COMPARISON OF SELF-MONITORING TECHNIQUES FOR TRACKING EATING AND EXERCISE BEHAVIORS

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COMPARISON OF SELF-MONITORING TECHNIQUES FOR TRACKING EATING AND EXERCISE BEHAVIORS

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Self-monitoring of eating and exercise behaviors has traditionally been done in a detailed manner. Finding ways to simplify this approach would decrease the time involved in the recording process, which may improve long-term adherence to tracking eating and exercise behaviors during weight loss. The purpose of this study was to investigate the effect of two self-monitoring methods for tracking eating and exercise behaviors within the context of a 16 week correspondence-based weight loss intervention.

Subjects for this investigation were forty-two overweight adult men and women, ages 21 to 45 with a BMI of 25 to 35 kg/m^2. Subjects were randomized to one of two self-monitoring conditions: 1) detailed self-monitoring (DSM) and 2) detailed self-monitoring transitioning to abbreviated self-monitoring (TSM). Participants in both groups recorded eating and exercise behaviors in diaries that were completed daily and returned to investigators each week for review. Participants in the DSM group recorded detailed information about the type, quantity, calories and fat grams of food consumed and type, duration, and rating of perceived exertion (RPE) of exercise. Participants in the transitional (TSM) group self-monitored eating and exercise behaviors using the detailed (DSM) approach during weeks 1-8, but *transitioned* to an abbreviated diary during weeks 9-16. This diary allowed participants to simplify self-monitoring by using check marks to estimate the quality and quantity of foods eaten, and amount of exercise

completed daily. Unlike the DSM group, specific details of eating and exercise were not recorded.

A repeated measures design was utilized for this study. The independent variable was type of self-monitoring. The primary dependent variable was completion of eating and exercise diaries; secondary dependent variables were body weight, dietary intake and physical activity. The major finding of this investigation was that both groups were similar with regard to the amount of weight lost, food diary completion scores and changes in eating and exercise behavior. Consequently, this study identified an alternative tracking method (i.e., TSM) that may be less effortful, and provides a similar outcome as detailed self-monitoring.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

To my parents,

Pete and Shirley Cifranick,

for always believing in me.

PREFACE

I would like to express my gratitude to the following people for assisting with the completion of my doctorate. First and foremost, I would like to thank my dissertation advisor, John Jakicic, Ph.D., for providing me the opportunity to work on this project, which was funded through his Physical Activity and Weight Management Research Center at the University of Pittsburgh. Dr. Jakicic generously shared his expertise and knowledge throughout this experience, and for that, I will be forever grateful. Thanks are extended to Amy Otto, Ph.D., Kara Gallagher, Ph.D., and Marsha Marcus, Ph.D. for their valuable input as dissertation committee members.

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1. INTRODUCTION AND RATIONALE

Obesity and overweight in the United States have reached epidemic proportions over the past 20 to 30 years. Surveys estimate 64.5 percent of U.S. adults are overweight (BMI 25.0-29.9 kg/m^2), while 31 percent of this same group is classified as obese (BMI $\geq$ 30.0 kg/m^2)[1]. Prevalence of extreme obesity (BMI $\geq$ 40 kg/m^2) has also increased from 0.78% to 2.2% over the past decade[2]. Obesity is considered to be a chronic disease and is a risk factor for many chronic disease conditions including cardiovascular disease, type 2 diabetes, hypertension, dyslipidemia and colon, breast, endometrial, cervical, ovarian, prostate, and gall bladder cancers[3-6]. In addition, obesity has been associated with increased mortality[7-9]. Beyond the physical effects, there are psychosocial consequences of being overweight or obese (e.g., prejudice, discrimination in employment opportunities and earnings, decreased health-related quality of life and negative body image)[10-12] as well as significant economic costs. Obesity is estimated to cost this nation greater than 100 billion dollars per year[13], and alarmingly, lifetime future costs of this disease are presently being compared to those for smoking[14, 15]. Consequently, these factors support and underscore the public health need to continue to identify and modify treatment approaches to overweight and obese conditions.

Many factors contribute to the development of overweight and obesity, and as such, treatment approaches include diet therapy, modification of physical activity patterns, behavior therapy techniques, pharmacotherapy, surgery, or combined therapy[6]. While research has determined that a traditional diet of 1000 to 1500 calories per day will promote weight loss in

most individuals[16-22], studies also report synergistically positive effects on weight management when exercise is added to a diet therapy approach[23]. Exercise has also been found to have health benefits independent of weight management[24-27]. Current physical activity guidelines recommend adults achieve a minimum of 30 minutes of moderate-intensity activity on most, preferably all days of the week to reduce the risk of chronic disease development[28]. However, recommendations for using exercise to promote weight loss or prevent weight regain are approximately 60 minutes of activity daily[29-31]. Individuals have been found to be more successful at losing weight via calorie reduction and exercise when these interventions are done in conjunction with behavior therapy[20, 32, 33].

When combining the effects of diet, physical activity and behavior therapies on weight management, self-monitoring of eating and exercise behaviors has been shown to be an effective strategy for improving weight loss outcome, therefore, it is an important component of behavioral weight management programs[16, 34]. When self-monitoring is not incorporated into a weight loss treatment plan, individuals fail to effectively self-regulate eating and exercise behaviors[34]. Studies that have examined the results of standard behavioral weight loss programs report participants who consistently track eating and exercise behaviors have greater weight loss than those who self-monitor less regularly[35]. However, programs traditionally have clients record these behaviors in great detail[16, 36] which can be a time-consuming process. Consequently, individuals find it difficult to maintain consistent eating and exercise records over time[34]. In addition, the forms used to monitor these behaviors can be complicated and cumbersome to use. While it is important to provide participants feedback on these behavioral records, if it is not frequent, consistent and/or immediate enough, individuals typically fail to continue the self-regulation process[34, 37-39].

Studies show that individuals must be actively engaged in the process of self-monitoring for effective self-regulation of behavior to occur[34]. Additional factors that interfere with active self-monitoring are those that disrupt a person's typical daily routine (e.g. travel, schedule changes, interpersonal conflicts, holidays, and celebrations)[36]. Although these barriers are unavoidable in most people's lives, when they appear in conjunction with an individual's attempt to monitor eating and exercise behaviors in a detailed and often cumbersome manner, the process may become a burden too great for most people to maintain. Consequently, identifying alternative tracking methods that help to simplify self-monitoring, while providing the same outcome effect, may improve long-term adherence to tracking eating and exercise behaviors during weight loss.

1.1. Statement of Problem

The purpose of this study was to investigate the utility of two self-monitoring techniques for tracking eating and exercise behaviors, as well as, determine the effect of these tracking techniques on body weight and eating and exercise behavior.

This study specifically examined the following:

Primary Aim:

1. To compare two different self-monitoring techniques for tracking eating and exercise behaviors (high detail and high detail transitioning to low detail) combined with weekly feedback on completion of eating and exercise records in overweight adults.

Secondary Aims:

1. To examine changes in body weight using two different self-monitoring techniques (high detail and high detail transitioning to low detail) for eating and exercise behaviors combined with weekly feedback in overweight adults.

2. To compare two different self-monitoring techniques (high detail and high detail transitioning to low detail) combined with weekly feedback on changes in eating behaviors in overweight adults.

3. To compare two different self-monitoring techniques (high detail and high detail transitioning to low detail) combined with weekly feedback on changes in exercise behaviors in overweight adults.

1.2. Hypotheses

1.2.1. Primary Hypothesis:

There will be a significantly greater completion of eating and exercise records in the transitional self-monitoring (TSM) group compared to the detailed self-monitoring (DSM) group.

1.2.2. Secondary Hypotheses:

1. There will be a significantly greater change in body weight in the transitional self-monitoring (TSM) group compared to the detailed self-monitoring (DSM) group.

2. There will be a significantly greater change in eating behavior in the transitional self-monitoring (TSM) group compared to the detailed self-monitoring (DSM) group.

3. There will be a significantly greater change in exercise behavior in the transitional self-monitoring (TSM) group compared to the detailed self-monitoring (DSM) group.

2. REVIEW OF THE LITERATURE

The primary purpose of this study was to investigate the effect of two self-monitoring techniques for tracking eating and exercise behaviors. Additionally, this study examined the impact of self-monitoring intensity on weight loss and eating and exercise behaviors in overweight adults. This chapter provides a review of the related literature supporting the significance and rationale of this proposed study.

2.1. Obesity and Overweight: Prevalence in the United States

The prevalence of overweight and obesity in the United States have consistently been increasing over the past 20 to 30 years based on estimates from national surveys[3]. Results from the National Health and Nutrition Examination Survey (NHANES) conducted between 1999-2000 indicate that 64.5 percent of U.S. adults, 20 years of age and older, are either overweight or obese[1, 3]. These estimates indicate that the prevalence of overweight has increased by approximately 8 percentage points compared to estimates from NHANES III[3] which was conducted between 1988-1994. Increasing trends have also been observed for obesity prevalence rates, with obesity rates doubling between NHANES II (1976-1980) and NHANES 1999-2000 from 15 percent to 31 percent respectively[1, 3]. These prevalence rates are illustrated in Figure 1. The increase in prevalence rates of overweight and obesity appear to be occurring in all age groups, genders, races and ethnicities; consequently public health concern is heightened over the implications of these events.

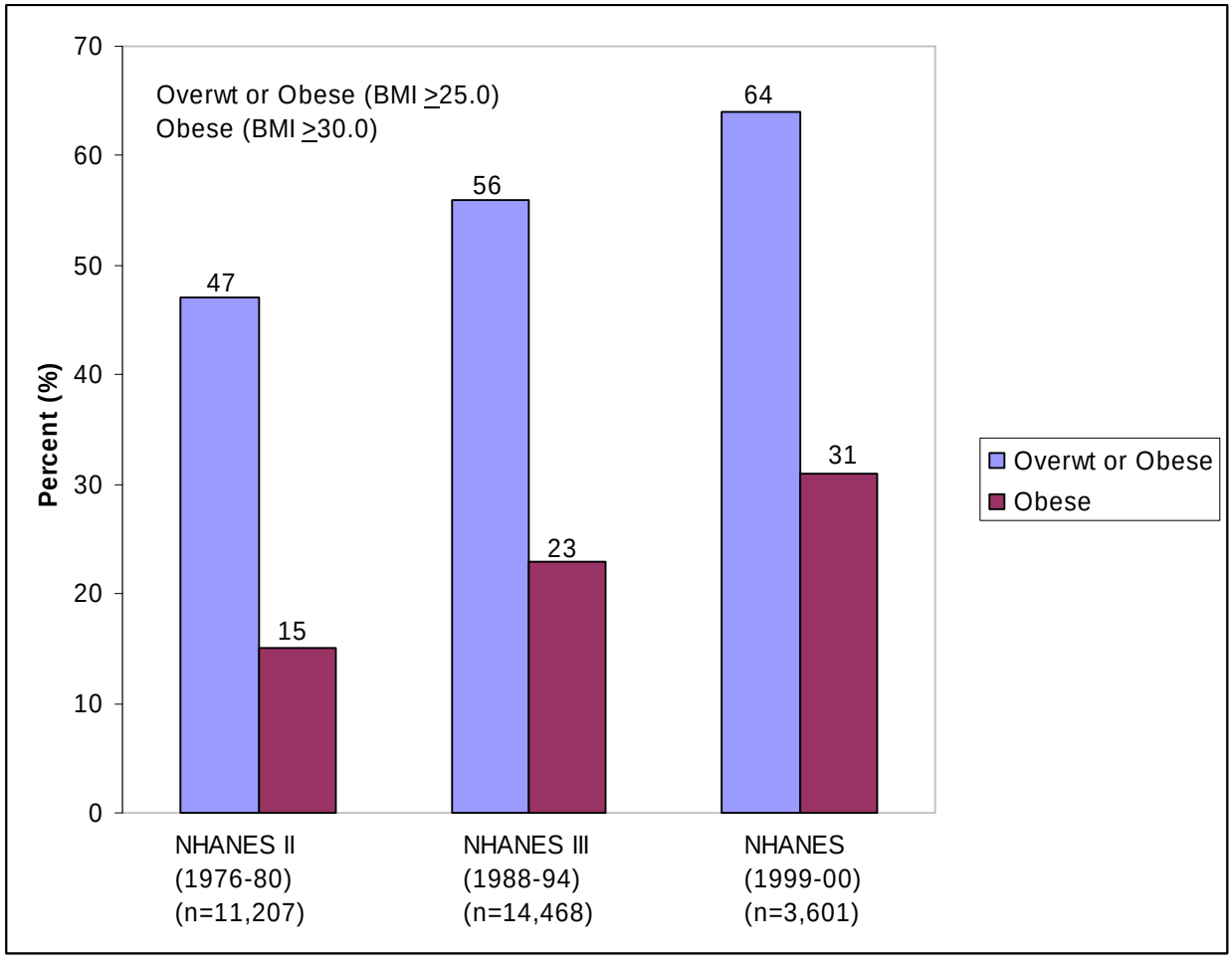

Figure 1: Prevalence of Overweight and Obesity Among US Adults, Age 20-74 Years

Adapted from Centers for Disease Control and Prevention website[40]

2.2. Defining Overweight and Obesity

Body mass index (BMI), also known as the Quetelet index, is commonly used as a measure of overweight and obesity. The BMI is computed by the following equation: BMI = (weight measured in kilograms) / (height measured in meters)^2. Body mass index is commonly used in research and clinical settings to classify individuals into underweight, normal weight, overweight, obese, and morbidly obese categories (see Table 1). These categories have been determined based on the J-shaped (see Figure 2) or U-shaped curves illustrating the relationship

between BMI and relative risk of morbidity and mortality[12, 41]. For example, it has been shown that relative risk for cardiovascular disease (CVD) increases concurrently with increasing BMI in all population groups[6]. Studies on overweight men (BMI 25.0 kg/m^2 to 29.9 kg/m^2) and overweight and obese women (BMI ≥29.0 kg/m^2) reported the relative risk of developing coronary heart disease (CHD) was 1.7 (95% confidence interval (CI) 1.10-2.69) and 1.5 (95% CI 1.1-2.1) respectively, when compared with normal weight peers[42, 43]. In men, the relative risk for CHD increased to 2.6 (95% CI 1.54-4.42) at BMIs of 29.0 to 32.9 kg/m^2 and 3.4 (95% CI 1.67-7.09) at BMIs of ≥33 kg/m^2 when compared to men with BMIs <23.0 kg/m^2[43]. Gray[41] found similar results when assessing the relation between BMI and incidence of CHD as well as other common conditions caused by excess body fat (refer to Figure 2).

Table 1: Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risks

			-	-
			-	-

Note: Adapted from NHLBI Clinical Guidelines[6]
[a]Disease risk for type 2 diabetes, hypertension, and CVD.
[b]Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

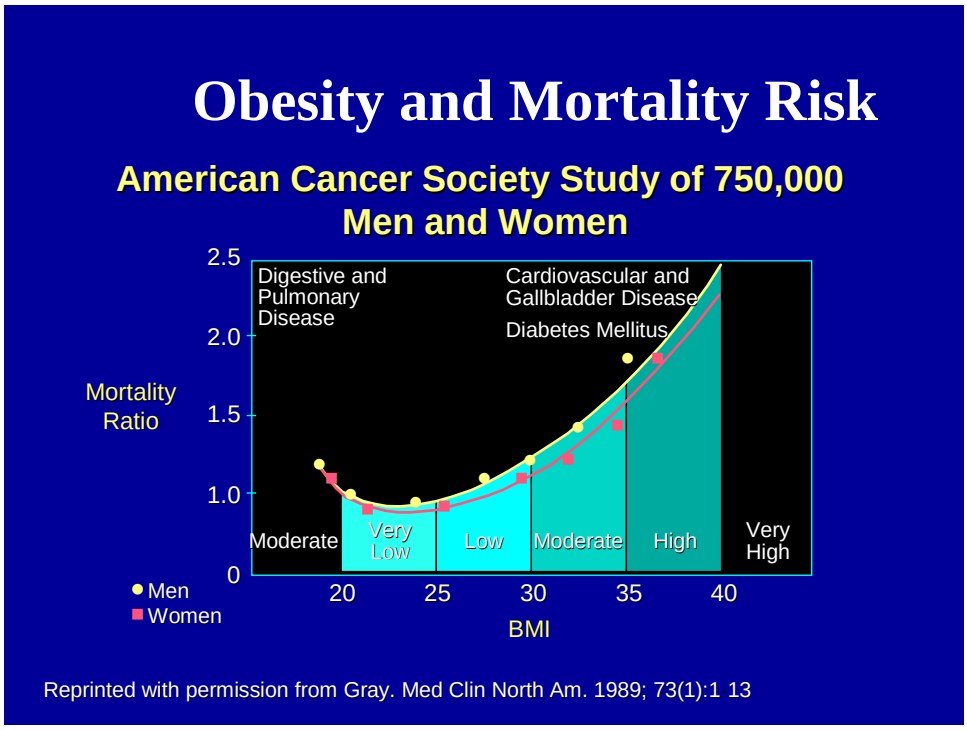

Figure 2: Obesity and Mortality Risk

The impact of excess body weight on health-related outcomes may be further influenced by the distribution of body fatness. Central fat distribution (i.e., abdominal fat deposition), independent of fat storage in other anatomical sites of the body, increases the risk for chronic disease and premature death[44]. Traditionally waist-to-hip ratio (WHR), the circumference of the waist divided by that of the hip, has been used to estimate body fat distribution and overall health risk. More specifically, health risk is considered to be very high when WHR exceeds 0.80 in women and 0.95 in men[45]. However, recently the focus has shifted to measuring waist circumference alone to predict health risk because it relates more strongly to direct measures of abdominal fat accumulation[6, 44]. A high waist circumference is an independent predictor of risk over and above that of BMI for type 2 diabetes, dyslipidemia, hypertension and CVD in people with a BMI between 25 and 34.9 kg/m^2[6]. For example, women with a waist

circumference exceeding 30 inches have twice the risk of developing coronary heart disease when compared to their slimmer peers[45]. The sex-specific waist circumference cut points, which indicate an increase in relative risk, are defined in Table 1. Note however, at very high BMIs ($\geq$35 kg/m^2) waist circumference has little added power of predicting chronic disease risk beyond that of BMI because, in these individuals, waist circumference is usually greater than the cut points noted in Table 1.

2.3. Public Health Implications of Overweight and Obesity

Obesity is considered to be a chronic disease with major public health implications[4]that may increase mortality[7]. It is estimated that approximately 300,000 annual deaths in the United States are associated with overweight and obesity [11]. For example, women enrolled in the prospective Nurses' Health Study had an increase in mortality with weight gains of 10 kg or more since the age of 18; more specifically, those with the highest BMI ($\geq$32 kg/m^2) had the highest relative risk (RR) of death (RR, 2.2; 95% CI, 1.4 to 3.4) when compared to women at normal weights[7]. In another prospective study of more than 1 million adults in the United States[46], Calle et al. found the highest mortality rates among the heaviest women (RR, 1.89; 95% CI , 1.62 to 2.21). This association between increased mortality and increased body weight has also been observed in men. In the same study by Calle et al., the heaviest men had the highest relative risk of death (RR, 2.68; 95% CI, 1.76 to 4.08)[46]. Similarly, body weight and mortality were directly related in a study that followed middle-aged men for 27 years. Results of the least biased analyses, which focused on men who never smoked, found the heaviest group had 1.67 times (95% CI, 1.29 to 2.17) the mortality risk of the lightest group[47]. These associations between increased body weight and mortality may be a result of the increase in

numerous chronic diseases and risk factors that are prevalent in overweight and obese individuals.

2.3.1. Coronary Heart Disease

It has been clearly demonstrated that an increase in body weight is associated with an increase in coronary heart disease. Moreover, the relative risk for cardiovascular disease (CVD) risk factors and CVD incidence increases concomitantly with increasing BMI in all population groups[6]. Manson et al. reported that higher body weights in women participating in the Nurses' Health Study were associated with an increased risk of developing coronary heart disease[7, 48]. Among women with the highest body weights (i.e., BMI $\geq$32 kg/m^2), who had never smoked, the relative risk of death from cardiovascular disease was 4.1 (95% CI, 2.1 to 7.7) when compared with the risk of women with BMIs below 19 kg/m^2[7]. Another study by Calle et al. found the risk of death from cardiovascular disease to be significantly increased at any BMI >25 kg/m^2 in women. The same study also found high body weights (i.e., BMI >26.5 kg/m^2) in men to be the most predictive of death from cardiovascular disease (RR, 2.9; 95% CI, 2.37 to 3.56)[46]. In a large prospective study examining the relation between weight and subsequent risk of coronary heart disease, incidence of disease increased progressively with increasing body mass index[49]. After age and lifestyle factors were adjusted, men with BMIs $\geq$30 kg/m^2 had twice the risk (RR, 2.09; 95% CI, 1.45 to 3.03) of the normal weight reference group (BMI 20 to 21.9 kg/m^2) of developing coronary heart disease. The above findings underscore the potential impact of excess body weight on the development of coronary heart disease in overweight and obese individuals.

The link between excess body weight and coronary heart disease may be a result of the increase in traditional coronary heart disease risk factors being present in overweight and obese

adults. These risk factors may include hypertension, dyslipidemia (i.e., hypercholesterolemia, hypertriglyceridemia, decreased high-density lipoprotein cholesterol and increased low-density lipoprotein cholesterol), hyperglycemia and hyperinsulinemia[6, 50-52]. Using data from NHANES II, Van Itallie investigated the relationship between overweight and hypertension, elevated cholesterol and diabetes, and found all three conditions to be more common in overweight individuals than in those who are not overweight[53]. A summary of these findings is presented in Table 2.

Table 2: Summary of the Relative Risk of Hypertension, Hypercholesterolemia and Diabetes for Overweight Adults

Age Range (yrs)	Hypertension	Hypercholesterolemia	Diabetes Mellitus
20-75	2.9	1.5	2.9
20-45	5.6	2.1	3.8
45-75	1.9	1.1	2.1

*95% CI not available

A direct and independent relationship between blood pressure and weight has been shown in a substantial number of well-designed studies. Data from NHANES II revealed overweight adults are 2.9 times more likely to have hypertension than non-overweight adults[53]. Using NHANES III data, Brown et al.[54] found men (age 29 to 39 years) to have a 7-fold increase in the prevalence of high blood pressure at the highest BMI ($\geq$30 kg/m^2) and women (<60 years of age) to have a 2- to 4-fold increase at BMIs of $\geq$27 kg/m^2 when compared to the lowest (<25 kg/m^2) BMI categories. A large international study demonstrated that a 10 kg higher body weight translated to an estimated 12 percent increased risk for coronary heart disease[55].

More recent summaries of evidence from a substantial number of randomized controlled trials recommend weight loss to lower elevated blood pressure, elevated blood glucose levels,

elevated levels of total cholesterol, LDL-cholesterol and triglycerides, and raise low levels of HDL-cholesterol[6].

2.3.2. Type 2 Diabetes Mellitus

In recent years there has been an increase in the prevalence of type 2 diabetes mellitus[56-59], and excess body weight may contribute to this increasing prevalence rate. For example, results from the Behavioral Risk Factor Surveillance System (BRFSS) found prevalence of diabetes increased by approximately 9 percent for every kilogram increase in self-reported body weight; moreover, a significant correlation was found between the prevalence of obesity and diabetes ($r = 0.64$, $P < 0.001$)[60]. Studies on both men[49, 52, 61, 62] and women[63-65] have found type 2 diabetes development to be associated with weight gain after the age of 18 years.

Colditz et al. studied a large cohort of women enrolled in the Nurses' Health Study and found BMI to be the primary predictor of risk for diabetes[64]. Compared to women with consistent weight (i.e., gain/loss of <5 kg), and after adjusting for age and BMI at the age of 18 years, the relative risk (and 95% CI) for diabetes in women with weight gains of 5.0 to 7.9 kg, 8.0 to 10.9 kg, and 20 kg or more was 1.9 (CI 1.5 to 2.3), 2.7 (CI 2.1 to 3.3), and 12.3 (CI 10.9 to 13.8) respectively. In comparison, women in this study who lost more than 5.0 kg reduced their risk for diabetes by 50% or more. Hu et al.[65] followed female nurses for 16 years and determined, in this population, 61 percent of the cases of type 2 diabetes could be attributed to overweight (BMI $\geq$25 kg/m^2). More specifically, the relative risk for type 2 diabetes was 38.8 (95% CI, 31.9 to 47.2) for women with a BMI of 35.0 kg/m^2 or higher, 20.1 (95% CI, 16.6 to 24.4) for those with a BMI of 30.0 to 34.9 kg/m^2, and 7.59 (95% CI, 6.27 to 9.19) for women

with a BMI of 25.0 to 29.9 kg/m^2 when compared to women having a BMI of less than 23.0 kg/m^2[65].

Likewise, BMI was the dominant risk factor for diabetes in three studies done on men. Perry et al. found the risk of type 2 diabetes increased rapidly as BMI increased; relative risk was 11.6 (95% CI, 5.4 to 16.8) at a BMI of 27.9 kg/m^2 or higher when compared to men with a BMI of 22.9 kg/m^2 or lower[61]. Similarly, Chan et al. found men with BMIs between 31.0 to 32.9 kg/m^2 had a relative risk of 11.6 (95% CI, 6.3 to 21.5) compared to men with BMIs less than 23.0 kg/m^2, however, at BMIs between 33.0 to 34.9 and ≥35 kg/m^2, relative risk of type 2 diabetes increased to 21.3 (95% CI, 11.4 to 41.2) and 42.1(95% CI, 22.0 to 80.6) respectively[62]. Shaper et al. found similar results, noting significant increases in relative risk for diabetes at BMIs of 26 kg/m^2 or higher[49] (see Table 3).

Table 3: Summary of the Relative Risk of Diabetes for Adult Men

Body Mass Index (kg/m^2)	***Adjusted Relative Risk (95% CI†)**
20	1.00
22	1.12 (0.49 to 2.55)
24	1.83 (0.86 to 3.91)
26	3.58 (1.71 to 7.49)
28	5.20 (2.44 to 11.04)
30	9.68 (4.60 to 20.39)

***Adjusted for age, smoking, social class, alcohol intake, and physical activity.**
†Confidence Interval

Obesity is also associated with diabetes risk factors[66]. Metabolic studies suggest that obesity and upper body fat distribution are associated with hyperinsulinemia, insulin resistance and impaired glucose tolerance[52, 59, 62, 67-69]. Both relative body weight and waist hip ratio (WHR) were independent predictors of fasting glucose in a study of premenopausal women. Increasing WHR was linked to increasing fasting plasma insulin levels ($r = 0.47$, $P < 0.001$) and

insulin and glucose levels after a glucose challenge ($r = 0.53$, $P < 0.001$; $r = 0.50$, $P < 0.001$, respectively). Obesity level was similarly correlated with these metabolic markers[70]. The association between obesity, upper body fat distribution, and hyperglycemia in the presence of hyperinsulinemia reflects insulin resistance[68]. Analysis from six prospective studies found obesity, including BMI and central adiposity, to be a strong predictor in the progression from impaired glucose tolerance to diabetes[71].

2.3.3. Cancer

There has been an increase in scientific evidence supporting the association between excess body weight and cancer. These cancers may include colon, breast, endometrial, cervical, ovarian, prostate and gall bladder[3-6, 14, 72, 73]. Lew et al.[72] used the findings from a large-scale investigation conducted by the American Cancer Society to examine variations in mortality by weight among 750,000 men and women; results found relative mortality from cancer increased steadily with increasing overweight. For men, mortality rates increased from 131% for those 20% overweight, to 154% for men 40% overweight, and to an estimated 185% for men 50% overweight; similar results were found among overweight women. In addition, men and women who were 40% or more overweight had a respective 33% and 55% higher mortality rate from cancer. Another study examining the relationship between overweight and cancer found higher mortality rates from colorectal and prostate cancers in overweight men while significantly higher mortality rates were found in overweight women from cancer of the gall bladder, breast, cervix, endometrium, uterus and ovary[74]. Table 4 summarizes the weight index categories and respective mortality ratios for these forms of cancer.

Table 4: Mortality Ratios for Cancer Sites at Which Incidence of Overweight is Greater Than Average Weight [73]

Site of Cancer	Percent of Recommended Body Weight			
	110% - 119%	120% - 129%	130% - 139%	140% +
MALE				
Colon, rectum	- - - - - - - - - -	- - - - - - - - - -	1.53	1.73
Prostate	- - - - - - - - - -	1.37	1.33	1.29
FEMALE				
Endometrium	1.36	1.85	2.30	5.42
Uterus	- - - - - - - - - -	1.81	1.40	4.65
Cervix	- - - - - - - - - -	1.51	1.42	2.39
Ovary	- - - - - - - - - -	- - - - - - - - - -	- - - - - - - - - -	1.63
Gall bladder	1.59	1.74	1.80	3.58
Breast	- - - - - - - - - -	- - - - - - - - - -	- - - - - - - - - -	1.53

*95% CI not available

2.3.4. Additional Health Complications

Excess body weight has also been associated with other health-related conditions which include sleep apnea, chronic hypoxia and hypercapnia, gallbladder disease, degenerative joint disease and the exacerbation of osteoarthritis [5, 75].

Obesity contributes to the development of obstructive sleep apnea (OSA) by increasing the propensity for upper-airway obstruction, indirectly caused by the deposition of adipose tissue in the pharynx[76]. In turn, the amount of adipose tissue correlates with the severity of OSA. Millman et al. studied female subjects with obstructive sleep apnea (OSA) and found them to have higher BMIs and a greater degree of body fat when compared with NHANES I and II normative data. Findings revealed a significant correlation between the apnea hypopnea index (which measures frequency of episodes of apnea and hypopnea per hour of sleep) and BMI, triceps skinfold, subscapular skinfold, sum of skinfolds and waist circumference (see Table 5)[77]. Obesity is also a significant ($p < 0.001$) risk factor for sleep apnea in men. Table 6 shows the odds ratios (OR) estimating the increased risk of sleep-disordered breathing for

various measures of body habitus in men; note that a single standard deviation (SD) increase in any standard measure reflects at least a 3-fold increase in the occurrence of OSA[78].

Table 5: Correlation of severity of OSA with body fat distribution

	Apnea Hypopnea Index*
BMI, kg/m^2	0.41†
Triceps Skinfold	0.44†
Subscapular Skinfold	0.47†
Sum Skinfold	0.47†
Waist Circumference	0.42†
Waist Hip Ratio	0.18

*These numbers represent *r* values.
† $p \leq 0.05$

Table 6: Odds Ratios for Sleep-Disordered Breathing* and Anthropometric Measures in Men

Measure	**Standard Deviation (SD) of Covariate**	**Odds Ratio** for a 1-SD† Increment in Covariate**	**95% Confidence Interval**
BMI (kg/m^2)	5.67	4.17	2.89-6.04
Girth (cm)			
Waist	15.29	4.12	2.91-5.83
Hip	12.65	3.86	2.71-5.53
Waist Hip Ratio	0.09	3.41	2.27-5.13
Skinfolds (mm)			
Bicep	6.76	2.76	2.02-3.77
Tricep	7.43	2.49	1.85-3.34

*Defined as an apnea-hypopnea score of 5 or higher
**Odds Ratios for comparison with subjects whose apnea-hypopnea scores were below 5.
†Adjusted for sampling design

The association between obesity and gallbladder disease has been documented in several studies[79-83]. In an autopsy study, Sturdevant and colleagues found 43% of the men who were 9.1 kg or more overweight had gallstones. In comparison, only 16% of the normal weight men had stones[80]. Willet et al.[83] found the risk of gallbladder disease to be 2 to 3 times as high

in both men and women with a BMI of 26 kg/m^2 when compared to the leanest group. A study by Stampfer and colleagues[81] revealed a strong linear relationship between BMI and incidence of gallstones; women with a BMI greater than 45 kg/m^2 had a 7-fold risk (RR, 7.36; 95% CI, 5.28 to 10.26) compared to women with a BMI less than 24 kg/m^2 . These findings were similar to data from a large cohort of women which found those with a mean BMI of 38.3 kg/m^2 had an estimated incidence of gallbladder disease 2 to 6.25-fold higher (depending on age) than women with a mean BMI of 23.0 kg/m^2[82].

Excessive weight causes additional strain on the joints which can lead to degenerative joint disease[12]. Obesity is a primary risk factor for the development of osteoarthritis (OA) in the knee, hands[84] and hips[85]. While the association of weight with hip and hand OA is not as strong or consistent across studies, population-based investigations consistently show that overweight persons are at higher risk of knee OA than non-overweight controls[85]. Data from NHANES I found obese women (BMI >30 to ≤35 kg/m^2) had a much higher rate of OA [RR, 3.87 (95% CI 2.63 to 5.68)] than their normal weight peers. This risk increased to 4.8 (95% CI 2.77 to 8.27) for men in the same overweight category (BMI >30 to ≤35 kg/m^2) compared to men of normal weight[86]. In a study of twins, those who had OA of the knee were 3 to 5 kg heavier than their twin counterparts with no OA disease. Furthermore, significant increases of 9 to 13% in risk of developing OA were observed for every kilogram increase in body weight[84]. Hochberg et al. confirmed that both men and women in the highest BMI category had significantly increased odds [OR = 2.40 (95% CI 1.32 to 4.35) and OR = 4.34 (95% CI 1.89 to 9.98), respectively] of established knee OA[87].

2.3.5. Economic Cost

In addition to the direct impact of overweight and obesity on health-related parameters, excess body weight also has a significant economic impact on society. It has been estimated that obesity costs the United States approximately 117 billion dollars annually in direct and indirect costs[13]. Direct cost is defined as the cost of treating a health condition related to overweight and obesity, with indirect costs including items such as lost wages or lost productivity resulting from the development of overweight and obesity. It also appears that these costs will continue to increase; Gorsky et al. predict that adverse health effects of obesity in middle-aged adults will increase by 16 billion dollars over the next 25 years[88].

2.4. Treatment Approaches/Interventions

While there appears to be undisputed agreement in the scientific community regarding the health risks of overweight and obesity, there is less agreement on strategies for treating them. Treatment approaches for the management of overweight and/or obesity include dietary therapy, modifying physical activity patterns, behavior therapy techniques, pharmacotherapy, surgery or combined therapy [6]. This literature review will investigate the combined effects of diet, exercise and behavior therapies on the overall management of weight.

2.5. Dietary Considerations for Weight Control

2.5.1. Energy Intake

The National Institutes of Health recommend weight loss in any adult with a BMI $\geq$25 kg/m^2[32]. A review of the literature on body weight reveals energy intake reduction plays a significant role in the promotion of weight loss. Wadden states that initial therapy for significantly overweight persons should include a traditional diet of 1000 to 1500 calories per

day combined with a program of lifestyle modification[16]. A similar calorie range is frequently used by other researchers[17-22], as well as commercial weight loss programs across the country. The diet should create a deficit of 500 to 1,000 calories per day to promote a 1 to 2 pound weight loss per week[32]. There is no evidence to date that a faster rate of weight loss will improve long-term outcomes[33]. Thirty-four randomized calorie controlled diet trials reported weight losses when subjects received 1000 to 1200 calories per day[6]. In addition, the provision of structured meal plans prescribing what subjects should consume at each meal, have been shown to result in significantly greater weight loss[18].

2.5.2. Macronutrient composition

Over the years there has been a proliferation of diet programs recommending various combinations of macronutrient compositions for weight loss. The most conventional dietary approach to weight control, recommended by leading research and health professions, is a high-carbohydrate (55-60% total calories), reduced-fat (20-30% total calories), energy-deficit diet[32, 89, 90]. Such diets have a long history of use and have been studied extensively[6]. The overall goal of this diet is to provide sufficient food choices, allowing for nutritional adequacy and compliance, while producing a slow, but steady rate of weight loss[91]. Although low fat diets without targeted calorie restriction have been shown to promote weight loss[32, 92, 93], weight reduction is greatest when calorie restriction is combined with a low fat diet[32, 94-96].

Low-carbohydrate, high-protein, high-fat diets have become increasingly popular over recent years despite a scarcity of scientific evidence supporting their advantage over conventional diets for weight loss[97]. Currently, there are more studies that refute the claim that low-carbohydrate diets, in the absence of calorie restriction, have a metabolic advantage over low-fat diets[91]. Alford et al. examined the effect of varying levels of carbohydrate (25%,

45% and 75%) content in subjects following a 1200 calorie diet for 10 weeks[98]. Results indicated weight loss occurred in all groups with no significant differences in weight loss among the groups. Golay et al.[99] found mean weight loss to be similar between groups receiving diets equally low in energy (1200 calories) but with varying levels of carbohydrate (25% vs 45%), during a 12 week period. More recently, three research teams conducted studies of longer duration, 6 months[100, 101] to 1 year[102], to compare very low-carbohydrate diets with calorie-restricted low-fat diets on body weight. All three study findings were consistent; more weight was lost by subjects on the low-carbohydrate diet at 6 months. However, Foster and colleagues found the weight difference between the low-fat and low-carbohydrate diet groups disappeared at 12 months[102]. In all but one of these studies[100], the researchers attributed the greater weight loss to be due to a larger reduction in overall calorie intake, rather than a direct effect of macronutrient composition. Upon review of the scientific literature on various types of weight loss diets, Freedman et al. make a similar conclusion; diets that reduce calorie intake result in weight loss, irrespective of macronutrient composition[91]. Overall, studies suggest that specific changes in macronutrient composition impact body weight by ultimately decreasing total energy intake.

Over the past decade, it is unclear whether Americans have increased total energy intake while making little change in overall activity patterns[103] or decreased activity with no change in energy intake[104, 105]. One thing that remains clear is that physical activity plays a role in the etiology and treatment of overweight and obesity. Research studies indicate synergistically positive effects on weight control when exercise is added to a conventional high-carbohydrate, reduced-fat, energy-deficit diet[23]. This underscores the need to address energy intake, as well as, energy expenditure during treatment.

2.6. Exercise Considerations for Weight Control

Earlier treatments of obesity focused solely on diet interventions, yet more recent studies have found exercise to enhance weight loss at all time points. Results of two studies that compared diet without versus diet with an exercise component, found the addition of exercise improved weight loss in both the short- and long-term[106, 107]. It should be noted however, that physical activity alone has only slight effects on weight loss[105]. A meta-analysis of the past 25 years of weight loss research compared programs consisting of 21 weeks of aerobic exercise versus 15 weeks of calorie restriction and found weight losses to be 2.9 kg and 11 kg, respectively[108]. Clearly, the impact of physical activity and exercise on weight loss is modest. Research generally shows that adding mild to moderate exercise to diet therapy does not significantly add to the amount of initial weight lost[20, 109]. However, studies reveal that weight loss programs that include exercise consistently result in less weight regain during the maintenance phase[20, 22, 23, 32, 106, 109]. Consequently, sustained exercise appears to be most helpful in preventing or slowing the regaining of weight following initial treatment.

Data from the National Weight Control Registry (NWCR) further supports this notion. Individuals within this registry have lost at least 30 pounds and have been successful at maintaining a required minimum weight loss of 13.6 kg for 5 years; those successful at maintaining their weight are said to average 2800 calories per week of physical activity [110, 111]. Moreover, McGuire and colleagues[112] found individuals in this registry who regain weight report a decrease in energy expenditure, via physical activity, of 1000 calories per week in addition to an increased intake of dietary fat.

When emphasizing the use of physical activity to promote weight loss, programs typically recommend participants gradually reach an energy expenditure goal of 1000 calories

per week in activity (i.e., total of 10 miles per week)[20, 22, 32, 113]. For example, during the initial weeks of treatment, an individual can start by walking at a moderate intensity (e.g.: 55% maximum heart rate) for 100 minutes per week (i.e., total of 5 miles per week), then increase to 150 minutes per week at a slightly higher intensity (e.g.: 70% maximum heart rate), and finally increase to 200 minutes per week (i.e., total of 10 miles per week) of more intense walking (e.g.: 80% maximum heart rate). Ratings of perceived exertion (RPE) can also be utilized to monitor exercise intensity.

While exercise intensity has been found to affect a magnitude of change in cardiorespiratory fitness[31, 114], it has not been shown to produce differential effects on body weight[21, 114]. Duncan et al. manipulated walking intensity in women over a 24 week period (strolling vs. brisk walking vs. aerobic walking) but kept the amount of walking the same across groups. Results revealed intensity of exercise had a linear, dose-response effect on $VO_{2\ max}$ across all walking groups; aerobic walkers had the greatest increase in $VO_{2\ max}$ (+5.0 mL/kg per minute), brisk walkers had moderate increases (+3.0 mL/kg per minute) and strollers had only minimal increases (+1.4 mL/kg per minute). However, intensity of the exercise had no effect on body weight over the 24 week period. Jakicic and colleagues[21] found similar results when comparing the effects of different durations and intensities of exercise on weight loss and cardiorespiratory fitness over 12 months. Findings revealed larger amounts of exercise (longer duration) were associated with a greater magnitude of weight loss (difference was not statistically significant), but higher intensity exercise did not significantly increase weight loss. This suggests that energy expenditure, rather than exercise intensity, is important for changes in body weight[21].

Although the energy expenditure goal of 1000 calories per week is considered to be standard treatment for many weight loss programs, and public health recommendations[28, 115, 116] for physical activity suggest a minimum of 30 minutes of moderate-intensity physical activity on most, preferably all, days of the week (i.e., minimum of 150 minutes per week), studies show higher levels of physical activity may be necessary for controlling body weight. Jakicic et al. found subjects who exercised *more than* 200 minutes per week had greater weight losses over those exercising 150 to 200 minutes or less than 150 minutes[17]. More recently, Jakicic and colleagues found women exercising 200 minutes or more per week lost significantly more weight than those exercising less than 150 minutes per week or those exercising inconsistently[21]. The consensus statement of the International Association for the Study of Obesity (IASO) recommends moderate-intensity activity of approximately 45 to 60 minutes per day to prevent individuals from becoming overweight or obese[29], while the Institute of Medicine[30] recommends a minimum of 60 minutes of exercise per day on most days of the week to maintain or control body weight. Moreover, Schoeller et al.[117] found 80 minutes per day (approximately 400 minutes per week) of moderate-intensity exercise was necessary for long-term weight maintenance. According to the American College of Sports Medicine (ACSM) there is a dose-response to exercise, whereby greater health and fitness benefits are derived from higher energy expenditures. This "dose continuum" is said to range from 700 to 2000-plus calories of energy expenditure per week[31]. A recent study by Donnelly et al. set a minimum energy expenditure goal of 2000 calories per week which resulted in weight gain prevention in young women and weight reduction in young men[118]. Two studies by Jeffery and colleagues[22, 113] found that subjects exercising at a 2500 calorie per week activity level had the best long-term weight loss. While these data support the notion of an "exercise dose

continuum"[31], they clearly point out that research has yet to determine the optimal amount of exercise needed for long-term weight loss/maintenance.

Exercise has also been found to have health benefits independent of body weight. In a study by Barlow and colleagues[24], moderate and high fit men in the highest BMI categories (27-30 kg/m^2 and >30 kg/m^2) had lower mortality rates than their low fit counterparts. Similarly, Wei et al. found low fitness to be an independent predictor of mortality in all body mass index groups after adjusting for other predictors of mortality[25]. In a study by Lee and colleagues[26], unfit lean men had a 2-fold risk (RR, 2.07; 95% CI, 1.16 to 3.69) of all-cause mortality when compared to fit, lean men (RR,1.0) and fit, obese men (RR, 0.92; 95% CI, 0.65 to 1.31). Similar observations were noted with regard to mortality from cardiovascular disease; relative risk of death in fit obese men was 1.35 (95% CI, 0.66 to 2.76) compared to 3.16 (95% CI, 1.12 to 8.92) in unfit lean men. Farrell and colleagues[27] did a similar study on women and found moderately fit (RR, 0.48; 95% CI 0.34 to 0.68) and highly fit (RR, 0.57; 95% CI, 0.40 to 0.82) women had a significantly lower risk of mortality ($p = 0.002$) then low fit women (RR, 1.0). These studies indicate that fit individuals have greater longevity than their unfit counterparts irrespective of weight status. However, it remains that individuals with BMIs ≥ 25 kg/m^2 should attempt to reduce body weight by a minimum of 5 to 10% to reduce overall risk of chronic disease[33].

2.7. Behavior Therapy

Weight loss programs can improve long-term outcomes by using a behavior therapy approach[33]. Behavior therapy for weight loss refers to a set of principles and techniques used to help individuals adopt new eating, activity and thinking habits[119]. Behavioral treatment for the obese individual originated in 1967 with Stuart's belief that "only two common

characteristics have been observed in obese persons: a tendency to overeat and a tendency to under-exercise"[120]. While some studies support this oversimplified belief, others acknowledge the complexity of the etiology of obesity, pointing not only to the individual but also to biological and environmental determinants[121]. Even so, most of the treatment approaches for obesity are primarily aimed at modifying energy intake, energy expenditure, or both[16]. Hundreds of studies since the sixties have examined the efficacy of behavior therapy for obesity (i.e., the teaching of a new set of behaviors with which to control weight) and shown it to be more effective than other conventional approaches[16, 120]. Behavior therapy stems from the Learning Theory which assumes eating and exercise behaviors have a learned component[20], thereby providing individuals with strategies for overcoming barriers to diet and physical activity compliance by teaching new or modified behaviors. Behavioral treatment examines the consequences (i.e., reinforcement) of eating and physical activity; behaviors with pleasant consequences are likely to be repeated while behaviors that produce negative results are less likely to be practiced on a regular basis[20, 122]. Randomized trials indicate that behavior therapy, when combined with other weight loss approaches, provides the additional benefit of reinforcing changes in diet and physical activity that produce weight loss in obese individuals. The most successful therapy for both weight loss and maintenance is thought to be a combination of behavior therapy, reduced calorie intake and increased physical activity[20, 32].

Long-term follow-up of persons receiving behavior therapy for weight loss indicates cessation of continued behavioral intervention results in weight gain in most individuals. Consequently, long term success in weight control requires that the individual learn a new set of behaviors[6, 23].

2.8. Behavioral Treatment of Weight

In a review of twenty-two randomized controlled trials comparing behavioral treatment methods, no one method was found to be superior to any other with regard to its effect on weight loss. However, interventions that utilized several behavioral strategies appeared to effect the greatest loss in weight[6]. Behavioral treatment for weight loss may include components such as problem-solving, relapse therapy, social support, goal setting, stimulus control, and self-monitoring of eating and exercise behaviors.

2.8.1. Problem-Solving

Problem- solving helps individuals identify solutions to current, past, or future problems related to eating and exercise, and as such, is a useful behavioral component of weight control. It is typically broken down into three main steps: 1) defining the problem, 2) brainstorming possible solutions, and 3) implementing one of the solutions. Problem-solving efforts help the overweight individual navigate the obstacles that impede successful weight management. Studies by Perri et al. support the benefits of a problem-solving approach to weight control [123-126]. One study in particular [126] found individuals receiving problem-solving therapy (PST) in addition to standard behavior therapy (BT) had significantly greater long-term weight loss than individuals receiving standard behavior therapy alone (10.8 kg vs. 4.1 kg respectively). In addition, individuals in the PST group achieved clinically significant losses of 10% or more in body wt when compared to the BT group (35% vs. 6% respectively).

2.8.2. Relapse Therapy

Relapse therapy teaches individuals a set of skills that can be used to overcome setbacks and sustain behavioral changes necessary for weight control. Strategies include frequent therapist contact, problem-solving, structured meal plans, self-monitoring, anticipating high-risk

situations and cognitive restructuring (i.e., stopping negative thoughts such as, “I’m a failure”, “I blew it”, “Why even try”). Grilo et al.[127] examined situational antecedents of relapse episodes and how dieters cope with temptations to overeat. Findings revealed cognitive and behavioral relapse coping responses to be equally associated with positive outcomes. Baum et al [128] found relapse therapy to be effective in long-term weight management: following behavioral treatment, participants in a minimal-contact group experienced significant weight regain, while those receiving relapse therapy combined with post-treatment therapist contacts maintained end-of-treatment weight losses.

2.8.3. Social Support

Studies suggest that social support may improve long-term maintenance of weight loss[129, 130]. Wing and Jeffery [129] studied two types of social support: natural support and experimentally manipulated support. Natural support was examined by comparing participants who joined a weight-loss program alone versus those who joined with three friends or family members. Social support was experimentally induced through the use of intragroup activities and intergroup competitions. Results found individuals who were recruited with friends had better weight losses than those recruited alone at the end of a 4 month treatment period, as well as at 10 month follow-up. Both recruitment strategy and experimentally induced support affected the study outcome. The highest completion rates and weight-loss maintenance were found in the individuals recruited with friends and treated with a high level of experimentally manipulated social support (i.e., 95% completed treatment and 66% maintained wt loss in full from months 4 to 10). In contrast, individuals who were recruited alone and given standard behavioral support had completion and weight maintenance rates of 76% and 24%, respectively.

2.8.4. Goal Setting

A study by Foster et al. [131] revealed dramatic differences between individuals' expectations and professional recommendations for desirable weight loss outcomes; participants often expect to lose unreasonable amounts of weight during treatment. This can adversely affect self-efficacy, mood, body image and self-esteem which may result in relapse[132]. It is currently recommended that weight loss programs help overweight and obese individuals set realistic goals, such as, reducing body weight by 5 to 10 percent. This modest amount of weight loss has been found to significantly decrease the severity of obesity-related risk factors[6].

2.8.5. Stimulus Control

Stimulus control refers to the cues associated with inappropriate eating. Stimulus control strategies teach individuals how to control such cues by avoiding or reducing exposure to them (e.g. avoid all-you-can eat buffets; store foods out of sight) [133]. Despite the common use of stimulus control in behavioral treatment packages for weight management, there have been no studies done to date that specifically focus on stimulus control techniques[134].

While there appears to be limited empirical evidence supporting the independent benefits of goal setting, problem solving, stimulus control, social support and relapse therapy on weight management, studies have shown self-monitoring to be consistently associated with better weight control[34].

2.8.6. Self-Monitoring

Self-monitoring is the backbone of behavior therapy[120] and involves the systematic observation and recording of one's own behavior[38]. Self-monitoring is considered to be the most important initial step in self-control[135], as well as a prerequisite to other self-control techniques[136], because it provides an ongoing record of the behavior to be controlled. Self-

monitoring is a skill that must be learned and practiced by the participant after the desired behavior is identified, explained and demonstrated by the interventionist[136]. However, before moving to the more narrow focus of self-monitoring related to weight management, a broader look at self-control or self-regulation is necessary for understanding why self-monitoring must be learned.

The importance of recording one's own behavior is related to individuals using some skill they learned in situations outside of where they originally learned the skill. Individuals are said to self-regulate. In the self-regulation process, from a social learning theory perspective, it is said that an individual must self-monitor or attend to his or her behavior; self-evaluate or compare what they are doing with what they ought to be doing; and self-reinforce or feel satisfied. Bandura[137] tells us that people, as part of self-regulation, make causal contributions to their own motivation and action; consequently, their beliefs' function as determinants of their motivation. More recently in Bandura and Locke[138], these beliefs are described as "embodying feed-forward self-regulation". People are more than just "planners and fore thinkers, they are self-regulators as well". As such, they self-monitor and regulate their actions with an ongoing self-evaluation and by doing things that give them satisfaction (i.e., self-reinforcement) while avoiding actions that result in dissatisfaction (i.e., self-censure). These combined components result in awareness with self-monitoring as the initial step.

Self-monitoring food intake facilitates awareness of dysfunctional eating habits and excess caloric intake by both interventionist and subject; consequently, it is considered to be the primary assessment tool in the behavioral treatment of obesity[139]. Studies on weight control suggest self-monitoring causes a spontaneous decrease in calorie intake[120]. Subjects typically begin by recording information related to instances of eating, such as the time of day, type and

amount of food eaten daily, and in some cases, caloric and fat values. Concomitantly, or as treatment progresses, subjects also monitor exercise, rate of eating, emotional state, and place where eating occurs, as well as antecedent and consequent thoughts and actions. The recommendation that subjects monitor variables in addition to food intake is reinforced by the inconsistent relationships observed between dysfunctional eating habits and obesity in a variety of weight loss studies[139]. Examination of the diary by both interventionist and participant can lead to the identification of patterns that surround undesired behaviors[136].

Repeatedly, studies show weight loss is more successful when individuals self-monitor eating and exercise behaviors[34-38]; therefore overweight and obese individuals should be taught how to self-monitor such behaviors to improve overall weight loss[33]. Self-monitoring has been shown to correlate significantly with short- and long-term weight loss, and as such is considered to be one of the most important elements of treatment[16]. McGuire and colleagues found individuals in the NWCR who regained weight exhibited a decline in self-monitoring over time[112]. Despite research endorsing its effectiveness, self-monitoring continues to be a secondary factor in the treatment of weight loss[36].

Although research has shown that individuals who consistently self-monitor eating and exercise behaviors lose more weight than those who self-monitor less regularly[35, 36], few weight control studies over the past 30 years have focused directly on self-monitoring or evaluated how consistency of self-monitoring affects weight loss[36, 38]. One study that did[37], found obese groups that were taught self-monitoring techniques were more likely to complete the entire treatment intervention, and they lost 63% more weight than obese groups that did not self-monitor. Baker and Kirschenbaum[36] investigated the use of consistent self-monitoring as a coping mechanism for weight control during the holidays and found the only

individuals that averaged any weight loss over this stressful period were those that were extremely consistent (i.e., nearly perfect) at self-monitoring. This type of monitoring has been referred to as "obsessive-compulsive self-regulation"[140]. Similar results were obtained by Boutelle et al. whereby considerable weight was lost by subjects demonstrating highly consistent self-monitoring, while weight gain occurred in those exhibiting minimal amounts[35]. Results of another study by Boutelle et al. found the self-monitoring group had significantly better weight management than the control group over a preholiday, holiday and postholiday period[38].

2.8.6.1. Barriers to Self-Monitoring

When investigating obese subjects' responses to hypothetically stressful situations, Drapkin et al. found those who had difficulty dealing with negative situations were more likely to have lapses in weight loss treatment[141]. Past studies suggest individuals effectively self-regulate a variety of behaviors when actively engaged in self-monitoring, however when discontinued, "self-regulation failure" occurs[34]. Factors that appear to interfere with effective self-regulation are coined "high-risk" because they typically disrupt a person's normal daily routine (e.g.: travel, schedule changes, interpersonal conflicts, increased periods of entertaining or socialization)[36] and thus, become barriers to self-monitoring behavior. Another barrier to self-monitoring behavior pertains to time constraints. Physically recording dietary intake and exercise/activity can be a time-consuming process that eventually becomes a burden to the point that individuals stop doing it. Lack of immediate feedback to subjects regarding their overall performance or progress is yet another barrier to effective self-regulation[34, 37, 38].

2.8.6.2. Possible Alternatives for Successful Self-Monitoring

In order to maximize the benefits of self-monitoring, it is important to provide feedback to individuals based on that monitoring. Consistent follow-up by the researcher or therapist via telephone, mailings, fax, emails, voicemails or face-to-face sessions helps to identify problem areas, facilitate process engagement and reinforce positive behavior changes, as well as, the importance of self-monitoring[34, 37]. Amount and frequency of the feedback provided appear to be more important than the actual content[38]. In a study by Tate et al., subjects in the behavior therapy intervention group received weekly feedback that addressed their overall progress, dietary intake, energy expenditure and answers to questions while the comparison group received no weekly feedback. Results found the behavior therapy intervention group lost significantly more weight than the comparison group[39], suggesting feedback may be one way to improve and/or maintain self-monitoring.

In addition to providing subjects with frequent feedback, researchers must find ways to simplify the traditional self-monitoring approach in order to decrease the time involved in the recording process. Self-monitoring of eating and exercise behaviors is traditionally done in a detailed manner[16, 36]. However, even when educated on the critical role self-monitoring plays in weight loss, subjects often fail to maintain consistent, detailed records[34]. A recently completed, unpublished study conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh compared detailed self-monitoring diaries with abbreviated self-monitoring diaries of overweight individuals following a home-based weight loss program. Results found subjects in the detailed self-monitoring condition had greater weight loss than those in the abbreviated self-monitoring condition (6.92 kg vs. 3.36 kg) after 16 weeks. Interestingly, debriefing subjects at the completion of the study revealed that individuals

in the abbreviated self-monitoring condition would have preferred being transitioned to the abbreviated version following a short period of detailed self-monitoring, while subjects in the detailed self-monitoring condition felt they could have tracked eating and exercise behaviors with less detail over time. Consequently, transitioning subjects from detailed self-monitoring to an abbreviated form of self-monitoring may be another weight loss approach worth considering. This "transition approach" may allow individuals to gain a better understanding of eating and exercise behaviors early on, while providing the convenience of minimal tracking after appropriate habits are established. It is important to note however, that the benefits of a "transition approach" over a traditional self-monitoring approach have not yet been established.

2.8.6.3. Importance of Simplifying Self-Monitoring

Because obesity and overweight in the United States have reached epidemic proportions, there is a public health need to continue to identify and modify treatment approaches to these conditions. The majority of the population is also faced with time constraints and daily or periodic schedule disruptions that may interfere with effective coping mechanisms. Therefore, alternative tracking methods that are easier to complete must be identified to help facilitate more effective self-monitoring and improve overall compliance in tracking eating and exercise behaviors, which in the end, may improve weight loss outcomes.

3. METHODS

3.1. Subjects

The subjects for this investigation were forty-two overweight adult men and women participating in a weight loss study at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. Participants were 23 to 45 years of age and had a BMI of 28 to 35 kg/m^2. Inclusion and exclusion criteria for participation in this study are listed in Table 7.

Table 7: Study Inclusion/Exclusion Criteria

Inclusion Criteria:
• Male or Female
• 21-45 years of age
• Body Mass Index = 25-35 kg/m^2
• Ability to provide informed consent
Exclusion Criteria:
• Recent weight loss of $\geq$ 10 lbs within previous 6-12 months
• Currently taking psychotropic medication or having received treatment for a psychological disorder in the previous 6 months
• Type I or Type II diabetes, hypothyroidism, or other medical conditions which would affect energy metabolism
• Women currently pregnant, pregnant within the previous six months, or planning on becoming pregnant within the next 6 months
• Non-medicated resting systolic blood pressure $\geq$160 mmHg or non-medicated resting diastolic blood pressure $\geq$100 mmHg, or taking medication that would affect blood pressure
• Taking medication that would affect resting heart rate or the heart rate response during exercise (e.g., beta blocker)
• History of myocardial infarction or valvular disease
• History of orthopedic complications that would prevent optimal participation in the exercise component (e.g., heel spurs, severe arthritis)

3.2. Recruitment and Screening Procedures

The participants for this study were recruited from advertisements in local Pittsburgh newspapers (see Appendix A) and by voice mail messages sent to the audix of employees at the University of Pittsburgh. Interested participants were given a number to call, whereby trained staff was available to provide a brief description of the study, as well as, perform a telephone screen to determine initial eligibility. Once the risks of participating in the phone screen were reviewed (see Appendix B: Risk Review Form) and verbal consent was obtained according to IRB procedures, the telephone screen was completed (see Appendix C: Phone Screen Interview and Appendix D: Contact Tracking Form). Participants deemed eligible for the study were scheduled for an orientation session (see Figure 3).

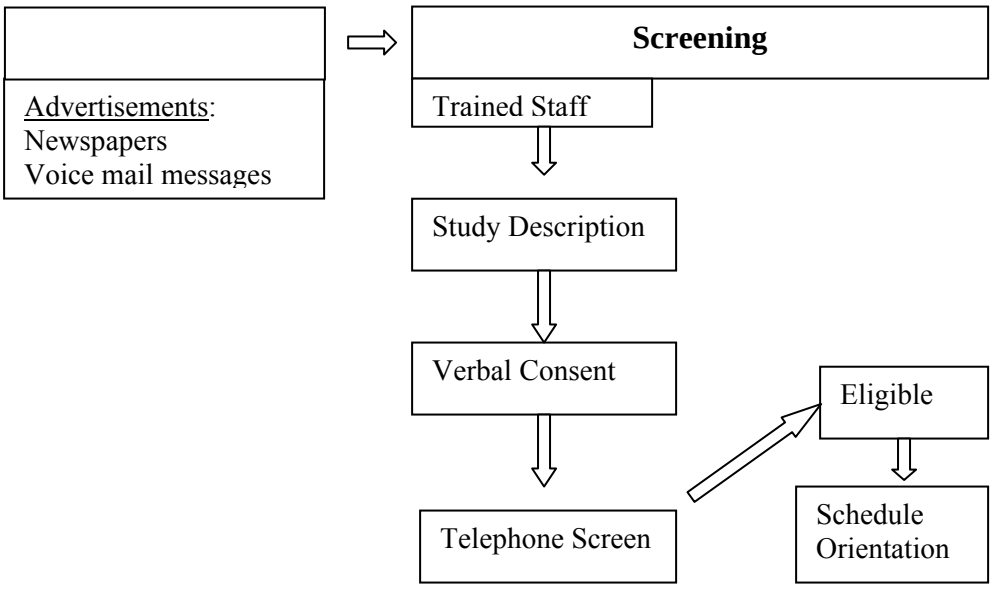

Figure 3: Subject Recruitment and Screening

During the orientation session, screening of participants continued. At that time, they completed a physical activity readiness questionnaire (PAR-Q) and detailed health history form (see Appendix E) to rule out medical conditions that would contraindicate exercise, dieting and/or weight loss. Participants who answered yes to any question on the PAR-Q were referred to their primary care physician and deemed ineligible to participate in the study. In addition, resting seated blood pressure was measured using a standard blood pressure cuff and standard measurement techniques. If resting blood pressure was high (≥160/100 mmHg), the participant was referred back to his/her primary care physician and deemed ineligible to participate in the study.

During the orientation session, the procedures and design of this investigation were explained to each individual who qualified for the study, and written consent to participate was obtained in accordance with the policy of the Institutional Review Board (IRB) at the University of Pittsburgh (IRB #0307101). A copy of the consent form and IRB permission to carry out this investigation can be found in Appendix F.

3.3. Experimental Procedures

This was a 16-week behavioral weight loss study that randomized participants to one of two self-monitoring conditions: 1) detailed self-monitoring (DSM) and 2) detailed self-monitoring transitioning to abbreviated self-monitoring (TSM).

3.3.1. Detailed Self-Monitoring (DSM)

Participants assigned to this group were instructed to self-monitor eating and exercise behaviors using a weekly diary that was completed each day and returned to the investigator each week for review. Participants were instructed to mail the diaries to the investigator in postage paid envelopes; they also received a weekly telephone prompt reminding them to return

their diaries. Within the diary, participants were instructed to record the date, types and quantities of foods consumed, calories, and fat grams. Nutritional information was obtained from product food labels and from published nutrition estimates that were provided to the participants. Subjects were instructed to indicate (with a check mark) the day of the week and any meals or snacks that were skipped during the course of the day. In addition, they were instructed to record the following information regarding exercise: type of exercise, minutes/week, minutes/session, and exercise rating of perceived exertion (RPE). If they did not exercise, there were instructed to select from a list of "reasons" for not exercising. An example of this diary is included in Appendix G.

The diaries were reviewed weekly by the researcher and returned to the participant with feedback on strategies to improve eating and exercise behaviors. In addition, participants received a printed weekly behavioral lesson that targets healthful changes in eating and exercise behaviors. An example of the lesson topics is presented in Table 8. The lessons are similar to what is typically provided in standard behavior change programs. This information was mailed to participants weekly.

3.3.2. Detailed Self-Monitoring Transitioning to Abbreviated Self-Monitoring (TSM)

Participants assigned to this group were instructed to self-monitor their eating and exercise behaviors using the detailed (DSM) approach during the first 8 weeks of the study (see above for specific information regarding DSM approach). Following 8 weeks of participation using the detailed diaries, participants *transitioned* to an abbreviated eating and exercise diary for the remaining 8 weeks of the study. During weeks 9-16, participants were instructed to self-monitor their eating and exercise behaviors using a weekly food and exercise diary that was to be completed each day and returned to the investigator each week for review. Within this diary,

participants were instructed to *estimate* the quality (i.e., fat content) and quantity (i.e., size based on calorie content) of their meals and snacks by placing a check mark in one of four boxes (i.e., small, medium, large or supersize) for each of these categories (i.e., fat and calorie content). Participants were instructed to indicate (with a check mark) the day of the week and any meals or snacks that were skipped during the course of the day. They were also instructed to record (with a check mark) whether or not exercise was completed on a daily basis. Options for exercise duration were ≤15 minutes, 16-30 minutes, 31-45 minutes, 46-60 minutes and >60 minutes. If participants exercised, they were asked to record RPE. If they did not exercise, participants were asked to choose from a list of "reasons" for not exercising. Unlike the DSM group, specific details (actual food measurement, calories, fat grams, type of exercise) of these behaviors were not recorded. An example of this diary is included in Appendix H.

Table 8: Example of Behavioral Lesson Topics

Session	Topic
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	Building Social Support
13	Eating in Social Situations
14	Problem Solving
15	Barriers to Exercise
16	Looking Forward

Participants were instructed to mail the abbreviated diaries to the investigator in postage paid envelopes; they also received a weekly telephone prompt reminding them to return their diaries. The diaries were reviewed weekly by the researcher and returned to the participant with feedback on strategies to improve eating and exercise behaviors. In addition, participants received a printed weekly behavioral lesson that targets healthful changes in eating and exercise behaviors. This lesson was identical to the one received by the DSM group (see Table 8) and was mailed to participants weekly.

3.4. Assessment Procedures

Outcomes of this study were assessed at 0 and 16 weeks on all participants. The following assessments (i.e., body weight, height, dietary intake and physical activity) were performed in the Physical Activity and Weight Management Research Center at the University of Pittsburgh (assessments took approximately 30 minutes to complete for each participant during each assessment period).

3.4.1. Weight

Body Weight was measured at weeks 0 and 16 on a calibrated medical balance-beam scale (Health-O-Meter, Bridgeview, IL) to the nearest 0.25 pound. Participants were dressed in a light-weight hospital gown.

3.4.2. Height

Height was measured with a calibrated wall-mounted stadiometer (Perspective Enterprises, Portage, MI) to the nearest 0.1 cm. Participants were instructed to remove their shoes and stand upright, placing backs of heels against the wall during the measurement.

3.4.3. Education

Education level was assessed using a lifestyle questionnaire (Appendix I) that asked participants to record the highest level of education completed. This information was used to determine whether education level affects the outcome of a correspondence-based study that is delivered by mail.

3.4.4. Diet

Dietary Intake was assessed at weeks 0 and 16 using an updated version (Block 98) of the Block Food Frequency Questionnaire (FFQ). The original Block FFQ was developed using national dietary data (NHANES I and II) to construct the food list, portion sizes, and nutrient database of this questionnaire[142]. It is a quantitative FFQ that has previously been validated[143]. In the 1990s this questionnaire was revised into an eight-page booklet (Block 98) that incorporated new survey data from NHANES III. The revised questionnaire queries 109 food items, inquires about usual food portion sizes and provides references for estimating them. In addition, it includes questions related to participant demographics and health, dietary supplement use, restaurant eating, and use of fat or low-fat foods[144].

3.4.5. Physical Activity

Physical Activity was assessed using the Paffenbarger Physical Activity Questionnaire (Exercise Habits) (Appendix J) at weeks 0 and 16. This questionnaire assesses exercise patterns across treatment groups. The Exercise Habits questionnaire queries the participant on the average number of flights of stairs climbed and the number of city blocks walked for each of the past 7 days. These values are converted into kilocalorie scores (e.g., 1 city block = 8 kcal and 1 flight of stairs = 4 kcal) as defined by Paffenbarger and colleagues[145, 146]. In addition, participants reported the time spent over the past week in sports, fitness or recreational activities.

The activities were categorized as light, moderate, or hard based on standard MET values outlined in the compendium of physical activities[146]; kcal/wk of leisure time physical activity were computed using the equations provided by Paffenbarger et al.[145, 147].

Following baseline assessment and randomization, all participants attended a one-hour meeting in the Physical Activity and Weight Management Research Center at the University of Pittsburgh to receive information about the results of the randomization process. In addition, dietary and exercise components of the study were described in detail.

3.5. Treatment Components

All participants received a home-based behavioral weight program that was delivered by mail. This program included a dietary intervention and aerobic exercise prescription.

3.5.1. Diet Intervention

During the initial meeting at the Physical Activity and Weight Management Research Center at the University of Pittsburgh, participants were given structured meal plans to facilitate weight loss and adoption of healthful eating behaviors. Meal plans included daily calorie and fat goals as well as suggested serving sizes of selected foods. Participants weighing less than 200 pounds were placed on a 1200 calorie per day diet and those weighing 200 pounds or greater were placed on a 1500 calorie per day diet. During this meeting, a registered dietitian taught participants how to decrease fat in their diet to 20-30% of total calorie intake. In addition they were taught how to read the meal plans provided, how to record eating behavior in the food diary, how to return weekly food diaries, and other basic nutrition principles.

3.5.2. Exercise Intervention

The exercise prescription was taught by an exercise physiologist who explained the exercise protocol, including demonstration of moderate intensity exercise, how to monitor

exercise intensity using the Borg 15 Point RPE Scale, and how to progressively increase duration of exercise sessions. Participants were given a home-based exercise prescription that consisted of aerobic exercises similar to brisk walking 5 days per week. The total exercise duration was initiated at 20 minutes per day during weeks 1 through 4 (i.e., 100 min/wk), increased to 30 minutes per day during weeks 5 through 8 (i.e., 150 min/wk), and progressed to 40 minutes per day during weeks 9 through 16 (i.e., 200 min/wk) of the intervention (see Appendix K). Because it has previously been shown that daily exercise accumulated across multiple 10-minute bouts may be beneficial for increasing exercise participation at the onset of the intervention, participants were encouraged to progressively increase their exercise throughout the treatment period using this strategy[19] . During weeks 1 through 8, subjects were instructed to exercise at an intensity that corresponds to 11 through 13 on the Borg 15 Point RPE Scale (i.e., fairly light to somewhat hard). During weeks 9 through 16, exercise intensity was increased to a level that corresponds to 11 through 15 on the Borg 15 Point RPE Scale (i.e., fairly light to hard).

3.6. Experimental Variables

The independent variable for this investigation is type of self-monitoring (DSM, TSM). The main dependent variable is completion of eating and exercise diaries. Secondary dependent variables are body weight, dietary intake and physical activity. Completion of diaries was defined as follows:

DSM group: Each day, out of 112 possible recording days (16 weeks x 7 days/wk), the DSM diary was rated for completion by examining whether or not subjects recorded total calories and fat grams. Each meal was scored as follows: No = 0 and Yes = 1 for a maximum possible score of 6 for total calories and fat grams (e.g.: if subjects recorded

total calories and fat grams for each of the following meals (breakfast, am snack, lunch, pm snack, dinner, late snack) they received a score of 6).

TSM group: Completion of diaries was scored as above (see DSM group) during weeks 1–8. At the time of transition (i.e., weeks 9-16), subjects were scored based on whether or not they rated dietary intake (i.e., estimated size/calorie and fat content) by checking the appropriate boxes on the abbreviated diary. Each meal was scored as follows: No = 0 and Yes = 1 for a maximum possible score of 6 (e.g.: if subjects estimated calorie and fat content by checking the boxes for each of the following meals (breakfast, am snack, lunch, pm snack, dinner, late snack) they received a score of 6).

Two undergraduate nutrition students were trained to rate the detailed and abbreviated diaries for completion. Each student independently rated the diaries by using a Weekly Diary Summary form (see Appendix L). Any discrepancies between the rater's findings were brought to the attention of the primary investigator and resolved prior to data analysis.

3.7. Statistical Considerations and Power Analysis

Power calculations were computed based on expected improvements in the number of eating and exercise diaries completed. Current studies being done at the Physical Activity and Weight Management Research Center at the University of Pittsburgh, under the direction of Dr. John Jakicic, indicate that approximately 70-80% of eating and exercise diaries are completed in the first 6 months of treatment with a standard deviation of approximately 25%. Based on an alpha of 0.05 and power of 0.70, 25 participants per group are required to detect a 15% difference between the groups (DSM, TSM). Individuals were identified in the database by subject ID number only.

All analyses were performed using SPSS statistical software (Version 12.0) and statistical significance was defined at $p < 0.05$. Between group differences based on randomized group assignment for age, weight, height, and body mass index were analyzed using independent t-tests. A chi-square analysis was used to determine if there were differences between the groups for gender or education level.

Data were analyzed for number of diaries completed, number of weeks body weight was reported, and number of reminders that need to be sent using independent t-tests to examine between group differences. A repeated measures (Group x Time) analysis of variance (ANOVA) was performed to examine the number of meals reported in the diaries at weeks 1-4, 5-8, 9-12, and 13-16 by group (DSM versus TSM). In addition, analyses were conducted to compare changes in body weight, dietary intake and physical activity between the treatment groups. Specifically, a two-factor repeated measure ANOVA, with time as the repeated factor, was conducted separately for each variable (body weight, dietary intake, physical activity). Significant findings were examined using independent t-tests with the p-value adjusted using the Bonferroni procedure. Moreover, correlation coefficients were computed between weight loss and total meals recorded in the diaries, number of reminders sent, number of diary weights recorded, and number of diaries returned across the 16 week intervention. All analyses were performed for completers, self-reporters + completers, and intent-to-treat, with these groups for analysis described in detail in Chapter 4.

4. RESULTS

The purpose of this study was to investigate the effect of two self-monitoring methods for tracking eating and exercise behaviors within the context of a 16 week correspondence-based weight loss intervention. A repeated measures design was utilized for this study. The independent variable was type of self-monitoring, Detailed Self-Monitoring (DSM) versus Transitional Self-Monitoring (TSM). The primary dependent variable was completion of eating and exercise diaries, with body weight, dietary intake and physical activity considered as secondary dependent variables.

4.1. Subject Characteristics

The subjects in this investigation consisted of 42 overweight adult men and women (6 males and 36 females) participating in a weight loss study at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. All of the participants were between 21 and 45 years of age, with body mass index (BMI) ranging from 25 to 35 kg/m^2. Descriptive statistics (mean $\pm$ standard deviation) for subjects are presented in Table 9. Independent t-tests revealed no significant baseline differences between randomized groups for age, height, weight and body mass index (BMI). Chi square analyses revealed no significant group differences in the proportion of men and women in each group ($p = .08$) or in the education levels of individuals randomly assigned to each group ($p = .16$).

Table 9: Baseline Characteristics of Total Subjects (N = 42) and for Detailed Self-Monitoring Group (N = 21) and Transitional Self-Monitoring Groups (N = 21).

	Total (N = 42)	Detailed Self-Monitoring (N=21)	Transitional Self-Monitoring (N=21)	Mean Difference Between Groups	P-value
	(mean ± s.d.*)	(mean ± s.d.*)	(mean ± s.d.*)	(mean ± s.e.m.§)	
Age (years)	36.0 ± 6.4	38.0 ± 5.9	35.0 ± 6.6	-3.0 ± 1.9	.14
Height (cm)	165.5 ± 7.0	164.5 ± 5.9	166.5 ± 8.0	2.0 ± 2.2	.37
Weight (kg)	89.0 ± 8.1	87.0 ± 7.5	90.0 ± 8.5	3.1 ± 2.5	.22
Body Mass Index (kg/m^2)	32.0 ± 1.6	32.0 ± 1.6	32.5 ± 1.5	0.4 ± 0.5	.45
Gender	%(N)	%(N)	%(N)	P-Value for Chi-Square for Group Comparison	
% Males	14.3% (N=6)	5% (N=1)	24% (N=5)	.08	
% Females	85.7% (N=36)	95% (N=20)	76% (N=16)		
Education Level	%(N)	%(N)	%(N)	.16	
% High School	4.8% (N=2)	9.5% (N=2)	0.0% (N=0)		
% Vocational Training	4.8% (N=2)	9.5% (N=2)	0.0% (N=0)		
% Some College	33.3% (N=14)	28.6% (N=6)	38.1% (N=8)		
% University Degree	38.1% (N=16)	28.6% (N=6)	47.6% (N=10)		
% Graduate Education	16.7% (N=7)	23.8% (N=5)	9.5% (N=2)		
Not Reported	2.4% (N=1)	0.0% (N=0)	4.8% (N=1)		

*s.d. - standard deviation

§s.e.m. - standard error mean differences

4.2. Retention Rates

Forty-two subjects initiated treatment in this study. Retention of participants who provided objective data at baseline and 16 weeks (N = 22) was 52%; these individuals are referred to as "completers". Retention increases to 64% (N = 27) when five subjects who did not attend the post-evaluation, but reported their weight by phone at the end of the study, were included in the sample; these subjects are referred to as "self-reporters + completers". Outcome analyses (described below) for diary completion and body weight data are performed with and without these 5 individuals; descriptive statistics (mean ± standard deviation) for these subjects are presented in Table 10. In addition, the data are also analyzed using intent-to-treat (ITT) analysis, whereby the baseline weight is carried forward for missing post-evaluation data (N = 42).

Analyses to compare completers versus self-reporters + completers versus intent-to-treat showed no significant differences between these individuals for age, weight, height, body mass index or percent of individuals based on gender or education (data not shown).

Table 10: Baseline Characteristics of Total Subjects (N = 42), Self-Reporters + Completers (N = 27), and Completers (N = 22).

	Total (N = 42)	Self-Reporters + Completers (N=27)	Completers (N=22)
	(mean ± s.d.*)	(mean ± s.d.*)	(mean ± s.d.*)
Age (years)	36.0 ± 6.4	36.5 ± 6.9	36.5 ± 7.0
Height (cm)	165.5 ± 7.0	163.7 ± 5.7	163.7 ± 5.7
Weight (kg)	89.0 ± 8.1	87.4 ± 6.4	87.6 ± 6.6
Body Mass Index (kg/m^2)	32.0 ± 1.6	32.6 ± 1.2	32.7 ± 1.2
Gender	%(N)	%(N)	%(N)
% Males	14.3% (N=6)	11.1% (N=3)	9.1% (N=2)
% Females	85.7% (N=36)	88.9% (N=24)	90.9% (N=20)
Education Level	%(N)	%(N)	%(N)
% High School	4.8% (N=2)	0% (N=0)	0% (N=0)
% Vocational Training	4.8% (N=2)	3.7% (N=1)	4.5% (N=1)
% Some College	33.3% (N=14)	25.9% (N=7)	27.3% (N=6)
% University Degree	38.1% (N=16)	44.4% (N=12)	45.5% (N=10)
% Graduate Education	16.7% (N=7)	22.2% (N=6)	22.7% (N=5)
Not Reported	2.4% (N=1)	3.7% (N=1)	0% (N=0)

*s.d. - standard deviation

4.3. Treatment Group Effect on Diary Completion

Independent t-tests were conducted separately to examine between group differences on number of diaries returned to the investigators, number of weeks in which body weight was recorded in the diary, and number of weekly reminders sent to participants who did not return a diary to the investigators for a given week (refer to Table 11). Data are presented as the average per week during weeks 1-4, 5-8, 9-12, and 13-16 for completers, self-reporters + completers, and for all randomized subjects (intent-to-treat).

Table 11: Data obtained from diaries across the 16-week intervention for the Detailed and Transitional Self-Monitoring Conditions.

	Intervention Groups		P-Value
	Detailed Self-Monitoring	Transitional Self-Monitoring	
Completers (N=22)	(N=10)	(N=12)	
Number Diaries Returned	14.0 ± 2.0	15.2 ± 1.4	.04
Number Diary Weights Recorded	12.7 ± 1.7	13.3 ± 2.7	.11
Number Reminders Sent	2.8 ± 3.3	2.0 ± 2.8	.63
Self-Reporters + Completers (N=27)	(N=13)	(N=14)	
Number Diaries Returned	11.2 ± 5.6	13.0 ± 5.7	.76
Number Diary Weights Recorded	9.9 ± 5.6	11.4 ± 5.4	.78
Number Reminders Sent	5.5 ± 6.0	3.9 ± 5.4	.53
Intent-to-Treat Analysis (N=42)	(N=21)	(N=21)	
Number Diaries Returned	7.5 ± 6.6	9.6 ± 6.8	.84
Number Diary Weights Recorded	6.4 ± 6.3	7.9 ± 6.8	.69
Number Reminders Sent	5.8 ± 5.9	6.3 ± 5.9	.96

4.3.1. Treatment Group Effect for the Number of Weekly Diaries Returned

Data were analyzed to examine the differences between treatment groups for the number of diaries returned to the investigators from baseline to 16 weeks. Results revealed a significant difference in the number of diaries returned (mean ± standard deviation) in DSM (14.0 ± 2.0) and TSM (15.2 ± 1.4) ($p = .04$) when data for completers ($N = 22$) were analyzed. When the data were analyzed for self-reporters + completers, the number of diaries returned was 11.2 ± 5.6 for DSM and 13.0 ± 5.7 for TSM, with no significant difference between the groups ($p = .76$). Similar results were shown for the intent-to-treat analysis, with 7.5 ± 6.6 and 9.6 ± 6.8 diaries returned for DSM and TSM, respectively ($p = .84$).

4.3.2. Treatment Group Effect on Diary Weights Recorded

Data were analyzed to compare the number of weeks a subject recorded a weekly weight in their returned diary across the 16-week intervention. Results revealed no significant difference between DSM (12.7 ± 1.7) and TSM (13.3 ± 2.7) ($p = .11$) when data for completers were analyzed. When the data were analyzed for self-reporters + completers, the number of weeks a subject recorded a weight in their diary was 9.9 ± 5.6 for DSM and 11.4 ± 5.4 for TSM ($p = .78$). Intent-to-treat analysis revealed no significant difference in the number of weeks that weight was recorded in the diary for DSM (6.4 ± 6.3 weeks) versus TSM (7.9 ± 6.8 weeks) ($p = .69$).

4.3.3. Summary of the Number of Weekly Reminders Sent to Participants

Data were analyzed to examine between group differences from baseline to 16 weeks for the number of weekly diary reminders sent to participants when they failed to return a diary. Results revealed no significant difference between DSM (2.8 ± 3.3) and TSM (2.0 ± 2.8) ($p = .63$) when data for completers were analyzed. When the data were analyzed for self-reporters + completers, the number of reminders sent was 5.5 ± 6.0 for DSM and 3.9 ± 5.4 for TSM ($p = .53$). Intent-to-treat analysis revealed number of reminders sent was 5.8 ± 5.9 for DSM and 6.3 ± 5.9 for TSM, with no significant difference between groups ($p = .96$).

4.3.4. Meals Recorded in Weekly Diary

There were a possible 42 meals per week (3 meals + 3 snacks/day x 7 days) that could be recorded in the diaries across the 16-week intervention. These were averaged at 4 week intervals for data analysis and presentation (see Figure 4). Only those subjects who returned a minimum of one diary per 4 week period were included in this analysis. Both DSM and TSM significantly increased the number of weekly meals recorded ($p < .001$), with no significant difference between groups (refer to Figure 4). Post-hoc data analyses were performed comparing weeks 1-

4 to 5-8, 5-8 to 9-12, and 9-12 to 13-16, with the p-value adjusted using the Bonferroni procedure (p-value = 0.05 / 3 = 0.016). Based on these post-hoc tests, the significant time effect resulted from a significant increase in the number of meals recorded in weeks 1-4 versus week 5-8 (p = .01), with no significant change from weeks 5-8 to weeks 9-12 or from weeks 9-12 to weeks 13-16.

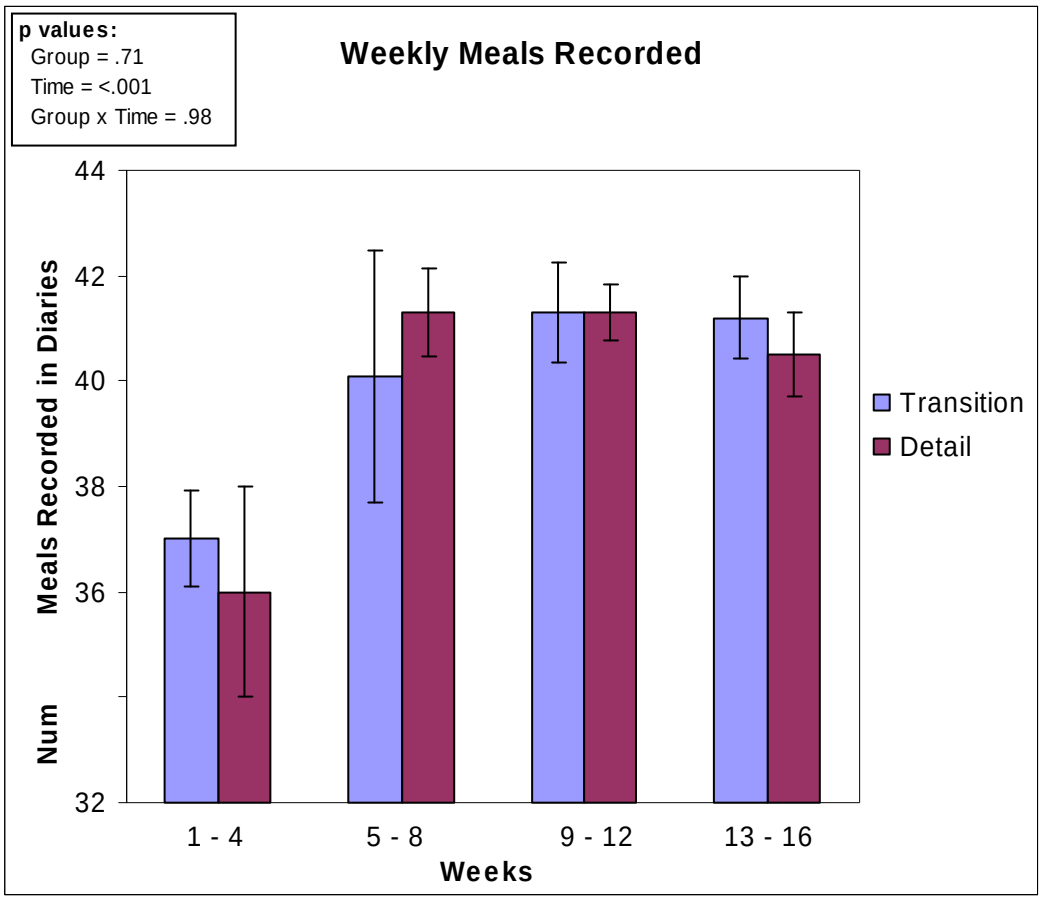

Figure 4: Average Weekly Meals Recorded in Diaries in 4 Week Intervals for Detailed (N=7) and Transition (N-11) Self-Monitoring Treatment Groups

4.4. Comparison of Weight Change between Treatment Groups

A two-factor repeated measure (Group X Time) analysis of variance (ANOVA), with time as the repeated factor, was performed to compare changes in body weight between treatment groups (refer to Table 12 and Figure 5). Results revealed a significant decrease in body weight from 0 to 16 weeks for completers in DSM (-7.5 ± 5.3 kg) and TSM (-7.6 ± 5.5 kg) ($p = <.001$), with no significant difference between the groups ($p = .91$). There was also a significant decrease in body weight for self-reporters + completers in DSM (-6.3 ± 5.4 kg) and TSM (-6.5 ± 6.0 kg) ($p < .001$), with no significant difference between the groups ($p = .51$). Results of the intent-to-treat analysis showed a similar pattern, with body weight decreasing significantly in both DSM (-3.9 ± 5.3 kg) and TSM (-4.3 ± 5.8 kg) ($p = <.001$), with no significant difference between the groups ($p = .30$). Changes in BMI revealed a significant pattern as that observed for change in body weight (refer to Table 12).

4.4.1. Correlates of Change in Body Weight

Correlation analyses were performed to examine the relationship between weight loss and total meals recorded, number of reminders sent, number of diary weights recorded, and number of diaries returned across the 16 week intervention. When analyzed for completers, significant correlation coefficients were $r = 0.47$, $r = -0.47$, $r = 0.54$ and $r = 0.53$, respectively ($p = \leq .03$). Analysis for self-reporters + completers showed significant correlation coefficients were $r = 0.53$, $r = -0.57$, $r = 0.55$ and $r = 0.54$, respectively ($p = \leq .004$). Significant correlation coefficients for intent-to-treat analysis were $r = 0.71$, $r = -0.54$, $r = 0.72$ and $r = 0.71$, respectively ($p = <.001$).

Table 12: Body Weight and Body Mass Index in the Detailed and Transition Self-Monitoring Treatment Groups at Baseline and 16 Weeks (mean ± standard deviation)

	Intervention Groups		P-Values		
	Detailed Self-Monitoring	Transitional Self-Monitoring	Group Effect	Time Effect	Group X Time Interaction
Body Weight (kg)					
Completers (N=22)	(N=10)	(N=12)	.91	<.001	.96
Baseline Body Weight (kg)	87.4 ± 6.4	87.8 ± 7.0			
16 Week Body Weight (kg)	79.9 ± 7.0	80.2 ± 9.8			
Self-Reporters + Completers (N=27)	(N=13)	(N=14)	.51	<.001	.94
Baseline Body Weight (kg)	86.4 ± 6.0	88.3 ± 6.8			
16 Week Body Weight (kg)	80.1 ± 6.9	81.8 ± 9.8			
Intent-to-Treat Analysis (N=42)	(N=21)	(N=21)	.30	<.001	.81
Baseline Body Weight (kg)	87.1 ± 7.5	90.2 ± 8.5			
16 Week Body Weight (kg)	83.2 ± 8.9	85.9 ± 11.5			
Body Mass Index (BMI = kg/m^2)					
Completers (N=22)	(N=10)	(N=12)	.55	<.001	.89
Baseline BMI (kg/m^2)	32.4 ± 1.4	32.9 ± 0.9			
16 Week BMI (kg/m^2)	29.7 ± 2.2	30.0 ± 2.5			
Self-Reporters + Completers (N=27)	(N=13)	(N=14)	.49	<.001	.91
Baseline BMI (kg/m^2)	32.3 ± 1.5	32.8 ± 0.9			
16 Week BMI (kg/m^2)	30.0 ± 2.2	30.4 ± 2.6			
Intent-to-Treat Analysis (N=42)	(N=21)	(N=21)	.61	<.001	.79
Baseline BMI (kg/m^2)	32.2 ± 1.6	32.5 ± 1.5			
16 Week BMI (kg/m^2)	30.7 ± 2.2	30.9 ± 2.6			

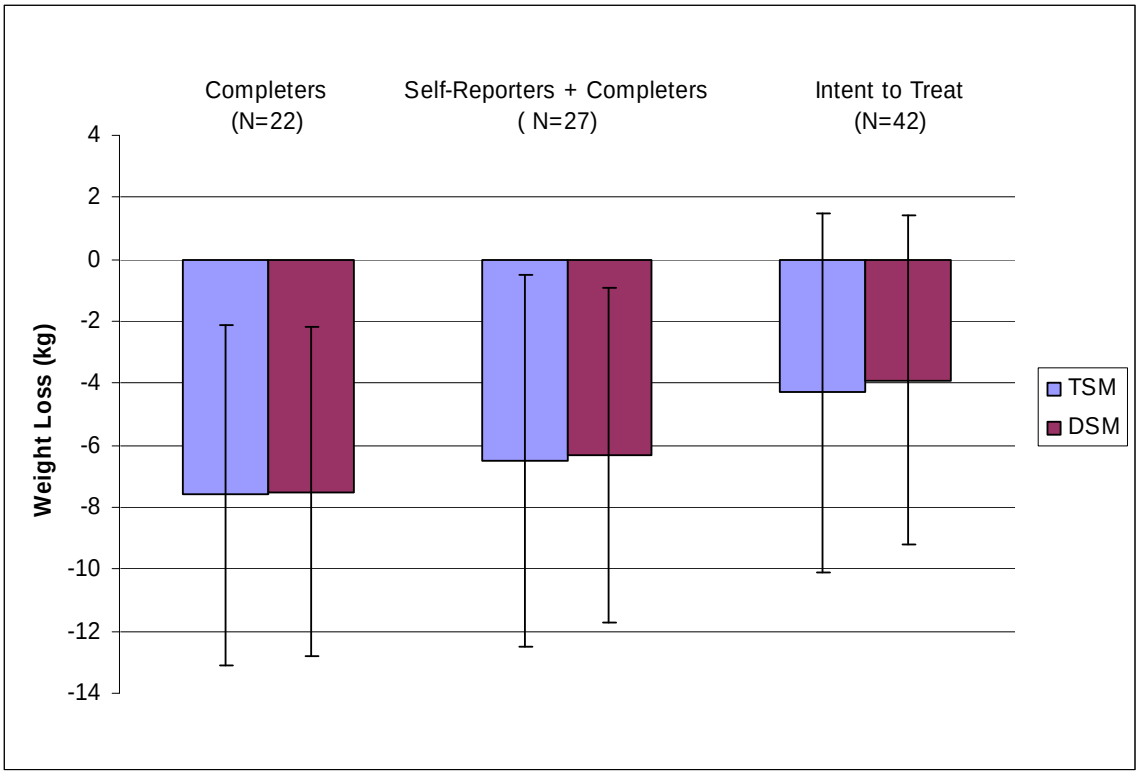

Figure 5: Weight Loss from 0 to 16 Weeks in Detailed (DSM) and Transitional (TSM) Self-Monitoring Groups (mean ± standard deviation).

Note: There were no significant differences between groups for completers, self-reporters + completers, or intent to treat analyses.

4.5. Energy Intake and Physical Activity from Baseline to 16 Weeks

4.5.1. Effect of Intervention on Energy Intake and Macronutrient Composition

Total energy intake and macronutrient composition (i.e., fat, carbohydrate and protein) were analyzed using a two-factor repeated measure (Group X Time) ANOVA, with time as the repeated factor. These data are presented in Table 13. Data from the food frequency questionnaire are only available for completers, and therefore data are presented for the 22 subjects who were classified as completers.

There was a significant decrease from 0 to 16 weeks for energy intake (DSM = 826 ± 965 kcal/d; TSM = 571 ± 765 kcal/d; p =.001) and percent dietary fat intake (DSM = 9.8% ± 8.1%;

TSM = 5.3% ± 8.1%; p = <.001). There was a significant increase from 0 to 16 weeks for percent dietary carbohydrate intake (DSM = 8.3% ± 8.8%; TSM = 4.9% ± 10.5%; p =.005) and percent protein intake (DSM =1.7% ± 2.8%; TSM = 1.5% ± 4.1%; p =.05). There was no significant difference between the groups for change in energy intake or macronutrient composition (p = >0.05). A similar pattern of results was shown for the self-report + completers analysis and the intent-to-treat analysis (data not shown).

Table 13: Total Energy Intake, Macronutrient Intake and Energy Expenditure in Leisure-Time Physical Activity at Baseline and 16 Weeks in Detailed and Transition Self-Monitoring Treatment Groups (mean ± standard deviation).

	Intervention Groups		P-Values		
	Detailed Self-Monitoring (N=10)	Transitional Self-Monitoring (N=12)	Group Effect	Time Effect	Group X Time Interaction
Energy Intake (kcal/d)					
Baseline	2094 ± 949	1960 ± 795	.98	.001	.50
16 Week	1268 ± 235	1389 ± 552			
Percent Dietary Fat Intake (%)					
Baseline	36.3 ± 5.4	37.3 ± 7.5	.15	<.001	.21
16 Week	26.5 ± 5.4	32.0 ± 7.0			
Percent Carbohydrate Intake (%)					
Baseline	48.4 ± 4.9	47.4 ± 9.6	.36	.005	.43
16 Week	56.7 ± 5.7	52.3 ± 10.7			
Percent Protein Intake (%)					
Baseline	15.8 ± 3.2	14.8 ± 3.7	.34	.05	.90
16 Week	17.6 ± 2.2	16.3 ± 3.5			
Physical Activity (kcal/wk)					
Baseline	1382 ± 1100	1254 ± 628	*.26	.04	.15
16 Week	2825 ± 3288	1521 ± 682			

*Because data were skewed, a non-parametric Mann-Whitney U test for change scores between treatment groups was performed. There was no significant difference between the treatment groups (p = .26).

4.5.2. Effect of Intervention on Physical Activity

Analysis of data for completers using a two-factor (Group X Time) repeated measures ANOVA showed a significant increase in energy expenditure (kcal/wk) in leisure-time physical activity in DSM (1382 ± 1100 to 2825 ± 3288 kcal/wk) and TSM (1254 ± 628 to 1521 ± 682 kcal/wk) ($p = .04$). Further examination revealed these leisure-time physical activity data were skewed. Consequently, change in physical activity data were analyzed using a non-parametric Mann-Whitney U test. Results of this analysis revealed no significant difference between the groups for change in leisure-time physical activity across the 16 week intervention ($p = .26$) (refer to Table 13).

Data from the weekly diaries were analyzed to examine the effect of the 16-week intervention on exercise patterns including duration of exercise (min/d), weekly exercise (min/wk), weekly exercise days (d/wk), and rating of perceived exertion (RPE). These data were based on subjects who returned a minimum of one diary per 4 week interval ($N = 18$), with the data presented as the mean across each 4 week period (weeks 1-4, 5-8, 9-12, and 13-16) (see Table 14). There were no significant time or group effects for min/d, min/wk, d/wk, or RPE.

Table 14: Diary Completion Data in 4 Week Intervals for Changes in Daily Exercise, Weekly Exercise, Weekly Exercise Days and Ratings of Perceived Exertion (RPE) in the Detailed and Transitional Conditions (mean ± standard deviation).

	Intervention Groups		P-Values		
	Detailed Self-Monitoring (N=7)*	Transitional Self-Monitoring (N=11)*	Group Effect	Time Effect	Group X Time Interaction
Exercise Duration (min/d)			.75	.19	.34
Weeks 1-4	29.3 ± 15.5	36.0 ± 23.8			
Weeks 5-8	30.2 ± 8.5	35.4 ± 25.0			
Weeks 9-12	30.0 ± 14.6	28.7 ± 14.5			
Weeks 13-16	27.6 ± 12.0	26.5 ± 15.0			
Weekly Exercise (min/wk)			.78	.57	.38
Weeks 1-4	182.1 ± 101.4	217.3 ± 148.0			
Weeks 5-8	211.2 ± 59.5	248.0 ± 175.0			
Weeks 9-12	208.5 ± 102.0	200.8 ± 101.7			
Weeks 13-16	193.0 ± 84.1	185.7 ± 105.2			
Exercise Days (d/wk)			.44	.78	.39
Weeks 1-4	4.5 ± 1.0	5.0 ± 0.9			
Weeks 5-8	5.5 ± 0.6	5.2 ± 1.6			
Weeks 9-12	4.8 ± 1.2	5.5 ± 1.2			
Weeks 13-16	4.3 ± 1.5	5.1 ± 1.7			
Rating of Perceived Exertion (RPE)			.22	.83	.16
Weeks 1-4	11.8 ± 0.4	12.0 ± 0.5			
Weeks 5-8	12.1 ± 0.5	11.6 ± 0.7			
Weeks 9-12	12.2 ± 0.5	11.8 ± 0.6			
Weeks 13-16	12.1 ± 0.6	11.7 ± 0.7			

*Data based on subjects with a minimum of one diary returned per 4 week interval.

5. DISCUSSION

5.1. Introduction

The primary purpose of this study was to investigate the effect of two self-monitoring techniques, detail self-monitoring (DSM) and high detail transitioning to low detail self-monitoring (TSM) for monitoring eating and exercise behaviors in overweight adults during participation in a weight loss program. In comparing these two self-monitoring techniques, secondary aims were to examine changes in body weight, eating behavior and exercise behavior.

The present study is the first to examine the benefits of a "transition" approach to self-monitoring over the more traditional approach. Few weight control studies over the past 30 years have focused directly on self-monitoring techniques or evaluated how consistency of self-monitoring affects weight loss[35-38]. Self-monitoring of eating and exercise behaviors has traditionally involved the detail of types, amounts, and nutritional composition of food consumed [16, 36]. However, while there is evidence to support the link between frequency of self-monitoring and weight loss [34-38], there is limited evidence that the detailed level of self-monitoring that is traditionally encouraged is necessary to maximize weight loss. Moreover, even when subjects are educated on the critical role self-monitoring plays in weight loss, they often fail to maintain consistent, detailed records[34], possibly because the act of recording dietary intake and physical activity are so time-consuming, it becomes burdensome to a point of cessation. Therefore, examining methods to simplify the traditional self-monitoring approach may decrease the time involved in the recording process, which may improve long-term adherence to tracking eating and exercise behaviors during weight loss, and possibly effect eating and exercise behavior overall.

5.2. Summary and Conclusions

It was hypothesized that there would be a significantly greater completion of eating and exercise records in the transitional self-monitoring (TSM) group compared to the detailed self-monitoring (DSM) group. This hypothesis was based on an unpublished study conducted at the Physical Activity and Weight Management Research Center at the University of Pittsburgh that compared detailed self-monitoring diaries with abbreviated self-monitoring diaries of overweight individuals following a home-based weight loss program. Results of this unpublished study found subjects in the detailed self-monitoring condition had greater weight loss than those in the abbreviated self-monitoring condition (6.92 kg vs. 3.36 kg) after 16 weeks. Interestingly, debriefing subjects at the completion of the study revealed those in the abbreviated self-monitoring condition would have preferred being transitioned to the abbreviated version following a short period of detailed self-monitoring, while subjects in the detailed self-monitoring condition felt they could have tracked eating and exercise behaviors with less detail over time. Consequently, it was determined that another weight loss approach worth considering would be to transition subjects from a detailed to abbreviated form of self-monitoring to allow them to gain a better understanding of monitoring eating and exercise behaviors early on, while providing the convenience of minimal tracking after appropriate habits were established.

The attrition rate in the current study was 48%, with 22 of the 42 randomized subjects completing this study. When individuals who provided a self-report of their body weight at the 16-week assessment period were included in the analyses, the attrition rate was reduced to 36%, with data available for 27 of 42 subjects at 16 weeks. It is important to note that this attrition did not differ between the DSM and TSM groups. Thus, this level of attrition may be a result of the intervention having minimal face-to-face contact between the participant and the interventionist,

with the intervention in this study being provided in a correspondence manner via mail. Similar levels of attrition have been shown in other minimal-contact intervention studies with Miller et al. [148] and Klem et al. [149] reporting attrition levels of 34% and up to 65%, respectively. This information should be considered when developing behavioral weight loss interventions, with enhanced amount of contact being provided when necessary to improve weight loss outcomes.

When the data were analyzed for the number of diaries returned (irrespective of diary content) across the 16 week intervention for subjects who completed the study (N = 22), results indicated the TSM group returned significantly more diaries than the DSM group. However, there were no differences between the groups with regard to the number of weekly body weights recorded in the diaries or the number of reminders sent each week to subjects who did not return a diary. In subjects who returned at least one diary per quarter, there were no differences between the groups on the number of meals recorded each week, minutes per day of exercise, total minutes per week of exercise, number of days per week subjects' exercised or average rating of perceived exertion (RPE). The "intent to treat" analysis and analysis of "self-reporters + completers" showed no significant difference between DSM and TSM for any of the above-mentioned outcome variables. These findings do not support the primary research hypothesis that the TSM group would complete more eating and exercise records than the DSM group.

It was hypothesized that because TSM was anticipated to increase self-monitoring, this would significantly increase weight loss compared to DSM. However, this hypothesis was not confirmed. While results from data analysis for "completers" showed significantly more diaries returned for TSM versus DSM (see Table 11), this did not result in greater weight loss in TSM versus DSM (see Table 12 and Figure 5). Despite this finding, a significant correlation was

shown between weight loss and frequency of self-monitoring (i.e., total meals recorded) for "completers" (r = 0.47), "self-reporters + completers" (r = 0.53**)** and "intent-to-treat" (r = 0.71). This suggests that the behavior of self-monitoring may be more important for weight loss than the detail of what is actually recorded with regard to food intake and physical activity.

Sperduto et al.[37] evaluated how consistency of self-monitoring affects weight loss. They found obese groups that were taught self-monitoring techniques were more likely to complete the entire treatment intervention, and they lost 63% more weight than obese groups that did not self-monitor. Baker and Kirschenbaum[36] investigated the use of consistent self-monitoring as a coping mechanism for weight control during the holidays and found the only subjects that averaged any weight loss over this stressful period were those who were extremely consistent (i.e., nearly perfect) at self-monitoring. Similar results were obtained by Boutelle et al. whereby considerable weight was lost by subjects demonstrating highly consistent self-monitoring, while weight gain occurred in those exhibiting minimal amounts[35]. Results of another study by Boutelle et al. found the self-monitoring group had significantly better weight management than the control group over a pre- to post-holiday period[38]. Although the primary point of these studies highlight the benefits of self-monitoring over none and the importance of continued self-monitoring for promoting weight loss, this study focused on determining whether a simplified approach might encourage better self-monitoring compliance, which in turn may extend the period of weight loss.

McGuire and colleagues found individuals in the National Weight Control Registry (NWCR) who regained weight exhibited a decline in self-monitoring over time[112]. Studies have shown that individuals effectively self-regulate a variety of behaviors when actively engaged in self-monitoring, however when discontinued, "self-regulation failure" occurs[34].

Factors that appear to interfere with effective self-regulation are coined "high-risk" because they typically disrupt a person's normal daily routine (e.g.: travel, schedule changes, interpersonal conflicts and time constraints)[36] and thus, become barriers to self-monitoring behavior. Unfortunately, "high-risk" factors were not measured in this current study to determine how the DSM or TSM interventions impacted these factors.

There was significant weight loss over the 16 week intervention for both groups however, there was no difference between the groups on the average amount of weight lost (DSM 7.5 kg; TSM 7.6 kg). This may have been a result of the changes in eating and exercise behaviors observed in this study. As shown in Table 13, there were similar changes in energy intake, macronutrient composition, and exercise in the DSM and TSM groups. Thus, considering that these behaviors impact energy balance, this most likely explains the lack of a difference in weight loss between DSM and TSM. However, because this study was 16-weeks in duration, it is unclear whether these intervention strategies would have a differential effect on weight loss beyond this initial intervention period.

5.3. Application of Findings

The major finding of this investigation was that both groups were similar with regard to the amount of weight lost, food diary completion scores and changes in eating and exercise behavior over the 16 week intervention. These findings do not support the primary or secondary research hypotheses that the TSM group would complete more eating and exercise records, exhibit more effective changes in eating and exercise behavior and lose significantly more weight than the DSM group.

The results do however show that a less effortful method of self-monitoring (i.e., TSM) is as effective at promoting diary completion, changes in eating and exercise behavior and weight loss

as the traditional method of detailed self-monitoring. Thus, the goal of this study was met because an alternative tracking method (TSM) was identified that provided the same outcome effect as detailed self-monitoring. This finding has important applications in obesity research. Traditional weight loss programs typically have clients record eating and exercise behavior in great detail[16, 36]; this is a time-consuming process that is difficult to consistently maintain over time[34]. If this barrier is removed by substituting a more simplified self-monitoring approach, it may improve long-term adherence to tracking eating and exercise behaviors, which in turn, may improve overall weight loss.

5.4. Limitations and Recommendations for Future Research

This study is not without limitations which could impact the results of this current investigation. Moreover, these factors should be considered for future research.

1. The attrition rate in this study ranged from 36% to 48%, which could have impacted the results of this study. This may have been a result of the correspondence nature of the intervention. Thus, future studies should identify the methods of enhancing adoption and maintenance of correspondence-based interventions for weight control. This may involve examining factors that are predictive of individuals who best may respond to this form of intervention.
2. This study was 16-weeks in duration, which limits the ability to understand how this correspondence intervention and self-monitoring using DSM or TSM impacted the study outcomes long-term. Future studies should examine the effectiveness of these interventions on weight loss and behavioral outcomes beyond 16-weeks of treatment.
3. The design of this study permitted the comparison of DSM and TSM, with TSM transitioning to a lower detail of self-monitoring from weeks 9 to 16. However, this

study did not include a lower detailed self-monitoring group that used this form of self-monitoring throughout the entire intervention period. Future studies should examine if this form of self-monitoring can be as effective as DSM and TSM within a behavioral weight loss intervention. Moreover, it may be important to examine the optimal time during the intervention for when self-monitoring should be transitioned from a detailed format to a lower detailed format.

4. The sample size for this study did not permit the secondary analysis of the data to determine if there was a differential response to the intervention based on gender, ethnicity, or other demographic characteristics. Future studies should examine the effectiveness of these interventions across diverse samples of subjects.
5. This study showed no difference in the desired outcomes between DSM and TSM. However, this intervention was implemented within a behavioral weight loss program, with weight loss being a desired outcome. It is unclear if a similar intervention would be effective for the prevention of initial weight gain that results in obesity, and this should be examined in future studies.

APPENDIX A

RECRUITMENT FLIER

Research Subjects Needed for
Home-Based Weight Loss and Exercise Study

Are you between 21 – 45 years of age?
Are you interested in changing your diet?

Do you exercise less than 3 days per week and are you interested in becoming more active? Men and women who meet the above criteria and who do not currently participate in structured exercise may be eligible to participate in a weight loss study to examine methods for tracking eating and exercise behaviors. Eligible subjects will participate in a 16 week home-based weight loss program and will receive eating and exercise information.

For more information please *call 412-648-4312*.

APPENDIX B

RISK REVIEW FORM

"Comparison of Self-Monitoring Techniques for Tracking Eating and Exercise Behaviors" Study

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:** Read the following information to the participant (excluding the words in bold).

   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 with internal funds from the Physical Activity & Weight Management Research Center.*

   Description Component of Informed Consent: We are interested in recruiting 75 men and women to participate in this study. This study will focus on examining methods for tracking eating and exercise behaviors during weight loss. To do this, eligible men and women will participate in a 16 week weight loss program that is delivered to you by mail that will assist you with changing your eating patterns to reduce the number of calories that you eat, and to increase the amount of exercise that you do through a home-based walking program. In addition, you will be given tools (such as recording forms and diaries) to monitor your eating and exercise behaviors. However some individuals will be asked to record these behaviors in greater detail. You will be randomly assigned to receive one of three ways to monitor your eating and exercise behaviors, which means that you can not select the type of recording that you will do, but that this will be determined by a method similar to flipping a coin. The three ways involve either recording very specifically the amount and types of food that you eat, and the numbers of calories and fat, along with the amount and type of exercise that you do, recording eating and exercise behaviors in less detail or recording in detail for a period of time and transitioning to recording in less detail. Throughout the program you will receive **weekly** information about changing eating and exercise behaviors by mail along with recording diaries and postage paid return envelopes. You will be asked to complete these diaries on a daily basis and return them in the postage paid envelopes to the investigators weekly. The investigators will review these diaries, provide written feedback, and will return them to you in order to assist you with changing your behaviors. Men and women who are eligible to participate in this study will undergo assessments of body weight, body composition to determine the amount of fat and lean weight on their body, and will also complete questionnaires about their eating and exercise behaviors. These assessments will be completed before you start the study and following 16 weeks of participation. Everyone will receive will receive exercise related material such as exercise clothing, hats or equipment valued at $50.

   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. I will take approximately 5 minutes to ask you all of the

questions. 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. If we complete the interview, I will ask you for some specific information (your complete name, date of birth, and mailing address). I will then schedule you to attend an orientation session that will explain all of the procedures of this study in greater detail. Again 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 than 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 & exercise 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: 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.

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 current and future care at a UPMC HS facility and any other benefits for which you qualify will be the same whether you complete this phone screening or not.

Do you have any questions related to any of the information that I have provided to you? **Staff member is to answer any questions or defer these questions to the Principal Investigator or Co-Investigator when appropriate prior to proceeding, If the individual would like more time to think about their participation prior to proceeding with the Phone Screen, provide them 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 (you can stop me at any time if you have additional questions), and you give me permission to ask you questions now as part of the initial Phone Screen?

Certification of Informed Consent: If "Yes" indicate the participant's agreement with this statement on the top of the next page, and sign your name and date the form, and then complete the Phone Screen. If "No", thank the individual for calling and <u>DO NOT</u> complete the Phone Screen.

APPENDIX C

PHONE SCREEN INTERVIEW

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

CERTIFICATION OF INFORMED CONSENT

I certify that I have 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

Eligible based on telephone screening: θ Yes θ No

1.

a. Age: ____ **(21-45)**

b. Date of Birth: _____

2. Current Weight: _____ pounds ***Office Use: BMI = _____(25-35 kg/m^2)***

3. Current Height: _____feet _____inches

4. Are you able to walk for exercise? θ **YES** θ No
   If "no", specify reason: _____

5. Do you currently exercise regularly at least once per week at a moderate intensity for at least 20 minutes? θ Yes **θ NO**
   If "yes", How many days per week? _____
   If "yes", How long have you been exercising this way?_____
   If "yes", What types of exercise have you been doing?
   _____

6. Do you currently engage in yoga or resistance training of any type? (For example, following videos, using free weights, tubing, etc.) θ Yes **θ NO**
   If "yes", How many days per week? _____
   If "yes", How long have you been exercising this way?_____
   If "yes", What types of exercise have you been doing?
   _____

7. 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	θ Yes **θ NO**	_____
b. Angina	θ Yes **θ NO**	_____
c. Hypertension	θ Yes **θ NO**	_____
d. Heart Attack	θ Yes **θ NO**	_____
e. Stroke	θ Yes **θ NO**	_____
f. Diabetes (sugar)	θ Yes **θ NO**	_____
g. Cancer	θ Yes **θ NO**	_____

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

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

Medication Name	Used to Treat:

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

11. Do you currently smoke? θ Yes **θ NO**
If "yes", specify: _____

12. Are you currently a member of another organized weight reduction program?
θ Yes **θ NO**
If "yes", specify: _____

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

14. Are you currently participating in other research studies? θ Yes **θ NO**
If "yes", specify: _____

15. Have you been a participant in a previous weight loss or exercise study?
θ Yes **θ NO**
If "yes", specify:_____

16 a. Are you currently pregnant? θ Yes **θ NO**
b. Have you been pregnant in the last 6 months? θ Yes **θ NO**
c. Do you plan on becoming pregnant in the next 12 months? θ Yes **θ NO**
If "yes", specify: _____

17. Do you plan to spend any time out of town on vacation or business in the next 12 months that may affect your ability to attend weekly group meetings? θ Yes **θ NO**
If "yes", specify: _____

18. Do you plan on relocating outside of the Greater Pittsburgh Area within the next 12 months? θ Yes **θ NO**
If "yes", specify: _____

APPENDIX D

CONTACT TRACKING FORM

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

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

Name: _____

Street Address: _____

City: _____ State: ___ Zip Code: _____

Home Phone: _____ Work Phone: _____

OFFICE USE ONLY: Eligible: θ yes θNo

Invited to Orientation: θ yes θNo 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 DOCUMENTION OF VERBAL CONSENT AND DEMOGRAPHIC STATISTICS.

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

APPENDIX E

SCREENING FORMS

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q)

Subject ID: _____ Date: _____

Please read the questions carefully and answer each one honestly.
Check YES or NO

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

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

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

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

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

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

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

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

GENERAL HEALTH HISTORY

Subject ID:_____

DATE: _____

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

				Approximate Date of Diagnosis	Describe the Problem
a.	Heart Attack	oyes	ono	_____	_____
b.	Angina (chest pain on exertion)	oyes	ono	_____	_____
c.	Irregular Heart Problems	oyes	ono	_____	_____
d.	Other Heart Problems	oyes	ono	_____	_____
e.	Stroke	oyes	ono	_____	_____
f.	Fainting Spells	oyes	ono	_____	_____
g.	High Blood Pressure	oyes	ono	_____	_____
h.	High Cholesterol	oyes	ono	_____	_____
i.	Thyroid Problems	oyes	ono	_____	_____
j.	Cancer	oyes	ono	_____	_____
k.	Kidney Problems	oyes	ono	_____	_____
l.	Liver Problems	oyes	ono	_____	_____
m.	Gout	oyes	ono	_____	_____
n.	Diabetes	oyes	ono	_____	_____
o.	Emotional/Psychiatric Problem	oyes	ono	_____	_____
p.	Drug/Alcohol Problems	oyes	ono	_____	_____

2. Do you have any medical problems that would prevent you from participating in a regular walking program? oyes ono
   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? oyes ono
   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? oyes ono

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) o Never
   (1) o Less than once/month
   (2) o 1-2 times/month
   (3) o1 day/week
   (4) o 2 days/week
   (5) o 3 days/week
   (6) o 4 days/week
   (7) o 5 days/week

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

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

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

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

Cigarettes	oyes	ono	_____
Pipe	oyes	ono	_____
Cigars	oyes	ono	_____
Chewing Tobacco	oyes	ono	_____

11. Do you plan to spend frequent time out of town on business or vacation during the next 18 months? oyes ono Please describe:_____
_____

12. Is it possible that you will relocate in the next 18 months? oyes ono Please describe: _____

WOMEN ONLY ANSWER THE FOLLOWING QUESTIONS

13. Are you currently pregnant? oyes ono

14. Were you pregnant within the past 6 months? oyes ono

15. Do you plan to become pregnant in the next 18 months? oyes ono

16. Have you gone through menopause or the change of life? oyes ono

17. Have you had a hysterectomy? oyes ono

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

19. Do you take :

Birth Control Pills?	oyes	ono
Estrogens (ie. Premarin)?	oyes	ono
Progesterone (ie. Provera)?	oyes	ono

APPENDIX F

IRB CONSENT AND PERMISSION FORMS

Approval Date: July 6, 2004
Renewal Date: July 5, 2005
University of Pittsburgh
Institutional Review Board
IRB # 0307101

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Comparison of Self-Monitoring Techniques for Tracking Eating and Exercise Behaviors

PRINCIPAL INVESTIGATOR: John M. Jakicic, Ph.D.
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SOURCE OF SUPPORT: Physical Activity & Weight Management Research Center

Why is this research being done?

Self-monitoring of eating and exercise behaviors is an effective strategy used during weight loss. In standard behavioral weight loss programs, individuals who consistently track eating and exercise behaviors have greater weight loss than those who self-monitor less regularly. However, individuals often find that maintaining consistent, detailed records of these behaviors is difficult. Thus, identifying

alternative tracking methods may improve long-term adherence to self-monitoring during weight loss. This study will investigate different self-monitoring techniques for tracking eating and exercise behaviors and will determine the effect of these tracking techniques on body weight and eating and exercise behaviors.

Who is being asked to take part in this research study?

You are being invited to take part in this research study because you are within the body weight range for this study, and are relatively healthy. People invited into this study have to be between 21-45 years of age. Women cannot be pregnant, and you will be required to accurately report whether you are pregnant to the investigators prior to beginning this study and during the study if your status should change. This study is being performed on a total of 75 individuals at the University of Pittsburgh.

What procedures will be performed for research purposes?

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:

1. You will complete a physical activity readiness questionnaire (PAR-Q), and this will take approximately 5 minutes to complete. You will also complete a detailed medical history, and this will take approximately 20 minutes to complete. These questionnaires will allow the investigators to determine if you have any significant medical condition that would indicate that exercise, dieting, or weight loss is unsafe for you.

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

These assessments will take place at the Physical Activity & Weight Management Research Center at the University of Pittsburgh and will be conducted by the Physical Activity & Weight Management Research Center staff. Your body weight, level of physical activity, and food intake will be measured. In addition, you will be asked to provide information about your health, exercise and diet habits. These assessments will take approximately 30 minutes to complete, and will be performed prior to beginning the study, and following 16 weeks of participation. A brief description of these assessments follows. The time required for each measurement is listed in parenthesis.

You will first be asked to complete a series of questionnaires which you will complete prior to your assessment and bring with you to your appointment. These questionnaires will provide information about your health, exercise and diet habits. These questionnaires take approximately 15 minutes to complete.

A. Exercise, Dietary Patterns, and Factors that Influence Behavior Change: You will complete questionnaires about the amount of exercise that you do, and the amount and types of foods that you eat. You will also complete questionnaires about factors such as your general health, and other things that may affect your exercise and eating behaviors.

The following assessments will be performed at the Physical Activity & Weight Management Research Center:

B. Body Weight, Height and Blood Pressure (5 minutes): Your body weight will be measured using a standard medical scale. Your height will be measured with a ruler that is attached to a flat wall. In addition, your resting blood pressure while seated will also be measured using a standard blood pressure cuff and standard measurement procedures. If it is determined that your resting blood pressure is high ($\geq$ 160/100) you will be referred back to your primary care physician and you may not be eligible for this study. In the event any other unsuspected disease or condition (musculoskeletal problems, etc.) is identified during the assessment procedures you will be referred back to your primary care physician.

C. Body Composition (5 minutes): Your body composition is the amount of fat weight and lean weight (muscle and bone) that you have on your body. Your body composition will be measured using a technique known as Bioelectrical Impedance Analysis (BIA). This procedure requires that a small electrode be placed on your hand, wrist, ankle, and foot. A low-level signal that is not harmful to you and that you will not feel is transmitted between the electrodes. There is no harm or risk associated with this procedure. Measurements of your waist and hip areas will also be made using a measuring tape.

D. Physical Activity (15 minutes): You will be asked questions about your exercise and physical activity behaviors. This will include answering questions about how much walking, stair climbing and specific sport or recreational activities you may do. In addition, you will be interviewed about our activity, sleeping and sitting behaviors.

Experimental Procedures

After completing these assessments, if you are still eligible to participate, you will participate in a home-based behavioral weight loss program consisting of diet and exercise treatment. This program will be delivered by mail. However, following the assessments, you will be asked to attend one session in person at the Physical Activity & Weight Management Research Center at the University of Pittsburgh. This session will be led by a team of exercise physiologists and registered dietitians and will last approximately 1 hour. During this session, we will explain the diet and exercise components of the weight loss program. The diet program that you will be placed on encourages you to decrease the amount of total calories and fat that you eat. If you are less than 200 pounds, you will be placed on a 1200 calorie per day diet. If you are 200 pounds or greater, you will be placed on a 1500 calorie per day diet. 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. In addition to the diet program, you will be given a walking program for exercise. You will be instructed to exercise 5 days per week, with the duration on each day increasing from 20 to 40 minutes over the study period. 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 55-70% of your maximal capacity, which is the equivalent of taking a brisk walk for most individuals. You will be provided with a scale to monitor and rate the intensity of exercise that you will be performing. You will be asked to exercise at an intensity that feels between light and somewhat hard and directions on how to do this will be explained to you during the initial session. You will record your exercise in a diary that is returned to the investigators weekly. In addition to the above, you will also be randomly assigned by chance (similar to flipping a coin) to participate in one of three groups. You will learn which group you have been assigned to at the initial session (following the assessment procedures). These groups are as follows:

A. Detailed Self-Monitoring (DSM): If assigned to this group you will be asked to record your eating and exercise behaviors for a period of 16 weeks. To do this, you will be asked to complete a diary every day that includes the number of calories that you eat, the amount of fat that you eat, and the amount of exercise that you do. You will return this diary to the investigators every week to be reviewed. We will provide you with self-addressed, stamped envelopes in order to return these diaries to us. The diary will then be returned to you with specific comments about how you can improve your eating and exercise behaviors. In addition, you will receive printed information every week to help you to make changes in your eating and exercise behaviors.

B. Abbreviated Self-Monitoring (ABSM): If assigned to this group you will be asked to record your eating and exercise behaviors for a period of 16 weeks. To do this, you will be asked to complete a diary every day that includes an estimate of the size of each individual meal or snack and an estimate of the amount of fat of each meal and snack. You will also record the length of time it took to eat each meal and snack. In addition, you will indicate on a weekly calendar the days that you participated in exercise of at least 15 minutes in duration. You will return this diary and calendar to the investigators every week to be reviewed. We will provide you with self-addressed, stamped envelopes in order to return these diaries to us. The diary and calendar will then be returned to you with specific comments about how you can improve your eating and exercise behaviors. In addition, you will receive printed information every week to help you to make changes in your eating and exercise behaviors.

C. Detailed Self-Monitoring *Transitioning* to Abbreviated Self-Monitoring (TSM): If assigned to this group you will be asked to record your eating and exercise behaviors for a period of 16 weeks. This group combines the two types of monitoring described above. For the first 8 weeks you will be asked to record your eating and exercise behaviors in detail. To do this, you will be asked to complete a diary every day that includes the number of calories that you eat, the amount of fat that you eat, and the amount of exercise that you do. For the remaining 8 weeks, you will be asked to complete a diary every day that includes an *estimate* of the size of each individual meal or snack and an *estimate* of the amount of fat of each meal and snack. You will also record the length of time it took to eat each meal and snack. In addition, you will indicate on a weekly calendar the days that you participated in exercise of at least 15 minutes in duration. Throughout the 16 weeks you will return diaries to the investigators every week to be reviewed. We will provide you with self-addressed, stamped envelopes in order to return these diaries to us. The diaries will be returned to you weekly with specific comments about how you can improve your eating and exercise behaviors. In addition, you will receive printed information every week to help you to make changes in your eating and exercise behaviors.

What are the possible risks, side effects, and discomforts of this research study?

The possible risks of this research study may be due to the exercise that you will be performing and the diet that will reduce the amount and types of foods that you will be eating.

Risks

Risks of Exercise: There are minimal risks associated with participating in a regular exercise program that is moderate in intensity. During this research study, it is possible that you may experience general fatigue related to participating in an exercise program. In addition, during exercise, your heart rate and blood pressure will increase, and under extreme conditions, this can lead to a serious cardiac event (i.e., heart attack). The risk of this happening to you is rare, because it occurs in less than 1% of people. Because some of the exercises that you will be asked to do will not be supervised by the staff, the staff can not provide medical assistance to you in the event of an emergency during these exercise sessions. Some people also experience general muscular soreness following the onset of an exercise program. Muscle soreness is commonly experienced during exercise training and occurs in 10-25% of people or 10-25 out of 100 people. However, in the event that muscle discomfort or pain limits your ability to exercise regularly, you will be asked to stop exercising and will be referred to your primary care physician.

Risks Associated with Assessment of Body Composition using BIA: There are no apparent risks associated with assessment of body composition using bio-electrical impedance. Therefore, the risk of an adverse event is rare (occurs in less than 1% of people or less than 1 out of 100 people).

What are the possible benefits from taking part in this study?

There are also possible benefits of this research study due to the exercises that you will be performing. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study. The benefits of participation in an exercise program have been shown to include improvements in physical fitness (cardiorespiratory), weight control, 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 I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

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.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

Will I be paid if I take part in this research study?

If you complete this 16-week study and participate in the assessment at the end of the study, regardless of group assignment, you will receive exercise related material such as exercise clothing, hats or equipment valued at $50.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers and their associates who provide services at 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 the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. You will not receive any monetary payment for, or associated with, any injury that you suffer in relation to this research.

Who will know about my participation in this research study?

Any information about you obtained from or for this research study 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. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will <u>not</u> involve the use or disclosure of your identifiable medical information.

Who will have access to identifiable information related to my participation in this research study?

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

> Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.
>
> In unusual cases, your research records may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators 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.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

Is my participation in this research study voluntary?

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

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.)

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

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

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

If I agree to take part in this research study, can I be removed from the study without my consent?
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.
In the event you are removed from the study, any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you were withdrawn may continue to be used and disclosed by the investigators for the purposes described above.

****
****
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 have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have 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

University of Pittsburgh

3500 Fifth Avenue
Ground Level
Pittsburgh PA 15213
(412) 578-3414
(412) 578-8553 (fax)

Institutional Review Board

MEMORANDUM

TO: John M. Jakicic, Ph.D.
FROM: Terrance Schwinghammer, Pharm.D., Vice Chair
DATE: September 12, 2003

SUBJECT: IRB #0307101: Comparison of Self-Monitoring Techniques for Tracking Eating and Exercise Behaviors

Thank you for addressing the concerns of the Institutional Review Board regarding the above-referenced proposal. This version of your protocol and consent form(s) has been approved by Committee F.

Please note that the advertisement that was submitted for review has been approved as written. Please note that the waiver for the requirement to obtain a written informed consent for the telephone screening has been approved.

Please include the following information in the upper right-hand comer of all pages of the consent form:

Approval Date: July 30, 2003
Renewal Date: July 29, 2004
University of Pittsburgh
Institutional Review Board
IRB #0307101

Adverse events which occur during the course of the research study must be reported to the IRS Office, Please call the IRS Adverse Event Coordinator at 412-578-8565 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration data noted above for annual renewal as required by Assurance No. M-1259, given to DHHS by the University of Pittsburgh.

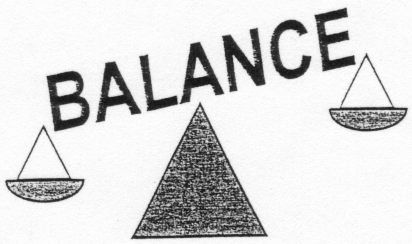
If your research proposal involves an investigational drug, please forward a copy of this approval later along with a copy of the Cover Sheet, protocol. consent form(s) and drug brochure to Investigational Drug Service, PUH Pharmacy.

Please be advised that your **research study may be audited periodically by the University of Pittsburgh Research Conduct** and Compliance Office.

TS:cc

APPENDIX G

DETAILED DIARY



FOOD AND EXERCISE RECORD

CALORIE GOALS:	FAT GOALS:
DAILY _____	DAILY _____
WEEKLY _____	WEEKLY _____

WEEKLY EXERCISE GOALS:

_____ MINUTES / WEEK

_____ MINUTES / DAY

_____ DAYS / WEEK

_____ TARGET HEART RATE

NAME: _____ **WEEK:** _____

DATE: _____

CHECK BOX FOR DAY OF WEEK:

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

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

RPE Scale

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

NAME: _____

START DATE: _____ **WEEK:** _____

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

TIME OF DAY	TYPE OF EXERCISE	DURATION OF SESSION	RPE

☐ **DID NOT EXERCISE TODAY:**

REASON FOR NOT EXERCISING (SELECT ONE OF THE FOLLOWING)

☐ LACK OF TIME FOR EXERCISE
☐ EXERCISE WAS INCONVENIENT
☐ LACK OF MOTIVATION FOR EXERCISE
☐ NEEDED A REST DAY FROM EXERCISE
☐ OTHER _____

APPENDIX H

ABBREVIATED DIARY

FOOD AND EXERCISE RECORD

CALORIE GOALS:	FAT GOALS:
DAILY _____	DAILY _____
WEEKLY _____	WEEKLY _____

WEEKLY EXERCISE GOALS:

_____ MINUTES / WEEK

_____ MINUTES / DAY

_____ DAYS / WEEK

_____ TARGET HEART RATE

NAME: _____ **WEEK:** _____

DATE: _____

CHECK BOX FOR DAY OF WEEK:

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

FOOD OR BEVERAGE AMOUNT AND DESCRIPTION
BREAKFAST: ☐ DID NOT EAT BREAKFAST
CALORIES: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
FAT: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
MORNING SNACK: ☐ DID NOT EAT MORNING SNACK
CALORIES: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
FAT: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
LUNCH: ☐ DID NOT EAT LUNCH
CALORIES: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
FAT: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
AFTERNOON SNACK: ☐ DID NOT EAT AFTERNOON SNACK
CALORIES: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
FAT: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE

RPE Scale

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

NAME: _____

START DATE: _____ **WEEK:** _____

FOOD OR BEVERAGE AMOUNT AND DESCRIPTION
DINNER: ☐ DID NOT EAT DINNER
CALORIES: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
FAT: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
EVENING SNACK: ☐ DID NOT EAT EVENING SNACK
CALORIES: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE
FAT: ☐ SMALL ☐ MEDIUM ☐ LARGE ☐ SUPER SIZE

DURATION OF EXERCISE TODAY	AVERAGE RPE
☐ ≤15 MINUTES	
☐ 16-30 MINUTES	
☐ 31-45 MINUTES	
☐ 46-60 MINUTES	
☐ > 60 MINUTES	

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

APPENDIX I

LIFESTYLE QUESTIONNAIRE

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

2 Employment Status: Are you currently working for pay full or part-time?

θ_1 Yes

θ_2 No (**GO TO QUESTION #5)**

4 If you are not working for pay, which of the following best describes you?

θ_1 a homemaker

θ_2 retired or disabled

θ_3 a student

θ_4 not currently employed

6 Marital Status:

θ_1	Married	
θ_2	Separated	
θ_3	Divorced	***If NOT Married, go to Question #9***
θ_4	Widowed	
θ_5	Never Married	

7 Number of adults living in household including yourself. θθ

8 Number of children under age 18 living in household. θθ

WEIGHT HISTORY

9a. What is the most you have weighed, not counting pregnancies? θθθ pounds

10a. What is the least you have weighed since age 18? θθθ pounds

11. How much would you like to weigh? θθθ pounds

		YES	NO
13.	Have you ever participated in an organized weight loss program (e.g., Weight Watchers, TOPS, etc.)	θ_1	θ_2
15.	Are you currently dieting to maintain you current weight?	θ_1	θ_2

16. Put a check to indicate whether you were: extremely underweight, underweight, normal weight, overweight, or extremely overweight at each of the following ages:

		Extremely Underweight	Underweight	Normal Weight	Overweight	Extremely Overweight	Not Applicable
b.	Elem. School	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6
d.	High School (15-18 yrs)	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6
f.	26-35 yrs	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6
h.	46-55 yrs	θ_1	θ_2	θ_3	θ_4	θ_5	θ_6

17. Check the number of times in your life you have **intentionally** lost the number of pounds shown below (e.g., through diet, exercise, a formal weight control program, etc.)

		NEVER	1-2	3-5	6-10	More than 10
b.	How often have you lost 20-49 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
d.	How often have you lost 80-99 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5

18. Check the number of times in your life you have **unintentionally** lost the number of pounds shown below (e.g., because of illness, injury, etc.)

		NEVER	1-2	3-5	6-10	More than 10
b.	How often have you lost 20-49 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5
d.	How often have you lost 80-99 pounds?	θ_1	θ_2	θ_3	θ_4	θ_5

19. If you gained weight, how much would your weight have to increase before you considered this weight gain to be significant?

***Please select one of the following.*

a.	< 5 pounds?	θ_1
b.	5-10 pounds?	θ_2
c.	11-15 pounds?	θ_3
d.	16-20 pounds?	θ_4
e.	> 20 pounds?	θ_5

APPENDIX J

PAFFENBARGER PHYSICAL ACTIVITY QUESTIONNAIRE

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

EXERCISE HABITS

☐$_1$Yes ☐$_2$No

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

θθ Flights per day

θθ Blocks per day

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

θ less active than usual

θ more active than usual

θ about as active as usual

θ Yes θθ times per week; Activity:

θ No

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.)	θθ	θθ
b) Moderate Activity (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)	θθ	θθ
c) Light Activity (office work, driving car, strolling, personal care, standing with little motion, etc.)	θθ	θθ
d) Sitting Activity (eating, reading, desk work, watching TV, computer work, listening to the radio, etc.)	θθ	θθ
e) Sleeping or reclining	θθ	θθ

APPENDIX K

EXERCISE PROGRESSION

Exercise Progression for Intervention Groups

AEROBIC EXERCISE **Days per Week** **Weeks 1 – 16**	**DSM**	**TSM**
	5	5
Minutes/Day min/wk)		
Weeks 1-4	20 (100)	20 (100)
Weeks 5-8	30 (150)	30 (150)
Weeks 9-16	40 (200)	40 (200)
Exercise Intensity	**RPE**	**RPE**
Weeks 1-8	11-13	11-13
Weeks 9-16	11-15	11-15

APPENDIX L

WEEKLY DIARY SUMMARY FORMS

Diary Study - Weekly Diary Summary (Detailed)

Eating Behaviors

Day	***Breakfast Choices***		***Snack Choices (Breakfast/Lunch)***		***Lunch Choices***		***Snack Choices (Lunch/Dinner)***		***Dinner Choices***		***Snack Choices (after Dinner)***	
	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete
Mon												
Tues												
Wed												
Thurs												
Fri												
Sat												
Sun												

Exercise Behaviors

Day	Time of Day	Type of Exercise	Duration	RPE	Did Not Exercise	Reason for Not Exercising				
						Lack of Time	Lack of Motivation	Inconvenient	Rest Day	Other
Mon										
Tues										
Wed										
Thurs										
Fri										
Sat										
Sun										

Name: _____ Week: _____ Body Weight: _____

Diary Study - Weekly Diary Summary (Abbreviated)

Eating Behaviors

Day	*Breakfast Choices*		*Snack Choices (Breakfast/Lunch)*		*Lunch Choices*		*Snack Choices (Lunch/Dinner)*		*Dinner Choices*		*Snack Choices (after Dinner)*	
	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete	Complete	Not Complete
Mon												
Tues												
Wed												
Thurs												
Fri												
Sat												
Sun												

Exercise Behaviors

Day	Duration of Exercise Today					RPE	Did Not Exercise	Reason for Not Exercising				
	≤15 minutes	16-30 minutes	31-45 minutes	46-60 minutes	>60 minutes			Lack of Time	Lack of Motivation	Inconvenient	Rest Day	Other
Mon												
Tues												
Wed												
Thurs												
Fri												
Sat												
Sun												

Name: _____ Week: _____ Body Weight: _____

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