THE SHORT-TERM EFFECT OF A BALANCED DEFICIT DIET ON RESTING ENERGY EXPENDITURE IN OVERWEIGHT AND OBESE MALES AND FEMALES

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There is variability in the pattern of weight change in response to a weight loss intervention (i.e., slowing of subsequent weight loss, cessation of weight loss, weight regain). A reduction in resting energy expenditure (REE) may partially explain the observed variability. Few studies have examined the effect of initial weight loss on change in REE. **PURPOSE:** To examine the change in REE in response to weight loss across a 4-week period in overweight and obese males and females. **METHODS:** Thirty-seven subjects (body mass index 25.0-39.9 kg/m^2; males = 14, females = 23) participated in a 4-week intervention with random assignment to an Experimental Group or a no treatment Control Group. The experimental group was instructed to reduce energy intake to 1200-1500 kcal/d and participate in 100 min/wk of moderate aerobic exercise. The control group was instructed to maintain current eating and exercise behaviors. Assessments of body weight, body composition, and REE were conducted at 0 and 4 weeks. REE was expressed as absolute REE (kcal/d), REE relative to body weight, (kcal/kg/d), REE relative to lean body mass (kcal/kgLBM/d). **RESULTS:** Thirty-five subjects completed the study (94.6%). There were significant differences ($p<0.05$) for change in outcomes between the experimental and control groups for body weight (-3.3$\pm$1.7 vs. 0.6$\pm$1.1 kg) lean body mass (-0.6$\pm$0.9 vs. 0.2$\pm$0.9 kg), absolute REE (-205.8$\pm$193.0 vs. -11.4$\pm$ 140.6 kcal/d), and REE relative to lean body mass (-3.3$\pm$2.9 vs. -0.4$\pm$2.6 kcal/kgLBM/d). There was a trend toward a significant difference between the

groups ($p = .07$) for REE relative to body weight (-1.4±1.9 vs. -0.3±1.5 kcal/kg/d). When the groups were combined, there was a correlation between change in REE and change in body weight was $r=0.41$ ($p<.05$), and change in REE and change in lean body mass was $r=0.44$ ($p<.01$). **CONCLUSIONS:** Results indicate that absolute and relative REE are significantly reduced in response to weight loss over a 4-week period. The modest correlations between change in REE and both body weight and lean body mass may suggest that additional physiological mechanisms influence REE during the acute phase of weight loss.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

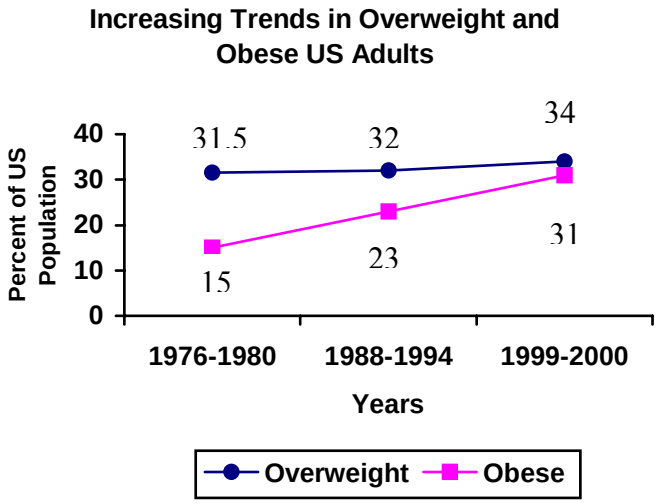
CHAPTER I

INTRODUCTION AND RATIONALE

1.1 Introduction

The percentage of adults in the U.S. population that are overweight and obese continues to rise. Based on the National Health and Nutrition Examination Survey (NHANES) conducted between 1999 and 2000, approximately 34% of American adults are classified as overweight, defined as a body mass index (BMI) of 25.0 to 29.9 kg/m^2, and approximately 30% are classified as obese (BMI $\geq$ 30 kg/m^2) totaling 64% of American adults who are either overweight or obese (21,22). As illustrated in Figure 1.1, although the prevalence rates of overweight adults has not increased significantly, the prevalence of obesity has doubled when comparing national surveys conducted over the past 20 to 30 years (21, 22).

Figure 1.1 Rates of overweight and obesity as a percentage of the US population



The rising prevalence of US adults who are either overweight or obese is a concern because of the association with increasing rates of chronic health conditions

including heart disease, diabetes, cancer, and associated risk factors such as, hypertension, hyperlipedemia, and hyperinsulimea (13, 37). Several studies, however, have indicated that many of these health risks associated with overweight and obesity can be reduced with weight loss (4, 27, 43, 57). This may be a result of significant improvements in coronary heart disease (CHD) risk factors and type II diabetes observed with even modest weight reduction (i.e., 10% of initial body weight) (4, 43, 57).

Examination of weight loss interventions appears to demonstrate that the pattern of weight loss varies across the intervention period (24, 28, 51, 52). For example, Wadden et al. (51) reported from a 52 week intervention utilizing diet and aerobic exercise, attenuation in weight loss resulting from a 1200 kcal/d diet with mean weight loss varying from 1.45 kg/week in the initial week of treatment to 0.10 kg/week in the final weeks of treatment. This slowing of weight loss is consistent with a prior study by Wadden et al. also utilizing diet and aerobic exercise, reporting mean weight loss of 0.82 kg/week for weeks 0-5, 0.73 kg/week for weeks 6-9, 0.43 kg/week for weeks 10-13, 0.58 kg/week for weeks 14-17, 0.40 kg/week for weeks 18-21, 0.43 kg/week for weeks 21-25, and 0.17 kg/week for weeks 25-48 in the group prescribed 1200 kcal/d (52).

Moreover, significant weight regain of approximately 46%, 61%, and 71% of weight lost have been reported within 1, 2, and 3 years respectively following initial weight loss (1, 5, 6, 49, 51). Therefore, it is important to understand the factors that contribute to these patterns of weight loss and regain.

There may be physiological mechanisms that contribute to changes in pattern of weight loss in response to an intervention. One potential physiological factor may be resting energy expenditure (REE), which is the largest determinant of daily energy

expenditure (15). It has been demonstrated that a reduction in REE corresponds to a slowing of subsequent weight loss and an increase in the rate of weight regain (24, 28, 52). Therefore, changes in REE during the weight loss process may partially explain the observed pattern of weight change in response to treatment. However, under-reporting or poor compliance to dietary or exercise interventions may also be a contributing factor to the slowing of weight loss.

1.2 Rationale

While a failure to comply with behavioral changes to diet and/or exercise may be partially responsible for difficulty in weight control, there may be physiological processes that can also contribute to observed patterns of weight change. One potential factor which may influence changes in body weight, and the focus of this study, is a reduction in resting energy expenditure (REE) that may correspond to energy restriction (16, 24). It appears that REE decreases significantly with energy restriction with and without the inclusion of aerobic exercise within the initial 3-5 weeks of treatment (28, 30, 52, 53). Further, the observed reduction in REE appears to occur regardless of whether REE is expressed in absolute (kcal/d) or relative terms based on total body weight (kcal/kg/d) or lean body mass (kcal/kg LBM/d) (16, 29, 52, 53).

1.3 Statement of the problem

The purpose of this study was to examine the change in resting energy expenditure (REE) while consuming a reduced calorie diet combined with aerobic exercise across a 4-week period in overweight and obese males and females compared with a no treatment control.

1.31 Sub-problems

1. To examine the change of absolute change in REE (kcal/d) in the experimental condition compared to the control condition.

2. To examine the relative changes in REE based on total body weight (kcal/kg/d) and lean body mass (kcal/kg LBM/d) in the experimental condition compared to the control condition.

3. To examine the change in total body weight (kg) in the experimental condition compared to the control condition.

4. To examine the change in lean body mass (kg) in the experimental condition compared to the control condition.

1.4 Hypothesis

It was hypothesized that overweight and obese males and females in the experimental condition would show a significant reduction in resting energy expenditure as a result of consuming a 1200-1500 kcal/d diet combined with aerobic exercise for a 4-week period when compared to the control condition.

1.41 Sub-hypotheses

It was hypothesized that as a result of the four-week intervention:

1. REE relative to changes in total body weight (REE/kg) would be significantly reduced in the experimental condition compared to the control condition.

2. REE relative to changes in lean body mass (REE/kgLBM) would be significantly reduced in the experimental condition compared to the control condition.

3. Total body weight would be significantly reduced in the experimental condition compared to the control condition.

4. Lean Body Mass (LBM) would not be significantly reduced in the experimental condition compared to the control condition.

CHAPTER II

REVIEW OF RELATED LITERATURE

2.1 Introduction

This study examined the time-course of change in resting energy expenditure (REE) in overweight and obese males and females over a 4-week period. Subjects were randomly assigned to an experimental condition (prescribed a reduced calorie diet + aerobic exercise) or a control condition (no intervention). Additional measures included body weight and body composition. REE is expressed as an absolute value (kcal/d), relative to body weight (kcal/kg/d), and relative to lean body mass (kcal/kg LBM/d). The following literature review was conducted to justify the need for this study.

2.2 Obesity: Public health concern

Obesity and overweight is an increasing public health problem in the United States. As illustrated in Chapter I, Figure 1.1, the prevalence rates overweight and obese adults total 64% when combined. Based on the National Health and Nutrition Examination Survey (NHANES), the prevalence of overweight, defined as a body mass index (BMI) of 25.0 to 29.9 kg/m^2 increased from the 1976-1980 survey (31.5%) to the 1999-2000 survey (34%) (21, 22). Moreover, the prevalence of obesity (BMI $\geq$ 30 kg/m^2) has doubled (from 15% to 31%) during this same period of time (21, 22).

The increasing prevalence of overweight and obesity is of concern because of the corresponding increase in health-related outcomes observed with an increase in body weight. For example, research has shown that obesity is associated with chronic health

conditions such as heart disease, diabetes, cancer, hypertension, dyslipidemia, and hyperinsulimea (13, 26, 37, 44).

It appears that mortality increases with a corresponding increase in BMI. A prospective study (37) examined the association between BMI and both overall morbidity and mortality in 115,195 U.S. women, and showed that the relative risk of death from all causes was lowest in women with BMI values < 19 kg/m^2. Moreover, there was a 60% greater relative risk in women with BMI values > 27 kg/m^2 compared to women with BMI < 19 kg/m^2 with the risk more than doubling in women with BMI $\geq$ 29 kg/m^2. Data from 5 prospective cohort studies and 1991 national statistics on body mass index distributions, population size, and overall deaths was used to estimate the number of deaths annually that are attributable to obesity in both men and women in the United States. The mean estimate of deaths attributable to obesity in the United States was 280,184. Moreover, 80% of the estimated obesity-attributable deaths occurred among individuals with a body mass index (BMI) greater than 30 kg/m^2 (2).

2.3 Effect of weight reduction on morbidity and mortality

Several studies have indicated that weight loss reduces health risks associated with overweight and obesity (4, 27, 43, 57), with significant improvements in CHD risk factors that can be observed with even modest weight reduction, (i.e., 10 % of initial body weight) (4, 57). A review by Anderson et al. (4) concluded that for each kilogram (kg) of weight lost, there is a decrease in fasting serum cholesterol (1.0%), low-density lipoprotein cholesterol (0.7%), triglycerides (1.9%), systolic blood pressure (0.5%), diastolic blood pressure (0.4%), and blood glucose (0.2%), with an increase in high-density lipoprotein cholesterol (2.0%).

The risk for development of type II diabetes mellitus appears to be reduced with weight loss as well. In a prospective study by Resnick et al. (43), overweight men and women were followed for 10 years to determine the effects of weight gain and weight loss and their association with the risk of type II diabetes. The results showed that, compared to overweight men and women who remained weight stable, each kg of weight gained was associated with a 49% increase in risk of developing diabetes in the following 10 years, with each kg of weight lost being associated with a 33% lower risk of diabetes in the following 10 years.

Research has also demonstrated that mortality in overweight adults with obesity related co-morbidities is reduced with weight loss of approximately 10% of initial body weight (57). It has also been shown that a weight loss of 20-29 lb is associated with a 25% reduction in total mortality (RR = 0.75; 95% CI 0.67-0.84), and a 28% reduction in CVD and diabetes mortality (RR = 0.72; 0.63-0.82) in overweight individuals with diabetes who reported intentional weight loss compared to overweight individuals with diabetes who did not report intentional weight loss (56). Because of the increased risk of mortality and morbidity due to overweight and obesity, and the improvement in mortality and morbidity resulting from weight loss, it is important to better understand the mechanisms that may affect success of weight loss and weight control in U.S. adults.

2.4 Patterns in weight loss across intervention periods

It appears that the pattern of weight loss varies across intervention periods primarily connected to differences in the rate of weight loss between treatment groups and/or changes in the pattern of weight loss within the same treatment group over time.

Examples of variation in patterns of weight loss include slowing in rate of weight loss, cessation of weight loss, and even weight regain (24, 28, 51, 52).

The mean rate of weight loss between time points within treatment groups appears to slow over time (28, 51, 52). Wadden et al. (51) studied 21 overweight females who were randomized to a balanced deficit diet, which is a reduced calorie diet balanced to meet guidelines for macronutrient composition, and instructed to consume 1200kcal/d for 52 weeks compared to a very low calorie diet (VLCD) group. Aerobic exercise was also introduced in both groups at week 8. The mean loss of weight in the 1200 kcal/d group during the first week of treatment was 1.45 kg/week. From weeks 2-5 the mean weight loss was 0.65 kg/week compared to 0.32 kg/week from weeks 13-17, and 0.29 kg/week during weeks 17-26. The mean weight loss for weeks 26-52 was 0.10 kg/week. These findings are consistent with a previous study by Wadden et al. (52) that also demonstrates this attenuation in weight loss over time in a similar study comparing a balanced deficit diet group (BDD) to a VLCD group and the inclusion of aerobic exercise at week 8 in both groups. The mean weight reduction per week for the balanced deficit diet (BDD) group was 0.82 kg/week in weeks 0-5, 0.73 kg/week in weeks 6-9, 0.43 kg/week in weeks 10-13, 0.58 kg/week in weeks 14-17, 0.40 kg/week in weeks 18-21, 0.43 kg/week in weeks 21-25, and 0.17 kg/week in weeks 25-48.

There are a number of factors that may influence this variability in patterns of weight loss in response to intervention programs. One potential contributing behavioral factor is caloric intake. The study by Wadden et al. (52) demonstrated differences in weight loss across 48 weeks between consuming 1200kcal/d versus a very low calorie diet (VLCD) consisting of 420 kcal/d for 16 weeks followed by re-alimentation to 1200-

1500 kcal/d for weeks 24-48. Aerobic exercise was introduced in both groups at week 8. The VLCD group lost approximately 26.0kg versus 12.6kg in the 1200 kcal/d group through the initial 21 weeks of treatment. However, some of the weight lost was regained in the VLCD group during weeks 22-48 (consuming 1200-1500 kcal/d) while the 1200 kcal/d group continued to lose weight, resulting in total weight losses of 21.6kg in the VLCD group compared to 18.2kg in the 1200 kcal/d group. These data suggest that a lower caloric intake elicits greater reductions in weight in the short-term, but may not allow subjects to maintain weight losses once re-alimented to a balanced deficit diet.

The inclusion of exercise is another behavioral factor that may contribute to differences between groups in response to weight loss treatment. The inclusion of exercise has been shown to increase the amount of weight lost in some studies (29, 33). In a study by Jakicic et al. (32) that combined aerobic exercise with caloric restriction for weight loss, analysis of data demonstrated a dose response relationship with exercise and weight lost. When grouped by total minutes of exercise per week, subjects who exercised $\geq$ 200 minutes per week lost significantly more weight (~13.1 kg) compared to subjects who exercised 150-200 minutes per week (~8.5 kg) and subjects who exercised < 150 minutes per week (~3.5 kg). Increased weight loss resulting from the addition of exercise is most likely due to an increase in energy expenditure compared to non-exercisers.

A physiological factor that may impact differences in response to weight loss treatment is resting energy expenditure. Resting energy expenditure has been shown to impact the response to weight loss treatment in several studies (24, 28, 52), with a reduction in REE that corresponds to slowing of subsequent weight loss (28, 52). It appears that the rate at which subjects reduce body weight is decreased as REE decreases

from baseline values (52). The study by Wadden et al. (52) in 1994 which compared a BDD group utilizing 1200 kcal/d to a VLCD group demonstrated the following mean reduction in body weight in the BDD group per week: weeks 0-5 (0.82 kg/week), weeks 6-9 (0.73 kg/week), weeks 10-13 (0.43 kg/week), weeks 14-17 (0.58), weeks 18-21 (0.40 kg/week), weeks 21-25 (0.43 kg/week), and weeks 25-48 (0.17 kg/week). REE measures taken at the same time points represent a corresponding reduction in REE from baseline values: weeks 0-5 (193 kcal/d), weeks 6-9 (214 kcal/d), weeks 10-13 (266 kcal/d), weeks 14-17 (251 kcal/d), weeks 18-21 (224 kcal/d), weeks 22-25 (188 kcal/d), and weeks 25-48 (203 kcal/d) (52).

A study by Henson et al. (28) demonstrated attenuation in the rate of weight lost in 14 moderately obese women consuming an 800kcal/d diet for 9 weeks that was not impacted by the inclusion of aerobic exercise from weeks 3-6. REE was measured at baseline and at the end of weeks 3, 6, and 9. REE was decreased by 13% at week 3, 12% at week 6, and 17% at week 9. A progressive slowing in the rate of weight lost was evident over the three-week increments with a 4.1 kg loss by week 3, 3.0 kg loss from weeks 4-6, and 2.4 kg loss from weeks 7-9. These results suggest a potential link between reduction in REE with a corresponding slowing of weight loss.

While there are a number of factors, both behavioral and physiological, that may be partially responsible for inconsistencies in response to weight loss treatments, for the purpose of choosing one focal point, resting energy expenditure will be the focus of this study.

2.5 Factors influencing resting energy expenditure

Several studies show that energy restriction during weight loss treatment corresponds to decreases in REE with both short-term and long-term interventions (7, 16, 28, 34, 52). A meta-analysis conducted by Ballor et al. (7) based on 60 different group means from 33 studies averaging 12 weeks in length indicated that collectively, dietary restriction resulted in an absolute reduction in REE of approximately 12%. When adjusted for reduction in body weight, the relative reduction in REE (kcal/kg/d) was less than 2%.

Although reductions in REE have been attributed to other factors such as loss of lean body mass (LBM), loss of total body weight (TBW), and genetic differences (12, 29, 52, 53), other studies have demonstrated significant reductions in REE independent of changes in TBW and/or LBM (16, 18, 30, 34, 52). In a study by Leibel et al. (34), obese women were reduced to 10% below initial body weight through caloric restriction. This 10% weight loss after approximately 6-14 weeks of treatment corresponded to a reduction in REE of 4 kcal/kgLBM/d (~240 kcal/d reduction independent of changes in LBM).

A number of weight loss studies that have examined changes in REE with caloric restriction and weight loss have demonstrated that there is a significant reduction in REE when expressed relative to LBM (kcal/kgLBM/day) within 10 days to 5 weeks of initiating treatment (30, 52, 53). These same studies have reported that there is no significant reduction in REE relative to changes in LBM (kcal/kgLBM/day) post-treatment (12-48 weeks). This suggests that the initial reduction in REE in these studies was not due to changes in LBM. Wadden, et al. (52) instructed 9 obese females to

consume a 1200 kcal/d balanced deficit diet for 48 weeks with aerobic exercise introduced at week 8. Results showed that there was a significant decrease in mean REE adjusted for changes in lean body mass (9.1 $\pm$ 4.1%) within 5 weeks of initiation of treatment. Adjusted REE measured after 48 weeks of treatment was no longer significant due to LBM lost over time. These data suggest that the initial reduction in REE may have been a result of caloric restriction and not a lowered LBM. In this same study, the reduction in REE apparent early in the weight loss process corresponds with a slowing of the rate of weight lost (as discussed in section 2.4).

Although several studies have examined the relationship between caloric restriction and reduction in REE, a limited number of these studies have examined changes in REE in the acute phases of treatment during a reduced calorie diet utilizing 1200-1500 kcal/d diet. Hill et al. (30) and Weinsier et al. (53) measured changes in REE within the first 10-21 days of initiating treatment and showed reduction in REE of 13% and 6% respectively. However, a limitation to these studies is that both studies prescribed patients to adhere to an 800kcal/d diet.

In addition, it is not clear as to whether a decrease in LBM triggers a decrease in REE in the acute phase of weight loss or if a decrease in REE may be directly linked to reduced caloric intake. By including measurement of changes in REE relative to LBM, this study may provide information to help better understand the link between change in REE and change in LBM. If it is found that initial change in REE occurs independent of change in LBM, future studies may examine change in REE in comparison to change in LBM as a result of caloric restriction and weight loss over a longer period of time to determine the relationship between these two factors.

If reduction in REE can be detected and adjusted for early in the weight loss process, manipulation of factors that contribute to a reduced REE may counter attenuation of rate of weight loss corresponding to a reduction in REE. If it is found that caloric deficit is an independent factor impacting REE, the level of caloric deficit could potentially be adjusted to minimize reduction in REE. The implication of these findings may contribute to the development of treatment programs that improve success rates in weight loss.

2.6 Summary

The prevalence of overweight and obesity continues to increase and is at epidemic proportions in the United States (21, 22). It has been demonstrated that overweight and obesity increase the risk of morbidity and mortality in adults when compared to those of normal weight, primarily from cardiovascular disease through co-morbidities associated with being overweight and obese such as hypertension, diabetes, and atherosclerosis (13, 37). It has also been shown that even modest reductions in weight can decrease the risk of morbidity and mortality in overweight and obese adults (4, 57).

Current strategies for weight loss appear to show variability in the pattern of weight loss during weight loss treatment programs (24, 28, 51). Therefore, it is important to gain a better understanding of physiological factors that influence energy balance and weight loss. As mentioned, REE appears to decrease with caloric restriction and weight loss and therefore may be an important physiological parameter to examine. Because studies examining the reduction in REE in the initial phase of weight loss treatment programs (weeks 1-4) are limited, this study will contribute to the literature regarding this

process. Therefore, the focus of this study was to examine the change in absolute and relative changes in REE over a 4-week period.

CHAPTER III

METHODOLOGY

3.1 Subjects

Thirty-seven overweight (BMI = 25.0 to 29.9 kg/m^2) or obese (BMI = 30.0 to 39.9 kg/m^2) males and females participated in this study. Subjects were randomly assigned to either an experimental condition (reduced calorie diet) or a control condition (no intervention). Subjects were excluded based on the following criteria:

1. Post-menopausal (self-reported)
2. Diagnosis of cardiovascular disease:
    a. Previous occurrence of a myocardial infarction
    b. Previous occurrence of stroke
    c. Presence of an uncontrolled cardiac arrhythmia
3. Diagnosis of metabolic diseases:
    a. Hypothyroidism or hyperthyroidism
    b. Type I or type II diabetes
    c. Other metabolic diseases that may affect metabolism
4. Uncontrolled hypertension (systolic blood pressure > 140 mmHg and/or diastolic blood pressure > 90 mmHg or currently taking medication to control blood pressure)

5. Currently taking medications that affect heart rate:

    a. Beta Blockers

    b. Calcium Channel Blockers

    c. Other medications known to affect heart rate

6. Currently taking medications that affect metabolic rate or dietary intake:

    a. Appetite suppressants

    b. Fat-loss supplements

    c. Thyroid medications (i.e., Synthroid)

    d. Psychotropic medications that affect appetite or metabolic rate

7. Participation in a research project involving weight loss or physical activity within the previous 12 months

8. Loss of > 10% of their body weight within the previous 12 months

9. Participation in any other research study that may impact the outcome of this study

10. Currently pregnant (self reported), pregnant in the previous 6 months or planning on becoming pregnant in the next 6 months

11. Currently being treated for cancer

12. Report being treated for any cardiovascular, orthopedic, psychological, neurological, or metabolic disorder or any other medical condition that could impact body weight, diet, or physical activity.

13. Physical activity > 3 days per week for $\geq$ 20 minutes per day over the previous 6 months

14. Cigarette smoking

15. Inability to attend weekly sessions or possibility of relocating out of the Pittsburgh area during the study period

Subjects were recruited with fliers and other media campaigns (see Appendix H for example). Males and females who expressed interest were provided a telephone number to call to be screened by research staff to determine initial eligibility (Appendix I). Those who were eligible to participate were invited to attend an orientation session at which time the study was described in greater detail. At the conclusion of the orientation session, interested participants signed an informed consent (Appendix A) at which time all questions regarding risks and benefits as well as purpose and procedures of this study were addressed. Volunteers completed a physical activity readiness questionnaire (PAR-Q) (Appendix B) and general health history questionnaire (Appendix C) prior to participation in this study, and information obtained from these questionnaires was used to determine participant eligibility. The PAR-Q and the general health history questionnaire were evaluated by a member of the research staff. If a volunteer answered yes to any of the exclusion criteria on the general health history questionnaire, he or she was excluded from participating in this study. If a volunteer answered yes to any of the questions on the PAR-Q, he or she was required to provide a physician's consent (Appendix D) in order to participate in this study. The University of Pittsburgh Institutional Review Board approved all experimental procedures.

3.2 Experimental design

This study was a randomized controlled experimental design. Subjects were randomly assigned to either an experimental condition (reduced calorie diet of 1200-1500 kcal/d + 100 minutes per week of aerobic exercise) or a control condition (no intervention) for a period of 4 weeks. The following outcome measures were assessed: height, weight, resting energy expenditure (REE), and body composition via bioelectrical impedance analysis (BIA) at 0 and 4 weeks in all subjects. In addition, physical activity and dietary intake were assessed as process measures.

Figure 3.1 Time-course of experimental design

Experimental Group	Reduced energy intake (1200-1500 kcal/d) 100 minutes of moderate physical activity per week				
Control Group	No change in energy intake No change in energy expenditure from physical activity				
	↑ Week 0 Assessment	↑ Week 1 Weight Only in Experimental Group	↑ Week 2 Weight Only in Experimental Group	↑ Week 3 Weight Only in Experimental Group	↑ Week 4 Assessment

3.3 Assessments

Assessments were conducted at weeks 0 and 4. Assessments consisted of the following measures:

1. Height and weight
2. Resting Energy Expenditure (REE)
3. Body Composition via Bioelectrical Impedance Analysis (BIA)
4. Dietary Intake
5. Physical Activity

Height and weight: Height was measured to the nearest 0.5 inch via a stadiometer (Detecto Inc., Webb City, MO), and weight was measured to the nearest 0.5 pound using a medical balance-beam scale (Detecto Inc., Webb City, MO). Subjects were weighed while wearing a medical gown to standardize weight measurements for each assessment. Height and weight was used to calculate body mass index (BMI) by dividing weight in kilograms (kg) by height in meters squared (m^2).

Resting Energy Expenditure (REE): REE was measured via the dilution technique using a Sensor-Medics 2900 metabolic measuring cart (Yorba Linda, CA) and a plastic canopy (8, 20). Subjects were instructed to fast for at least 12 hours the night before testing, and to avoid consumption of any over-the-counter medications. Subjects were also instructed to abstain from all vigorous physical activity the day before testing, and to transport themselves to the Physical Activity and Weight Management Research Center in a vehicle on the morning of the day of testing. Patients were questioned verbally regarding their adherence to the aforementioned pre-testing recommendations prior to testing.

REE was measured between the hours of 7:30-10:30am. Measurements of each patient were performed at week 0 and at week 4. REE measurements were taken at the completion of the subject resting in a supine position in a darkened room for a period of thirty minutes. Following this 30-minute rest period, subjects were placed under the canopy in a supine position for a 5-minute steady state measurement period. Criteria for establishing a stable measure of REE was a steady state consisting of five consecutive data points with a range of no more than 150 kcal/d which approximates the 5% criteria used by Jakicic et. al. (33), that significantly correlated ($r = 0.92$, $p < 0.001$) with Foster's

techniques finding steady state at a coefficient of variation (standard deviation/mean) of no more than 5% for both VO_2 and CVO_2 (24, 32). Data was collected until 5 consecutive data points meeting the aforementioned criteria were obtained. The average value for volume of oxygen consumed (VO_2) and volume of carbon dioxide produced (VCO_2) from the five consecutive measures were used to calculate REE via software using the equation below (54):

REE = [VO2 L (3.941) + VCO2 L (1.11)] 1440 min/day

where:

REE = Resting Energy Expenditure (kcal/d)

VO_2 = Volume of oxygen consumed

VCO_2 = Volume of carbon dioxide produced

L = Liters

REE is expressed as an absolute value (kcal/d), relative to body weight (kcal/kg/d), and relative to lean body mass (kcal/kg LBM/d).

Body Composition: Measurement of body composition to determine LBM was performed using bioelectrical impedance analysis (BIA) on the same morning as REE measurement using a RJL BIA-101A (RJL Systems, Inc., Clinton Twp, MI) four terminal impedance analyzer. This instrument was calibrated throughout the study using a 500-Ω resistor according to the procedures recommended by the manufacturer. BIA was assessed with subjects in a supine position. The skin surface was cleaned using rubbing alcohol prior to applying Unitrac disposable electrodes. Once the alcohol on the skin surface was dry, electrodes were placed on the right side of the body at the following four

sites: between the styloid processes of the ulna and the radius (E1), distal end of the second and third metacarpals (E2), between the lateral malleolus and the medial malleolus (E3), and the distal end of the first and second metatarsals (E4). There was a minimum of 8 cm between electrodes E1 and E2, and electrodes E3 and E4. LBM was estimated using a generalized equation and an obesity-specific equation.

Process measures:

Physical Activity: Physical activity was measured using a Paffenbarger Physical Activity Questionnaire (40, 41), which examines the previous week of physical activity, as illustrated in Appendix E, at 0 and 4 weeks. This questionnaire required approximately 5 minutes to complete.

Dietary Intake: Dietary intake was measured in all subjects at 0 weeks using the 1998 version of the Food Frequency Questionnaire (Block-98 Dietary Data Systems, Berkeley, CA) (Appendix F), and on a weekly basis in the Experimental Group using a food diary. ExperimenTal Subjects were requested to fill out the food diary on a daily basis, and reviewed by a research staff member on a weekly basis for completion and adherence to dietary recommendations..

3.4 Experimental interventions

Subjects were randomly assigned to either an experimental condition or a control condition for a period of 4 weeks.

Dietary intake for control condition: Subjects assigned to the control condition were instructed to maintain their current eating and activity behaviors as well as their current body weight for the 4-week period. Dietary intake was measured using the 1998 version of the Food Frequency Questionnaire (Block-98 Dietary Data Systems, Berkeley,

CA) at baseline to assure no difference between groups at baseline. It was estimated that there should be no significant change in body weight in subjects in the control condition. Therefore, compliance to dietary intake recommendations in the control condition was defined as a change in body weight of no more than 1kg compared to baseline over the 4-week period of this study.

Dietary intake for experimental condition: Subjects assigned to the experimental condition were instructed to reduce their energy intake to 1200-1500 kcal/d (depending on his/her starting weight), which is consistent with guidelines established by the American College of Sports Medicine (3), and were instructed to reduce fat intake to 20-30% of total dietary intake, which is within the established limits for Dietary Reference Intakes (DRI) (47). Subjects were provided with sample meal plans and menus developed by registered dietitians to assist them with making appropriate food selections. Subjects were instructed to record their eating behaviors in a weekly food diary that was reviewed weekly by the intervention staff. Subjects participating in eating behaviors inconsistent with the recommendations for this study were counseled by the registered dietitian affiliated with this study.

Physical Activity: Physical activity recommendations in the experimental condition consisted of 100 minutes of exercise per week (20 minutes per day, 5 days per week). The prescribed intensity of the exercise was moderate ($\leq$70% of age-predicted maximal heart rate), which is the equivalent of brisk walking for most individuals. Subjects were instructed to record their exercise in a weekly exercise diary that was reviewed weekly by the intervention staff. Subjects participating in exercise that is inconsistent with the

recommendations for this study were counseled by the study affiliated exercise physiologist.

Treatment Meetings and Contacts: Subjects were instructed to attend weekly group meetings for weeks 1-4. The group intervention meetings were conducted in a period of 45-60 minutes. During these face-to-face interactions the interventionist integrated behavioral strategies for adopting and maintaining exercise into the intervention. These behavioral strategies were based primarily on social cognitive theory and included the following: self-monitoring, stimulus control, problem solving, relapse prevention, social assertion, goal-setting and feedback, and cognitive strategies to overcome negative thinking. These strategies were blended into didactic sessions which were lead by a registered dietitian, exercise physiologist, or health psychologist with experience conducting weight loss intervention groups. A list of the lesson topics for the group sessions is included in Appendix G.

3.5 Experimental variables

3.51 Primary dependent variables

1. Resting Energy Expenditure (REE) (kcal/d): measured at weeks 0 and 4 using the methods described in section 3.3.
2. Changes in relative REE based on changes in total body weight (kcal/kg/d) and lean body mass (kcal/kg LBM/d): measured at weeks 0 and 4

3.52 Secondary dependent variables

1. Total Body Weight: measured at weeks 0 and 4
2. Lean Body Mass: measured at weeks 0 and 4.

3.53 Independent variable

1. Group: Experimental vs. Control: subjects were randomly assigned to either the experimental condition (reduced calorie diet of 1200-1500 kcal/d + 100 minutes of moderate exercise per week) or to the control condition (no change in energy intake or exercise).

3.6 Potential confounding factors

Dietary compliance: Efforts were made to control for results influenced by subjects in both the experimental and control conditions that may not adhere to the dietary protocol. Efforts to ensure compliance to dietary intake recommendations for subjects in the experimental condition required them to:

1. Maintain a food diary on a daily basis with daily totals of calories consumed

2. Maintain a weekly average energy intake of 1200-1500 kcal/d $\pm$ 10%

4. Weigh in on a weekly basis at the Physical Activity and Weight Management Research Center.

5. Lose $\geq$ 1 lb per week

A staff member met with each experimental subject on a weekly basis to review food diaries during which time the subject was also weighed. A staff member and/or a registered dietitian from the University of Pittsburgh counseled subjects who were non-compliant to the intervention.

Efforts to ensure compliance to dietary intake recommendations for subjects in the control condition required them to:

1. Weight measured pre and post intervention at the Physical Activity and Weight Management Research Center.

2. Maintain weight (defined as a change of no more than 1kg) at 0 and 4 weeks of the study.

In addition, subjects in the control condition were offered a delayed intervention following their participation in this 4-week study. This delayed intervention was consistent with the intervention provided to the Experimental Group.

Physical activity: Subjects who are not adherent to physical activity recommendations may also potentially create a bias in the results of the study. Physical activity in both experimental and control subjects were assessed at baseline and at the end of the 4-week intervention. All subjects filled out the Paffenbarger physical activity questionnaire on the same day as all other assessments. Compliance to physical activity in the Experimental Group was measured by expressing each subjects exercise in minutes, which should equal 100 minutes per week +/- 10%. Compliance to physical activity recommendations in the Control Group was measured by comparing physical activity to each individual's baseline measures.

3.7 Statistical analysis

Thirty subjects utilizing a large effect size and alpha set to 0.05 yields a power of 0.67. We were able to recruit 37 subjects which yields a power slightly higher than 0.67. The effect size used was based on data available for change in REE from previously published investigations. Wadden et al. (52) demonstrated a decrease in REE of 9.1 $\pm$ 4.1% within 5 weeks for an effect size of 2.22. Hill et al. (29) found a decrease in REE of 61.95 $\pm$ 24.2 kcal/d within 12 weeks for an effect size of 2.56. Weinsier et al. (53) demonstrated a decrease in REE of 393 $\pm$ 716 kJ/d within 10 days for an effect size of 0.56. The average effect size of these three studies is 1.78.

Statistical analysis to address the primary hypothesis for this study included a two-factor (condition x time) repeated measures analysis of variance (ANOVA). Group (Experimental versus Control) was considered as the between subject factor, with Time (0 and 4 weeks) considered as the within subjects factor. A secondary analysis using a two-factor repeated measure ANOVA was conducted based on blocks (BMI values of 25.0 – 29.9 kg/m^2 and 30.0 – 34.9 kg/m^2) for the purpose of detecting potential differences between these groups. Data was analyzed based on subjects met criteria for a valid resting energy expenditure (REE) test and subjects who did not. Results are presented for both groups. In order to be included in the analysis for subjects with a valid REE measurement, subjects must have met the criteria established for a valid REE test as described in section 3.3.

Significant interactions and main effects were examined using the Tukey post-hoc procedure. The relationship between change in REE and change in lean body mass (LBM) was included in the analysis. Results show correlation coefficients which examine the relationship between these two factors

Chapter IV

Results

The purpose of this study was to examine the 4-week effect of a low-calorie diet and aerobic exercise on absolute (kcal/d) and relative (kcal/kg/d and kcal/kg LBM/d) resting energy expenditure (REE) in overweight and obese adults. Secondary dependent variables were body weight and lean body mass. This study was a randomized clinical weight loss intervention with assessments performed at 0 and 4 weeks of participation. The primary independent variable was intervention group (Experimental Group versus Control Group). The Experimental Group participated in a 4-week behavioral weight loss program to change eating and physical activity behaviors, whereas the Control Group was instructed not to reduce body weight or change eating and physical activity.

4.1 Subject characteristics

The subjects in this investigation were 37 adults (males = 14 and females = 23). Subjects were between the ages of 18 and 55 years old, with a body mass index (BMI) ranging from 25.0 to 39.9 kg/m^2. Descriptive statistics are presented in Table 4.1. There were significant differences between BMI groups at baseline for the following characteristics: BMI, percent body fat, and resting energy expenditure (REE) relative to subjects' lean body mass (REE/kgLBM/d), and this is illustrated in Table 4.1. Primary outcome analyses were performed with all subjects included.

A total of 37 subjects were randomized to either the Experimental Group or the Control Group. Of these 37 subjects, 35 subjects provided data at baseline and 4 weeks, which yielded a 94.6% retention rate. Of the 35 subjects who provided data at baseline and 4 weeks, there were 4 who did not meet the stringent criteria for achieving a steady

state REE as described in Chapter 3. Therefore the total number of subjects who provided valid data at baseline and 4 weeks was 31 subjects or 83.8% of subjects.

Table 4.1 Characteristics of Subjects at Baseline

Variable	BMI (kg/m^2)	All Subjects (n=37)	Experimental (n=18)	Control (n=19)
Age (years)	Total (25.0-39.9)	42.4±7.8	41.3±8.1	43.5±7.5
	25.0 - 29.9	43.2±8.5 (N=7)	44.3±10.4 (N=4)	41.7±7.1 (N=3)
	30.0 - 34.9	43.1±7.8 (N=20)	40.0±7.5 (N=7)	45.2±7.6 (N=13)
	35.0 - 39.9	40.1±7.5 (N=8)	41.2±8.5 (N=5)	38.3±6.8 (N=3)
Height (cm)	Total (25.0-39.9)	170.0±10.9	168.2±11.8	171.7±9.9
	25.0 - 29.9	171.9±11.2	167.1±8.1	178.3±13.0
	30.0 - 34.9	171.5±10.6	172.7±13.6	170.7±8.6
	35.0 - 39.9	164.0±10.5	160.9±7.6	169.2±14.4
Body Weight (kg)	Total (25.0-39.9)	93.3±12.4	90.5±13.7	95.8±11.0
	25.0 - 29.9	87.0±13.2	81.6±10.3	94.1±15.3
	30.0 - 34.9	93.2±11.4	92.3±16.6	93.7±8.1
	35.0 - 39.9	99.3±12.9	94.9±10.2	106.6±15.6
BMI (kg/m^2)	Total (25.0-39.9)	32.6±2.9	32.6±3.2	32.5±2.6
	25.0 - 29.9	$29.3±0.8^{A}$	$29.1±1.0^{A}$	$29.4±0.7^{A}$
	30.0 - 34.9	$32.1±1.4^{A}$	$31.8±1.4^{A}$	$32.1±1.4^{A}$
	35.0 - 39.9	$36.8±1.3^{A}$	$36.6±1.2^{A}$	$37.2±1.7^{A}$
Percent Body Fat (% Fat)	Total (25.0-39.9)	38.3±6.6	39.2±6.9	37.5±6.3
	25.0 - 29.9	$32.0±5.6^{Ac}$	$32.9±6.6^{A}$	$30.9±5.1^{A}$
	30.0 - 34.9	$37.8±5.3^{Bc}$	$38.0±5.3^{B}$	37.6±5.6
	35.0 - 39.9	$45.0±3.6^{AB}$	$45.9±2.3^{AB}$	$43.6±5.4^{A}$
Energy Intake (kcal/d)	Total (25.0-39.9)	2134±1288	2159±1315	2111.1±1298.7
	25.0 - 29.9	1579±498	1434±532	$1772.7±469.3^{a}$
	30.0 - 34.9	2076±1231	2527±1555	$1764.2±883.9^{B}$
	35.0 - 39.9	2781±1728	2078±1210	$3952.6±2056.5^{aB}$
Physical Activity (kcal/d)	Total (25.0-39.9)	517.3±422.9	460.3±428.9	565.4±423.3
	25.0 - 29.9	393.7±244.2	413.5±301.8	367.3±201.0
	30.0 - 34.9	533.6±435.7	535.6±583.9	532.5±360.6
	35.0 - 39.9	584.9±530.3	392.2±303.8	906.0±743.1
Resting Energy Expenditure (kcal/d)	Total (25.0-39.9)	2067.4±444.9	2030.8±551.2	2098.1±344.3
	25.0 - 29.9	1933.4±306.3	1806.1±321.9	2103.2±224.5
	30.0 - 34.9	2082.8±506.6	2157.7±749.8	2042.5±346.7
	35.0 - 39.9	2146.0±398.5	2033.1±373.7	2334.0±437.7
Resting Energy Expenditure (kcal/kg/d)	Total (25.0-39.9)	22.0±2.7	22.2±3.1	21.9±2.5
	25.0 - 29.9	22.2±1.3	22.0±1.4	22.5±1.5
	30.0 - 34.9	22.2±3.4	22.9±4.4	21.8±2.9
	35.0 - 39.9	21.5±1.6	21.3±1.8	21.8±1.4
Resting Energy Expenditure (kcal/kg LBM/d)	Total (25.0-39.9)	35.9±4.1	36.6±4.1	35.2±4.1
	25.0 - 29.9	$32.9±3.1^{A}$	32.9±2.0	$32.8+4.8^{A}$
	30.0 - 34.9	$35.6±3.8^{B}$	36.8±4.2	34.9±3.7
	35.0 - 39.9	$39.2±3.3^{AB}$	39.4±3.3	$38.9±4.0^{A}$

BMI groups with same lower case superscript demonstrate statistically significant at $p \leq 0.07$
BMI groups with same upper case superscript demonstrate statistically significant at $p \leq 0.05$

4.2 Change in body weight and BMI

Repeated measures ANOVA (group x time) revealed a significant interaction ($p \leq .001$) for the change in body weight from baseline to 4 weeks in the Experimental Group compared to the Control Group. This significant interaction effect reflects the 3.3 $\pm$ 1.7 kg weight loss observed in the Experimental Group versus the 0.6 $\pm$ 1.1 kg weight gain observed in the Control Group. These results are illustrated in Figure 4.1 and shown in Table 4.2. Similar results were demonstrated for the analysis of BMI data with a reduction of 1.2 $\pm$ 0.6 kg/m^2 in the Experimental Group versus a 0.2 $\pm$ 0.4 kg/m^2 increase in the Control Group (p-value for Group X Time Interaction Effect $\leq$ .001). These results are shown in Table 4.2.

Figure 4.1. Change in Body Weight by Group.

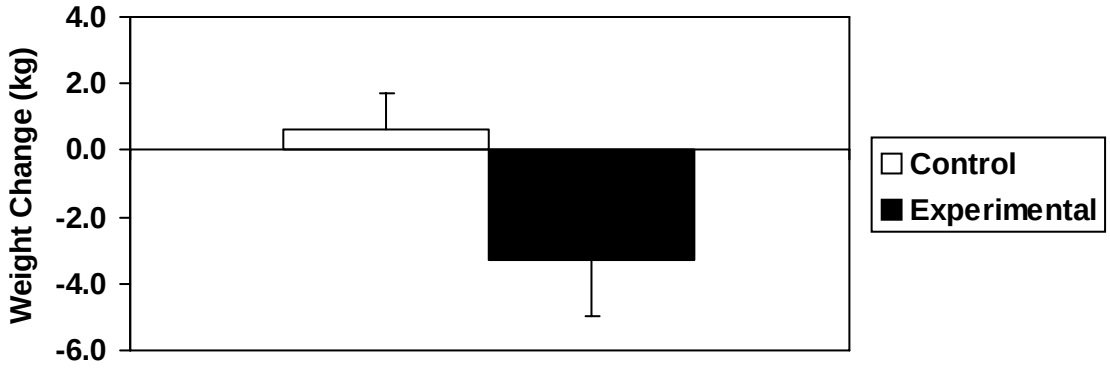


Table 4.2 Changes in outcomes variables between groups from 0 to 4 weeks.

Outcome Variable	Assessment Period	Experimental (n=16)	Control (n=19)	p-value		
				Time Effect	Group Effect	Group X Time
Body Weight (kg)	0 weeks	90.5±13.7	95.8±11.0	<0.001	0.09	<0.001
	4 weeks	87.1±13.7	96.4±11.2			
Body Mass Index (kg/m^2	0 weeks	32.6±3.2	32.5±2.6	<0.001	0.57	<0.001
	4 weeks	31.4±3.2	32.7±2.7			
Percent Body Fat (%)	0 weeks	39.2±6.9	37.5±6.3	<0.001	0.76	<0.01
	4 weeks	37.4±7.3	37.7±6.4			
Lean Body Mass (kg)	0 weeks	55.1±11.3	60.1±10.5	0.22	0.16	<0.05
	4 weeks	54.5±11.1	60.2±10.7			
Resting Energy Expenditure (kcal/d)	0 weeks	2030.8±551.2	2098.1±344.3	<0.001	0.27	<0.01
	4 weeks	1825.1±494.0	2086.8±348.2			
Resting Energy Expenditure (kcal/kg/d)	0 weeks	22.2±3.1	21.9±2.5	<0.01	0.80	0.07
	4 weeks	20.8±3.5	21.6±2.3			
Resting Energy Expenditure (kcal/kg LBM/d)	0 weeks	36.6±4.1	35.2±4.1	< .001	0.98	<0.01
	4 weeks	33.3±3.7	34.8+2.7			
Physical Activity (kcal/wk)	0 weeks	460.3±428.9	565.4±423.3	< .001	.40	<0.01
	4 weeks	1136.1±613.9	754.3±638.2			

4.3 Change in Body Composition

Body composition data are presented in Table 4.2. Repeated measures ANOVA (group x time) revealed a reduction in percent body fat in the Experimental Group (-1.8 ± 1.4%) compared to the Control Group (0.2 ± 0.8%) across the 4 week study period (interaction effect <0.001). Analysis of lean body mass (LBM) data also showed a

significant decrease in the Experimental Group (-0.6 ± 0.9 kg) compared to the Control Group (0.2 ± 0.9 kg) from baseline to 4 weeks (interaction effect < 0.05).

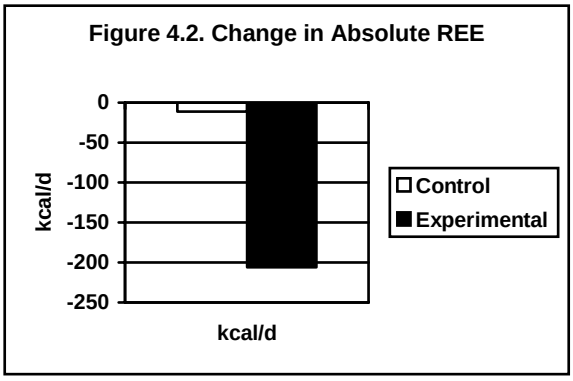
4.4 Change in Resting Energy Expenditure

Repeated measures ANOVA (group x time) revealed a significant interaction effect ($p<0.01$) for the change in REE when comparing the Experimental Group (-205.8 ± 193.0 kcal/d) to the Control Group (-11.4 ± 140.6 kcal/d). These results are shown in Table 4.2 and illustrated in Figure 4.2. A similar pattern of results was found for analysis of change in REE relative to body weight with the Experimental Group decreasing by 1.4 ± 1.9 kcal/kg/d and the Control Group decreasing by 0.3 ± 1.5 kcal/kg/d (p-value for interaction effect = 0.07) (see Figure 4.3). A significant interaction effect ($p<0.01$) was also observed for the change in REE relative to LBM with the Experimental Group decreasing by 3.3 ± 2.9 kcal/kgLBM/d compared to the decrease of 0.4 ± 2.6 kcal/kgLBM/d for the Control Group (see Figure 4.3).

Examination of the REE data revealed that four subjects, two in the Experimental Group and two in the Control Group, did not meet the stringent criteria for achieving a steady state REE as described in Chapter 3. Therefore, data were analyzed removing those individuals who did not meet the REE criteria from the analyses and these data are presented in Table 4.3. When data from subjects meeting the REE measurement criteria were analyzed, the change in absolute (kcal/d) and relative (kcal/kg/d and kcal/kgLBM/d) REE were greater in the Experimental Group compared to the Control Group.

Data were also analyzed to examine potential gender effects on the changes in REE. These analyses demonstrated that change in absolute REE (kcal/d) and relative REE adjusted for change in body weight (kcal/kg/d) and change in lean body mass

(kcal/kgLBM/d) were not influenced by gender. Because of the lack of a significant gender effect, these data are not presented.



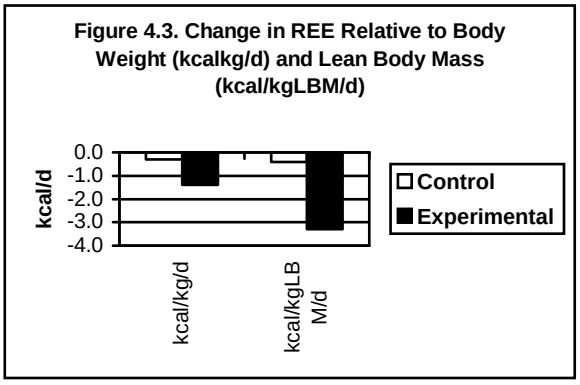


Table 4.3 Comparison of change in REE for subjects who met criteria for a valid REE test vs. subjects who did not meet criteria for a valid REE test.

		All Subjects N = 35	Subjects who met criteria N = 31	Subjects who did not meet criteria N = 4
Resting Energy Expenditure (kcal/d)	Experimental	-205.8±193.0 (N=16)	-187.2±194.8 (N=14)	-335.9±163.9 (N=2)
	Control	-11.4±140.6 (N=19)	-14.3±148.8 (N=17)	-13.8±7.8 (N=2)
p-value		P < 0.01	P < 0.01	P = 1.00
Resting Energy Expenditure (kcal/kg/d)	Experimental	-1.4±1.9 (N=16)	-1.2±2.0 (N=14)	-2.6±0.7 (N=2)
	Control	-0.3±1.5 (N=19)	-0.3±1.6 (N=17)	0.1±0.1 (N=2)
p-value		P = 0.07	P = 0.19	P < 0.05
Resting Energy Expenditure (kcal/kgLBM/d)	Experimental	-3.3±2.9 (N=16)	-3.2±3.1 (N=14)	-4.1±0.4 (N=2)
	Control	-0.4±2.6 (N=19)	-0.5±2.8 (N=17)	0.4±0.4 (N=2)
p-value		p < 0.01	P < 0.05	P < 0.01

4.5 Change in physical activity

Repeated measures ANOVA (group x time) revealed a significant interaction ($p \leq 0.1$) in change in physical activity when comparing the Experimental Group to the

Control Group at baseline and at 4 weeks (675.8 ± 551.8 vs. 188.9 ± 405.1kcal/wk). These results are shown in Table 4.2.

4.6 Effect of baseline BMI on changes in weight, body composition, and REE

Results for each variable were analyzed based on baseline BMI with subjects categorized as 25-29.9 kg/m^2, 30-34.9 kg/m^2, and 35-39.9 kg/m^2. Results indicated that both change in body weight and change in REE/kgLBM/d were significantly influenced by category of baseline BMI ($p \leq 0.05$). These results are presented in Table 4.4.

Table 4.4 Changes in outcomes variables between groups based on baseline body mass index (BMI) category.

Outcome Variable	Baseline BMI Category (kg/m^2)	Experi-mental (n=16)	Control (n=19)	p-value		
				Group Effect	BMI Effect	Group X BMI
Body Weight (kg)	25.0-29.9	-3.2±0.6	-0.2±0.9	≤ .05	≤ .05	.78
	30.0-34.9	-3.3±2.4	0.7±1.2			
	35.0-39.0	-3.5±1.1	1.1±0.9			
Body Mass Index (kg/m^2	25.0-29.9	-1.2±0.3	-0.2±0.9	≤ .001	.76	.46
	30.0-34.9	-1.1±0.8	0.2±0.4			
	35.0-39.0	-1.4±0.5	0.4±0.3			
Percent Body Fat (%)	25.0-29.9	-1.9±0.5	0.5±1.3	≤ .001	.91	.40
	30.0-34.9	-2.0±2.0	0.3±0.8			
	35.0-39.0	-1.3±0.5	-0.3±0.5			
Lean Body Mass (kg)	25.0-29.9	-0.7±1.0	-0.6±0.7	≤ .05	.27	.23
	30.0-34.9	-0.3±1.1	0.2±0.9			
	35.0-39.0	-0.8±0.4	-0.9±0.8			
Resting Energy Expenditure (kcal/d)	25.0-29.9	-138.9±123.6	-4.2±135.5	≤ .001	.11	.61
	30.0-34.9	-139.2±164.4	2.6±129.1			
	35.0-39.0	-352.6±220.3	-78.8±226.6			
Resting Energy Expenditure (kcal/kg/d)	25.0-29.9	-0.8±1.4	-0.1±1.7	.13	.08	.64
	30.0-34.9	0.3±1.8	-0.1±1.4			
	35.0-39.0	-2.9±1.9	-1.1±2.2			
Resting Energy Expenditure (kcal/kg LBM/d)	25.0-29.9	-2.1±1.8	-0.1±2.1	≤ .05	≤ .05	.71
	30.0-34.9	-2.1±1.7	-0.1±2.4			
	35.0-39.0	-6.0±3.4	-2.2±4.2			
Physical Activity (kcal/wk)	25.0-29.9	476.1±166.4	31.3±189.0	≤ .05	.49	.17
	30.0-34.9	646.6±587.1	322.6±397.7			
	35.0-39.0	876.5±715.9	-232.7±268.2			

Table 4.5 Correlates of demographic variables with Resting Energy Expenditure.

Resting Energy Expenditure (kcal/d)							
Variable	**BMI (kg/m^2)**	**All Subjects (n=35)**		**Experimental (n=16)**		**Control (n=19)**	
		Baseline	4 Weeks	Baseline	4 Weeks	Baseline	4 Weeks
Body Weight (kg)	Total (25.0-39.9)	0.82**	0.77**	0.88**	0.72**	0.74**	0.78**
	25.0 - 29.9	0.93** (n=7)	0.99** (n=7)	0.96* (n=4)	1.00**(n=4)	0.99 (n=3)	0.99 (n=3)
	30.0 - 34.9	0.77** (n=20)	0.73** (n=20)	0.86** (n=7)	0.79* (n=7)	0.62* (n=13)	0.64* (n=13)
	35.0 - 39.9	0.95** (n=8)	0.93** (n=8)	0.95* (n=5)	0.77 (n=5)	0.96 (n=3)	1.00*** (n=3)
Lean Body Mass (kg)	Total (25.0-39.9)	0.84**	0.89**	0.89**	0.90**	0.78**	0.89**
	25.0-29.9	0.93** (n=7)	0.94** (n=7)	0.95*** (n=4)	0.90 (n=4)	0.98 (n=3)	1.00** (n=3)
	30.0-34.9	0.86** (n=20)	0.91** (n=20)	0.93** (n=7)	0.96** (n=7)	0.80** (n=13)	0.86** (n=13)
	35.0-39.9	0.90** (n=8)	0.93** (n=8)	0.90* (n=5)	0.71 (n=5)	0.94 (n=3)	1.00* (n=3)

Change in Resting Energy Expenditure (kcal/d)				
Variable	**BMI (kg/m^2)**	**All Subjects (n=35)**	**Experimental (n=16)**	**Control (n=19)**
Change in Body Weight (kg)	Total (25.0-39.9)	0.41*	-0.16	0.19
	25.0 - 29.9	0.48 (n=7)	0.31 (n=4)	-0.33 (n=3)
	30.0 - 34.9	0.27 (n=20)	-0.35 (n=7)	0.18 (n=13)
	35.0 - 39.9	0.56 (n=8)	-0.24 (n=5)	1.00*** (n=3)
Change in Lean Body Mass (kg)	Total (25.0-39.9)	0.44**	0.46	0.15
	25.0-29.9	0.47 (n=7)	0.42 (n=4)	0.70 (n=3)
	30.0-34.9	0.45* (n=20)	0.83* (n=7)	0.06 (n=13)
	35.0-39.9	0.58 (n=8)	0.45 (n=5)	0.85 (n=3)

* indicates correlation statistically significant at $p<0.05$
**indicates correlation statistically significant at $p<0.01$
***indicates correlation statistically significant at $p\leq0.06$

4.7 Correlates of REE

4.71 Correlations between REE and body weight

Table 4.5 displays the correlation coefficients representing the relation between REE and body weight. REE was significantly correlated with body weight at baseline and at 4 weeks when analyzed for the Experimental Group (baseline: r = .88; 4 weeks: r=

.72; p < 01) and the Control Group (baseline: r = .74; 4 weeks: r = .78; p < .01). When the groups were combined similar results were shown (baseline: r = 0.82; 4 weeks: r = 0.77; p < .01). Data by BMI category are also presented in Table 4.5.

Table 4.5 displays the correlation coefficients representing the relation between change in REE and change in body weight. When the Experimental and Control groups were combined, the change in REE was significantly correlated with the change in body weight (r = .41, p < .05). However, the change in REE was not significantly correlated with change in body weight when analyzed separately for the Experimental Group (r = -0.16, p > .05) or the Control Group (r = 0.19, p > .05). Data by BMI category are also presented in Table 4.5.

4.72 Correlations between REE and lean body mass

Table 4.5 displays the correlation coefficients representing the relation between REE and lean body mass (LBM). REE was significantly correlated with LBM at baseline and at 4 weeks when analyzed for the Experimental Group (baseline: r = .89; 4 weeks: r= .90; p < 01) and the Control Group (baseline: r = .78; 4 weeks: r = .89; p < .01). When the groups were combined similar results were shown (baseline: r = 0.84; 4 weeks: r = 0.89; p < .01). Data by BMI category are also presented in Table 4.5.

Table 4.5 displays the correlation coefficients representing the relation between change in REE and change in lean body mass (LBM). When the Experimental and Control Groups were combined, change in REE was significantly correlated with change in LBM (r = .44, p < .01). Change in REE was not significantly correlated with change in LBM when analyzed for the Experimental Group (r = -0.46, p > .05) and the Control Group (r = -0.18, p > .05). Data by BMI category are also presented in Table 4.5.

Chapter V

Discussion

5.1 Introduction

Weight loss programs using low-calorie diets with and without the inclusion of aerobic exercise have been shown to reduce resting energy expenditure (REE) (7, 15, 28, 34, 52), and these studies have partially attributed this reduction in REE to the reduction in total body weight and loss of lean body mass over the intervention period. However, few studies have examined these factors during the initial few weeks of weight loss. This investigation aimed to assess the effect of weight loss achieved through the combination of a reduction in energy intake and increase in aerobic exercise on change in resting energy expenditure over the initial 4 weeks of a weight loss intervention. Therefore, the primary aims of this investigation were to evaluate the effect of a low-calorie diet combined with aerobic exercise over a period of 4-weeks on resting energy expenditure, body weight, and lean body mass. Further, we aimed to examine the relationship between change in REE and in both total body weight and lean body mass.

5.2 Conclusions

Body Weight. Results of this study demonstrated significant ($p \leq .001$) weight loss in the Experimental Group compared to the Control Group (-3.4 $\pm$ 13.7 kg vs. 0.6 $\pm$ 11.1 kg) over the 4-week period, supporting our initial hypothesis. This approximates a mean weight loss of 1.9 lbs/wk (0.85 kg/wk) in the Experimental Group. This magnitude of weight loss is similar to the magnitude resulting from interventions implementing a similar energy intake (1200kcal/d) (24, 51, 52). For example, Wadden et al. reported average weight losses of 1.45 kg/week and 0.82 kg/week in response to interventions

with similar recommendations in diet and exercise (51,52). Moreover, the average weight loss per week from this study is within the recommended guidelines for weight loss established by the American College of Sports Medicine (ACSM) of 1-2 pounds per week (3).

Although our study did not have a valid measure to examine the change in dietary intake across the intervention and control periods, data from other studies may provide some understanding of the energy intake in this study. For example, weight loss in this current study was similar to the weight loss reported by Wadden et. al. (1990, 1994) in which energy intake was prescribed at approximately 1200 kcal/d (51, 52). In a similar manner, the current study prescribed energy intake at 1200-1500kcal/d. This, this may indicated that energy intake was similar across these studies. However, it would still be advantageous to include a valid and reliable measure of energy intake in future studies when examining the change in REE with weight loss.

Body Composition. Results of this study demonstrated a significant ($p \leq .001$) reduction in percent body fat in the Experimental Group compared to the Control Group ($-1.9 \pm 7.1\%$ vs. $0.2 \pm 6.3\%$) as presented in Table 4.2. The results in response to the intervention are comparable to other studies of this approximate duration. For example, Henson et al. reported a reduction in percent body fat of 2.7% and 1.1% in response to a 6-week intervention combining energy restriction with and without exercise, respectively (30). In addition, the current study also demonstrated a significant ($p \leq .05$) reduction in lean body mass in the Experimental Group compared to the Control Group (-0.6 ± 11.1 vs. 0.1 ± 10.6) (see Table 4.2). These findings do not support the hypothesis that there would be no significant reduction in lean body mass in the Experimental compared to the

Control Group. In a study of similar duration (3 weeks) but with a more aggressive dietary recommendation that included only 800 kcal/d, Henson et al. reported no significant change in LBM (28). However, in a study of somewhat longer magnitude, deGroot et al. reported a reduction in LBM of 3.2kg in response to 8 weeks of a diet consisting of 800 kcal/d diet (16).

A potential limitation of this study when examining the change in body composition is the use of bio-electrical impedance analysis (BIA). This technique may have limitations for accurately assessing body composition in response to weight loss in overweight adults when compared to other methods. Although BIA has been found to be a valid method of measurement for assessing body composition when compared to hydrostatic weighing ($r= 0.77$), the standard error of estimate (SEE) was found to be slightly higher (4.2%) than the conventionally accepted error (3.8%) established by Lohman et. al. (36) for field applicable methods (19,36). Thus, for future studies, the use of other methods of assessing body composition such as dual energy x-ray absorptiometry (DEXA) which has been shown to offer an SEE < 3%, may offer a more accurate measure of the various components of body composition (42). This may allow for an enhanced understanding of the effects of weight loss on changes in the different compartments of body composition (e.g., lean tissue, fat tissue, water, bone mineral, etc.

Previous research appears to demonstrated that the inclusion of aerobic training, resistance training, or the combination of both to a weight loss intervention consisting of caloric intakes ranging from 500-1500kcal/d does not significantly influence change in lean body mass (17, 29, 39, 50). These data appear to demonstrate that LBM is reduced with weight loss; however, the reported percentage of weight lost from LBM appeared to

vary across different studies with a range from 10% to 43% of total weight lost from LBM (need references here). This range of change in LBM may be a result varying caloric intakes and exercise recommendations across studies. Hill et. al. reported significant differences between LBM loss in subjects prescribed a diet (800 kcal/d) plus walking program vs. subjects who were prescribed diet only (800 kcal/d). The diet only subjects lost 43 +/- 4% of weight from lean body mass vs. a 26 +/- 4% loss in lean body mass in the diet plus exercise group. (30). This may warrant further investigation comparing varying levels of caloric restriction with aerobic and/or resistance exercise.

Resting Energy Expenditure. Results of this study also demonstrated a significant reduction in absolute resting energy expenditure (REE) in the Experimental Group compared to the Control Group, with the Experimental Group having a reduction in REE of approximately 205 kcal/d (see Table 4.2). These findings support the hypothesis that weight loss would result in a significant reduction in REE in response to weight loss when compared to a weight stable Control Group. These findings are similar to those found in other published studies with similar methods. For example, Wadden et al. reported a reduction of 193 kcal/d in REE after 5 weeks of a 1200 kcal/d intake (28, 52). These findings may have clinical significance. For example, if physical activity and energy intake were to remain constant, a difference in total daily energy expenditure of approximately 200 kcal/d would result in a slowing of weight loss by approximately 0.41 pounds per week or approximately 1.75 pounds per month assuming 3,500 kcal is equal to one pound of body weight. This may explain the slowing of weight loss over time that is typically observed in clinical weight management programs. Therefore, to compensate

for this reduction in REE, programs may need to continuously adjust physical activity and energy intake levels to maintain a constant rate of weight loss.

Results of this study demonstrate a trend for the Experimental Group to have a greater reduction in REE relative to total body weight (kcal/kg/d) compared to the Control Group (-1.4$\pm$ 3.3 kcal/kg/d vs. –0.3 $\pm$ 2.4 kcal/kg/d). When examining change in REE relative to LBM (REE/kgLBM/d), the results demonstrated a significant ($p \leq .01$) reduction in Experimental Group compared to the Control Group (-3.3 $\pm$ 3.9 kcal/kgLBM/d vs. –0.4 $\pm$ 3.4 kcal/kgLBM/d). These reductions in REE expressed as kcal/kg/d and kcal/kgLBM/d are similar to results reported in other studies. For example, Henson et al. reported a similar magnitude of reduction of 1.4 kcal/kg/d and 3.4 kcal/kgLBM/d over a 3 week period in response to an 800 kcal/d diet (28). Our findings support the hypothesis that overweight and obese males and females would have a reduction in REE relative to change in body weight (kcal/kg/d) and LBM (kcal/kg/d) in the Experimental Group when compared to the Control Group.

Correlations. Results of this study demonstrated that REE was significantly correlated with body weight at baseline and at 4 weeks when analyzed separately for both the Experimental and Control groups as well as when the groups were combined, with correlations ranging from 0.72 to 0.88 (see Table 4.5). These results appear to be similar to the correlations between body weight and REE reported by others. For example, Nieman et al. (39) reported correlations of approximately r=0.72 between REE and body weight when assessed weekly for a period of 5 weeks. The current study also demonstrated that change in REE was modestly correlated with change in body weight (r=0.41, see Table 4.5). This correlation is somewhat lower than the r=0.76 correlation

between change in weight and change in REE reported by Weyer et al. (55). This potential difference in findings may be explained by the fact that Weyer et al. examined this question in response to weight gain, whereas the current study examined this question in response to weight loss. Therefore, this may warrant further investigation.

The results of this study also demonstrated that REE was significantly correlated with LBM at baseline and at 4 weeks with correlations ranging from 0.78 to 0.90 as presented in table 4.5. However, the correlation between change in LBM and change in REE was more modest at r=0.44. By comparison, Elliot et al. (18) reported a correlation of r=0.89 between REE and LBM following a 16-week diet consisting of 300 kcal/d diet for 8 weeks followed by a 1100-1400 kcal/d diet for an additional 8 weeks. The modest correlation between the change in LBM and change in REE reported in the current study may suggest that the initial reduction in REE is not completely explained by the reduction in LBM. Thus, this may warrant further investigation to explain additional physiological and metabolic mechanisms contributing to the reduction in REE in the early stages of weight loss.

There may be additional physiological mechanisms that may impact REE. Hill et. al. reported that thyroid hormone triiodothyronine T_3 declined significantly ($p < .05$) during a weight loss intervention including a 800kcal/d diet recommendation. Reduction in T_3 levels may reduce resting metabolic rate since a symptom of hypothyroidism is a reduction in T_3 levels. In addition, food restriction has been shown to increase levels of neuropeptide Y (NPY) which has been shown to reduce energy expenditure (46). Food restriction also appears to reduce levels of the hormone leptin in the body, which has also been shown to slow REE (46). Another potential factor contributing to reduction in REE

is reduced levels of uncoupling proteins 2 (UCP2) and 3 (UCP3) (14, 23, 25). Although the function of these homologs is not completely understood, studies suggest that their potential to uncouple mitochondrial respiration in model systems indicates that they may increase metabolic rate and fuel utilization. Of importance is that there appears to be a genetic influence on UCP2 and UCP3 (14, 23, 25), which may influence the effect of these factors on metabolisms and body weight regulation.

5.3 Limitations and Future Research

This investigation is not without limitations which could impact the application of the observed results. The following recommendations should be considered for future research:

1. This study examined the change in REE in response to weight loss over a 4-week period. While providing data on the initial response of REE in response to a 4-week intervention, this provides limited data on the time-course of change in REE over a longer period of time. Thus, future research should examine the time-course of the change in REE in response to weight loss over a longer observation period.
2. This study had a sufficient sample size to compare the Experimental and Control groups for the primary outcomes. However, the sample size was inadequate to sufficiently examine the effect of other demographic characteristics on REE in response to weight loss. For example, when separated by BMI category the sample sizes in many of these categories were relatively small, which may limit the interpretation of these analyses due to insufficient statistical power. Thus, future studies should consider recruiting subjects in sufficient numbers to allow

for additional analyses based on BMI, age, gender, and other demographic characteristics.

3. This study used the combination of energy restriction and physical activity within the weight loss intervention. While effective for weight loss, this approach does not allow for the examination to determine if these intervention components would have differing effects on the outcomes of this study (REE, weight, body composition). These factors may affect the relationship between these outcome variables, which may be impacted by differing physiological and metabolic mechanisms. Future studies should examine the independent and combined effects of these intervention strategies on changes in REE in response to weight loss.
4. There are potential limitations in the measurements used in this study. For example, BIA was used to assess body composition, and there may be limitations to this technology when examining body composition in overweight and obese adults (19,36). Moreover, physical activity and dietary intake were assessed using self-report, and it has been demonstrated that overweight adults inaccurately report their level of exercise and dietary intake (35). Therefore, future studies in this area should consider the use of objective measurement techniques that have been shown to have acceptable validity and reliability.
5. Energy intake in this study was assessed at baseline, but was not assessed at the conclusion of the 4-week intervention period. Thus, this study is unable to determine the effect of changes in dietary intake on observed changes in body weight, body composition, or REE. Future studies should include a valid and

reliable measurement of dietary intake periodically throughout the intervention period.

6. This study did not measure additional physiological or metabolic mechanisms that may contribute to changes in body weight, body composition, or REE. Future studies should include these key measures to better understand the impact of an intervention on these factors and how these factors contribute to body weight control and REE.

5.4 Summary

The purpose of this study was to examine the 4-week effect of a low-calorie diet and aerobic exercise on absolute (kcal/d) and relative (kcal/kg/d and kcal/kg LBM/d) resting energy expenditure (REE) in overweight and obese adults. Secondary aims included the examination of change in body weight and lean body mass (LBM) as well as the correlation of these variables with change in REE. Results of this study demonstrated that as a result of a 4-week weight loss regimen combining a low-calorie diet and moderate aerobic exercise, there was a significant reduction in REE (kcal/d) and REE relative to LBM (kcal/kgLBM/d), with a trend toward statistical significance in REE relative to total body weight (kcal/kg/d). The modest correlations between the change in REE and change in body weight and LBM suggest that additional factors may contribute to alterations in REE in response to weight loss. Future studies should further examine these important research questions related to body weight regulation and the contribution of energy expenditure.

Appendix A

Informed Consent

Approval Date: November 1, 2005
Modification Approval: January 18, 2006
Renewal Date: October 31, 2006
University of Pittsburgh
Institutional Review Board
IRB #0511001

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: PERCEIVED IMPORTANCE AND WILLINGNESS TO ENGAGE IN WEIGHT LOSS BEHAVIORS AMONG OVERWEIGHT ADULTS

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SOURCE OF SUPPORT: School of Education

Approval Date: November 1, 2005
Modification Approval: January 18, 2006
Renewal Date: October 31, 2006
University of Pittsburgh
Institutional Review Board
IRB #0511001

DESCRIPTION:

The number of overweight and obese adults in the United States has been increasing at a rapid rate. Both reducing your food intake and increasing your exercise are important components of a weight loss program. This study will examine factors that may influence your use of weight loss strategies and how these factors affect your weight loss process, and the short-term effects of reduced calorie intake on resting energy expenditure (REE) in overweight and moderately obese women. Resting Energy Expenditure (REE) is the number of calories you burn in energy to allow your body to perform basic functions such as breathing, having your heart beat, and other functions to sustain life.

You are being invited to take part in this research study because you are within the body weight range for this study, have not lost more than 10% of your body weight within the past year, and do not have any medical conditions that would prohibit you from participating in moderate to vigorous activity. People invited into this study have to be men or women between 18-55 years of age. Women participants cannot be pregnant, and if you are a woman you will be required to accurately report whether you are pregnant to the investigators prior to beginning this study and during the study if your status should change. This study is being performed on a total of 50 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 eligibility is unsafe for you.

If you are a woman and report a pregnancy during the previous six months, report that you are currently pregnant, that you plan to become pregnant in the next six months, or if you become pregnant during the study period then you will not be eligible to participate or continue participating in the study. If you are pregnant you will be excluded from this study since the study requirements of decreasing the amount and types of food that you eat and increasing your level of physical activity may be harmful to your health and the health of your unborn child.

Participant's Initials____

You will also be required to provide written clearance from your personal physician before starting this study. You will be provided a Physician Consent form and it will be your responsibility to have this form signed by your personal physician and returned to the principal investigator prior to participating in the experimental procedures of the weight loss program described below.

Experimental Procedures:

If you qualify to take part in this research study, you will undergo the following experimental procedure assessments which will be conducted on weekdays during the hours of 7:30 AM to 10:30 AM at the University of Pittsburgh's Physical Activity and Weight Management Research Center:

Body Weight and Height: Your body weight will be measured in private room 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, 12, and 24 weeks during this study.

Exercise, Dietary Patterns, and Factors that Influence Behavior Change: You will complete questionnaires about the amount of exercise that you do in the presence of study personnel which will take approximately 20 minutes. You will also be given questionnaires to take home and complete on your own time. These questionnaires will include information about the amount and types of foods that you eat, your mood, general health, and other factors that may affect your exercise and eating behaviors. You will be required to complete approximately 12 different questionnaires at 0, 12, and 24 weeks during this study. It is estimated that you will be able to complete these questionnaires in approximately 60-90 minutes. In addition, you will complete 1 questionnaire at 0, 4, 8, 12, 16, 20, and 24 weeks, and 1 questionnaire only at week 24. It is estimated that you will able to complete these additional questionnaires in approximately 5-10 minutes.

Note: One of the questionnaires that you will complete will provide information about your mood and if you have symptoms of depression. If it is determined that you have symptoms of depression then you will be notified immediately and will be referred to your primary care physician for follow-up screening. If this is extreme and requires immediate medical care, and you are in the presence of the study investigators, you will be transported to the hospital.

Resting Energy expenditure (REE): Resting Energy Expenditure (REE) is the number of calories you burn in energy to allow your body to perform basic functions such as breathing, having your heart beat, and other functions to sustain life. On the morning of the test you will need to be transported to the research center by car, mass transportation such as a bus, or other from of motorized transportation. You will also be required not to participate in exercise or other vigorous forms of activity for at least one day (24 hours) before completing this measurement. You will also be required to avoid all food and beverages (other than water), and over-the-counter medications for 12 hours before this measurement.

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After arriving at the research center on the day of this test, you will lie in a resting position for 30 minutes. The air that you breathe out (exhale) will then be measured for an additional 15-30 minutes using a metabolic cart. A metabolic cart is a machine that allows investigators to determine how much air you breathe in and out, and how much of that is oxygen and carbon dioxide. This information will allow the investigators to determine how many calories you burn if you were to remain in a resting position all day. This will require that a plastic canopy be placed over your head as this will allow all of the air you breathe out to be analyzed. It is important for you to realize that you will not breathe any special mixes of air, but rather will breathe normal room air. This test just allows for that air to be measured to determine your resting energy expenditure.

This test will be performed twice, one time before you start the study and then 4 weeks after the study begins. This test will require approximately 60 minutes to complete for each measurement period.

Body composition: 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. There is no harm or risk associated with this procedure. This test will require approximately 15 minutes to complete at each measurement period. This test will be performed twice, one time before you start the study and then 4 weeks after the study begins.

Description of the Weight Control Program:

If you consent to participate in this study you will be assigned to one of two weight loss interventions. Your assignment to the weight loss intervention will be random, which means that you can not choose your group but rather this is determined in a method that is similar to flipping a coin. These weight loss groups are: 1) Weight Loss Intervention Group, or 2) Delayed Weight Loss Intervention Group. These weight loss groups are described below.

1. Weight Loss Intervention Group: If you are assigned to the weight loss intervention group you will receive the following

   a.) Group Meetings and Contacts: You will attend a total of 24 weekly group meetings over 6 months at the University of Pittsburgh's Physical Activity and Weight Management Research Center. You will not have the ability to select the day or time of the group meetings, but rather the group meetings will be held ad a set day and time and this information will be provided to you prior to you agreeing to participate in this study. Each group meeting will last 45 to 60

Participant's Initials____

minutes. These weekly meetings will be held on the same night every week, and the group will have approximately 20 to 25 members that will be dieting and participating in exercise to lose weight. If you decide to discontinue your participation in this weight loss program you will need to provide written notification to the principal investigator listed on page 1 of this document.

b) Diet: It will be recommended that you reduce the amount of food that you eat and change some of your food choices. This will result in you eating few calories and reducing the amount of 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. You will also be taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this will be returned to the investigators weekly.

c) Exercise: It will be recommended that you increase your participation in regular exercise. You will be instructed to exercise 5 days per week, with the walking duration on each day increasing from 20 to 40 minutes during the first 12-weeks of the program, and you will maintain this level of exercise throughout the remainder of the program. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. Brisk walking will be recommended, however you can self-select to participate in other forms of activity for your exercise provided you follow the guidelines described above. You will record your exercise in a diary that is returned to the investigators weekly.

2. Delayed Weight Loss Intervention Group: If you are assigned to the Delayed Weight Loss Intervention group you will receive the following:

a) Group Meetings, and Contacts: Following your baseline assessment you will participate in a 4 week period where you will be instructed to maintain your current eating and exercise behaviors that will allow you to maintain your body weight. Following this 4-week period, you will then attend a total of 24 weekly group meetings over 6 months at the University of Pittsburgh's Physical Activity and Weight Management Research Center. You will not have the ability to select the day or time of the group meetings, but rather the group meetings will be held at a set day and time and this information will be provided to you prior to you agreeing to participate in this study. 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 20-25 members that will be dieting and participating in exercise to lose weight. If you decide to discontinue your participation in this weight loss program you will need to provide written notification to the principal investigator listed on page 1 of this document.

Participant's Initials____

b) Diet: Following your baseline assessment you will participate in a 4 week period where you will be instructed to maintain your current eating behaviors that will allow you to maintain your body weight. Following this 4-week period, it will be recommended that you reduce the amount of food that you eat and change some of your food choices. This will result in you eating few calories and reducing the amount of 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. You will also be taught how to decrease the amount of fat that you eat, and will be encouraged to decrease fat intake to 20-30% of your total calories. You will record the food that you eat in a diary, and this will be returned to the investigators weekly.

c) Exercise: Following your baseline assessment you will participate in a 4-week period where you will be instructed to maintain your current exercise behaviors that will allow you to maintain your body weight. Following this 4-week period, it will be recommended that you increase your participation in regular exercise. You will be instructed to exercise 5 days per week, with the walking duration on each day increasing from 20 to 40 minutes during the first 12-weeks of the program, and you will maintain this level of exercise throughout the remainder of the program. You will be allowed to divide your exercise into periods of at least 10 minutes to make it easier for you to exercise. You will exercise at an intensity of 60-70% of your maximal capacity, with is the equivalent of taking a brisk walk for most individuals. Brisk walking will be recommended, however you can self-select to participate in other forms of activity for your exercise provided you follow the guidelines described above. You will record you exercise in a diary that is returned to the investigators weekly.

RISKS and BENEFITS:

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

Risks of Exercise: There are risks associated with participating in an exercise program. During exercise, you may experience a serious cardiac event (i.e., heart attack), an arrhythmia (i.e. irregular heart beat), or chest pain. The risk of a serious cardiac event, arrhythmia, or chest pain would be infrequent (less than 10% or less than 10 persons out of 100 people). In addition, during exercise, you may experience an increase in heart rate, an increase in blood pressure, shortness of breath, or general fatigue. The risk of increased heart rate and blood pressure, shortness of breath, or general fatigue is common (greater than 10% or more than 10 out of 100 people. Because the exercise sessions that you will be asked 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.

Participant's Initials____

Risks of Reducing Your Caloric and Fat Intake: Consuming a moderately low fat and low calorie diet appears to be safe and effective for weight loss. However, if you reduce your calorie or fat intake below recommended levels you may experience dry skin and thinning of your hair. This is common and occurs in 1% to 25% of people (1 to 25 out of 100 people). You may also experience problems with your gall bladder like Cholelithiasis (also known as gallstones). Symptoms for this condition include abdominal pain or back pain. If severe, surgery may be required to remove your gall bladder. This is infrequent and occurs in less than 1% of people (less than 1 out of 100 people).

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 common because this occurs in more than 10% of people (more than 10 out of 100 people). To minimize the occurrence of these risks you will be allowed to take the questionnaires home and complete them at your leisure provided they are returned to the investigators by the date specified to you.

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 more than 10% of people (more than 10 out of 100 people).

Risk Associated with measurement of Body Composition using BIA: It is infrequent that you will feel any discomfort as a result of participating in the body composition measurement using the BIA (occurs in less than 10% of people or less than 10 out of 100 people).

Risk Associated with Measurement of Resting Energy Expenditure (REE): Risks associated with measurement of REE may include mild discomfort as a result of having the plastic canopy placed over your head. This is common to occur during the assessment (occurs in more than 10% of people or more than 10 out of 100 people), but bay be more common in those individuals who are uncomfortable in enclosed areas.

Participant's Initials____

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 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.

Benefits of Reducing your Caloric 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.

If you are assigned to the Weight Loss Intervention Group you will be paid $25 for completing the assessment following 4-weeks of the intervention, $25 for completion of the assessments following 12-weeks of the intervention, and $25 for completing the assessments following 24-weeks of the intervention.

If you are assigned to the Delayed Weight Loss Intervention Group you will be paid $25 for completing assessments following the 4-week period where you are to maintain your body weight, $25 for completion of the assessments following 12-weeks of the intervention, and $25 honorarium for completion of the assessments following 24-weeks of the intervention.

Participant's Initials____

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 or a co-investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by 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.

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

Participant's Initials____

Approval Date: November 1, 2005
Modification Approval: January 18, 2006
Renewal Date: October 31, 2006
University of Pittsburgh
Institutional Review Board
IRB #0511001

The investigators listed on the first page of this authorization (consent) form and their research staff will or may have access to identifiable information (which may include your identifiable medical record information obtained as part of the initial screening and physician consent) related to your participation in this research study.

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

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

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

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

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

Participant's Initials____

Approval Date: November 1, 2005
Modification Approval: January 18, 2006
Renewal Date: October 31, 2006
University of Pittsburgh
Institutional Review Board
IRB #0511001

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 effect 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 effect 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 or medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

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

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

****

Participant's Initials____

Approval Date: November 1, 2005
Modification Approval: January 18, 2006
Renewal Date: October 31, 2006
University of Pittsburgh
Institutional Review Board
IRB #0511001

VOLUNTARY CONSENT

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

Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

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

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

Appendix B

Physical Activity Readiness Questionnaire (PAR-Q)

Physical Activity Readiness Questionnaire (PAR-Q)

Subject ID: _____ Date: _____

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

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

   □yes □no

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

   □yes □no

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

   □yes □no

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

   □yes □no

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

   □yes □no

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

   □yes □no

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

   □yes □no

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

Appendix C

General Health History Questionnaire

GENERAL HEALTH HISTORY

Subject ID:_____

DATE: □□/□□/□□

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

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

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

   If yes, please describe the problem:_____

   _____

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

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

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

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

6. Over the last 6 months, on how many weekdays (Monday through Friday) do you usually drink wine, beer, or liquor on average?

(0) □ Never
(1) □ Less than once/month
(2) □ 1-2 times/month
(3) □ 1 day/week
(4) □ 2 days/week
(5) □ 3 days/week
(6) □ 4 days/week
(7) □ 5 days/week

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

8. Over the last 6 months, on how many weekend days (Saturday and Sunday) do you usually drink wine, beer, or liquor?

(0) □ Never
(1) □ Less than once/month
(2) □ 1-2 times/month
(4) □ 1 weekend day/week
(5) □ 2 weekend days/week

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

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

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

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

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

WOMEN ONLY ANSWER THE FOLLOWING QUESTIONS

13. Are you currently pregnant? □yes □no

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

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

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

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

18. When was your last menstrual period? DATE:□□/□□/□□

19. Do you take :

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

Appendix D

Physician's Consent/Medical Clearance

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

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

Your patient _____ has asked to participate in a diet and exercise program at the University of Pittsburgh. This is a 6 month research study designed to help patients change their eating and exercise habits and to examine the impact that this will have on weight loss. This will involve the following:

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

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

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

4. A list of additional factors that you should consider are listed on the attached sheet.

****

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

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

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

_____

_____

_____ _____

Signature of Physician Date

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

Inclusion Criteria

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

Exclusion Criteria

1. Report participating in a research project involving weight loss or physical activity in the previous 12 months.
2. Report participating in any other research study that may impact the outcome of the current proposed study.
3. Report a weight loss of >10% of their body weight in the previous 12 months.
4. Report participating in regular physical activity (defined as 30 minutes per day three or more days per week) over the previous six months.
5. Currently pregnant, report pregnancy during the previous 6 months, or plan on becoming pregnant in the following six months.
6. Report being treated for any cardiovascular, orthopedic, psychological, neurological, or metabolic disorder or any other medical condition that could impact body weight, diet, or physical activity.
7. Report a history of heart disease, stroke, myocardial infarction, angina, diabetes, or cancer.
8. Report taking any medications and/or supplements that would affect heart rate or blood pressure responses to exercise.
9. Report taking any medications and/or supplements that could affect metabolism and/or weight loss.
10. Report an inability to attend weekly sessions or possibility of re-locating out of the greater Pittsburgh area during the study period.

Appendix E

Paffenbarger Physical Activity Questionnaire

Office Use Only			
Subject ID #:		**Assessment #:**	

EXERCISE HABITS

1. Was there anything about the past week that made exercising especially different for you in terms of extended illness, injury, or vacation?

☐$_1$Yes ☐$_2$No

*If "NO", please complete this questionnaire about this past week.
*If "YES", please complete this questionnaire about the previous week.

2. First, we are interested in the number of flights of stairs you climbed on average **EACH DAY** in this past week. We only want to know the number of flights you climb going <u>*UP*</u> - not down.
One Flight = 10 steps if you know the number of steps.

☐☐ Flights per day

3. Next, we want to know how many city blocks or their equivalent you walked on average **EACH DAY** in this past week. We are only interested in walking done out of doors and walking done indoors for the sole purpose of exercise. We do not want walking done around the house or at work.
Consider that 12 city blocks = 1 mile.

☐☐ Blocks per day

4. Were there any sports, fitness, or recreational activities in which you participated during the past week? We are interested only in time that you were physically active.
(Note: all walking should only be included in Question 3)

Sport, Fitness, or Recreation	**Times per Week**		**Average Time per Episode**	***Office Use Only***
a.	☐☐		☐☐☐ Minutes	☐
b.	☐☐		☐☐☐ Minutes	☐
c.	☐☐		☐☐☐ Minutes	☐
d.	☐☐		☐☐☐ Minutes	☐

5. Would you say that during the past week (the week used for questions 2-4) you were:

□ less active than usual
□ more active than usual
□ about as active as usual

6. At least once per week, do you engage in regular activity akin to brisk walking, jogging, bicycling, etc. long enough to work up a sweat, get your heart thumping, or get out of breath?

□ Yes □□ times per week; Activity: _____
□ No

7. On a usual weekday and a weekend day, how much time (to the nearest 1 hour) do you spend on the following activities? ***The total for each day should add to 24 hours***

Sport, Fitness, or Recreation	**Usual Weekday Hours per Day**	**Usual Weekend Day Hours per Day**
a) Vigorous Activity (digging in the garden, strenuous sports, jogging, aerobic dancing, sustained swimming, brisk walking, heavy carpentry, bicycling on hills, etc.)	☐☐	☐☐
b) Moderate Activity (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)	☐☐	☐☐
c) Light Activity (office work, driving car, strolling, personal care, standing with little motion, etc.)	☐☐	☐☐
d) Sitting Activity (eating, reading, desk work, watching TV, computer work, listening to the radio, etc.)	☐☐	☐☐
e) Sleeping or reclining	☐☐	☐☐

Appendix F

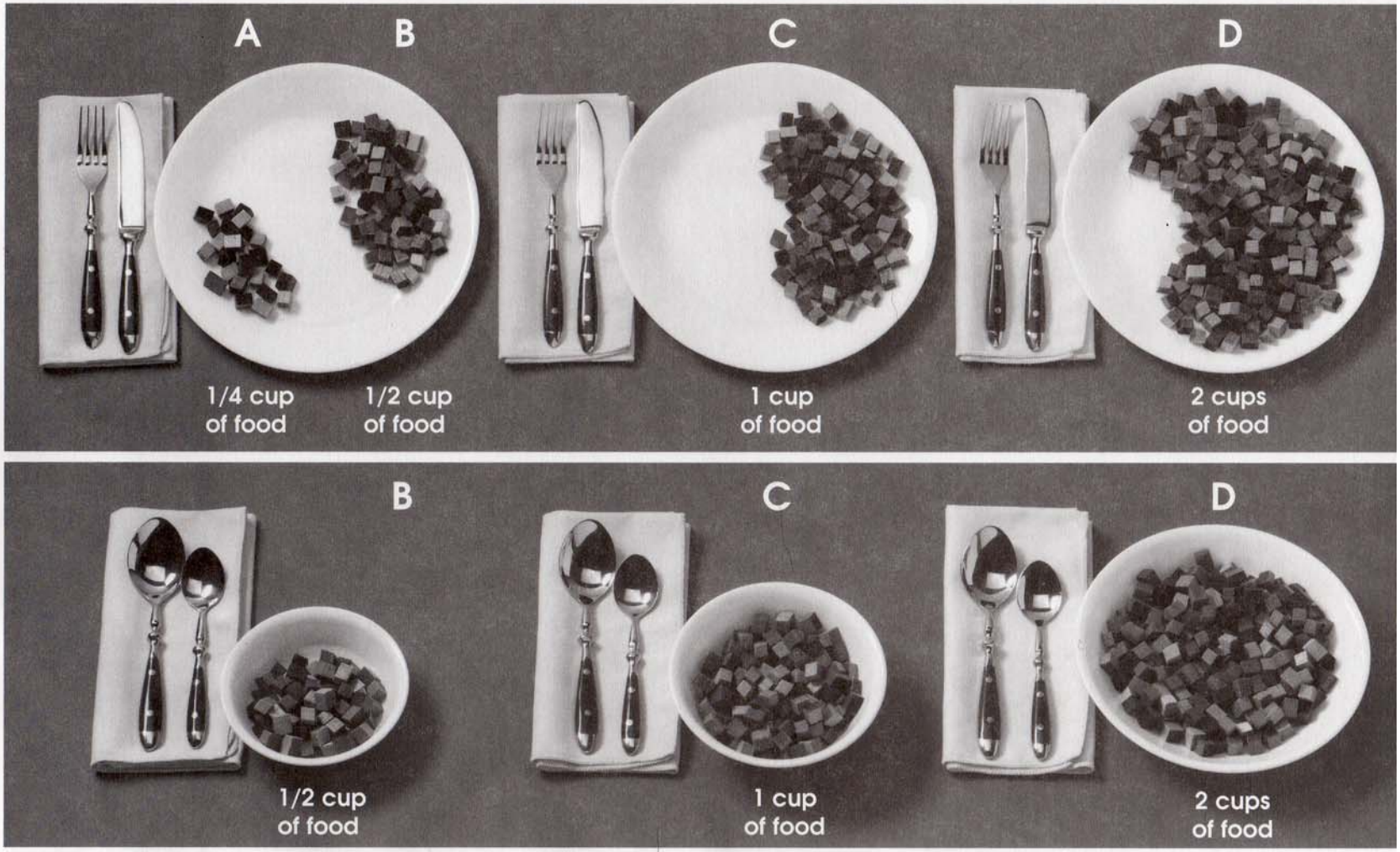
Food Frequency Questionnaire

FOOD QUESTIONNAIRE

Serving Size Choices

Keep this in front of you while you are filling out The Food Questionnaire. You may use either the plates or the bowls to help you choose your serving size.

Choose A, B, C or D: **A** = 1/4 Cup of Food **B** = 1/2 Cup of Food **C** = 1 Cup of Food **D** = 2 Cups of Food



RESPONDENT ID NUMBER

TODAY'S DATE

	DAY	YEAR
Jan		
Feb		
Mar	00	1998
Apr	11	1999
May	22	2000
Jun	33	2001
Jul	4	2002
Aug	5	2003
Sep	6	2004
Oct	7	2005
Nov	8	2006
Dec	9	2007

FOOD QUESTIONNAIRE

This form is about the foods you usually eat. It will take about 30 - 40 minutes to complete.

- **Please answer each question as best you can. Estimate if you aren't sure.**
- **Use only a No. 2 pencil.**
- **Fill in the circles completely, and erase completely if you make any changes.**

Please print your name in this box.

SEX
- Male
- Female

If female, are you pregnant or breast feeding?
- No
- Yes
- Not female

AGE

WEIGHT pounds

HEIGHT ft. in.

First, a few general questions about what you eat.	AVERAGE USE IN THE PAST YEAR								
	LESS THAN ONCE per WEEK	1-2 per WEEK	3-4 per WEEK	5-6 per WEEK	1 per DAY	1 1/2 per DAY	2 per DAY	3 per DAY	4+ per DAY
About how many servings of vegetables do you eat, per day or per week, not counting salad or potatoes?	○	○	○	○	○	○	○	○	○
About how many servings of fruit do you eat, not counting juices?	○	○	○	○	○	○	○	○	○
How often do you eat cold cereal?	○	○	○	○	○	○	○	○	○
How often do you use fat or oil in cooking?	○	○	○	○	○	○	○	○	○

What kinds of fat or oil do you usually use in cooking? MARK ONLY ONE OR TWO

- Don't know, or Pam
- Stick margarine
- Soft tub margarine
- Butter
- Butter/margarine blend
- Low-fat margarine
- Corn oil, vegetable oil
- Olive oil or canola oil
- Lard, fatback, bacon fat
- Crisco

PLEASE DO NOT WRITE IN THIS AREA

240878

During the past year, have you taken any vitamins or minerals regularly, at least once a month?

○ No, not regularly ○ Yes, fairly regularly →

(IF YES) WHAT DID YOU TAKE FAIRLY REGULARLY?

VITAMIN TYPE	HOW OFTEN					FOR HOW MANY YEARS?					
	DIDN'T TAKE	A FEW DAYS per MONTH	1-3 DAYS per WEEK	4-6 DAYS per WEEK	EVERY DAY	LESS THAN 1 YR.	1 YEAR	2 YEARS	3-4 YEARS	5-9 YEARS	10+ YEARS
Multiple Vitamins. Did you take...											
Regular Once-A-Day, Centrum, or Thera type	○	○	○	○	○	○	○	○	○	○	○
Stress-tabs or B-Complex type	○	○	○	○	○	○	○	○	○	○	○
Antioxidant combination type	○	○	○	○	○	○	○	○	○	○	○
Single Vitamins (not part of multiple vitamins)											
Vitamin A (not beta-carotene)	○	○	○	○	○	○	○	○	○	○	○
Beta-carotene	○	○	○	○	○	○	○	○	○	○	○
Vitamin C	○	○	○	○	○	○	○	○	○	○	○
Vitamin E	○	○	○	○	○	○	○	○	○	○	○
Folic acid, folate	○	○	○	○	○	○	○	○	○	○	○
Calcium, alone or combined with something else	○	○	○	○	○	○	○	○	○	○	○
Zinc, alone or combined with something else	○	○	○	○	○	○	○	○	○	○	○
Iron	○	○	○	○	○	○	○	○	○	○	○
Selenium	○	○	○	○	○	○	○	○	○	○	○

If you took Once-a-day, Centrum or Thera-type multiple vitamins, did you usually take types that ○ contain minerals, iron, zinc, etc. ○ do not contain minerals ○ **don't know**

If you took vitamin C or vitamin E:

How many milligrams of **vitamin C** did you usually take, on the days you took it?
○ 100 ○ 250 ○ 500 ○ 750 ○ 1000 ○ 1500 ○ 2000 ○ 3000+ ○ Don't know

How many IUs of **vitamin E** did you usually take, on the days you took it?
○ 100 ○ 200 ○ 300 ○ 400 ○ 600 ○ 800 ○ 1000 ○ 2000+ ○ Don't know

Did you take any of these supplements at least once a month?

○ Ginkgo ○ Ginseng ○ St. John's Wort ○ Kava Kava ○ Echinacea ○ Melatonin ○ DHEA
○ Glucosamine/Chondroitin ○ Something else ○ Didn't take these

---

The next section is about your <u>usual</u> eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions to answer for each food:

HOW OFTEN, on average, did you eat the food during the past year?
*Please DO NOT SKIP any foods. Mark "Never" if you didn't eat it.

HOW MUCH did you usually eat of the food?

*Sometimes we ask how <u>many</u> you eat, such as 1 egg, 2 eggs, etc., ON THE DAYS YOU EAT IT.
*Sometimes we ask "how much" as A, B, C or D. LOOK AT THE ENCLOSED PICTURES. For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat.
(If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D=2 cups.)
*Sometimes we made the "D" column a darker color. This is just to remind you to make sure you really eat that large a serving.

EXAMPLE: This person drank apple juice twice a week, and had one glass each time. Once a week he ate a "C" sized serving of rice (about 1 cup).

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MON.	2-3 TIMES per MON.	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
Apple juice	○	○	○	○	○	●	○	○	○	How many glasses each time	● 1	○ 2	○ 3	○ 4
Rice	○	○	○	○	●	○	○	○	○	How much each time	○ A	○ B	● C	○ D

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME How many glasses on the days you drink it?				
How often do you drink the following beverages?														
Tomato juice or V-8 juice	○	○	○	○	○	○	○	○	○	How many glasses **each time**	○ 1	○ 2	○ 3	○ 4
Real 100% orange juice or grapefruit juice, including fresh, frozen or bottled	○	○	○	○	○	○	○	○	○	How many glasses **each time**	○ 1	○ 2	○ 3	○ 4

When you drink orange juice, how often do you drink a calcium-fortified brand?
○ Usually calcium-fortified ○ I don't know
○ Sometimes calcium-fortified ○ I don't drink orange juice
○ Hardly ever calcium-fortified

Other real fruit juices like apple juice, prune juice, lemonade	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3	○ 4
Kool-Aid, Hi-C, or other drinks with added vitamin C	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3	○ 4
Drinks with some juice in them, like Sunny Delight, Juice Squeeze	○	○	○	○	○	○	○	○	○	How many bottles	○ 1	○ 2	○ 3	○ 4
Instant breakfast milkshakes like Carnation, diet shakes like SlimFast, or liquid supplements like Ensure	○	○	○	○	○	○	○	○	○	How many glasses or cans	○ 1	○ 2	○ 3	○ 4
Glasses of milk (any kind)	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3	○ 4

When you drink glasses of milk, what kind do you usually drink? **MARK ONLY ONE:**
○ Whole milk ○ Reduced-fat 2% milk ○ Low-fat 1% milk ○ Non-fat milk
○ Rice milk ○ Soy milk ○ I don't drink milk or soy milk

HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW MUCH EACH TIME				
Regular soft drinks, or bottled drinks like Snapple (not diet drinks)	○	○	○	○	○	○	○	○	○	How many bottles or cans	○ 1	○ 2	○ 3-4	○ 5+
Beer or non-alcoholic beer	○	○	○	○	○	○	○	○	○	How many bottles or cans	○ 1	○ 2	○ 3-4	○ 5+

What kind? **MARK ONLY ONE:** ○ Regular beer ○ Light beer ○ Non-alcoholic beer ○ I don't drink beer

Wine or wine coolers	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3-4	○ 5+
Liquor or mixed drinks	○	○	○	○	○	○	○	○	○	How many drinks	○ 1	○ 2	○ 3-4	○ 5+
Glasses of water, tap or bottled	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3-4	○ 5+
Coffee, regular or decaf	○	○	○	○	○	○	○	○	○	How many cups	○ 1	○ 2	○ 3-4	○ 5+
Tea or iced tea (not herb teas)	○	○	○	○	○	○	○	○	○	How many cups	○ 1	○ 2	○ 3-4	○ 5+

What do you usually add to coffee? **MARK ONLY ONE:**
○ Cream or half & half ○ Nondairy creamer ○ Milk ○ None of these

What do you usually add to tea? **MARK ONLY ONE:**
○ Cream or half & half ○ Nondairy creamer ○ Milk ○ None of these

Do you usually add sugar (or honey) to coffee? ○ No ○ Yes IF YES, how many teaspoons each cup? ① ② ③-④ ⑤+

Do you usually add sugar (or honey) to tea? ○ No ○ Yes IF YES, how many teaspoons each cup? ① ② ③-④ ⑤+

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240878

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
How often do you eat each of the following fruits, just during the 2-3 months when they are in season?														
Raw peaches, apricots, nectarines, while they are in season	○	○	○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
Cantaloupe, in season	○	○	○	○	○	○	○	○	○	How much	○ 1/8	○ 1/4	○ 1/2	○ 1
Strawberries, in season	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Watermelon, in season	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Any other fruit in season, like grapes, honeydew, pineapple, kiwi	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
How often do you eat the following foods all year round? Estimate your average for the whole year.														
Bananas	○	○	○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
Apples or pears	○	○	○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
Oranges or tangerines	○	○	○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
Grapefruit	○	○	○	○	○	○	○	○	○	How much	○ 1/2	○ 1	○ 2	○ 3
Canned fruit like applesauce, fruit cocktail, or dried fruit like raisins	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D

HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW MUCH EACH TIME				
Eggs, including egg biscuits or Egg McMuffins (Not egg substitutes)	○	○	○	○	○	○	○	○	○	How many eggs each time	○ 1	○ 2	○ 3	○ 4
Bacon	○	○	○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Breakfast sausage, including sausage biscuits	○	○	○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Pancakes, waffles, French toast, Pop Tarts	○	○	○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Breakfast bars, granola bars, Power bars	○	○	○	○	○	○	○	○	○	How many	○ 1	○ 2	○ 3	○ 4
Cooked cereals like oatmeal, cream of wheat or grits	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
High-fiber cereals like All Bran, Raisin Bran, Fruit-n-Fiber	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D

Which high-fiber cereal do you eat most often? **MARK ONLY ONE:** ○ All Bran or Bran Buds ○ Raisin Bran ○ Fiber One, Fruit-n-Fiber, etc. ○ Something else ○ I don't know ○ I don't eat it

Product 19, Just Right or Total cereal	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
Any other cold cereal, like Corn Flakes, Cheerios, Special K	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
Milk or milk substitutes on cereal	○	○	○	○	○	○	○	○	○	How many oz. on cereal	○ 3 oz.	○ 4-5 oz.	○ 6-7 oz.	○ 8+ oz.
Yogurt or frozen yogurt	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cheese, sliced cheese or cheese spread, including on sandwiches	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4

When you eat cheese, is it ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ Don't know/don't eat

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240878

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D

How often do you eat the following vegetables, including fresh, frozen, canned or in stir-fry, at home or in a restaurant?

Broccoli	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Carrots, or mixed vegetables or stews containing carrots	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Corn	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Green beans or green peas	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Spinach	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Mustard greens, turnip greens, collards	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
French fries, fried potatoes or hash browns	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
White potatoes not fried, incl. boiled, baked, mashed & potato salad	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Sweet potatoes, yams (Not in pie)	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cole slaw, cabbage	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Green salad	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Raw tomatoes, including in salad	○	○	○	○	○	○	○	○	○	How much	○ 1/4	○ 1/2	○ 1	○ 2
Salad dressing	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4

Is your salad dressing ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ Don't know/don't use

HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW MUCH EACH TIME				
Any other vegetable, like okra, squash, cooked green peppers	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Refried beans or bean burritos	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Chili with beans (with or without meat)	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Baked beans, black-eye peas, pintos, any other dried beans	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Vegetable stew	○	○	○	○	○	○	○	○	○	Which Bowl		○ B	○ C	○ D
Vegetable soup, vegetable beef, chicken vegetable, or tomato soup	○	○	○	○	○	○	○	○	○	Which Bowl		○ B	○ C	○ D
Split pea, bean or lentil soup	○	○	○	○	○	○	○	○	○	Which Bowl		○ B	○ C	○ D
Any other soup, like chicken noodle, chowder, mushroom, instant soups	○	○	○	○	○	○	○	○	○	Which Bowl		○ B	○ C	○ D
Spaghetti, lasagna or other pasta with tomato sauce	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cheese dishes without tomato sauce, like macaroni and cheese	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Pizza, including carry-out	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
Do you ever eat chicken, meat or fish? ○ Yes ○ No **IF NO, SKIP TO NEXT PAGE**														
Hamburgers, cheeseburgers, meat loaf, at home or in a restaurant	○	○	○	○	○	○	○	○	○	How much meat	○ 1/8 lb.	○ 1/4 lb.	○ 1/2 lb.	○ 3/4 lb.
Tacos, burritos, enchiladas, tamales, etc. with meat or chicken	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
How do you like beef cooked? ○ Rare ○ Medium ○ Well done ○ I don't eat beef														
Pork chops, pork roasts, or dinner ham	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat meat, do you ○ Avoid eating the fat ○ Sometimes eat the fat ○ Often eat the fat ○ I don't eat meat														
Veal, lamb or deer meat	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Ribs, spareribs	○	○	○	○	○	○	○	○	○	How many ribs	○ 3-4	○ 5-6	○ 7-8	○ 9+
Liver, including chicken livers or liverwurst	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Gizzard, pork neckbones, chitlins, pigs feet, etc.	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Mixed dishes with beef or pork, like stew, corned beef hash, stuffed cabbage, meat dish with noodles	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Mixed dishes with chicken, like chicken casserole, chicken & noodles, pot pie or in stir-fry	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Fried chicken, at home or in a restaurant	○	○	○	○	○	○	○	○	○	# medium pieces	○ 1	○ 2	○ 3	○ 4
Chicken or turkey not fried, such as baked, grilled, or on sandwiches	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat chicken, do you ○ Avoid eating the skin ○ Sometimes eat the skin ○ Often eat the skin														

HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW MUCH EACH TIME				
Oysters	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Other shellfish like shrimp, scallops, crabs	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Tuna, tuna salad, tuna casserole	○	○	○	○	○	○	○	○	○	How much of the tuna	○ A	○ B	○ C	○ D
Fried fish or fish sandwich, at home or in a restaurant	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Other fish, not fried	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Hot dogs, or sausage like Polish, Italian or chorizos	○	○	○	○	○	○	○	○	○	How many	○ 1	○ 2	○ 3	○ 4
Are your hot dogs ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ Don't know/don't eat them														
Boloney, sliced ham, turkey lunch meat, other lunch meat	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Are your lunch meats ○ Usually low-fat or turkey ○ Sometimes low-fat ○ Hardly ever low-fat														

HOW OFTEN	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
Noodles, macaroni, pasta salad	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Tofu, bean curd	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Meat substitutes, such as veggie burgers, Gardenburgers	○	○	○	○	○	○	○	○	○	How many patties	○ 1	○ 2	○ 3	○ 4
Chinese food, Thai or other Asian food, not counted above	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Snacks like potato chips, corn chips, popcorn (not pretzels)	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D

Are these snacks ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ Don't know/don't eat

HOW OFTEN	NEVER	FEW/ YEAR	ONCE/ MONTH	2-3 TIMES/ MONTH	ONCE/ WEEK	TWICE/ WEEK	3-4 TIMES/ WEEK	5-6 TIMES/ WEEK	EVERY DAY	HOW MUCH EACH TIME				
Peanuts, other nuts or seeds	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Crackers	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Doughnuts, Danish pastry	○	○	○	○	○	○	○	○	○	How many	○ 1	○ 2	○ 3	○ 4
Cake, sweet rolls, coffee cake	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D

Are they ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ Don't know/don't eat

Cookies	○	○	○	○	○	○	○	○	○	How many	○ 1-2	○ 3-5	○ 6-7	○ 8+

Are your cookies ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ I don't know/don't eat

Ice cream, ice milk, ice cream bars	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D

Is your ice cream ○ Usually low-fat ○ Sometimes low-fat ○ Hardly ever low-fat ○ I don't know/don't eat

Pumpkin pie, sweet potato pie	○	○	○	○	○	○	○	○	○	How many slices	○ 1/2	○ 1	○ 2	○ 3
Any other pie or cobbler	○	○	○	○	○	○	○	○	○	How many slices	○ 1/2	○ 1	○ 2	○ 3
Chocolate candy, candy bars	○	○	○	○	○	○	○	○	○	How many bars	○ 1 small	○ 1 medium	○ 1 large	○ 2 large
Other candy, not chocolate, like hard candy, caramel, jelly beans	○	○	○	○	○	○	○	○	○	How many pieces	○ 1-2	○ 3-5	○ 6-7	○ 8+

PLEASE DO NOT WRITE IN THIS AREA

HOW OFTEN	NEVER OR A FEW TIMES PER YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	2 TIMES per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	2+ TIMES per DAY	HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
Biscuits or muffins	○	○	○	○	○	○	○	○	○	How many **each time**	○ 1	○ 2	○ 3	○ 4
Rolls, hamburger buns, English muffins, bagels	○	○	○	○	○	○	○	○	○	How many **each time**	○ 1/2	○ 1	○ 2	○ 3
Dark bread like rye or whole wheat, including in sandwiches	○	○	○	○	○	○	○	○	○	How many slices **each time**	○ 1	○ 2	○ 3	○ 4
White bread or toast, including French, Italian, or in sandwiches	○	○	○	○	○	○	○	○	○	How many slices **each time**	○ 1	○ 2	○ 3	○ 4
Corn bread, corn muffins	○	○	○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Tortillas	○	○	○	○	○	○	○	○	○	How many **each time**	○ 1	○ 2	○ 3	○ 4
Rice, or dishes made with rice	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Margarine (not butter) on bread or on potatoes or vegetables, etc.	○	○	○	○	○	○	○	○	○	How many pats (tsp.)	○ 1	○ 2	○ 3	○ 4
Butter (not margarine) on bread or on potatoes or vegetables, etc.	○	○	○	○	○	○	○	○	○	How many pats (tsp.)	○ 1	○ 2	○ 3	○ 4
Gravy	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4
Peanut butter	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4
Jelly, jam, or syrup	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4
Mayonnaise, sandwich spreads	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4
Catsup, salsa or chile peppers	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4
Mustard, soy sauce, steak sauce, barbecue sauce, other sauces	○	○	○	○	○	○	○	○	○	How many Tbsp.	○ 1	○ 2	○ 3	○ 4

Did you use the pictures to choose your serving size on this form? ○ Yes ○ No ○ I didn't have any pictures.

Would you say your health is ○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

How many times have you gone on a diet? ○ Never ○ 1-2 ○ 3-5 ○ 6-8 ○ 9 or more

Did you ever drink more beer, wine or liquor than you do now? ○ Yes ○ No

How many hours do you watch television or video, per day or per week on average?
○ None ○ 1-6 hours/week ○ 1 hour/day ○ 2 hours/day ○ 3 hours/day ○ 4+ hours/day

Do you smoke cigarettes now? ○ No ○ Yes
IF YES, On the average about how many cigarettes a day do you smoke now?
○ 1-5 ○ 6-14 ○ 15-24 ○ 25-34 ○ 35 or more

What language do you usually speak at home or with friends?
○ English ○ Spanish ○ Something else ○ English & something else equally

What is your ethnic group? (MARK ONE OR MORE)
○ Hispanic or Latino ○ Black or African American ○ American Indian or Alaska Native
○ White, not Hispanic ○ Asian ○ Native Hawaiian or Other Pacific Islander

Thank you very much for filling out this questionnaire. Please take a minute to go back and fill in anything you may have skipped.

PLEASE DO NOT WRITE IN THIS AREA

240878

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Appendix G

Example of Lesson Topics

Sample Outline of Lesson Topics

Session	
1	The Behavioral Approach to Changing Eating and Exercise Habits
2	Healthy Food Choices
3	Physical Environment – Stimulus Control
4	Programmed Exercise
5	Understanding and Changing Coronary Heart Disease Risk Factors
6	Eating Patterns
7	Lifestyle Exercise
8	Changing the Quality of Your Diet
9	Eating Out in Restaurants
10	Thoughts and Weight Control
11	Exercising for Aerobic Fitness
12	High-Fiber Low-Fat Eating
13	Eating in Social Situations
14	Problem Solving
15	Barriers to Exercise
16	Recipe Modification
17	High Risk Situations
18	Assertion and Eating
19	Building Social Support
20	Incorporating Strength Training into Your Exercise Program
21	Motivation
22	Problem Solving Revisited
23	Getting Back on Track
24	Looking Forward

Appendix H

Example of Recruitment Flier

EXAMPLE OF RECRUITMENT FLIER

Research Subjects Needed for
Weight Loss Study

Are you 18-55 years of age?
Are you overweight and interested in losing weight?
Do you exercise less than 3 days per week and are you interested in becoming more active?

Women and Men who meet the above criteria and do not currently participate in a weight loss or exercise program may be eligible to participate in a 6-month study to examine strategies to achieve weight loss. This study is being conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. Eligible subjects will be compensated for their participation in this study.
Women who are pregnant are not eligible to participate in this study.

For more information please call 412-488-4172

Appendix I

Recruitment Form

RECRUITMENT FORM

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

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

   Investigators Component of Informed Consent: This study is being conducted by Dr. John M. Jakicic and colleagues at the University of Pittsburgh.
   Source of Support Component of Informed Consent: This study is sponsored by the School of Education.
   Description Component of Informed Consent: We are interested in recruiting 50 men and women to participate in this study. This study will focus on examining strategies for weight loss and the effect of weight loss on resting energy expenditure and body composition. To do this, eligible individuals will participate in a 6-month program that will assist you with changing your dietary habits and increasing your exercise. You will receive a weight loss program that includes changes in your diet and exercise. You will also attend group meetings weekly for 6 months. Please understand that these meetings will be held at the University of Pittsburgh in Southside, and meetings will start between 5:30 and 6:15 in the evening, and these will be held on (Day of Week to be determined). Individuals who are eligible to participate in this study will undergo assessments. These assessments will be completed before you start the study, 4 weeks after your initial assessments, and following at 12 and 24 weeks of participation I the weight loss program. In addition, eligible individuals will complete questionnaires about their exercise and other health-related behaviors before starting the study and following at 4, 8, 12, 16, 20 and 24 weeks of participation. Everyone will be paid $25 in the form of a check upon completion of the 4 week, 12-week and 24-week assessments which means that you can earn a total of $75 in incentives for your participation in this study.

   If you are interested in participating in this study, I will need to ask you a few questions about your demographic background and questions about your physical health and medical history to determine if you appear to be eligible to participate in this study. It will take approximately 5 minutes to ask you all of the questions. If we complete the interview, I will ask you for some specific information (your complete name, date of birth, and mailing address) so that we can contact you regarding your participation in this study. I will then schedule you to attend an orientation session that will explain all of the procedures of this study in greater detail. The average time to complete this Phone Screen is approximately 5 minutes."
   Risks and Benefits Component of Informed Consent: The only known risk to you for completing the Phone Screen is that it will take a few minutes of your time and you may experience disappointment if it is determined that you are not eligible to participate in the larger study. It is likely that you will experience one or both of these situations by completing this Phone Screen, which means that this occurs in more that 25% of people (more than 25 out of 100 people). The benefit of completing this Phone Screen is that you may be able to participate in the weight loss study that I described to you.
   Costs and Payments Component of Informed Consent: You will not incur any cost nor will you receive any payment for participating in the Phone Screen.

Confidentiality Component of Informed Consent: If your answer to a particular question tells me clearly that you will not be eligible for this study, I will stop the interview, and not ask you any more personal questions.
Right to Participate or Withdraw from Participation Component of Informed Consent: Your participation in this phone screen is voluntary. You may refuse to answer any of the questions asked. Your responses to these questions are confidential, and the information related to your health history or current behaviors that you are about to give me will be destroyed after this interview.

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

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

Phone Screen Interview

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

Verbal Assent was given to:_____
Signature

Date _____

Eligible based on telephone screening: □ Yes □ No

---

1. Gender: □Male □Female

2.a. Age: □□ **(18-55)** 2.b. Date of Birth: □□/□□/□□

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

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

4. Current Weight: □□□ pounds ***Office Use: BMI = _____(25-39.9 kg/m^2)***

5. Current Height: □feet □□inches

6. Are you able to walk for exercise? □ YES □ No
   If "no", specify reason: _____

7. Do you currently exercise regularly at least once per week at a moderate intensity for at least 20 minutes? □ Yes □ NO
   If "yes", How many days per week? _____
   If "yes", How long have you been exercising this way?_____

8. Have you ever been told by a doctor or other medical person that you have any of the following conditions? If "yes", Specify:
   a. Heart Disease □ Yes □ NO _____
   b. Angina □ Yes □ NO _____
   c. Hypertension □ Yes □ NO _____
   d. Heart Attack □ Yes □ NO _____
   e. Stroke □ Yes □ NO _____
   f. Diabetes (sugar) □ Yes □ NO _____
   g. Cancer □ Yes □ NO _____

9. Are you presently being treated by a doctor or other medical person for any other physical or psychological problems? □ Yes □ NO
   If "yes", specify: _____

10. Do you take any prescription medications (includes psychotropics)? □ Yes □NO
    If "yes", specify the following:

Medication Name	Used to Treat:

11. Are you taking any medications for the purpose of weight loss? □ Yes □ NO
    If "yes", specify: _____

12. Do you currently smoke? □ Yes □NO
    If "yes", specify: _____

13. Are you currently a member of another organized exercise or are you participating in an organized weight reduction program?
    θ Yes θ NO
    If "yes", specify: _____

14. Have you lost 10 or more pounds within the past year? □ Yes □ NO
    If "yes", specify number of pounds: ____Method used:_____

15. Are you currently participating in other research studies? □ Yes □ NO
    If "yes", specify: _____

16. Have you been a participant in a previous exercise or weight control study? □ Yes □NO
    If "yes", specify:_____

WOMEN ONLY COMPLETE THE FOLLOWING QUESTIONS

17. Are you currently pregnant? □ Yes □ NO
    A. Have you been pregnant in the last 6 months? □ Yes □ NO
    B. Do you plan on becoming pregnant in the next 6 months? □ Yes □ NO
    If "yes", specify: _____

18. Do you plan to spend any time out of town on vacation or business in the next 6 months that may affect your ability to attend weekly group meetings?
    □ Yes □ NO
    If "yes", specify: _____

18. Do you plan on relocating outside of the Greater Pittsburgh Area within the next 6 months?
    □ Yes □ NO
    If "yes", specify: _____

Contact Tracking Form (Stepped Care Study)

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

Date: _____/_____/_____ Staff Member Completing Form: _____

Name: _____

Street Address: _____

City: _____ State: ___ Zip Code:_____

Home Phone: _____ Work Phone: _____

OFFICE USE ONLY: Eligible: ☐ yes ☐No

Invited to Orientation: ☐ yes ☐No Date:____/____/____

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

PAGE 1 WILL BE RETAINED FOR DEMOGRAPHIC STATISTICS

PAGES 2-3 MUST BE SHREDDED AT THE CONCLUSION OF THIS INTERVIEW

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