured. Your heart rate will be measured using an electrocardiogram, which is also known as an ECG. The ECG will require that electrodes be placed on the chest and abdomen areas of your body. You will continue to walk on this treadmill until you reach a heart rate that is 85 percent of your maximal capacity, which is the highest heart rate you can achieve and is estimated by subtracting your age from 220 beats per minute, and then the test will be stopped. During this test you will breathe in and out through a sterilized (cleaned to prevent the spread of germs and disease) mouthpiece and will wear a set of nose clips so that no air flows through your nose. The air that you breathe will be measured by a machine known as a metabolic cart. This will provide information about the amount of oxygen that you need when you are exercising. Fitness will be measured at 0, 3, and 6 months during this study. A staff member who is certified as an Exercise Specialist by the American College of Sports Medicine and at least one additional staff member will conduct this test. No other study participants will be in the testing room during this assessment. If during this test it is determined that you have a medical condition that makes it unsafe for you to exercise or lose weight you will no longer be permitted to participate in this study, and you will be referred to your primary care physician for medical follow-up.

E. Muscular Strength (15 minutes): Muscular strength refers to the maximum amount of weight you can lift and is specific to each muscle group. Your muscular strength will

be estimated for upper and lower body by having you perform one weight lifting exercise that uses the chest muscles and one that uses the leg muscles. You will be asked to lift the maximum amount of weight you can lift 1 time when performing a seated chest press (which uses the chest muscles) and single leg extension (which uses the leg muscles) on an exercise machine. Muscular strength will be measured at 0, 3, and 6 months during this study.

F. Physical Function (20 minutes): Physical function refers to how well you can perform common tasks. Your physical function will be measured by having you perform a series of tasks that include the following: a 50 foot walk while carrying 2 shopping bags weighing approximately 10 pounds each, sitting down and getting out of a chair 5 times, balancing on your left leg for up to 60 seconds, balancing on your right leg for up to 60 seconds, stepping up and down twice on a step that is approximately 20 inches high. These tasks will be measured at 0, 3, and 6 months during this study.

G. Exercise, Dietary Patterns, and Factors that Influence Behavior Change (60 minutes): You will complete questionnaires about the amount of exercise that you do, and the amount and types of foods that you eat. You will also complete questionnaires about factors such as your mood, general health, and other things that may affect your exercise and eating behaviors. Participants who have a positive score on the mood measure that is being used in this study will be referred to their personal physician or other appropriate medical personnel for follow-up care. These questionnaires will be completed at 0, 3, and 6 months during this study.

Weight Control and Exercise Procedures

After completing these assessments you will be randomly assigned to one of **four** groups to assist you with your weight loss and exercise behaviors. Random assignment is similar to flipping a coin to determine the group that you will be in. The groups are described below.

A. Standard Behavioral Weight Control Group:

1.) Group Meetings and Contacts: You will attend weekly group meetings for 6 months. Each group meeting will last 45 to 60 minutes. These weekly meetings will be held on the same night every week, and the group will have approximately 25 members that will be dieting and participating in exercise to lose weight.

2.) 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 pounds or greater, you will be placed on a 1500 calorie per day diet. If you are more than 250 pounds, you will be placed on an 1800 calorie per day diet. You will also be

taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this information will be provided to the investigators weekly.

3.) Exercise: You will be given a walking program for exercise. You will be instructed to exercise 5 days per week, with the duration on each day increasing from 20 to 60 minutes over the 6 month program. One of these sessions will be performed at the Physical Activity and Weight Management Research Center under the supervision of the investigators, and the other four sessions will be performed on your own not under the supervision on the investigators. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. You will record your exercise in a diary, and this information will be provided to the investigators weekly.

4.) Website Access: You will be provided access to a website that will provide you information about your participation in this study. You are not required to use this website, but if you want to use this website you will need to provide your own computer and internet access. This website will provide you a study calendar, information about how to change your eating and exercise behaviors that will also be provided to you in the group meetings, and you can enter your daily eating and exercise information.

B. Standard Behavioral Weight Control plus Resistance Exercise Group:

1.) Group Meetings and Contacts: You will attend weekly group meetings for 6 months as described above for the Standard Behavioral Weight Control Group.

2.) Diet: You will be placed on the same diet as described above for the Standard Behavioral Weight Control Group.

3.) Exercise: You will be given a walking program for exercise that is the same as the exercise described above for the Standard Behavioral Weight Control Group.

4.) Website Access: You will be provided access to a website as described above for the Standard Behavioral Weight Control Group.

5.) Resistance Exercise: In addition to the exercise described above you will perform resistance exercise. This will involve the use of resistance exercise bands and an inflated exercise ball, with this equipment provided to you by the investigators. At each group session you will be taught resistance exercises that will use this equipment, and you will be asked to perform these exercises on your own for an additional 4 days each week. Written instructions and illustrations will be provided to you to assist you in performing these exercises. As the exercise becomes easier for you additional resistance will be added by changing the exercise band or how you are using the exercise ball. You will report your resistance exercise to the investigators each week.

C. Standard Behavioral Weight Control plus Mindfulness Meditation:

1.) Group Meetings and Contacts: You will attend weekly group meetings for 6 months as described above for the Standard Behavioral Weight Control Group.

2.) Diet: You will be placed on the same diet as described above for the Standard Behavioral Weight Control Group.

3.) Exercise: You will be given a walking program for exercise that is the same as the exercise described above for the Standard Behavioral Weight Control Group.

4.) Website Access: You will be provided access to a website as described above for the Standard Behavioral Weight Control Group.

5.) Mindfulness Meditation: Mindfulness meditation involves you performing relaxation exercises and positive thinking related to your weight loss efforts. At each group session you will be taught how to perform these relaxation and positive thinking exercises, and you will be asked to perform these exercises on your own for the remaining days of the week. To assist you, an audio CD will be provided to you that will guide you through these exercises. You will report your completion of these mindfulness meditation exercises to the investigators each week.

D. Technology-Based Weight Loss Intervention Group:

1.) Contacts: You will not attend in-person meetings during this study. Rather, you will receive a weekly email message from the investigators related to your weight loss efforts. In addition, the investigators will provide you with weight loss information through the use of a secured website that you will access with your own computer. You will be responsible for providing your own computer and access to the internet for this study. You will also need to demonstrate to the investigators that you can use a computer and access the internet.

2.) Measuring Body Weight: You will be instructed to weight yourself at least 2 days per week. You will be provided an electronic scale by the investigators. This scale will be plugged into your existing telephone line at your home so that these body weights will automatically be sent to the investigators. You will be responsible for providing and maintaining a usable telephone line, but a cell phone can not be used as the telephone line to transmit these body weights for this study. You will also be required to limit access to this scale to only yourself, and others in your household should not use this scale during

this study. This scale will be returned to the investigators at the completion of this study.

3.) Diet: You will be placed on the same diet as described above for the Standard Behavioral Weight Control Group.

4.) Exercise: You will be given a walking program for exercise that is the same as the exercise described above for the Standard Behavioral Weight Control Group.

RISKS and BENEFITS:

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

Risks

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

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

E. 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).

F. 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 10% to 25% of people (10 to 25 out of 100 people). You may also experience problems with your gall bladder that may include symptoms such as intense abdominal pain that increases from a few minutes to hours, back pain, nausea or vomiting. Other symptoms may include, bloating, gas **and indigestion.** This is rare and occurs in less than 1% of people (less than 1 out of 100 people).

G. Risk Associated with Participating in the Group Intervention: Attending group sessions has been shown to be effective for weight loss. However, attendance at these sessions may involve you sharing information about yourself and your weight loss efforts to other group members. You can elect not to share this private information about yourself to other group members. Members of the group will be instructed to keep all information shared in the group sessions confidential. However, because the investigators can not guarantee that all group members will keep this information confidential, there is risk that group members may share information about the group session with individuals not participating in this study. The risk of this happening to you is common because this may occur in 10-25% of people (10-25 out of 100 people).

There are also possible benefits of this research study that may be due to the exercises that you will be performing and the diet that will reduce the amount and types of foods that you

will be eating. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study.

Benefits

A. 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. These costs will be paid by the sponsor of this research study.

You will be paid $25 for completing the assessments following 3 months, and $25 for completing the assessments following 6 months.

COMPENSATION FOR INJURY:

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

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

CONFIDENTIALITY:

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

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g. physician office) records. The

information that will be recorded will be limited to information concerning medical clearance from your physician to participate in this research study. This may include information related to coronary heart disease risk factors such as blood pressure, blood cholesterol, or other medical conditions that may increase the risk of heart disease and/or indicate that exercise participation may be unsafe for you. This information will be used to determine whether it is safe for you to participate in this research study.

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

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

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

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

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical record information) related to your participation in this research study for 5 years following the completion of this study, as per University policy, or when such is approved by the sponsor of this study, whichever should occur last.

RIGHT TO PARTICIPATE or WITHDRAW FROM PARTICIPATION:

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

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

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

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

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

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed a listed investigator. I understand that I may contact the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

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

_____ _____

Participant's Signature Date

VERIFICATION OF EXPLANATION

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

_____ _____

Investigator's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any question the individual has about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

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