DISSERTATION

DEVELOPMENT AND EVALUATION OF A LIFESTYLE PHYSICAL ACTIVITY INTERVENTION FOR OBESE SEDENTARY WOMEN

Submitted by

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WE HEREBY RECOMMEND THAT THE DISSERTATION PREPARED UNDER OUR SUPERVISION BY CINDY LOUISE BYFIELD ENTITLED **DEVELOPMENT AND EVALUATION OF A LIFESTYLE PHYSICAL ACTIVITY INTERVENTION FOR OBESE SEDENTARY WOMEN** BE ACCEPTED AS FULFILLING IN PART REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY.

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ABSTRACT OF DISSERTATION

DEVELOPMENT AND EVALUATION OF A LIFESTYLE PHYSICAL ACTIVITY INTERVENTION FOR OBESE SEDENTARY WOMEN

Physical inactivity has been established as an independent predictor of cardiovascular disease (CVD) mortality in both lean and obese individuals[1]. Increasing physical activity and cardiorespiratory fitness (CRF) in obese individuals attenuates the comorbidities associated with obesity and the reduction in risk is comparable to that of smoking cessation[1]. Despite the benefits of physical activity, prevalence of physical inactivity is high, particularly among obese women. Recent evidence indicates that lifestyle physical activity programs that are based on behavior change theory are an effective alternative to traditional exercise programs in promoting the adoption of physical activity in sedentary individuals[2].

The primary aim of this study was two-fold: 1) Develop a 24-week, theory-based lifestyle physical activity intervention for obese sedentary women; 2) Evaluate the effectiveness of this intervention by assessing changes in physical activity and CRF after 24 weeks of intervention and 24 weeks of follow-up. Secondary aims were to examine the effect of the

[1] U.S. Dept. of Health and Human Services. *Physical Activity and Health. A Report of the Surgeon General.* Atlanta: U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.

[2] Dunn, A.L., B.H. Marcus, J.B. Kampert, M.E. Garcia, H. Kohl, and S.N. Blair. Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness. JAMA 281:327-334, 1999.

Lifestyle intervention on dietary practices, CVD risk factors, and psychological measures of behavior change.

Fifty-eight obese sedentary women were randomized into the Lifestyle intervention developed for this study (n=29) or a "Usual Care" intervention (n=29). After 24 weeks, significant improvements in physical activity, CRF, Body Mass Index (BMI), diastolic blood pressure, self-efficacy, and eight of the 10 processes of change occurred among Lifestyle participants. No changes in these variables were observed among Usual Care participants. Attrition was significantly lower among Lifestyle participants than among Usual Care participants.

After 48 weeks, levels of physical activity, CRF, and self-efficacy were significantly higher than baseline among Lifestyle participants but not among Usual Care participants. LDL-cholesterol levels were significantly lower in Lifestyle participants at 48 weeks but systolic blood pressure was significantly higher. BMI was significantly higher at 48 weeks than at baseline among Usual Care participants but not among Lifestyle participants.

The Lifestyle intervention developed for this study was effective in producing significant improvements in physical activity, cardiorespiratory fitness, LDL-cholesterol, and self-efficacy among obese sedentary women.

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Introduction

Cardiovascular disease (CVD) is the leading cause of death in the United States for both men and women (8). Physical inactivity has been established as an independent risk factor for CVD and an important contributor to non-insulin dependent diabetes mellitus, obesity, and some forms of cancer (8, 194). In fact, as many as one-third of all deaths in the U.S. from CVD, colon cancer, and type 2 diabetes have been attributed to physical inactivity (192).

Despite the benefits of exercise, many people remain sedentary. Less than 15% of US adults exercise at the recommended level and more than 40% engage in no physical activity at all (191). The U.S. Dept. of Health and Human Services (HHS) recently listed physical inactivity as one of the top ten "leading health indicators" in the Healthy People 2010 initiative and set a goal to "increase the proportion of adults who engage regularly, preferably daily, in moderate physical activity for at least 30 minutes per day to 30%"(191).

Physical inactivity is also a major contributor to the recent and dramatic increase in obesity prevalence (32, 85). As many as one in every two Americans are likely to be overweight or obese, defined by a Body Mass Index (BMI) of 25 or greater, a 25% increase over the past three decades (64). Obesity itself is a major risk factor for coronary heart disease (CHD), the predominant form of CVD, and the risk increases dramatically as degree of overweight increases (8, 147).

However, mounting evidence within the last 20 years has demonstrated a strong, inverse relation between all-cause or CVD mortality and physical activity and fitness in both lean and obese individuals (29, 30, 62, 112). Several studies have indicated that fit individuals with higher levels of BMI, percent body fat, fat mass, fat-free mass, and waist girth have significantly lower death rates than unfit individuals with similar body habitus measurements and obese fit men have similar death rates as lean fit men (18, 21, 112). Evidence from randomized clinical trials has shown that increasing physical activity and fitness in obese individuals attenuates the comorbidities associated with obesity, such as dyslipidemia, hyperinsulinemia, and hypertension, and thereby reduces CVD risk (19, 29, 46, 78, 98, 183). Considering the poor long-term success of intentional weight loss efforts among many obese individuals (107, 195), a focused effort to increase physical activity and fitness in obese individuals may be a more successful approach to improving health outcomes in this population.

Yet the prevalence of sedentary behavior among the obese is not likely due to a lack of knowledge regarding the health benefits of exercise. Hundreds of well-controlled trials over the last 40 years have provided solid evidence on the physiological effects of exercise training.

These studies have allowed scientists to be able to specifically quantify the dose of exercise necessary to improve physiological fitness parameters. This work has led to the development of the "exercise prescription", a method for prescribing the recommended amount of exercise in terms of *frequency* (3-5 times a week), *intensity* (from 40%-50% to 85% of maximal aerobic power), and *duration* (20 to 60 minutes per session)(7). The American College of Sports Medicine (ACSM) and other groups have utilized the exercise prescription for promoting exercise in both clinical and community settings and to the general public as well (7).

The fact that so many people remain sedentary suggests that options to the structured exercise prescription may be needed. Recent public health recommendations by ACSM, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Surgeon General to "accumulate 30 minutes or more of moderate intensity activity on most days of the week" have also emphasized the health value of "lifestyle physical activity"(149, 157). This type of activity includes gardening, housework, short sessions of walking or stair climbing, and other short bouts of activity integrated into one's daily routine.

Researchers have speculated that lifestyle physical activity may be more appealing to sedentary individuals by making physical activity more convenient and less intimidating than traditional forms of exercise (52). This type of activity may also be effective in helping obese individuals become more physically active as it is less strenuous and as mentioned, less intimidating, than traditional exercise regimes. Obese individuals face a combination of physical and psychological barriers to physical activity that are not typically addressed within traditional exercise or weight management programs. Creative interventions are needed to help obese individuals overcome these barriers and adopt a physically active lifestyle (192).

Researchers have also speculated that the adoption of physical activity may lead to the adoption of other health-related behaviors, such as healthful dietary practices (196). Observational studies have indicated that physical activity participation is associated with adherence to dietary guidelines (42) and eating a healthful breakfast (35). However, recent studies have indicated that active individuals do not systematically choose foods that are low in fat content; thus, for purposes of maintaining energy balance and reducing CVD risk in obese individuals, physical activity programs should include nutritional guidelines (190). Whether providing this information within the context of a physical activity intervention will improve dietary practices is unknown.

Interventions that have been the most successful in promoting behavior change are developed using theoretical models as a guide. Two models that have become increasingly popular with interventionists are the Transtheoretical Model for Behavior Change (164) and Bandura's theory of self-efficacy (16). Recent advances in these two models have identified specific cognitive and behavioral strategies that are important in changing health-related behavior (131). These strategies have been found to be effective in changing sedentary behavior in non-obese individuals but, to date, no data exists as to whether these strategies are effective in promoting physical activity among obese sedentary women.

Thus, there were four main objectives for this research study:

1. Develop a physical activity intervention specifically for obese sedentary women that incorporates theoretical models for behavior change and new recommendations for promoting physical activity in sedentary individuals.

2. Determine the effect of the intervention on physical activity and cardiorespiratory fitness levels over 24 weeks of intensive intervention and 24 weeks of follow-up (24 and 48 weeks from baseline).

3. Determine the effect of the intervention on diet composition and CVD risk factors.

4. Determine if changes in psychological measures are predictive of changes in physical activity and cardiorespiratory fitness.

Chapter 1

Literature Review

CARDIOVASCULAR DISEASE

Cardiovascular disease (CVD) is the leading cause of mortality for both men and women in the United States, causing nearly one million deaths each year (8). Coronary heart disease (CHD), one type of CVD, accounts for more than half of all CVD mortality, taking the lives of approximately 500,000 people each year (8). Although many believe CVD to be mostly a "man's disease", more women than men have died from CVD every year since 1984 (8). In fact, more women die from CVD than the next 14 causes of death combined (8). For Colorado women, as in all 50 states, CVD is the leading cause of death, causing approximately 311 deaths per 100,000 women (8).

The misconception that CVD occurs mostly in men is at least partly due to the fact that men suffer heart attacks an average of 10 years earlier in life than women do (8). Until the onset of menopause, a woman's risk of having a heart attack is relatively low. After menopause, the incidence of CVD events in women rises dramatically, equaling the incidence in men. One in ten women between the ages of 45 and 64 have heart disease – one in four women have heart disease after the age of 65 (174).

Mortality data fails to capture the amount of suffering endured by those who survive a CVD event, such as a myocardial infarction or stroke. Improved medical care of acute CVD events has enabled more people to survive a CVD event but, in most cases, not without some pain or disability. For every fatal myocardial infarction, two are non-fatal (71). Of the one million heart attack survivors, approximately half suffer loss of normal ventricular function and almost 14 million Americans have angina, a history of myocardial infarction, or both (71).

In addition, the financial costs of CVD are quite staggering. Approximately $287 billion are spent annually on CVD medical care (combined direct and indirect costs) and, for the year 2000, costs are projected to reach $326.6 billion (8, 71). Because there has been a significant decline in age-adjusted mortality rates for CHD over the last 30 years in the United States (71), it may appear that these costs should also decline. However, because more patients are likely to survive an acute CVD event, and because the prevalence of CVD increases with advancing age and an increasing percentage of the population is over the age of 65, there has been a paradoxical *increase* in the overall prevalence of CVD (71).

Risk Factors for CVD

Assessing the probability of having or developing a given disease involves assessing one's risk for that disease. Risk "factors" are entities that have been found to be associated with developing a given disease at some point in the future (71). Risk factors can be causal in nature or they may simply serve as markers of risk (71). They can include genetic factors, blood test results, personal and lifestyle habits, and physical examination data (71).

According to the American Heart Association, primary risk factors for CVD include cigarette smoking, high blood cholesterol, hypertension, physical inactivity, overweight and obesity, and diabetes mellitus (8). The AHA also considers these risk factors as modifiable by changes in lifestyle. Risk factors that are not modifiable include age, family history, and menopausal status for women (71).

It is important to note that CVD is rarely caused by the presence of a single risk factor; it is more common for several risk factors to be present in a single person (71, 93). Moreover, not all risk factors carry equal weight in their contribution to the development of CVD. For instance, cigarette smoking is known to be a more powerful risk factor for CVD than high blood cholesterol levels (8). However, diabetes is a more potent risk factor than cigarette smoking in women, and in men, the reverse is true (174).

Recent research has indicated that physical inactivity and/or low physical fitness are more robust risk factors for CVD in both men and women than what was previously believed. Powell et al.(160) conducted a meta-analysis of all available studies investigating physical inactivity as a risk factor for CHD and concluded that inactivity is as strong of a predictor for CHD as cigarette smoking. Until 1992, the AHA considered physical inactivity only as a secondary risk factor but mounting evidence of the inverse relationship between physical activity and CVD mortality prompted the AHA to designate it as a primary risk factor (56).

Physical inactivity also plays a significant role in the development and treatment of obesity and, as stated earlier, obesity itself is a risk factor for CVD. Therefore, the following literature review will focus primarily on the interrelationships among physical activity, cardiorespiratory fitness, obesity, and CVD, as well as the literature on the behavioral aspects of changing sedentary behavior.

PHYSICAL ACTIVITY, CARDIORESPIRATORY FITNESS, AND CVD

Physical activity and cardiorespiratory fitness are interrelated but each may act independently to favor health outcomes (114). Physical activity, defined as "any bodily movement produced by skeletal muscles that requires energy expenditure" (36), is an optional behavior whereas cardiorespiratory fitness is an achieved condition. Habitual physical activity is a major determinant of cardiorespiratory fitness, but other factors are involved as well, such as age, sex, heredity, and medical status (192). Tests of cardiorespiratory fitness can be used as a measure of physical activity with the understanding that factors other than activity can influence the results (81). Haskell and colleagues (81) report that the magnitude of these other factors are reduced when changes in fitness are measured to validate changes in physical activity.

Evidence has been accumulating for the past two decades that indicate an inverse relation exists between physical activity and mortality, primarily from CVD (19, 29) and all causes (30, 62, 170). Studies demonstrating this relationship actually date back as early as 1713 when the good health of foot messengers ("runners") was compared to that of sedentary workers (tailors and cobblers) who tended to die at younger ages (165). A century later Smith (179) noted a higher death rate among British tailors than among farm workers. In 1923, Sivertsen and Dahlstrom (176) classified Minnesota men according to occupational activity and wrote of increasing mortality with decreasing physical activity on the job.

Within the last 30 years, the studies examining the association between physical activity and CVD or all-cause mortality have generally been prospective cohort studies. In most cases, researchers classified subjects according to physical activity or fitness categories and then determined the mortality rates within each category over a specified time period. More recently, investigators have examined mortality rates of subjects who did or did not increase their physical activity or fitness level over time. Both types of studies are presented here.

In 1962, Taylor et al (187) tested the hypothesis that men who were physically active on the job had lower CHD death rates than men who were in sedentary occupations. Clerks (deemed sedentary) and switchmen or section men (deemed physically active) from the U.S. Railroad Industry were enrolled as subjects. To participate in the study, subjects had to have worked for 10 years by 1951 and still be employed in 1954. Mortality rates between 1955 and 1956 were used for analysis; only deaths of men between the ages 40-64 were included in the study.

A total of 1978 deaths occurred during that time period. The age-adjusted death rates per 1000 were 7.62 for section men, 10.29 for switchmen, and 11.83 for clerks, with the differences statistically significant. However, the authors did not control for other factors that contribute to CHD mortality, such as smoking, diet, or obesity.

Men working for the railroad industry were again enrolled in what is called the US Railroad Study (n = 3043), comprising one cohort of the Seven Countries Study (177), an investigation of the predictors of CHD among 16 cohorts in seven different countries. This time the investigators were interested in the association of leisure time physical activity (LTPA), not occupational physical activity, and mortality. For this analysis, data was collected on 2562 while railroad workers between the ages of 22 and 79 who were not retired at baseline and who had not been diagnosed with CVD. Between 1957 and 1960, the men were examined medically and queried about their frequency and duration of participating in more than 50 different types of LTPA, using the Minnesota LTPA Questionnaire (186). Using this data, energy expended in kilocalories (kcals) per week on LTPA was calculated. In addition, energy expenditure (in kcals per week) was partitioned among light-to-moderate activities and intense activities, such as backpacking, jogging or running, swimming, shoveling snow, etc. The men were followed for mortality until 1977.

As expected, the age-adjusted mortality rates declined with increasing LTPA. After further adjustments were made to control for other CHD risk factors, such as cigarette smoking, blood pressure, and serum cholesterol levels, a significant, inverse relation between LTPA and all-cause mortality persisted. The data show that the least active men had 1.21 times the mortality rate (95% confidence interval 1.03 – 1.42) of the most active men during the follow-up period.

Studies by Morris and colleagues (39, 144, 145) laid the groundwork for much of what we know today about physical activity and CHD. Their studies of London bus drivers and conductors, British civil servants and postal workers, indicated that both occupational and leisure-time physical activity were inversely associated with CHD. However, they found that the association only existed with vigorous sporting activities – those activities that required approximately 7.5 kcals/minute. The CHD death rate among men who engaged in such activities was half the death rate of men who were considered sedentary. These observations held true for categories of men with or without other CHD risk factors, such as smoking, high body mass index, hypertension, and family history of CHD.

Across the Atlantic, Paffenbarger and colleagues were also interested in the relationship between physical activity and CHD. Their initial investigations involved examining data from the College Alumni Health Study (156) and studies of San Francisco longshoremen (155). Their findings also demonstrated an inverse relationship between physical activity and CHD mortality. However, Paffenbarger and colleagues wanted to take things one step further by quantifying the number of years added to life from being physically active.

To do this, the investigators enrolled 16,936 men, ages 35-74, from the Harvard Alumni Health Study – an ongoing, prospective cohort study of CHD predictors among Harvard University undergraduates, who were free of CHD or CVD at baseline (1962 – 1966)(153). Baseline assessments included a detailed questionnaire about their daily physical activity – how many stairs they climbed each day, how many city blocks they walked, whether they engaged in sports or recreational activities and how much they spent in those activities, etc. The data were then classified into light (5 kcal/min energy expenditure), vigorous (10 kcal/min), or mixed (7.5 kcal/min). The kcals expended in the different levels of activity were then tallied and used to obtain an index of weekly energy expenditure.

The results showed the age-adjusted mortality rates among the men declined with increasing amounts of physical activity – those expending 3000 – 3499 kcal/wk had only 0.46 the mortality rate of those expending <500 kcal/wk. The inverse association held after classifying the men into age groups of 35-49, 50-59, 60-69, and 70 – 84, and was significant, regardless of the presence or absence of other risk factors, such as smoking, being overweight, gaining weight since college, hypertension, or college athleticism.

The investigators then estimated the number of deaths in the cohort that might have been prevented if all the men had expended >2000 kcals/wk. The result was 16.1%, second only to not smoking (22.5%). Being physically active was also more important than avoiding hypertension (6.4%).

Lastly, the researchers attempted to determine how many years could be added to one's life, up to the age of 80, by being physically active. Comparing men who expended >2000 kcals/wk to those who expended <500 kcals/wk and controlling for differences in smoking, hypertension, weight change since college, and family history of CHD, they determined that, on average, two extra years could be added to the alumni's life from a physically active lifestyle.

Throughout the 1980s, several other large-scale investigations of physical activity and CHD or CVD mortality have had similar results. The well-known MRFIT study (Multiple-Risk Factor Intervention Trial) (120), published in 1987, found an inverse association between physical activity and CHD death rates but with an unexpected twist. This data indicated that moderate-intensity activity was more efficacious in lowering mortality rates than vigorous activity. Men who engaged in regular activity that was of moderate intensity experienced a 27% reduction in mortality rate whereas the men who engaged in vigorous activity had a nonsignificant 13% reduction in mortality.

At this point, the majority of studies on physical activity and mortality had included only male subjects and had assessed only self-reported physical activity. The Aerobics Center Longitudinal Study, published in 1989 by Blair et al (30), was one of the first, and largest, studies to include women and to assess cardiorespiratory fitness. In this study, 10,244 men and 3,210 women, ages 20 – 60, most of who were white and of middle to upper socioeconomic status (SES), were enrolled as participants. All subjects had received a medical examination at the Cooper Institute for Aerobics Research in Dallas, between 1970 and 1981, which included a maximal treadmill exercise test to determine maximal oxygen uptake, or "VO_2 max". Subjects were classified into quintiles of fitness level, specific for each sex and age group, based on total treadmill test time and followed for mortality for an average of eight years.

For both genders, there was a strong inverse association between fitness level and all-cause mortality. The least fit women were four times more likely to die than the most fit women and the least fit men had a 3-fold increased mortality rate than the most fit men. These associations held true after additional adjustment for smoking, systolic blood pressure, serum cholesterol, serum glucose, BMI, and family history of CHD.

These investigators also wanted to quantify the number of deaths that may have been averted by regular physical activity i.e., if all subjects had fallen into Quintiles 2-4, instead of being in Quintile 1. For men, the estimated proportion of preventable deaths was 9%, ranking third after smoking and high cholesterol levels. For women, fitness was the most important factor, with a potential of preventing 15.3% of deaths.

Sandvik et al (170) also examined the relationship between physical fitness and overall mortality or CVD mortality. Physical fitness was measured as the total work performed on a bicycle ergometer during a symptom-limited exercise tolerance test. Male subjects between the ages of 40 and 59 working in Oslo, Norway, who were free of chronic disease were enrolled in the study between 1972 and 1975(n=2014). After a 16-year follow-up, 271 men had died (53% of the deaths from CVD). The remaining subjects were again tested for fitness and relative risks were determined for physical fitness and other CVD risk factors. The results showed physical fitness to be a graded, independent predictor of CVD mortality. Factors that were not independent predictors were resting heart rate, triglycerides, and body mass index.

The Association of Physical Activity and Mortality in Women

As stated earlier, most of the studies examining the association of physical activity or fitness and mortality have been conducted in men. In fact, the Surgeon General's 1996 report on physical activity and health (192) cited just three studies with women in its section on overall mortality, including the study by Blair and colleagues described above. In 1989 US Preventive Services Task Force report on exercise and health stated that the benefits of exercise in preventing CHD are known in men but that "efficacy in women is presumed on the basis of extrapolation"(67).

The few studies on physical activity and mortality in women have had mixed results. Some have found little or no effect (95, 116) while others have found profound effects (109). For studies measuring physical activity by questionnaire, the lack of an effect may be due to the focus of most physical activity questionnaires on activities that are more commonly performed by men than women. For example, a recent study by Sesso et al (173) reported no overall association of physical activity with CVD risk in middle-aged and older women. However, their assessment of physical activity included only the self-reported number of blocks walked, stairs climbed, and sports played each day. They did not query subjects about household chores, occupational or child-care activities, or participation in activities more commonly observed among women.

Still, several studies have found a positive relation of physical activity or fitness with CVD risk reduction in women. Kushi et al (109) found a graded, inverse association between self-reported physical activity and all-cause mortality among women enrolled in the Iowa Women's Health Study, a large prospective study of post-menopausal women with a seven-year follow-up.

Manson and colleagues (125) recently reported results of a large-scale prospective study of walking as compared with vigorous exercise in CHD prevention in women. Subjects were participants in the Nurses' Health Study (n = 72,488) and were between the ages of 40 and 65 years old and free of CVD or cancer at the time of entry in 1986. Detailed information on subjects' physical activity habits were ascertained by questionnaire to examine the degree to which total physical activity, walking time and pace, vigorous exercise, and change in activity level were associated with the incidence of CHD events.

Principal findings of this study included a significant, inverse association between brisk walking and coronary events. Vigorous exercise was also associated with similar risk reductions. Women who either walked briskly for a minimum of three hours per week or exercised vigorously for 90 minutes per week, CHD risk was r educed by 30 – 40%. Risk reductions were similar for both nonobese and obese women. The investigators stated that, on the basis of multivariate relative-risk analyses, one third of coronary events among middle-aged US women are attributable to physical inactivity.

The Association of Changes in Physical Activity or Fitness with CVD Mortality

The findings of an association between physical activity and CVD mortality raise important questions. For instance, do sedentary individuals gain the same health benefits and reduced mortality rates if they become physically active? At least three studies suggest that they do.

The first was conducted by Paffenbarger and colleagues (154). Utilizing data from Harvard alumni again (n = 10,629, all male), these investigators queried subjects in 1962 or 1966 on their physical activities, and then again in 1977. From this data they determined an index of total energy expenditure for each subject at both time points. Subjects were then followed for mortality until 1985.

The investigators determined that men who were initially sedentary (<2000 kcal/wk expended in physical activity) but who increased their activity to >2000 kcal/wk in moderately vigorous sports, had nearly the same mortality rate as men who were active at both time points. Both groups of men had a 41% reduction in CHD death rates when compared with men who were sedentary at both time points. With respect to intensity, men who did not engage in any vigorous activity at the first time point but who reported doing so in 1977, had a 23% lower mortality than those men who never reported engaging in vigorous activities at all, with the difference being statistically significant.

The Aerobics Center Longitudinal Study by Blair et al (23), described earlier, is probably the most well known study that addressed the issue of change in activity or fitness on mortality rates. An extended follow-up to this study allowed the investigators to examine changes in fitness in relation to all-cause mortality rates. Their results showed that men who were initially unfit, as determined by a maximal treadmill test, but who had become at least moderately fit at the time of the second evaluation eight years later, had an all-cause death rate 60% lower than unfit men who remained unfit.

The investigators also determined the magnitude of benefit associated with favorable changes in other CVD risk factors (such as smoking, hypertension, etc.). Change in physical fitness (from unfit to fit) demonstrated the greatest risk reduction (60%), smoking cessation was second (50% risk reduction). Interestingly, favorable changes in systolic blood pressure, blood cholesterol, or BMI were not associated with appreciable risk reductions during the follow-up period. The authors concluded, "low activity or fitness appears to be an independent risk factor for CVD, and has a comparable effect on risk at least as great as do other established precursors of mortality." (23).

The third study examining changes in physical activity or fitness and CVD risk reduction, and the only one to date with women as subjects, is the Nurses' Health Study conducted by Manson and colleagues (125). In addition to the findings presented earlier, these investigators reported lower CHD events in sedentary women who became active in middle adulthood. Specifically, women who reported exercising less than once a week in 1980 and then again in 1986, had significantly higher rates of CHD events than initially sedentary women who reported being active in 1986.

Intensity and Quantity of Physical Activity Necessary for CVD Risk Reduction

Another important question related to physical activity and CVD mortality relates to the intensity and quantity of activity needed to gain health benefits. Traditional exercise recommendations by the American College of Sports Medicine (ACSM) have specified exercise in terms of *frequency* (3-5 times per week), *intensity* (50% to 85% of maximal aerobic power), and *duration* (20 to 60 minutes per week)(7). This "exercise prescription" has been promoted by the ACSM and other groups for use in clinical settings, controlled exercise programs, and the general public. However, there is mounting evidence that lower intensities and lesser amounts of activity may be sufficient to produce significant health benefits. A brief review of this evidence is presented below.

Intensity. An extensive review by Haskell (80) revealed that in the majority of studies, reduced CHD mortality was associated with light to moderate intensity activities, such as walking, gardening, and household chores. Moderate-intensity physical activity is defined as any activity performed at an intensity of three to six METs (work metabolic rate/resting metabolic rate), with one MET being approximately equal to 3.5 ml of oxygen uptake per kilogram (kg) of body weight per minute. For most healthy adults, brisk walking at three to four mph is considered a moderate-intensity activity (119, 157). (See Table 1)

Duncan et al (50) investigated the question of whether high intensity activity is necessary to improve CVD risk factors. In a 24-week, randomized clinical trial among sedentary, premenopausal women, they examined the effects of walking intensity that varied across three treatment groups while keeping the distance and frequency constant. Treatment groups included strollers (walking pace of 4.8 km/hour), brisk walkers (6.4 km/hour), and aerobic walkers (8.0 km/hour). Each group walked 4.8 km per day, five days a week for 24 weeks on a track contained within the research facility. A control group remained sedentary for the entire 24 weeks.

As expected, maximal oxygen uptake increased significantly ($p<.0001$) and in a dose-response manner across treatment groups: aerobic walkers>brisk walkers>strollers. However, high-density lipoprotein cholesterol (HDL-C) concentrations were not dose related and increased

TABLE 1. Examples of Common Physical Activities for Healthy US Adults by Intensity of Effort Required in MET Scores and Kilocalories per Minute*

Light (<3.0 METs or <4 kcal·min^{-1})	Moderate (3.0-6.0 METs or 4-7 kcal·min^{-1})	Hard/Vigorous (>6.0 METs or >7 kcal·min^{-1})
Walking, slowly (strolling) (1-2 mph)	Walking, briskly (3-4 mph)	Walking, briskly uphill or with a load
Cycling, stationary (<50 W)	Cycling for pleasure or transportation (≤ 10 mph)	Cycling, fast or racing (>10 mph)
Swimming, slow treading	Swimming, moderate effort	Swimming, fast treading or crawl
Conditioning exercise, light stretching	Conditioning exercise, general calisthenics	Conditioning exercise, stair ergometer, ski machine
. . .	Racket sports, table tennis	Racket sports, singles tennis, racketball
Golf, power cart	Golf, pulling cart or carrying clubs	. . .
Bowling	. . .	. . .
Fishing, sitting	Fishing, standing/casting	Fishing in stream
Boating, power	Canoeing, leisurely (2.0-3.9 mph)	Canoeing, rapidly (≥4 mph)
Home care, carpet sweeping	Home care, general cleaning	Moving furniture
Mowing lawn, riding mower	Mowing lawn, power mower	Mowing lawn, hand mower
Home repair, carpentry	Home repair, painting	. . .

*From Pate et al (157)

significantly and to the same extent among aerobic walkers and brisk walkers. Decreases in body fat and total cholesterol levels were also as large with the moderate-intensity walkers as with the vigorous walkers. The investigators concluded that vigorous exercise is not necessary for weight loss or meaningful improvements in cholesterol and other blood lipid levels.

Data from the Nurses' Health Study (87) reveal substantial reductions in risk for type 2 diabetes mellitus in women who engage in moderate-intensity activity. This analysis included detailed data on 70,102 women in 11 U.S. states starting in 1986 and updated in 1988 and 1992. After adjusting for age, smoking, alcohol use, history of hypertension, and history of high cholesterol, relative risks (RR) of developing diabetes across quintiles of physical activity (least to most) were 1.0, 0.77, 0.75, 0.62, and 0.54 ($p<.001$). Among women who reported only moderate-intensity activity (no vigorous activity), multivariate RR's of diabetes across activity quintiles were 1.0, 0.91, 0.73, 0.69, and 0.58 ($p<.01$). Calculated energy expenditures from walking at a moderate intensity and from vigorous activity yielded comparable magnitudes in risk reduction.

Data from the Iowa Women's Health Study (109) indicated that moderate activity as infrequently as once per week elicited a reduced mortality risk of 0.78 (95% confidence interval, 0.64-0.96).

Lemaitre and colleagues (117) examined the association between intensity and the time spent in LTPA with risk for primary cardiac arrest (sudden cardiac death). Their analysis included two specific moderate-intensity LTPAs, gardening and walking, for exercise. Compared with sedentary control subjects, the odds ratios for primary cardiac arrest among subjects who performed only gardening activities for >60 minutes per week was 0.27, and among subjects who walked for > 60 minutes per week was 0.34 (95% confidence intervals, 0.11 – 0.67 and 0.16 – 0.75, respectively). These results suggest that regular participation in moderate-intensity activities, such as gardening or walking, are associated with substantial reductions in risk for sudden cardiac death.

Recently, Lee and Paffenbarger (113) examined the association of light, moderate, and vigorous intensity physical activity with longevity. Using data from the Harvard Alumni Study again, these investigators examined physical activity data from men followed for mortality until 1992 (n=13,485). Weekly energy expenditure levels were calculated from self-reported bouts of walking, stair climbing, and sports/recreation participated in on a daily basis. Multivariate analysis showed distance walked and storeys climbed independently predicted longevity. Light activities, regardless of energy expenditure, were unassociated with mortality rates, moderate intensity activities showed a trend for lower mortality rates, and vigorous activity clearly predicted lower mortality rates.

Adherence may be the most important factor in determining the importance of intensity. King et al (102) compared different formats and intensities of physical activity on cardiorespiratory fitness levels and found that improvement in VO_2 max was more related to consistency of activity than intensity. In fact, a lower-intensity program was equally as effective in improving VO_2 max in sedentary individuals as a higher intensity program, mainly because of better adherence.

Quantity. How much activity is needed to attain health benefits and/or increase longevity has also been an important question. According to recent recommendations by the Centers for Disease Control and Prevention (CDC) and ACSM (157), the health benefits of physical activity appear to accrue in near proportion to the total amount of activity performed, measured as either caloric expenditure or minutes of physical activity. This was clearly shown in the Harvard Alumni Health Study described earlier in which men who expended >2000 calories per week had a significantly lower CHD death rate than men who expended <500.

Other studies have estimated average caloric expenditures for the activity categories studied, allowing researchers to quantify the amount of physical activity associated with improved health outcomes. Leon et al (120) reported that approximately 30 minutes per day of light, moderate, and vigorous activity combined, equivalent to an average expenditure of 150 calories per day, was associated with a 36% lower risk of CHD mortality, after adjusting for CHD risk factors. Slattery et al (177) found that an extra 73 calories expended in activity per day (on average), when compared to the least active group, was associated with a 16% reduction in CHD mortality. This study also reported that a daily average of 150 calories greater expenditure in moderate activity was associated with a 27% reduction in CHD mortality. Helmrich et al (83) reported an inverse trend between calories expended in physical activity and development of Type 2 diabetes mellitus; an expenditure of 140-215 calories per day was associated with a 21% reduction in diabetes onset.

The majority of prospective studies indicate that the health benefits gained from increasing the amount of physical activity depend on the initial activity level (192). Thus, sedentary individuals stand to benefit the most from increasing their activity to the recommended level. Using data from five major prospective studies, Blair (19) plotted fitness or physical activity in relation to mortality and with the exception of one study, found that the gain in prognosis was greatest in subjects moving from the lowest to the next highest activity or fitness category. As the intensity of activity increased, the benefit plateaued.

Although there appears to be a dose-response relationship between energy expended as physical activity and reduced CHD mortality, the absolute difference in amount of physical activity in calories expended between the different levels of activity has not been determined. Other questions remain as well, including whether the total amount of caloric expenditure determines the relationship or the amount of caloric expenditure per unit of body weight. Nonetheless, the Surgeon General's Report on Physical Activity and Health offers the following conclusion based on the available evidence:

> **"Based on these studies, it is reasonable to conclude that activity leading to an increase in daily expenditure of approximately 150 kilocalories/day (equivalent to about 1000 kilocalories/week) is associated with substantial health benefits and that the activity does not need to be vigorous to achieve health benefit."** (192)

Intermittent versus Continuous Physical Activity

Several studies have suggested that intermittent bouts of activity are as likely to improve health outcomes as continuous activity. For example, in the MRFIT study described earlier, the types of activities engaged in by the men with the lowest mortality rate included lawn and garden work (80% of men), walking (65%), and home repairs (60%) (120). Although it was not possible to ascertain whether or not these activities were performed in single, continuous bouts, the nature of these activities suggest they were performed on an intermittent basis. Thus, the daily or weekly caloric expenditures reported by these men probably reflect an accumulation of activity rather than a single daily bout of activity.

Direct comparisons of intermittent and continuous activity have been conducted in at least four studies. Debusk et al (43) compared the effects of three separate 10-minute bouts of moderate to vigorous activity with one continuous 30-minute bout of activity of equal intensity in men. Maximal oxygen uptake increased significantly in all three groups with no significant differences between groups. Ebisu (54) randomized men into one of four groups of men, three exercise groups and one inactive control group. In each exercise group, subjects ran the same total distance, but in one, two, or three sessions daily. As in the DeBusk study, cardiorespiratory fitness improved in all three exercise groups with no significant differences between groups. Interestingly, HDL-C levels improved only in the group that ran three times per day.

These results appear to be true for women as well. Murphy and Hardman (146) assigned 47 sedentary women aged 44.4 ± 6.2 years to either three 10 minute walks per day (short bout group) or one 30-minute walk per day (long bout group) or no training (control). Each walking group was instructed to walk five days a week at 70 to 80% of maximal heart rate (3.5 to 4 mph) for ten weeks. At completion, VO_2max increased significantly in walkers but not in controls (short bout, +2.3 ± 0.1 mL/kg/min; long bout +2.4 ± 0.1 ml/kg/min; controls, -0.5 ± 0.1 ml/kg/min). Body fat, assessed by the sum of four skinfold thicknesses, decreased significantly in both groups, however, BMI and waist circumference decreased significantly only in the short bout group.

Jakicic and colleagues (89) also compared the effect of three 10-minute bouts of moderate activity to one 30 minute bout of activity per day on cardiorespiratory fitness, exercise adherence, and weight loss in overweight women in a behavioral weight control program. Subjects were assigned to either a short-bout exercise group (SB, n=28, age 40.4 ±5.9 yrs) or a long-bout exercise group (LB, n=28, age=40.9 ± 7.3 yrs). Both groups were instructed to walk five days a week, progressing from 20 to 40 minutes per day, for a period of 20 weeks. Both groups received the same behavioral weight control program and instructions on a low calorie diet plan (1200 – 1500 kcal/day, 20% of calories from fat). After 20 weeks, cardiorespiratory fitness improved by 5.6% and 5.0% in the SB and LB groups, respectively (both significantly different from baseline, $p<0.05$). Both groups lost similar amounts of weight (-8.9 ± 5.3 kg and -6.4 ± 4.5 kg, respectively), although there was a trend for greater weight loss in the SB group ($p<0.07$).

The self-reported exercise logs in this study provide interesting information regarding exercise adherence in overweight women. The SB group was instructed to walk for 10 minutes per session throughout the study in 2,3, and 4 sessions per day during weeks 1-4, 5-8, 9-20, respectively. Instead, the SB group reported walking for approximately 15 minutes per session throughout the study. During weeks 13-20, the SB group was unable to maintain four exercise bouts per day but was able to do three 15 minute bouts of walking per day. The authors concluded the latter regimen might fit better into the normal flow of a typical workday, i.e., a short-bout of exercise in the morning, another during a lunch break, and another short-bout in the evening.

Prevalence of Inactivity and Public Health Recommendations

Despite the known benefits of physical activity, many people remain sedentary. Forty percent of U.S. adults (18 years or older) engaged in no leisure time physical activity in 1997 and only 15% of adults were active for at least 30 minutes five or more days per week (age adjusted to the year 2000) (191). The data on women are less encouraging: more than 60% of U.S. women do not engage in the recommended amount of physical activity and 30% are not active at all (161, 192).

According to the National Health Information Survey (NHIS)(191), physical activity patterns vary with demographic characteristics. In general, the percentage of people reporting no LTPA is higher among women than men, among older adults than younger adults, and among the less affluent than the more affluent. Physical activity levels tend to peak in June and drop in December (37) and although they increase slightly for adults at retirement age (65 years), overall, physical activity levels decline with age (157, 161).

Perhaps not surprisingly, inactivity is more common among obese individuals than the nonobese. The 1996 Behavioral Risk Factor Surveillance System (BRFSS)(38), a cross-sectional telephone survey of adults aged 18 or older, revealed that levels of participation in physical activity were similar among normal weight and overweight individuals but were substantially lower in obese individuals. According to this survey, inactivity increased with increasing levels of BMI (normal, overweight, obese) for both men and women but were more marked in women (27.8%, 31.7%, and 40.9%, respectively) than men (26.8%, 25.6%, 32.7%). Moreover, participation in recommended amounts of physical activity by BMI category also declined more markedly in women than men: women (normal weight 30.7%, overweight 26.0%, obese 18.9%), men (normal weight 29.3%, overweight 29.2%, obese 23.5%).

The alarming prevalence of inactivity within the United States has prompted several leading health organizations to issue public health recommendations on physical activity and health. In 1992, the American Heart Association (AHA) issued the following "Statement on Exercise":

> **"Persons of all ages should include physical activity in a comprehensive program of health promotion and disease prevention, and should increase their habitual physical activity to a level appropriate to their capacities, needs, and interest.**
>
> **Activities such as walking, hiking, stair-climbing, aerobic exercise, calisthenics, jogging, running, bicycling, rowing, and swimming and sports such as tennis, racquetball, soccer, basketball, and touch football are especially beneficial when performed regularly. Brisk walking is also an excellent choice.**
>
> **The evidence also supports the notion that even low-intensity activities performed daily can have some long-term health benefits and lower the risk of CVD. Such activities include walking for pleasure, gardening, yardwork, housework, dancing, and prescribed home exercise. For health promotion, dynamic exercise of the large muscles for extended periods of time (30-60 minutes, 3-4 times weekly) is recommended." (65)**

In 1994, the Centers for Disease Control and Prevention (CDC) and the American College of Sports Medicine (ACSM) convened a panel of experts to review the scientific evidence on physical activity and health and develop a clear, concise public health message. Their final report states that all three branches of medical science – clinical, epidemiological, and experimental – have supported a conclusion that the associations between activity, fitness, and health are causal. This report states the following principles of causality have been met (157):

- **Consistency –** The association of physical inactivity and risk of CHD is observed in a number of settings and populations, with the better-designed studies showing the strongest association.
- **Strength –** The relative risk of CHD associated with physical inactivity ranges from 1.5 – 2.4, in increase in risk comparable with that observed for hypercholesterolemia, hypertension, and cigarette smoking.
- **Temporal Sequencing –** The observation of physical inactivity predates the diagnosis of CHD.
- **Dose Response –** Most studies demonstrate that the risk of CHD increases as physical activity decreases.
- **Plausibility and Coherence –** Physical activity reduces the risk of CHD through a number of physiological and metabolic mechanisms.

After reviewing the evidence on intensity and duration of physical activity and its effect on health, the CDC/ACSM panel made the following statement,

"We believe the most reasonable interpretation of the currently available data is that:

1. **Caloric expenditure and total time of physical activity are associated with reduced CVD incidence and mortality;**
2. **There is a dose-response relationship for this association;**
3. **Regular moderate physical activity provides substantial health benefits;**
4. **Intermittent bouts of physical activity, as short as 8-10 minutes, totaling 30 minutes or more on most days provide beneficial health and fitness effects. (157)**

The panel concluded by making the following recommendation for the general public:

"Every U.S. adult should accumulate 30 minutes or more of moderate-intensity physical activity on most, preferably all, days of the week." (157)

In 1997, the National Institutes of Health (NIH) Consensus Development Panel on Physical Activity and Cardiovascular Health also issued a formal report, stating,

"We recommend that all children and adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, or preferably all, days of the week. Intermittent or shorter bouts of activity (at least 10 minutes), including occupational, nonoccupational, or tasks of daily living, also have similar cardiovascular and health benefits if performed at a level of moderate intensity (such as brisk walking, cycling, swimming, home repair, and yardwork) with an accumulated duration of at least 30 minutes per day." (149)

Finally, the U.S. Dept. of Health and Human Services (HHS) recently listed physical inactivity as one of the top ten "leading health indicators" in the "Healthy People 2010" initiative (192). The ten year goals set by the HHS include the following:

- Reduce the proportion of adults who engage in no leisure time physical activity to 20%.
- Increase the proportion of adults who engage regularly, preferably daily, in moderate physical activity for at least 30 minutes per day to 30%

The Healthy People 2010 reports states,

"Encouraging any type or amount of physical activity in leisure time can provide important health benefits, compared to a sedentary lifestyle. Health promotion efforts need to identify barriers to physical activity faced by particular population groups and develop interventions that address these barriers."(191)

Lifestyle Physical Activity

Both the CDC/ACSM report and the NIH Consensus Conference report on physical activity state that the recommended 30 minutes of activity can be integrated into one's daily routine by increasing such activities as housecleaning, yardwork, walking short distances, and/or playing actively with children. Increasing time spent in daily activities such as these may be an alternative way of expending energy that, if done regularly, may decrease the risk for CVD and other chronic disease. According to Dunn and colleagues (52), this "lifestyle" approach to physical activity may be more appealing and less intimidating to those individuals who dislike exercise or who are unable to exercise for extended lengths of time.

The concept of lifestyle physical activity appears to be an extension of a recent shift in thinking from "exercise to promote fitness" to "physical activity to promote health" (33). Dr. William Haskell spoke of this paradigm shift in the J.B. Wolffe Memorial Lecture presented at the 1993 American College of Sports Medicine annual meeting, referring to the growing number of studies demonstrating reduced morbidity and mortality from increased moderate-intensity activity in sedentary individuals. Lifestyle physical activity originates from the same scientific foundation as the mortality studies but includes contributions from other fields, such as behavioral medicine and obesity research (51).

However, data on the effectiveness of a lifestyle approach in helping sedentary people become more active is limited. In addition, studies examining the adoption of lifestyle physical activity have been operationalized in different ways, e.g., increasing light and moderate intensity activities, increasing leisure time activity, or simply decreasing sedentary activity. Some studies have vaguely defined all types of physical activity and exercise under the category of lifestyle, along with other behaviors, such as smoking, seat belt use, and diet (51). Drawing on studies by Epstein et al (57, 58) and Blair et al (25), and the CDC/ACSM report on physical activity and health (157), Dunn and colleagues have defined "lifestyle physical activity" in the following way:

> **"Lifestyle physical activity is the daily accumulation of at least 30 minutes of self-selected activities, which includes all leisure, occupational, or household activities that are at least moderate to vigorous in their intensity and could be planned or unplanned activities that are a part of everyday life". (51)**

A key point in this definition is that these activities are not prescribed, they are *self-selected* and can be planned or unplanned (taking the stairs instead of the escalator). The fact that these activities can be accumulated in short bouts during the day rather than performed in one long bout of continuous activity is demonstrated in a conceptual drawing by Dunn et al (51) in Figure 1.

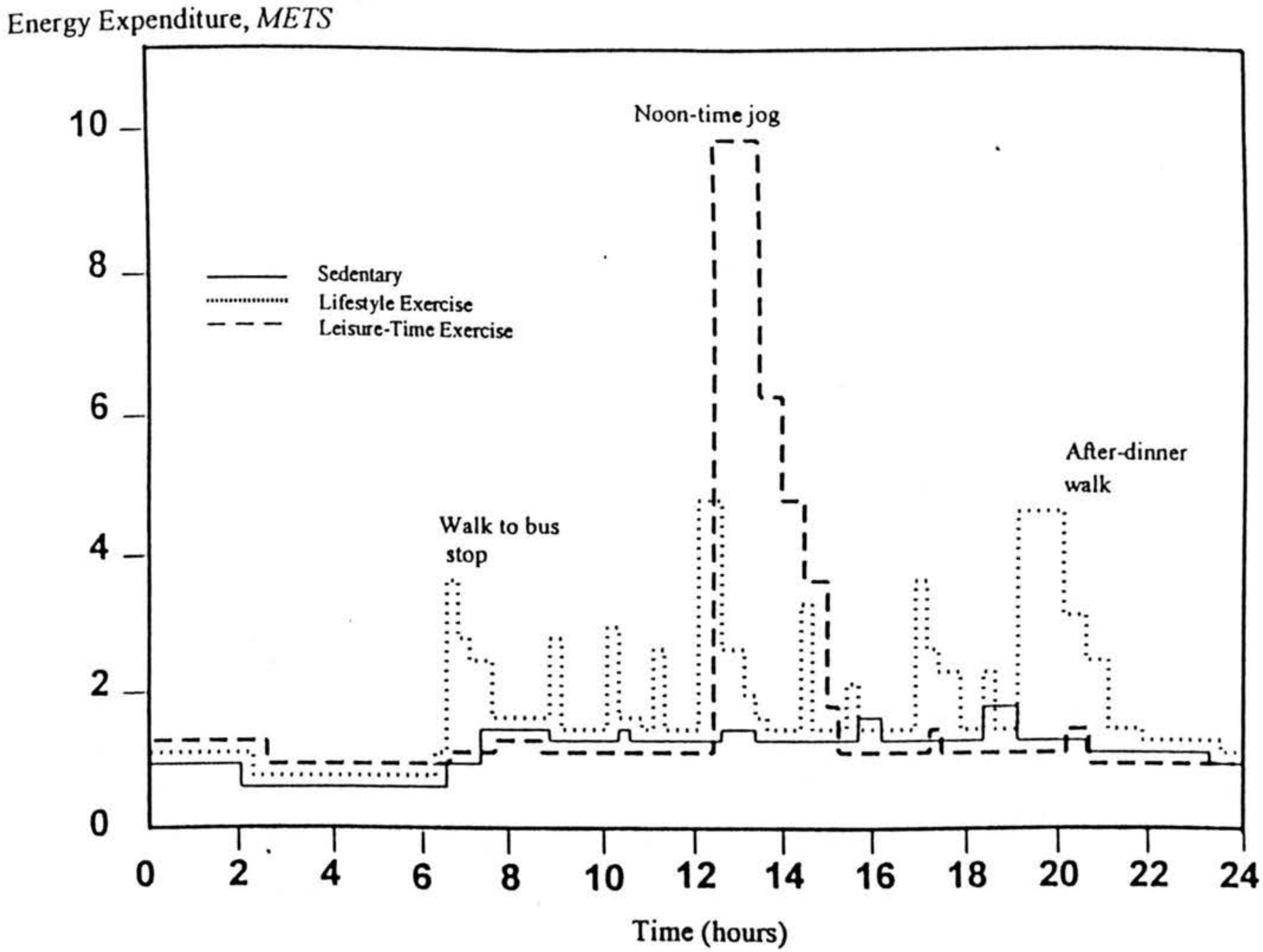


Figure 1. Conceptual figure of daily energy expenditure for a sedentary person (solid line), a person engaging in planned vigorous exercise during leisure time (dashed line), and lifestyle physical activity accumulated in moderate intensity bouts over the course of the day (dotted line). From Dunn et al (51).

Project Active

The largest study (to date) examining the effects of lifestyle activity on health outcomes is Project *Active*, a 24-month randomized activity on health outcomes is Project *Active*, a 24-month randomized clinical trial designed to compare the effects of a lifestyle physical activity program and a structured exercise program on physical activity, cardiorespiratory fitness, and other CVD risk factors in nonobese sedentary men and women (52).

Subjects in the "Lifestyle" group were advised to work toward achieving the CDC/ACSM criterion for physical activity of accumulating 30 minutes or more of moderate intensity activity on most days of the week. Subjects in the "Structured" group were given a traditional exercise prescription and a free pass to a fitness club. The lifestyle group met weekly to discuss ways in which they could integrate physical activity into their daily routine and to problem-solve any barriers they experienced. The type of activities the Lifestyle group participated in were varied and individualized and included spending more time playing outdoors with children, walking while on long conference calls (using a headset), and going for short walks during a lunch hour. The Structured group participants were expected to go to the fitness club and exercise according to their exercise prescription, i.e., at a given intensity and for a specified duration. Fitness club employees provided feedback and encouragement for those in the Structured group.

After 24 weeks of intervention, 78% of the Lifestyle participants and 85% of the Structured participants were meeting or exceeding the CDC/ACSM criterion for physical activity, which was verified by a significant increase in cardiorespiratory fitness in both groups. Significant reductions in total cholesterol, cholesterol/HDL ratio, diastolic blood pressure, and percent body fat were observed in both groups with no significant difference between groups.

After two years of follow-up, significant increases from baseline were observed again for both groups in physical activity and cardiorespiratory fitness, with no difference between groups. Significant decreases in blood pressure were also observed in both groups with no difference between groups. The decrease in percent body fat observed at 24 weeks was maintained at two years for both the lifestyle and structured groups. Both groups also showed small but insignificant improvements in total cholesterol and HDL-C levels at 24 months. The authors concluded that a lifestyle physical activity intervention is effective in increasing physical activity and improving cardiorespiratory fitness, body composition and blood pressure in sedentary nonobese men and women.

More research is needed to further define the effect of lifestyle activity on health outcomes. At the 1997 Physical Activity Interventions Conference held at the Cooper Institute of Aerobics Research in Dallas, Texas, a number of recommendations were developed for researchers and practitioners in the design and implementation of lifestyle physical activity interventions. These recommendations, published in 1998 (51), include the following:

1. It is important to test dissemination models to determine if lifestyle physical activity interventions can be effectively delivered on a large scale. This could include delivering interventions by mail and telephone, and also through new technologies such as the Internet.

2. Population surveys are needed to assess understanding of public health messages. For example, do individuals understand and actually perform moderate amounts and intensities of physical activity?

3. Basic dose-response research is needed to develop a better understanding of the effects of accumulating physical activity at various intensities of activity, particularly as related to groups of different ages, ethnicity, and health status. For example, elderly individuals may be able to maintain function by accumulating short bouts of light activities, while obese men and women may need to accumulate 60 minutes or more of moderate-intensity physical activity.

4. Longitudinal studies of 5 or more years in duration are needed to examine issues related to how well individuals are able to maintain activity and the health effects of maintaining physical activity over a lifetime.

5. Lifestyle approaches need to be tested in special populations, such as the underserved, chronically ill, disabled, or obese individuals.

6. A wider variety of environmental manipulations need to be tested for their efficacy. Further study also is needed on the effects of targeted messages on those who are least active.

7. Cost-effectiveness analyses need to be performed both on behavioral lifestyle physical activity interventions and on environmental manipulations.

Measurement of Physical Activity and Cardiorespiratory Fitness

To understand the interaction between physical activity and cardiovascular health status requires the use of an objective and reliable method for assessment of physical activity (81). However, physical activity is a complex behavior that can be characterized in various ways making accurate assessment in free-living populations difficult. There are numerous ways of measuring physical activity that, according to Westerterp (199), can be grouped into five general categories: behavioral observation; questionnaires (including diaries, recall questionnaires, and interviews); physiological markers (such as heart rate); calorimetry; and motion sensors. Because there are errors in all of these methods, the true validity of any one of them is unknown. The best available criterion with which these methods can be compared is calorimetry, or more specifically, doubly-labeled water (141, 199).

According to Westerterp (199), the doubly labeled water technique allows accurate measurement of average daily metabolic rate (ADMR) under unrestricted conditions for 1-3 week intervals. The activity level of an individual can be calculated by expressing ADMR as a multiple of basal metabolic rate (BMR), so that one's physical activity level is equal to ADMR/BMR. Three field methods for assessing physical activity have been validated with the doubly labeled water technique as a criterion measure: questionnaires, motion sensors, and heart rate monitoring (199).

In a review of validation studies using these three methods, Westerterp (199) reported the triaxal accelerometer motion sensor had the best correlation with doubly labeled water ($r=0.73$, $p<0.01$). Activity diaries, in which subjects are asked to record their physical activity over periods of 1-2 weeks were better than activity recalls, in which subjects are asked to recall their physical activity over the previous week ($r=0.72$, $p<0.01$ and $r=0.67$, $p<0.05$, respectively). Energy expenditure estimated with heart rate monitoring was the same as that determined from doubly labeled water but the individual variation was large: the reported extremes ranged between –17% and +52% (199).

All three of these methods have advantages and disadvantages. Advantages of questionnaires include low cost, ease of administration, minimal subject time and cooperation. Scoring is simple and both diaries and recall questionnaires cover the subject's normal daily activity pattern. Recall questionnaires are less likely to influence physical activity behavior than diaries (81, 199). The obvious disadvantage is that the data is self-reported and subjects can easily under- or over-estimate the time spent in physical activity or they may not recall details of their physical activity participation during the recall period. Heart rate monitoring is an objective method but it is affected by other factors, such as emotional stress and fitness level, and is generally not well-tolerated by subjects for time intervals representative of daily life (199). Motion sensors hold the most promise but issues of cost and comfort are still being addressed (199).

Furthermore, there are unique challenges to measuring physical activity in women. According to Ainsworth (3), much of a woman's moderate-intensity activity is performed in an unstructured setting and usually for short periods of time, intermixed with light-, moderate-, and sometimes vigorous activities. Most of these activities are household chores and/or family-care activities and are not the focus of most activity questionnaires and surveys. As noted earlier, studies using activity diaries to record physical activity have shown that women spend from 30 minutes to six hours per day in family- or household-related activities (3, 4). Activity patterns such as these make it difficult to estimate the time spent in moderate-intensity activity that is separate from other activities. Thus, activity diaries or recall questionnaires may provide a more accurate picture of physical activity in women than short, global surveys that focus primarily on recreational or leisure-time pursuits (3).

Measurement of Cardiorespiratory Fitness

Cardiorespiratory fitness is the ability to perform large muscle, dynamic, moderate-to-high intensity exercise for prolonged periods of time (69). This type of exercise is often referred to as "aerobic" exercise and is dependent on the functional state of the respiratory, cardiovascular, and skeletal muscle systems (81). Aerobic activity substantially increases cardiac output (volume load on the heart) with small increases in mean arterial blood pressure (pressure load on the heart) whereas heavy resistance or "isometric" exercise increases arterial blood pressure with a relatively small increase in cardiac output (81).

According to ACSM's guidelines for exercise testing and prescription (69), cardiorespiratory fitness is considered a health measure for the following three reasons: 1) low levels of cardiorespiratory fitness are associated with a significant increase risk of premature death from all causes and from CVD; 2) increases in cardiorespiratory fitness are associated with a reduction in death from all causes; and 3) high levels of cardiorespiratory fitness are associated with higher levels of habitual physical activity, which are also associated with reduced CVD mortality and other health benefits.

The "gold standard" criterion measure of cardiorespiratory fitness is maximal oxygen uptake or VO_2 max (69, 81). VO max is the product of maximal cardiac output (L/min) and arterial-venous oxygen difference (mL O_2 /L)(69). The most accurate method for assessing VO_2 max is by measuring the composition of expired air and respiratory volume during maximal exertion (81). However, this method requires expensive equipment and highly trained technicians, making it difficult to use in small-scale studies. Maximal oxygen uptake can also be estimated without the measurement of expiratory gases but this procedure requires an accurately calibrated exercise device, careful attention to a specific protocol, and cooperation by the subject. Haskell and colleagues (81) state that having subjects perform maximal tests to assess cardiorespiratory fitness carries a substantial burden for the subject, in terms of time, effort, and risk.

To reduce this risk or when direct measurement of VO_2 max is not feasible, a variety of submaximal exercise tests can be used to estimate

VO_2 max. The primary goal of submaximal exercise testing is to determine the heart rate (HR) response to one or more submaximal work rates and use the results to predict VO_2 max (81). Submaximal exercise tests make the following assumptions (69):

- A steady-state heart rate is obtained for each exercise work rate.
- A linear relationship exists between heart rate and work rate.
- The maximal heart rate for a given age is uniform
- Mechanical efficiency (VO_2 at a given work rate) is the same for everyone.

Although submaximal exercise testing is not as precise as maximal exercise testing, it provides a reasonably accurate assessment of an individual's fitness at a reduced cost and lower risk, and requires less time and effort on the part of the subject (69).

ACSM's guidelines for exercise testing recommend that HR be assessed using an electrocardiograph, heart rate monitor, or stethoscope and that the exercise test should be terminated when the subject reaches 85% of age-predicted maximal HR (220 – age)(69). In most submaximal exercise testing protocols, the average of the last two HR measurements, taken during the 5th and 6th minute, are used to estimate VO_2 max from a nomogram, such as the Astrand-Ryhming nomogram for submaximal cycle ergometry (see Appendix I). This value is then adjusted for age by multiplying the VO_2 max value by a correction factor developed for this protocol.

OBESITY AND CARDIOVASCULAR DISEASE

Obesity is also a major public health problem and an important risk factor for CVD. Epidemiologic data indicate the risk of death from all causes in obese individuals is increased by 50-100%, with most of this increased risk due to cardiovascular causes (192). Allison et al (5) recently estimated the number of annual deaths attributable to obesity among US adults as 280,000, with smokers included, and 325,000 with smokers excluded. Although direct evidence showing obesity causes CVD is not available, many observational studies have shown a higher prevalence of CVD exists among obese individuals when compared with normal-weight individuals (104, 111, 193).

The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) recently published guidelines for the identification, evaluation, and treatment of overweight and obesity in adults (148). The guidelines include a classification system for defining overweight and obesity that is similar to definitions used by the World Health Organization (WHO)(207) (see Table 2). Both systems are based on measures of body mass index (BMI), calculated as weight in kilograms divided by the square of height in meters.

TABLE 2. Weight Classification by Body Mass Index (BMI)[1]

NHLBI Terminology[2]	BMI Range	WHO Classification[2]
Underweight	<18.5	Underweight
Normal	18.5 – 24.9	Normal range
Overweight	25.0 – 29.9	Pre-obese
Obesity Class 1	30.0 – 34.9	Obese Class 1

Obesity Class 2	35.0 – 39.9	Obese Class 2
Obesity Class 3	> 40.0	Obese Class 3

[1]BMI, kg/m^2;
[2]NHLBI = National Heart, Lung, Blood Institute; WHO = World Health Organization

Obesity as a CVD Risk Factor

The association between obesity and CVD, particularly coronary heart disease (CHD), is presumably through its effect on risk factors, such as hypertension, dyslipidemia, impaired glucose tolerance, and type 2 diabetes mellitus (71). This relationship is modified by age, sex, body fat distribution, degree of fatness, and ethnicity (55, 105, 112). For instance, the risk for development of diabetes increases dramatically as the degree of overweight increases and the risk for developing CVD is much higher in individuals with diabetes than in individuals without diabetes (1).

Must and colleagues (147) recently examined the relationship between weight status and prevalence of CVD risk factors, including diabetes, hypertension, CHD, high blood cholesterol, and high blood pressure, by severity of overweight and obesity in US adults. Using data from the Third National Health and Nutrition Examination Survey (NHANES III), these researchers classified participants into one of the four levels of overweight or obesity established by the NHLBI and are presented in Table 3.

TABLE 3. Prevalence of Co-morbidity by Obesity Class and Sex[1]

Health Condition	*Underweight*	*Normal*	*Overweight*	*Obesity Class 1*	*Obesity Class 2*	*Obesity Class 3*
Men (n=6987)			**Weight Status Category[2]**			
Type 2 diabetes mellitus	4.69	2.03	4.93	10.10	12.30	10.65
Coronary heart disease	12.45	8.84	9.60	16.01	10.21	13.97
High blood cholesterol	6.66	26.63	35.68	39.17	34.01	35.63
High blood pressure	23.38	23.47	34.16	48.95	65.48	64.53
Women (n=7689)						
Type 2 diabetes mellitus	4.76	2.38	7.12	7.24	13.16	19.89
Coronary heart disease	12.07	6.87	11.13	12.56	12.31	19.22
High blood cholesterol	13.96	26.89	45.59	40.37	40.96	36.39
High blood pressure	19.81	23.26	38.77	47.95	54.51	63.16

[1]From Must et al. (147)
[2]All data are percentages. Weight categories are based on the National Heart, Lung, and Blood Institute classification of overweight.

There is evidence, however, from long-term observational studies that obesity may be a predictor of CHD independent of its effects on traditional risk factors (72, 128). Willett et al (202) examined data from the Nurses' Health Study and found that in middle-aged women without a history of diabetes or hypertension, higher levels of weight and weight gain after the age of 18 increased the risk for CHD. For women in this study with a BMI of 29 kg/m^2 or greater, 72% of their risk could be accounted for by their excess weight.

Body Fat Distribution and Risk for CVD

The distribution of body fat also plays an important role in determining health risk associated with obesity (148). Excessive body fat located within the abdominal area is referred to as "android obesity" whereas excess body fat in the hips and thigh region is called "gynoid obesity". Android obesity has been shown to reflect an accumulation of body fat around abdominal visceral organs and is closely associated with several metabolic disorders, including dyslipidemia, hypertension, and glucose intolerance (148). Data from the Framingham study indicate that CVD mortality increases with the degree of regional or abdominal obesity and that the effect is only partially mediated by the promotion of other known risk factors (94).

Because direct measurement of visceral fat by computerized tomography and magnetic resonance imaging are expensive and not feasible for routine clinical use, the measurement of waist circumference is considered an acceptable measure for assessing abdominal fat (148). The sex-specific cutoffs shown below are used to identify increased relative risk for developing any of the obesity-associated risk factors in most adults with a BMI of 25 to 34.9 (148):

Women > 35 inches (88 cm)

Men > 40 inches (102 cm)

In women, both waist circumference and the waist-to-hip ratio (WHR) appear to be independent risk factors for CHD. Rexrode et al (167) examined data from the Nurses Health Study to compare WHR and waist circumference measurements in determining risk for CHD in women. The cohort in this analysis included 44,702 women who provided waist and hip circumferences in 1986 and then followed for mortality for eight years. Subjects were free of CHD, stroke, or cancer at baseline. Results showed higher WHR and greater waist circumference measurements independently associated with a significantly increased age-adjusted risk for CHD. After adjusting for BMI and other CHD risk factors, women with a WHR of 0.88 or higher had a relative risk (RR) of 3.25 for CHD compared with women with a WHR of less than 0.72. Women with a waist circumference of 38 inches (96.5 cm) or more was associated with a RR of 3.06 (95% confidence interval, 1.54-6.10) for CHD.

A task force of the Obesity Education Initiative (OEI) of the NHLBI and NIH (148) issued a report in 1998 stating that more research is needed to better define the relationships between abdominal fat, body weight, and disease risk. In addition, the OEI recommended that measurements of abdominal fat be included in weight loss studies to better assess health improvement.

Prevalence of Overweight and Obesity

Overweight and obesity have become common worldwide over the past several decades. In the United States, four surveys conducted by the National Center for Health Statistics (NCHS) have provided data on the height and weight of representative samples of U.S. residents since 1960. These four surveys, the National Health Examination Survey (NHES, 1960-1962) and the National Health and Nutrition Examination Surveys I through III (NHANES I, 1971-1974; II, 1976-1980; and III, 1988-1994), have allowed scientists to observe the prevalence and trends of overweight and obesity in the United States over a 40-year period (37).

These surveys indicate that the age-adjusted prevalence of overweight, defined as a BMI of 25 or greater, remained relatively unchanged from 1960 to 1980, when 48% of adult men and 39% of adult women were considered overweight. By the 1988-94 survey, the prevalence of overweight had increased to 59% in men and 48% in women. The prevalence of obesity, using the NHLBI definitions described above, followed the same pattern: 10% of men and 15% of women were classified as obese in 1960-62 and 20% of men and 25% of women in the 1988-94 survey were obese, with most of that increase occurring after 1980 (63).

The United States is not alone in observing such a sharp and unexpected increase in the prevalence of overweight and obesity. Increases of greater than five percentage points in overweight and obesity prevalence among adults have also been noted in Canada (self-reported data), Finland (men only), New Zealand, the United Kingdom, and Western Samoa (63). Smaller increases have been reported in Australia, Brazil, China (men only), Germany, Israel, Mauritius, the Netherlands, and Sweden (self-reported data) (63).

The age-adjusted prevalence of overweight and obesity across the four surveys for women are presented in Table 4.

Table 4. Age-Adjusted Prevalence of Overweight and Obesity for Women in the United States, 1960 – 1994*

BMI Category**	NHES 1960-1962	NHANES I 1971-1974	NHANES II 1976-1980	NHANES III 1988-1994
25.0-29.9 Overweight (%)	23.6	23.6	24.3	24.7
30.0-34.9 Class I Obesity (%)	10.4	10.5	10.2	14.2
35.0-39.9 Class II Obesity (%)	3.3	3.8	4.2	6.8
> 40 Class III Obesity (%)	1.3	1.9	2.1	3.9

BMI=Body Mass Index; NHES=National Health Examination Survey; NHANES=National Health and Nutrition Examination Survey
*Adapted from Blair et al (115)
**Based on definitions for overweight and obesity in the National Institutes on Health Report for the Prevention and Treatment of Obesity (148)

Researchers at CDC conducted further assessment of the upward trend in obesity. Using data from a large population-based survey, Mokdad and colleagues (143) examined changes in the prevalence of obesity among US adults from 1991 to 1998. Data from all states participating in the BRFSS was examined for state-specific prevalence trends. The information obtained from each state was pooled to produce nationally representative estimates. BMI was calculated from self-reported weight and height and participants were classified as obese if their BMI was greater than or equal to 30 kg/m^2.

The researchers reported obesity increased from 12.0% in 1991 to 17.9% in 1998 (143). An increase in prevalence was observed in all states in both sexes, across all age groups, races, educational levels, and occurred regardless of smoking habits. The largest increases were found in the following groups: 18- to 29-year olds (7.1% to 12.1%), those with some college education (10.6% to 17.8%), and those of Hispanic ethnicity (11.6% to 20.8%). The increase in prevalence varied substantially by region (31.9% for mid-Atlantic and 67.2% for South Atlantic) and by state (11.3% for Delaware and 101.8% for Georgia). In Colorado, obesity prevalence increased from 8.4 % (0.72 SEM) in 1991 to 14.0% (0.96 SEM) in 1998, an increase of 66.6% (143).

Determinants of Obesity and the Obesity Epidemic

Obesity is the result of a positive energy balance that occurs over an extended period of time. It is a slow process and one that occurs by either small but sustained bouts of a positive energy balance or larger, more episodic bouts (85). Either way, the increased fat mass that occurs seems to help restore energy and macronutrient balance at a new steady-state weight that was higher than before (85).

The human body can defend itself against developing obesity by matching energy intake with energy expenditure but this ability can be overcome with a sufficient challenge, such as chronic overfeeding or chronically low levels of energy expenditure (85). A conceptual drawing by Hill and Melanson (85) in Figure 2 illustrates this concept. Unfortunately, it is not possible at the present time to determine the degree of overfeeding or inactivity necessary to override the body's capacity to regulate energy balance and cause weight gain to occur.

Although the exact cause of the increased prevalence of obesity in the U.S. is unclear, the law of thermodynamics suggests increases in caloric intake, decreases in energy expenditure, or both, must be involved. Genetic factors can contribute up to 70% of the variability in body fatness among individuals but they cannot explain the sudden increase in obesity prevalence (85). Rather, recent changes in the environment that exert constant pressure toward a positive energy balance are the most likely explanation.

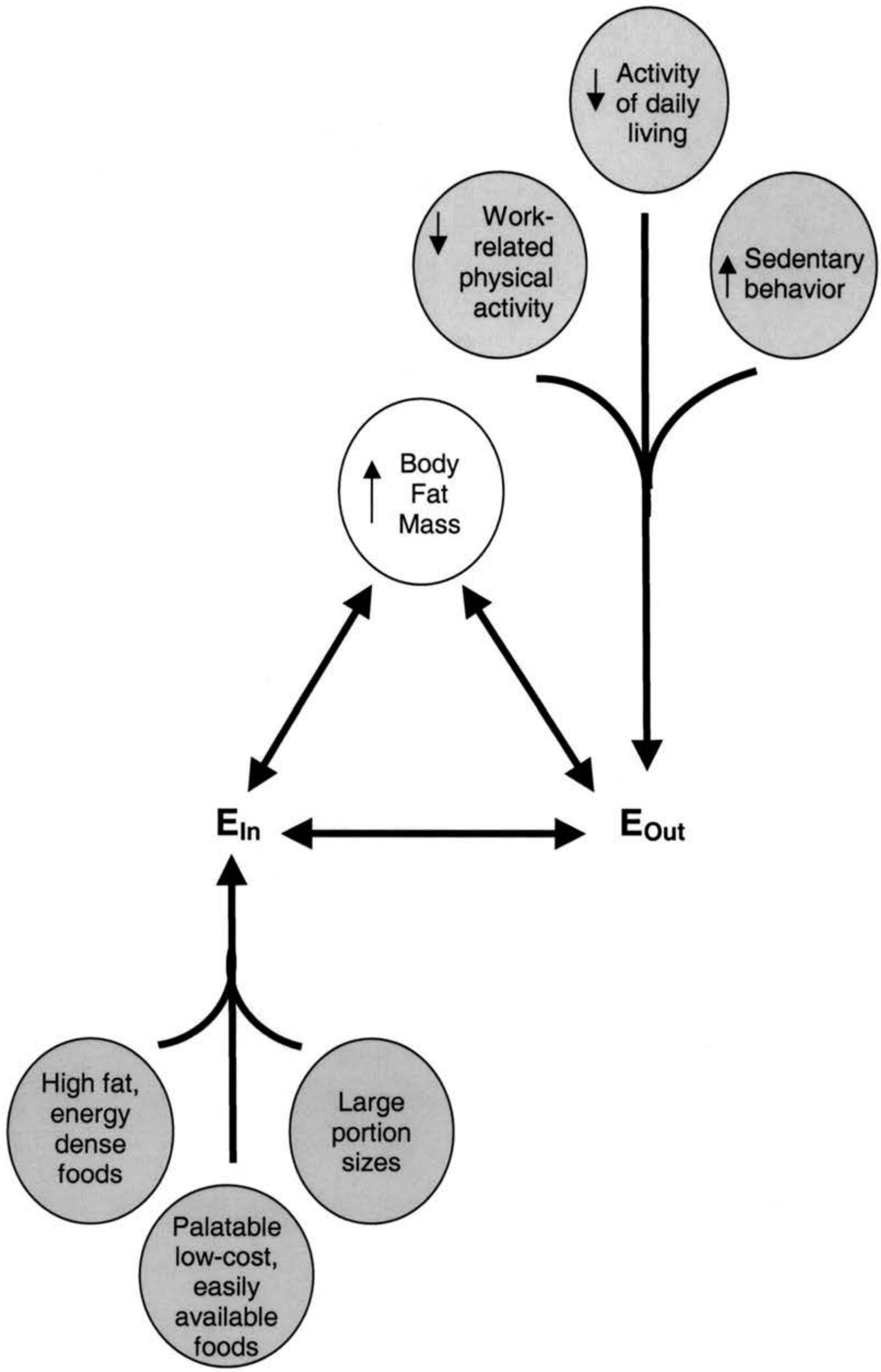


Figure 2. The Effect of Environmental Factors on Energy Balance. From Hill and Melanson (85).

These environmental changes include an abundant supply of inexpensive, convenient, highly palatable, energy dense foods combined with a lifestyle requiring low levels of energy expenditure (86). Obesity occurs rather easily in such an environment because the human body can only weakly defend itself against excess energy stores when food is prevalent and energy expenditure is so low (86). Hill and Peters (86) suggest that the contribution by the environment to obesity should be thought of in terms of how it increases the frequency of behaviors that increase risk of a positive energy balance. Thus, obesity should be considered as a "natural response to the environment" and not a result of defective physiology (86).

Even in individuals consciously restricting their food intake, the low level of energy required for contemporary daily living can sometimes produce weight gain. Bouchard and Blair provide the following three scenarios as possible explanations for the obesity epidemic (32):

a) a large proportion of the population is consuming more calories than individuals of past generations with no change in habitual daily energy expenditure;
b) for many people, there is abnormally low daily energy expenditure for a normal caloric intake;
c) for others, caloric intake per capita is actually lower than expected in comparison with previous generations but daily energy expenditure is, on the average, even lower.

The dramatic reduction in energy expenditure associated with physical activity is at least partly the result of increased mechanization in the workplace, laborsaving devices for the house and yard, and the ubiquitous use of computers at work and at home (32). However, the effects on energy expenditure from energy-saving devices in the home and workplace have not been definitively quantified. Some experts have estimated the average per capita decline in energy expenditure over the last two decades to be around 800 kcal/day (90). Fogelholm et al (66) reported a drop in work-related energy expenditure of 225 kJ-d occurred between 1982 and 1992.

On an individual basis, body weight and body composition are determined by an interaction between genes and the environment (86). Physical activity plays an important role in this interaction and a few researchers have attempted define this role. Samaras et al (169) examined the relation between physical activity and total-body and central abdominal fat, independent of genetic and other environmental factors, and the influence of physical activity in individuals who are genetically susceptible to generalized or central obesity, in 970 healthy female twins.

The cohort of twins ranged in age from 39 to 70, with a mean age of 55.5 years. BMI ranged from 16.4 to 44.0 kg, with a mean BMI of 24.4. There were 241 monozygotic pairs and 228 dizygotic pairs. Total-body and central body fat were assessed with dual-energy x-ray absorptiometry.

Physical activity was assessed by quantitative and semi-quantitative questionnaires.

The results showed that physical activity was the strongest independent predictor of total-body fat ($p=.009$) and central abdominal fat ($p<.001$) in a regression model that included age, diet, smoking, hormone replacement therapy (HRT) use, and socioeconomic status. Total-body and central abdominal fat were 5.6 kg and 0.44 kg lower, respectively, in twins who reported regular vigorous activity. In twins who were discordant for body weight (one normal-weight twin and one overweight twin), higher levels of physical activity were still associated with a 3.96 kg lower amount of total-body fat and 0.52-kg lower central abdominal fat.

Physical Activity in the Treatment of Obesity

Overweight and obesity are typically treated with low energy diets, exercise, or both. When evaluated separately, most studies have shown calorie restriction to be more effective in promoting weight loss in overweight or obese individuals than increased exercise (204). However, several studies suggest that adding physical activity to a calorie-restricted program is the most efficacious way of promoting weight and fat loss (142, 204).

The OEI report previously described reviewed the literature on this topic and classified data according to evidence-base categories (see

Table 5). This report was published in 1998 (148). The ACSM also convened a panel of experts to review the literature on physical activity in the treatment of obesity and obesity-associated comorbidities and their report was published in 1999 (20). Findings from both reports, along with findings from other studies, are included here.

TABLE 5. Categories of evidence[1]

Category A – Evidence is from endpoints of well-designed randomized clinical trials (RCT) (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendation is made. Category A, therefore, requires substantial numbers of studies involving substantial number of participants.

Category B – Evidence is from endpoints of intervention studies that include only a limited number of RCT, post hoc or subgroup analysis of RCT, or meta-analysis or RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.

Category C – Evidence is from outcomes of uncontrolled or nonrandomized trials or from observation studies.

Category D – Expert judgement is based on the panel's synthesis of evidence from experimental research described in the literature and/or derived from the consensus of panel members based on clinical experience or knowledge that does not meet the above-listed criteria. This category is used only in cases where the provision of some guidance was deemed valuable but an adequately compelling clinical literature addressing the subject of the recommendation was deemed insufficient to justify placement in one of the other categories (A through C)

[1] Adapted from the NHLBI Obesity Education Initiative on the identification, evaluation, and treatment of overweight and obesity in adults (148).

To address the question of whether exercise alone will produce weight loss, the OEI reviewed 12 randomized clinical trials (RCTs)(148).

In ten of the 12 articles, the reported mean weight loss was 2.4 kg (5.3 lb) or a mean reduction in BMI of 0.7 kg/m^2 in the exercise group compared to a control group. In three of the ten studies, weight loss was less than 2 kg or 4.4 lbs. A meta-analysis of 28 studies by Garrow and colleagues (73) of the effect of exercise alone on weight loss compared to control groups revealed that exercise elicits only a modest weight loss of 3 kg in men and 1.4 kg in women.

In studies that compared exercise alone to diet alone, most have reported that diet alone was more effective than exercise alone. In nine of ten RCTs reviewed in the OEI report, the diet-only group produced greater weight loss than exercise alone (148). Diet-only groups experienced, on average, a 3 kg greater weight loss than the exercise-only group. The OEI issued the following evidence statement:

> **"Physical activity, i.e., aerobic exercise, in overweight and obese adults results in modest weight loss independent of the effect of caloric reduction through diet. Evidence Category A." (148)**

Another important question regarding exercise in the treatment of obesity is to what extent does physical activity enhance long-term maintenance of weight loss. To date, this question has not been formally addressed in RCTs. Most of the data are restricted to observational studies and fall into Evidence Category C, according to the ASCM report (78). Several large-scale longitudinal studies cited by the ACSM expert panel indicate that physical activity and fitness attenuates age-related weight gain but does not always prevent weight gain or promote weight loss (78). An attenuation of weight gain through regular physical activity in obese individuals, however, is likely to help mitigate the comorbidities of obesity, such as glucose intolerance, hypertension, or dyslipidemia (46, 78).

One study that does support the hypothesis that physical activity prevents age-related weight gain is a prospective study by DiPietro and colleagues at the Cooper Institute of Aerobics Research in Dallas, Texas (46). These investigators followed 4599 and 724 women from 1970 to 1994. Body weight and cardiorespiratory fitness, determined by a maximal exercise test on a treadmill, were assessed on three different occasions during that time period. These three assessments allowed for an assessment of change in fitness from the first to the second examination as a way of predicting weight gain by the third examination.

The researchers found that each 1-minute improvement in treadmill time from the first to the second examination was associated with a 9% decrease in the odds of a 5-kg weight gain in women and a 14% decrease in men. The reduction in odds for gaining 10 kg were even lower with each 1-minute increase in treadmill time for both men and women, approximately 21% lower.

Supporting evidence for the role of physical activity in body weight regulation comes from cross-sectional and population studies which have consistently shown a negative relationship between levels of habitual physical activity and BMI (70, 178, 203). In addition, data from the

National Weight Control Registry, a compilation of data on individuals who have lost at least 30 lbs and maintained that loss for at least one year (140), suggests physical activity is a predictor of weight maintenance. The Registry includes data on at least 1047 men and women and reveals that one of the most striking characteristics of these weight-maintainers is the level of physical activity they engage in on a daily basis: an average of at least one hour of moderate to vigorous intensity activity.

Effect of Exercise on Fat Distribution

Another important question in relation to exercise in the treatment of obesity is whether exercise alters fat distribution, i.e., does exercise have any effect on abdominal obesity. As discussed earlier, higher levels of fat surrounding visceral organs in the abdominal region are associated with several metabolic disorders, such as dyslipidemia, hypertension, and glucose intolerance. The ACSM expert panel addressed this question by reviewing studies that examined the effect of exercise on abdominal girth in both men and women (14, 78).

Of the studies involving both sexes, five RCTs examined whether increased physical activity alone (without diet-induced weight loss) will reduce body weight and abdominal girth. Only one out of five RCTs reviewed reported a weight loss and reduced waist circumference from exercise alone. In one RCT and four nonrandomized trials where visceral and subcutaneous abdominal fat were measured outcomes, exercise alone did result in reductions in both compartments. The ACSM panel concluded,

> **"Physical activity, with or without a weight loss, is associated with reductions in visceral and abdominal subcutaneous tissue (Evidence Category C)"(78)**

The OEI also reviewed several RCTs in which physical activity had small effects on abdominal girth (148). One RCT reported a small reduction (0.9 cm) in men but not in women (184). Yet, larger studies conducted in Europe (172) and Canada (189) have reported favorable effects of physical activity on body fat distribution. These studies revealed an inverse association between physical activity and various indicators of abdominal obesity, such as waist circumference and waist-to-hip circumference ratio. The evidence statement issued by the OEI report states,

> **"Physical activity in overweight and obese adults modestly reduces abdominal fat. Evidence Category B."(148)**

Effects of Physical Activity on Cardiorespiratory Fitness in Obese Individuals

The OEI also reviewed studies on the effect of physical activity on cardiorespiratory fitness in obese individuals. Eleven RCTs found that physical activity increased VO_2 max in overweight or obese men and women by an average of 14% (ml/kg body weight) to 18% (L/min) (148). In the studies with only modest weight loss (<2%), exercise alone increased cardiorespiratory fitness by an average of 12% (L/min) to 16 % (ml/kg). The evidence statement issued states,

> **"Physical activity in overweight and obese adults increases cardiorespiratory fitness independent of weight loss. Evidence Category A". (148)**

Physical Activity in the Treatment of Obesity-Associated Comorbidities

A number of medical conditions associated with obesity, often referred to as comorbidities, are also risk factors for CVD, such as diabetes, hypertension, and dyslipidemia. The ACSM roundtable review states that although most of the evidence demonstrating obesity contributes to these conditions belongs in Category C, it is overwhelmingly strong (78). Moreover, it is well established that weight loss, either by diet, exercise, or both, generally produces favorable effects on these comorbidities (150). What is less clear is the effect of physical activity alone, independent of weight loss, on obesity comorbidities. The following is a brief review of studies directed at determining effects of physical activity without a concurrent weight loss, on the three most common comorbid conditions of obesity: diabetes, hypertension, and dyslipidemia.

Diabetes

Type 2 diabetes mellitus (DM) is major cause of CVD and all-cause mortality (1, 123, 182, 197) and has increased in prevalence in the last few decades (1). Population attributable risk (PAR) calculations have estimated 35% of type 2 diabetes mellitus can be attributed to sedentary living (19).

Current guidelines established by the American Diabetes Association define impaired fasting glucose as a fasting plasma glucose level from 110 to 125 mg/dl (6.1 to 6.9 mmol/L) and type 2 DM as a fasting plasma glucose level of 126 mg/dl (7.0 mmol/L) or more (1).

Dengel et al (44) and Katzel (97) have shown physical activity improves insulin action in obese men. Subjects in these studies, who were initially sedentary, performed moderate intensity aerobic exercise for 15 to 45 minutes, three days a week, over a 9- to 10- month period. Aerobic capacity improved but weight remained stable. Although neither group were glucose intolerant before the intervention, insulin levels during an oral glucose tolerance test (OGTT) following the intervention were improved (-17% and –19% area under the curve from OGTT, respectively).

Arciero and colleagues (11) recently demonstrated that short-term exercise is more effective than diet in promoting glucose uptake in obese men and women with abnormal glucose tolerance. For 10 days subjects followed either a low calorie diet (LCD) or an exercise training program (ET). Insulin secretion and action were compared between groups using a hyperglycemic clamp with superimposed arginine infusion and a high fat drink. After 10 days, body weight and fasting plasma glucose and insulin decreased significantly in both groups. Plasma insulin levels dropped by 40% in both groups during hyperglycemia and trends for reductions during the arginine infusion and high fat drink occurred. However, glucose uptake increased by 56% in the ET group, despite the low insulin levels, and by only 19% in the LCD group and this difference was significant ($p < 0.01$).

In a review by Kelley and Goodpaster (98) eight nonrandomized trials have reported positive effects of exercise training on insulin action. However, only four of these studies reported improved glucose tolerance (four reported no change) and the improvements were observed mostly in subjects with glucose intolerance and not among subjects with established type 2 DM. A key finding in most of these studies was that the exercise training produced improvement in insulin action within one week of intervention, indicating that physical activity can improve insulin action without a concomitant weight loss.

Several large-scale prospective studies have shown that regular physical activity can reduce the risk for developing type 2 DM (83, 126, 127). Manson et al (127) examined data from the Nurses Health Study to determine if an association exists between regular exercise and development of diabetes. This cohort included over 87,000 women between the ages of 34 and 59, all of whom were free of diagnosed diabetes, CVD, and cancer in 1980. During eight years of follow-up, subjects were followed for mortality. Results of the follow-up revealed that those who engaged in vigorous exercise at least once a week had an age-adjusted relative risk (RR) of type 2 DM of 0.67 ($p<.0001$) compared with women who did not exercise on a weekly basis. After adjusting for BMI, the risk reduction was attenuated but was still statistically significant (RR=0.84; p=0.005). Interestingly, there was no clear dose-response gradient of exercise frequency and the reduction in risk was the same for obese and nonobese women.

Wei et al (198) have conducted the only prospective study to date that uses cardiorespiratory fitness as an endpoint to examine the relationship between physical activity and type 2 DM. Subjects in this study were 8633 nondiabetic men, 7511 of whom did not have impaired fasting glucose at baseline. Cardiorespiratory fitness was assessed by maximal exercise testing on a treadmill. After adjusting for age, cigarette smoking, alcohol consumption, and parental diabetes, men in the low-fitness group at baseline had a 1.9-fold risk for impaired fasting glucose and a 3.7-fold risk for type 2 DM after six years, compared with those in the high fitness group. Age and BMI were also significantly associated with impaired fasting glucose and type 2 diabetes.

In general, most studies have found exercise improves glucose control and/or reduces the amount of medication needed to control blood glucose in obese patients with type 2 DM (98). Kelley and Goodpaster (98) note that more research is needed to determine the dose-response association between the length of exercise intervention, the training intensity, frequency, and the duration with effects on insulin action and glucose homeostasis (e.g., how much and what type of exercise is needed).

Hypertension

Over 50 million Americans have high blood pressure, 90% having mild to moderate hypertension (91). Hypertension is the single most important risk factor for stroke and one of many risk factors for CHD (8). The Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure Report V (JNC V)(91) define mild to moderate hypertension as blood pressures (BPs) in the range of 140–179/90-109 (systolic/diastolic readings).

The ACSM expert panel reviewed 44 RCTs pertaining to the effects of exercise on hypertension in obese individuals, including 68 study groups and 2674 participants (78). Most of the studies found that exercise training was most effective in hypertensive patients and generally elicited a reduction in both systolic and diastolic readings by 7.4 and 5.8 mm Hg, respectively. In addition, decreases in blood pressure were independent of weight loss and not related to initial body mass index. Most of the studies also found that exercise alone to be less effective in lowering blood pressure than diet alone (-3.5/-2.9 vs –5.43/-3.7 mm Hg, respectively). The ACSM expert panel issued two Evidence Statements on the effect of physical activity on blood pressure:

"Higher levels of physical activity or fitness are associated with a lower incidence of hypertension; the effect of overweight on this relationship is uncertain. (Evidence Category C)."(78)

"Dynamic aerobic training reduces blood pressure independent of changes in weight; the blood pressure lowering effect depends on the initial blood pressure, but not on BMI or age. (Evidence Category A)."(78)

Dyslipidemia

More than 99,000,000 Americans have total blood cholesterol levels of 200 mg/dl and higher (8). In 1997, 52,200,000 US women had total blood cholesterol levels of 200 mg/dl or higher (8). The American Heart Association considers cholesterol levels from 200 to 239 mg/dl as borderline high and levels above 240 mg/dl as high [Association, 2000 #81]. Low levels of high density lipoprotein cholesterol (HDL-C) and/or high triglyceride levels are also indicative of elevated risk for CVD (8). In both men and women, the risk of myocardial infarction is highest at lower HDL-C levels (37 mg/dl or lower in men, 47 mg/dl or lower in women) and higher total cholesterol levels, overall (8).

The National Cholesterol Education Program (NCEP) Adult Treatment Panel II (ATP II) (59) guidelines for individuals without CHD specify the following levels for high-risk lipid or lipoproteins:

- Total cholesterol (TC) $\geq$ 240 mg/dL (6.2 mmol/L)
- HDL-C < 35 mg/dl (0.9 mmol/L)
- LDL-C > 160 mg/dl (4.1 mmol/L) in patients with fewer than two risk factors >130 mg/dl in the presence of two or more risk factors
- Triglycerides (TG) > 399 mg/dl (4.6 mmol/L)

Stefanick (183) reports that the most common lipoprotein abnormality associated with obesity is "atherogenic dyslipidemia": elevated levels of both triglycerides and LDL-Cs and low HDL-C levels. Several observational studies have indicated that high LDL-C levels in overweight individuals appears to be related more to high intakes of cholesterol and saturated fatty acids than to BMI *per se* (78).

Stefanick (183) also reports on eleven RCTs of 5-12 months duration with sample size large enough to detect significant changes in HDL-C (and possibly other lipoproteins). In these studies, increased physical activity did not raise HDL cholesterol or lower triglyceride levels in overweight men and women unless there was a weight loss of greater than 2.5 kg. If the volume of physical activity was such that it produced a weight loss of at least 4.5 kg, HDL cholesterol levels typically increased and triglycerides decreased. In studies where increased physical activity was added to a low energy, low fat diet, significant reductions were observed in LDL cholesterol levels in both men and women.

Some studies have shown exercise to have minimal effects on blood lipid or lipoprotein levels in obese women. Ready et al (166) examined the effects of a six-month walking program on blood lipid levels in obese women. At completion, the walkers achieved a small but significant weight loss of 1.3 kg, compared to controls, but changes between groups in HDL and LDL levels were not significantly different. Total cholesterol

(TC) and triglyceride levels (TC) decreased slightly in the walking group by –0.12 and –0.30, respectively.

Fox et al (68) compared changes in CVD risk factors in obese women assigned to either one of two weight loss diets (-500 kcal/d vs. –700 kcal/d) or to a weight loss diet (-500 kcal/d) plus aerobic exercise and resistance training program for six months. No significant differences were found between groups for changes in weight or blood lipids. Although a weight loss occurred in all three groups (-6.6, 5.8, and 7.1 kg, respectively), HDL-C levels decreased, albeit slightly, in all three groups (-0.15, -0.08, and –0.06, respectively).

However, other studies have found exercise training to have beneficial effects on CVD risk profiles in obese women without a reduction in body weight or fat (45). One such study, conducted by Lamarche and colleagues (110), examined the relation between body fat loss and metabolic improvements following a six-month endurance exercise training program in 31 obese premenopausal women. The training program included five sessions of 90 minutes of moderate-intensity endurance exercise per week.

At completion, a mean body fat mass reduction of 2.6 kg was observed in 20 women whereas a mean *gain* of 2.8 kg body fat mass was observed in 11 women. Both groups had significant improvements in HDL-C (as well as subfractions of HDL-C) and significant reductions in LDL-C, total cholesterol, and fasting insulin levels. There were no initial differences in body composition between groups and self-reported caloric intake appeared to remain constant throughout the study. The authors concluded that the endurance training program appeared to compensate for any "deleterious" effects of the increase in fat mass that occurred among the women who gained body fat.

In Project *Active*, no differences were found between the Lifestyle and the Structured exercise groups for TC, TG, HDL-C, LDL-C, or the ratio of TC to HDL-C after six months of intervention (53). Within each group, a small but significant reduction in TC occurred over the six month period (-0.2 mmol/L and –0.3 mmol/L, respectively) but no changes in HDL-C levels occurred in either group.

Andersen and colleagues (10) compared changes in weight and lipid levels in obese women assigned to a behavioral weight loss program combined with either a lifestyle physical activity program or a structured exercise program. After six months, both groups lost weight (-7.9 kg and –8.3 kg, respectively) and improved cardiorespiratory fitness levels. Small but significant improvements in TC, LDL-C, and triglyceride levels were observed at six months in both groups with no difference between groups on any of the lipid or lipoprotein measures. Despite the increase in fitness, HDL-C levels decreased by approximately 10% in both groups, presumably because of the reduction in total cholesterol levels.

Based on the available data from RCTs, Stefanick (183) provided the following evidence statements for the ACSM roundtable report:

"Aerobic exercise training is unlikely to improve the lipoprotein profile in overweight men and women, unless it is combined with a hypocaloric diet; however, if the caloric reduction is achieved primarily by reducing saturated fat, benefits to HDL-C are likely to be reduced or eliminated, whereas improvements to LDL-C will be improved (Evidence Category A). The addition of exercise to a weight-reducing and/or reduced-fat diet produces only a modest effect to HDL-C, TG, and/or LDL-C compared with what is achieved by the diet alone (Evidence Category A)."

"Weight loss achieved by exercise with no dietary change (or by caloric restriction with no exercise change) is likely to improve HDL-C and TG in obese men with normal lipoproteins, whereas the evidence that exercise or weight loss improves these lipids in men with dyslipidemias is weak (Evidence Category A). Even less evidence exists to support a role for aerobic exercise in treating lipid disorders in obese women."

"Effects of energy expenditure through daily activities on lipoproteins has not been shown to differ from effects of structured physical activity; however the data are very limited at this time." (183)

Physical Activity in Reducing Morbidity and Mortality in Obese Individuals

The effects of physical activity and fitness on CVD risk factors is important as it provides a basis upon which recommendations can be made in both clinical and community settings for chronic disease risk reduction. However, the ultimate goal is to reduce morbidity and mortality from CVD and other chronic diseases or, at the very least, prevent an early mortality. Thus, in relation to obesity, researchers have asked the following questions (21): 1) do higher levels of physical activity or cardiorespiratory fitness reduce morbidity and mortality in obese persons and 2) do overweight or obese individuals who are physically active have a lower risk of morbidity and mortality than normal weight individuals who are sedentary. While more research is needed to fully understand the relationships among body weight, fitness, and mortality, a few studies have suggested that the answer to both questions is likely to be yes.

The first study was conducted by Barlow et al (18) in 1995 at the Cooper Institute for Aerobics Research in Dallas, Texas. These investigators examined the relation of cardiorespiratory fitness to mortality in overweight and normal weight men. More than 25,000 men participated in this study that began in 1970 and concluded in 1989. Fitness was measured by maximal treadmill tests and men were classified as normal-weight or overweight based on measurements of BMI. The principle outcome measure was cardiorespiratory fitness, as assessed by a maximal treadmill test.

Results indicated that all-cause death rates were inversely associated with cardiorespiratory fitness, being progressively lower across increasingly higher fitness categories in each of the following BMI stratum: <27, 27-30, or >30 (kg/m^2). The moderate- and high-fit men with a BMI > 30 had a relative risk of 0.29 relative to the low-fit men in this BMI stratum. In fact, the inverse gradients of mortality across fitness groups were the same for obese and nonobese men. The greatest difference in age-adjusted relative risk for all-cause mortality was observed in men with a BMI >30. A 15% lower risk was observed for each minute higher treadmill time for men in the latter BMI category versus a 9% lower risk for the men with a BMI <27.

Lee et al (112) examined another cohort of the previous study for associations between cardiorespiratory fitness, body composition, and all-cause mortality. Over 21,000 men between the ages of 30 and 83 were enrolled in this study and followed for mortality for eight years. The primary outcome measure was, again, cardiorespiratory fitness as assessed by a maximal treadmill test. Body composition was determined by hydrodensitometry and skinfold measurements. Waist girth measurements were also obtained in a subgroup of subjects (n=14,043). Subjects were assigned into categories of lean, normal, or obese based on body composition assessments, corresponding to $<25^{th}$, 25^{th} to $<75^{th}$, and $>75^{th}$ percentile scores. Subjects were also classified as having low, moderate, and high categories of fat mass, fat free mass (FFM), and waist circumference.

After adjusting for age, examination year, cigarette smoking, alcohol intake, and parental history of ischemic heart disease, unfit lean men had twice the death risk for all-causes than fit, lean men (relative risk: 2.07; 95% CI: 1.16, 3.69; p=0.01). Men who were fit and obese had significantly lower death rates for all-cause and CVD mortality than men who were lean and unfit. In addition, men with a waist girth of >99 cm had a relative risk of 0.95 for all-cause mortality whereas unfit men with a waist girth of <87 cm had a relative risk of 4.71 for the same endpoint.

The authors concluded that obesity did not appear to increase mortality risk in fit men and that "for long term health benefits, we should focus on improving fitness by increasing physical activity rather than relying only on diet for weight control."

Most of the studies on fitness and mortality in overweight or obese individuals have been done in men. The question of whether these results are true for obese women remains mostly unanswered. However, Farrell and colleagues recently presented preliminary data on the relation between BMI, cardiorespiratory fitness, and all-cause mortality in women at the American College of Sports Medicine annual meeting in Indianapolis, Indiana (62). Assessments were conducted at the Cooper Institute for Aerobics Research in Texas; therefore, assessment methods were the same as they were for the studies described above.

Subjects in this study were 7572 adult women examined at the Cooper clinic in the interval from January 1971 to December, 1994. Subjects were classified as normal, overweight, or obese, based on BMI of 18.5-24.9, 25-29.9, or 30 and greater, respectively. The average length of follow-up was 9.2 years. After adjusting for age, exam-year, health status, smoking status, and cardiorespiratory fitness, death rates for unfit normal weight women were significantly higher than those of obese women who were fit (41 vs 35 deaths per 10,000 woman-years of data). Farrell concluded that preliminary data indicate low cardiorespiratory fitness is a more important predictor of all-cause mortality in women than BMI.

CHANGING SEDENTARY BEHAVIOR

When a behavioral or biological factor is implicated as a major determinant of a chronic disease – especially a disease that is highly prevalent - studies that evaluate different approaches to changing the determinant are warranted (175). Physical activity is an important determinant for both CVD risk and obesity and until recently, very little was known about the behavioral aspects of this determinant. However, considerable progress has been made in recent years in delineating the various factors associated with physical inactivity. According to Blair et al (31), these factors include:

1. Demographic factors – Being older, black, female, poorly educated or overweight.
2. Cognitive factors – having the perception that there are no benefits from activity or that poor health precludes exercise, perceived lack of time, little enjoyment of activity, or a lack of confidence in one's ability to be active.
3. Personal attributes – low levels of self-motivation and self-regulatory skill, having inadequate social support, and activities that are less convenient, more costly, and more vigorous.

Recent research has also identified factors associated with physical activity specifically among women. One of these factors is the reduced amount of time women have for recreational and leisure time pursuits, especially if they work outside the home and/or care for young children.

Women spend from 30 minutes to six hours per day in household chores and family care activities and 4-16 hours per day in paid occupational activities (3, 4). Henderson and colleagues (84) report that caring for a family and maintaining a household are primary determinants for a lack of leisure time in women and affect the choices women make in relation to physical activity.

The most common barriers to physical activity cited by women include lack of time, lack of motivation, and lack of family support (60). In addition, many women place a higher value on family and community relationships than personal identity and individual choices (84). Henderson (84) refers to this concept as a woman's "ethic of care", describing how many women put the needs of others first, particularly the needs of their families, and their own personal needs last. These obligations leave little time for recreational activities and represent an important barrier to physical activity that is not typically addressed within traditional exercise or weight management programs (84).

Behavior Modification Techniques

Efforts to change sedentary behavior have traditionally involved the use of behavior modification techniques. These techniques include written agreements, behavior contracts, stimulus control, decisional balance sheets, and contingency reinforcement (100). These techniques are sometimes supplemented with cognitive-behavioral approaches, such as goal-setting, feedback, and self-monitoring (100). Several studies have shown these techniques to be equally effective when used alone or when integrated into intervention programs (106, 134). King et al (101) reports that behavior modification and cognitive-behavioral techniques are associated with a 10 – 75% increase in the frequency of physical activity when compared with a no-treatment control group.

Behavior modification techniques have also been used in the treatment of obesity, primarily aimed at changing eating behavior. The Obesity Education Initiative (OEI) task force of the NIH and NHLBI (148)(described earlier) reviewed 36 randomized trials to determine if behavior therapy provided additional benefits above and beyond the traditional approaches to weight loss, diet and physical activity. The results revealed that, in most studies, the addition of behavior therapy to a traditional weight loss program of calorie restriction and increased exercise resulted in greater weight loss than the traditional weight loss approach alone. However, after five years, the effect disappeared: behavior therapy was no better in its effect on maintaining weight loss than traditional weight loss programs were.

Dishman (47) contends that behavior change interventions that employ behavior modification techniques have not been shown to be any more effective than increased attention from attending professionals. This lack of convincing data may be due to problems in the research design, such as the short time span of many intervention studies (many are

<12 weeks), outcome measures have not included measures of activity or fitness changes, and many studies do not include control groups. However, in the few studies that have included no-treatment or minimal-treatment control groups, similar changes in activity and/or fitness were achieved in both groups making it difficult to conclude that that the behavioral approaches exerted an influence beyond that exerted by the social support and reinforcement provided in the group setting (47).

Dishman (47) suggests the use of a broader theoretical model for behavior change to promote physical activity in sedentary individuals. Although most psychological theories and models do include behavior modification techniques, they do so in a broader context, encompassing a wider range of factors that influence human behavior (163).

Theoretical Models for Behavior Change

Theories and models help researchers identify the complex factors involved in human behavior and facilitate a better understanding of how to change behavior. Two models that have received empirical support for their effectiveness in changing sedentary behavior include the Transtheoretical Model for Behavior Change and the self-efficacy component of Social Cognitive Theory (27, 47, 129, 135), both of which are briefly described below.

The Transtheoretical Model for Behavior Change

Sometimes referred to as the Stages of Change model, the Transtheoretical Model for Behavior Change was developed to provide a framework that describes how people change a problem behavior. The term "transtheoretical" is used to describe how the model uses a temporal dimension, the stages of change, to integrate principles and processes of change derived from different theories of intervention (164). The stages of change are labeled and described as follows:

Precontemplation – no intention of changing

Contemplation - seriously considering change

Preparation - making small changes

Action - actively engaged in changing behavior

Maintenance - continuation of change efforts for a period of at least six months.

Termination – individual faces zero temptation to regress and 100% self-efficacy

Movement through these stages is believed to occur in a cyclical manner, that is, some people may move back and forth between stages before reaching the maintenance stage. Some people may remain in one stage for a lifetime (164). Prochaska and Velicer (164) state that the following set of assumptions drive transtheoretical theory, research, and practice:

1. No single theory can account for all of the complexities of behavior change. Therefore, a more comprehensive model will most likely emerge from integration across major theories.

2. Behavior change is a process that unfolds over time through a sequence of stages.

3. Stages are both stable and open to change, just as chronic behavioral risk factors are both stable and open to change.

4. Without planned interventions, populations will remain stuck in the early stages. There is no inherent motivation to progress through the stages of intentional change as there seems to be in stages of physical and psychological development.

5. The majority of at-risk populations are not prepared for action and will not be served by traditional action-oriented prevention programs. Health promotion can have a much greater impact if it shifts from an action paradigm to a stage paradigm.

6. Specific processes and principles of change need to be applied at specific stages if progress through the stages is to occur. In the stage paradigm, intervention programs are matched to each individual's stage of change.

7. Chronic behavior patterns are usually under some combination of biological, social, and self-control. Stage-matched interventions have been primarily designed to enhance self-controls.

An advantage of using the Stages of Change model is the emphasis it places on the dynamic nature of behavior change. This model recognizes that change is not an all-or-nothing phenomenon and that people who stop performing a behavior may start again and may, subsequently, become successful in maintaining that behavior. In addition, the amount of progress an individual makes as a result of an intervention is a function of the stage they are in at the start of treatment. Thus, interventions designed for people who are ready to take action would most likely not work for those in the precontemplation or contemplation stage.

The transtheoretical model also includes ten "processes of change," which are strategies or techniques that people use to progress from one stage to the next (131, 164). According to Prochaska and Velicer (164), intervention programs that incorporate the processes of change may accelerate the progress of its participants through the stages of change, thereby increasing the adoption of exercise and improving maintenance of behavior change.

Five of these processes are considered "cognitive" processes and are primarily used to change ways of thinking. The remaining five are considered "behavioral" processes and are used to increase specific behaviors. Definitions of each process of change, according to Prochaska and Velicer (164), as well as examples of methods for incorporating each process into physical activity interventions, are described below:

Cognitive Strategies for Change

1. Consciousness Raising (CR). The primary aim of the CR process is to encourage the individual to read and think about physical activity or to increase their awareness of the need for physical activity. Providing information on the health benefits of physical activity and how the new recommendations for physical activity and health allow for frequent, shorter bouts of moderate-intensity activity is one method of employing CR.

2. Dramatic Relief (DR). DR is the process by which an individual is emotionally moved to change a behavior. Techniques for employing this strategy include role playing, personal testimonies, and viewing of videos or movies pertaining to the subject matter.

3. Self-Reevaluation (SR). SR is a cognitive appraisal of a problem behavior, such as physical inactivity, and the personal benefits of changing that behavior. SR has been referred to as "taking stock" of one's situation and how one would benefit by becoming more physically active. Techniques for this strategy include listing of

personal benefits from physical activity, seeing or hearing healthy role models, and imagery (visualizing oneself as an active person).

4. Environmental Reevaluation (ER). The primary aim of ER is to encourage an individual to recognize how their inactivity affects their social environment, particularly other family members. For example, California's anti-tobacco campaign included a brief television spot in which a middle-aged man, clearly in distress, says, "I always worried that my smoking would cause lung cancer. I was always afraid that my smoking would lead to an early death. But I never imagined that it would happen to my wife." The message "50,000 deaths per year due to passive smoking" then flashes across the screen (164). This television spot used both Dramatic Relief and Environmental Reevaluation to try to change behavior in smokers.

5. Social Liberation (SL). SL aims to provide the individual with supportive structures within one's environment for increasing physical activity, such as community programs, bike paths, walking trails, etc. SL also aims to provide the individual with social opportunities in which behavior change can take place, such as group activities or encouraging individuals to find a "buddy" to exercise with.

Behavioral Strategies for Change

1. Counterconditioning (CC). CC involves teaching individuals to engage in physical activity at times when it is likely to be most beneficial but when it is rarely done, e.g., when feeling stressed or tired. CC can be employed with "cognitive restructuring", a process in which an individual replaces negative thoughts with positive thoughts. Cognitive restructuring helps to change the way one thinks about a situation and not the situation itself.

2. Stimulus Control (SC). SC aims to help individuals set up their immediate environment so that it is conducive for physical activity. SC also includes controlling stimuli for sedentary activities. SC techniques for physical activity include placing walking shoes near the door, keeping a pair in the car, starting a garden. It also could be moving the television away from the main living area to the basement or other area of the house that is not so prominent.

3. Reinforcement Management (RM). The primary aim of RM is to teach individuals to reward or praise themselves for being physically active.

4. Helping Relationships (HR). HR is the strategy by which individuals are encouraged to find a friend or family member who will provide support for being active.

5. Self-Liberation (SL). SL involves building the belief or confidence that one can change, and making a commitment to one's self to act on this belief.

Several studies have applied the cognitive and behavioral strategies to increase exercise behavior (131), including Project *Active*, described earlier (see page 38). In this study, each of the ten processes were incorporated into the curriculum for the Lifestyle program. For example, Consciousness Raising was employed in several class sessions by introducing new information regarding physical activity and demonstrations of moderate-intensity activity. Helping Relationships was employed by having participants learn about the different types of social support and learning how to ask for support from family, friends, and co-workers.

The utilization of these strategies by participants was assessed using the Processes of Change questionnaire, developed by Marcus et al (131), which includes a separate subscale for each of the ten change processes. Participants completed the questionnaire before and after the intervention and scores were compared for changes over time. In addition, the investigators used logistic regression models to determine if changes in scores on the questionnaire predicted whether a participant would achieve the CDC/ACSM criterion for physical activity (accumulating 30 minutes of moderate physical activity on most days of the week). This was done by regressing the odds of achieving the CDC/ACSM criterion against the change since baseline in each process measure, adjusting for differences at baseline in age, gender, and baseline level of the measure. Results of this analysis were presented as odds ratios (OR). For instance, an OR of 3.6 was obtained for the process called "Helping Relationships" in the Lifestyle group. This means that, on average, if an individual increased their score on the Helping Relationships subscale by one unit, they would be 3.6 times more likely to achieve the CDC/ACSM criterion for physical activity.

The authors of Project Active state that this information is important for health professionals working with sedentary clients as it provides information on to how to help them adopt a physically active lifestyle. For example, one of the most effective processes was Substituting Alternatives (OR of 15), where participants were asked to replace sedentary activities with physical activity, such as walking the dog instead of watching television or walking around the building during a work break instead of sitting during the break. Knowing this, health professionals can emphasize this process when counseling sedentary clients or patients on how to change sedentary behavior.

Self Efficacy Theory

Bandura's theory of self-efficacy has also been useful in promoting behavior change (16). The concept of self-efficacy has been used to guide interventions designed for smoking cessation and other health behaviors in a variety of settings, e.g., community programs and physician offices. Self-efficacy, a central component of Social Learning Theory (17), is broadly defined as the beliefs one has regarding one's capabilities to engage successfully in a course of action sufficient to satisfy situational demands (17). Thus, self-efficacy is not concerned with actual skills to execute a specific task but, rather, perceptions about what can be done with those skills.

Self-efficacy has been reported to influence many social, psychological, and health outcomes and has consistently demonstrated its ability to predict exercise behavior (135). Self-efficacy has been positively associated with physical activity among men, women, older adults, overweight individuals, and persons with injuries or disabilities (49, 132, 137-139).

Clark and Dodge (40) note two important aspects of self-efficacy that are often overlooked by researchers or interventionists. The first is that self-efficacy is part of a reciprocal process that determines behavior. An interaction of personal, behavioral, and environmental factors produce not only the behavior but feelings of self-efficacy as well. These authors give the following description of self-efficacy as a self-regulatory process through which the individual shapes his or her environment and behavior to achieve a specific goal, such as engaging in physical activity:

> **"One draws from intrapersonal experiences (e.g., information, beliefs) and from external resources (e.g., advice from experts,**

role models) and engages in self-regulation, that is, one observes one's own behavior, makes judgements about it using a criterion (e.g., the behavior of a role model), tries out the new behavior, and reacts to the experience, that is, draws conclusions from the trial. One reaction relates to outcome expectations. If the behavior produced the desired outcome, the behavior is more likely to be tried again. Another reaction is the feeling of self-efficacy, the belief in one's own capacity. If one judges one capable of once again carrying out the behavior that produced the wished-for result, one is confident, feels efficacious. The greater the self-efficacy, the greater the likelihood that the behavior will be repeated." (40)

Another important aspect of self-efficacy, according to Clark and Dodge (40), is that self-efficacy is situation-specific. For example, one might feel confident in their ability to follow a prescribed diet plan for management of heart disease but have no confidence at all their ability to follow an exercise prescription. Thus, feelings of self-efficacy vary with tasks and behavioral challenges and are different from more global constructs, such as self-esteem (40).

McAuley and Courneya (136) have identified four primary techniques for improving self-efficacy for exercise or physical activity:

1. **Performance accomplishments or "mastery experiences"** – Being able to perform physical movements that are desirable to the individual and/or "mastering" a form of physical activity previously thought to be beyond one's capabilities.

2. **Social Modeling** – Looking to others with similar physical characteristics for motivation and information regarding their own prospects for success. Considered as most effective with sedentary and/or older individuals.

3. **Social Persuasion** – Providing information that may bolster one's belief in his or her own capabilities. Considered as more effective when combined with social modeling.

4. **Physiological States –** Teaching participants to modify or reinterpret their physical experiences with exercise. When sedentary individuals begin an exercise program they will most likely experience physiological stress, e.g., fatigue, muscle soreness, etc., and may interpret that as a negative consequence. Teaching individuals to anticipate various "aches and pains" and to monitor their progress by observing any changes in the degree of those symptoms as markers of improved conditioning can serve as another way to improve physical self-efficacy.

Physical Activity Interventions

King and colleagues (101) have defined the phrase "physical activity intervention" as "a set of targeted activities designed to foster increased physical activity in a population". There are several different types of physical activity interventions that are utilized by researchers and clinicians to encourage physical activity among individuals of all ages.

For adults, there are interventions in communities, in health care settings, in worksites, and at home. The 1996 Surgeon General's Report on Physical Activity and Health (192) states that these types of interventions, if widely applied, could have a significant impact on public health. Changes in environmental and public policy also have great potential for changing sedentary behavior. Examples include establishing walking or biking trails that connect homes with shopping areas, separating buildings from parking lots by green space, and making stairways in public buildings more accessible and attractive (168).

The Surgeon General's report also identifies the need for interventions that address the needs of special population groups, such as racial/ethnic groups, children, adolescents, the elderly, and overweight or obese individuals (192). These interventions should focus attention on reducing barriers to physical activity and aim to promote changes in activity patterns that are likely to be sustained. The report also highlights the importance of using theoretical models for behavior change as a guide for development and evaluation.

Effects of Physical Activity Interventions on Nutritional Practices

Interventions to promote physical activity may have a synergistic effect on other health behaviors (196). The two behaviors that seem to be the most affected by physical activity participation are nutritional practices and smoking (196). Thus, in addition to the direct effects of physical activity on health, physical activity participation may promote improvements in other behaviors that impact health as well (196). The evidence for improvements in nutritional practices is briefly reviewed here.

The nutritional practices that have been studied in relation to physical activity participation include caloric intake, diet composition (percent fat, carbohydrate, or protein, of total caloric intake), and various other nutritional practices, such as eating a good breakfast or following dietary guidelines (196). Observational studies have provided the strongest evidence for a positive association between physical activity and caloric intake but most of these studies have compared athletes with nonathletes. For instance, Smith and colleagues (180) compared the caloric intake of two collegiate swimming groups (synchronized and speed) with a sedentary control group over a 24-week period. Using 4-day dietary records, the swimmers' energy intake exceeded controls by 21%. In a study of long-distance runners versus controls, Blair et al (22) reported runners to exceed controls by about one-third in total caloric intake.

Intervention studies with non-athletes have had mixed results. Wood and colleagues (206) studied Stanford University employees randomly assigned to either a year-long exercise program or a sedentary control condition and found no significant differences in caloric intake between groups. Niemann et al (151) studied 36 obese women randomized to an exercise or sedentary control condition. The exercise group walked for 45 minutes, five times per week at a prescribed intensity. At six and 15 weeks from baseline, the exercise group had a significantly higher caloric intake than the sedentary controls. However, because obese women have been shown to under-report dietary intake (122), the results are to be viewed with caution.

Studies of the effects of physical activity participation on diet composition have also had mixed results. Early studies of clients tested at the Cooper Clinic in Dallas, Texas, for fitness level found no differences in diet composition of participants classified as improvers and those classified as non-improvers (indirect indicators of fitness levels)

(159). However, Blair and colleagues (24) later reported a positive relationship between level of physical activity and a number of nutritional practices, such as lower saturated fat intake and lower coffee consumption. These authors also reported on a number of dietary differences in clients who had undergone six full physical exams over time at the clinic (24). Subjects were divided into four groups in relation to their exercise habits: starters, continuers, intermittent, and sedentary. Continuers were those who remained active across their six physical exams; they consumed less total fat and saturated fat than the sedentary group. Intermittent exercisers were those who exercised on an intermittent basis and they consumed less total fat and unsaturated fat than the sedentary group. Lastly, starters, who had attempted an exercise regimen several times but were unable to maintain their regimen, were better than the sedentary group in terms of unsaturated fat intake and coffee consumption.

A number of studies have shown physical activity participation to be associated with more general indicators of healthful dietary practices. Canadian national surveys have reported a positive association between activity level and eating a nutritious breakfast (35) and with adherence to nutritional guidelines (42). The Campbell Survey on Well-Being of Canadians reported that individuals who reported being physically active in 1981 and 1988 were most likely to use the Canada Food Guide in their decisions about food choices than those who reported no physical activity in both years (42).

A question that some researchers have asked is whether physical activity or exercise training influences macronutrient preference (190). Macronutrient preference refers to a preferential taste for foods having a high content of a specific macronutrient. Tremblay and Drapeau (190) recently reviewed the literature for studies examining this question and concluded that neither short- or long-term exercise training has any effect on macronutrient preference. These authors contend that because active individuals do not systematically choose low fat foods, fat intake needs to be controlled if a negative energy balance is desired. For obese individuals, these authors state the following: "this thus implies that dietary advice is likely necessary to guide obese individuals toward good food selection instead of relying on the impact of physical activity to induce such changes"(190). No study to date has ever examined whether providing that information within the context of a physical activity intervention has any effect on caloric intake or diet composition in obese sedentary women.

Recommendations for Designing Physical Activity Interventions

A number of recommendations have been made for the design and delivery of physical activity interventions for sedentary populations. One of the first set of recommendations came from a report by Blair and colleagues that states the following:

> **"Physical activity education and intervention programs for health care professionals and the public should present alternatives to the traditional exercise prescription. Moderate levels of physical activity such as brisk walking should be promoted and the functional and health benefits of such activities emphasized. Lifestyle interventions in which increased activity is integrated into daily routines may be easier for many people to adopt than traditional programmed exercise." (31)**

This report also highlighted the importance of including behavior modification techniques that are likely to enhance behavior change, such as goal-setting and self-monitoring. In addition, providing feedback and social reinforcement are also important in changing sedentary behavior. Lastly, this report states that intervention programs should be tailored to life stage, stage of readiness, health and risk factor status, and other individual psychosocial and demographic characteristics.

In a review of research on physical activity interventions, Dishman (47) recommends a shift in focus from "exercise adherence to exercise adoption" is needed. Adherence refers to the level of participation achieved by an individual once he or she has agreed to undertake it. Exercise science research has typically focused attention on increasing exercise adherence among individuals who are already somewhat active or in the stages of becoming more active. Given the fact that a significant portion of the US population is completely sedentary, a more relevant research focus are methods for increasing initial attempts to become more active (28).

Dishman also contends that physical activity interventions should be targeted for individuals at risk for inactivity, such as the elderly, the less educated, women, and those who are overweight (47). To increase the likelihood of exercise adoption among these groups, interventions should be tailored to their preferences or needs. Moreover, because of the recent research on lifestyle physical activity, a reconceptualization of the definitions and measures of exercise adherence is needed (47). Dishman states, "evaluating an individual's energy expenditure throughout the week would likely provide a more sensitive measure with which to assess the effects of physical activity on health and function than would a narrow focus on scheduled exercise sessions" (47).

The National Institutes of Health released a Consensus Development Conference Statement on Physical Activity and Cardiovascular Health in 1995 (149) that provided general guidelines for planning or prescribing physical activity in sedentary individuals. These guidelines are as follows:

Physical activity need not be strenuous and is more likely to be initiated and maintained if the individual:

1. **Perceives a net benefit.**
2. **Chooses an enjoyable activity.**
3. **Feels competent doing the activity.**
4. **Feels safe doing the activity.**
5. **Can easily access the activity on a regular basis.**
6. **Can fit the activity into the daily schedule.**

7. **Feels that the activity does not generate financial or social costs that he or she is unwilling to bear.**
8. **Experiences a minimum of negative consequences such as loss of time, negative peer pressure, and problems of self-identity.**
9. **Is able to successfully address issues of competing time demands.**
10. **Recognizes the need to balance the use of labor-saving devices (e.g., power lawn mowers, golf carts, automobiles) and sedentary activities (e.g., watching television, use of computers) with activities that involve a higher level of physical exertion.**

The NIH report also emphasizes the importance of the individual's social environment in the process of adopting physical activity, such as spouses or friends, and highlights the need for behaviorally based interventions among adults for the primary prevention of CVD morbidity and mortality.

Lastly, Marcus et al (129) provided the following critical components for intervening with adults:

- Enhancing the perceived benefits of physical activity;
- Enhancing self-efficacy;
- Increasing intentions to exercise;
- Increasing enjoyment of physical activity;
- Enhancing social support;
- Including moderate intensity activity

These authors also state that it is important to remember that most people are sedentary and unmotivated to be physically active. Thus, interventions designed for individuals ready to start an activity program are not going to reach the majority of the population. Theories that acknowledge the varying levels of motivation, such as the stages of change model described earlier, may help to guide the development of more successful interventions by tailoring them to the appropriate level of motivation (129).

Designing Physical Activity Interventions for Obese Individuals

It is perhaps not surprising that physical inactivity is common among obese individuals (34). It *is* surprising that so little is known about the behavioral and attitudinal factors among the obese that inhibit or enhance regular physical activity. According to Wilfley and Brownell (201), more than 200 studies on various determinants of exercise behavior have been conducted in the last 30 years but very few of these studies involved obese individuals. What is known is that the attrition rate among the obese in traditional exercise programs is quite high (47).

The few articles available on promoting physical activity in the obese are helpful in developing physical activity interventions for this population. As stated earlier, interventions designed for high-risk population subgroups, such as the obese, should be designed with their needs and interest in mind. Careful attention must be taken to address the psychological and physical barriers to physical activity common among obese individuals, such as the ones described by Grilo et al (77) in Table 6:

Table 6. Psychological and Physical Barriers to Exercise in Obese Individuals[1]

Psychological barriers
- Previous negative experiences
  - Teased by peers
  - Poor performance
  - Picked last for teams
  - Feeling inadequate
- Lack of confidence
- Lack of knowledge or experience
- Shame of being observed

Physical barriers
- Burden of excess weight
- Low level of fitness

[1]Adapted from Grilo et al (77)

To enhance exercise adherence in obese individuals, Grilo and colleagues suggest avoiding the use of the exercise prescription (76). As described earlier, the traditional exercise prescription specifies the amount of exercise to be done in terms of frequency, intensity, and duration (e.g., 3 times a week at 70% maximum heart rate for a minimum of 15 minutes). This prescription implies an aerobic "threshold" must be passed for exercise to be beneficial, which may lead to an "all or none" way of thinking (e.g., "That effort fell short so why exercise at all?"). Although the threshold concept may be motivating for active individuals, it is likely to deter inactive and/or obese individuals.

Grilo and colleagues (77) also suggest emphasizing consistency over type and amount of activity for obese individuals, at least in the beginning. The initial goal is to establish a pattern in which activities the individual is willing and able to do are engaged in repeatedly, regardless of volume or intensity, at times and places that are convenient for that individual. Once consistency is established, the individual can focus on other aspects of exercise behavior. Table 7 presents recommendations for maximizing exercise adherence in obese individuals developed by these researchers.

Brownell (33) also contends that the traditional exercise prescription is not likely to promote the adoption of physical activity in obese persons for three main reasons. First, as stated earlier, the threshold concept implicit within the exercise prescription is likely to be interpreted to mean that exercise must be rigorous and difficult, or it has no value. Most obese individuals are not capable of vigorous exercise and attempts at doing so may prove to be taxing and painful. Second, while achieving a threshold is likely to improve maximal oxygen uptake, this may not be the goal for many obese persons. For many, weight loss, improved health, or greater quality of life may be their main goal. Lastly, the exercise prescription implies that cardiopulmonary function must be improved for exercise to improve health. As presented earlier, there is mounting evidence demonstrating the health benefits of lower levels of activity.

Other investigators have made similar recommendations. Bain et al (15) examined issues related to the design and delivery of an exercise program for overweight women. Individual interviews and focus groups

TABLE 7. Recommendations for Maximizing Exercise Adherence in Obese Persons[a]

General principles
Be sensitive to psychological barriers
Be sensitive to physical barriers
Decrease focus on exercise threshold
Increase focus on enhanced self-efficacy
Emphasize consistency and enjoyment, not amount and type
Begin at person's level of fitness
Encourage person to define routine activities as "exercise"
Focus on compliance and avoid emphasis of minor metabolic issues (e.g., whether to exercise before or after a meal)
Consider life-span developmental context
Consider sociocultural issues
Evaluate social support network
Specific interventions
Prescription
Provide clear information about importance of activity, including the psychological benefits
Maximize routine activity; daily activities are exercise
Maximize walking (e.g., park a greater distance from work)
Increase use of stairs in lieu of escalators
Incorporate a programmed activity that is enjoyable, fits with lifestyle, and is feasible as client's fitness improves
Behavioral
Introduce self-monitoring, feedback, and goal-setting techniques
Identify important targets other than weight loss, including physical changes, increased endurance, lowered resting heart rate
Use physical activity when tempted to overeat or when distressed
Stimulus control: increase exercise cues (e.g., reminders for increasing activity) and decrease competing cues (e.g., do not schedule exercise when it might conflict with work or social obligations)
Maintenance and relapse prevention
Use flexible guidelines and goal-setting, but avoid rigid rules
Identify potential high-risk situations for skipping exercise (e.g., stressful times, busy schedule)
Develop plans to cope with high-risk situations
Use exercise following dietary lapses to counteract caloric effects physically and, more importantly, to regain psychologically a sense of control, mastery, and commitment
Convey philosophy that one day lapsed does not a failure make
Use of minimal intervention strategies including phone contacts may foster exercise

[a]From Grilo et al (77).

were conducted with 50 obese women (mean body weight of 200 lbs.). Participants were asked to attend a series of five weekly, one-hour exercise sessions. These sessions were designed to provide a variety of experiences that would serve as a stimulus for group discussion of past and present exercise participation. Although no measurements of fitness changes were made, the data provided useful insights into the factors involved in exercise participation among this population.

A primary theme that emerged from the focus groups was a perceived social disapproval of body size that often generalized to perceived disapproval of the individual as a person. The majority of women stated that this was a major barrier to being physically active. All of the women were aware of the potential health benefit of exercise, although some were less familiar with information on intensity and frequency of exercise. Three factors influenced the types of activity they preferred: safety, physical comfort, and skill in the activity. However, the most powerful influences on exercise participation were the social circumstances of the exercise setting, e.g., the potential for being observed by outsiders and the body size of other class members. Suggestions provided by participants for the design and delivery of a successful exercise program for obese women include the following:

1. Limit participation to obese women only
2. Provide an instructor who is knowledgeable and sensitive to the needs of obese women
3. Allow participants to modify exercise as needed
4. Create an atmosphere where participants can discontinue an activity without embarrassment

5. Do not weigh people
6. Provide a room with limited visibility from the outside and preferably in a room with no mirrors
7. Provide an opportunity for discussion after the exercise session, including a time to give feedback to the instructor

Wing et al (205) reported the results of two studies of exercise adherence in overweight women in a behavioral weight loss program. One study investigated the use of a personal trainer who called participants regularly and met them at home or at work at scheduled times for a walk. The second study employed a lottery incentive for exercise adherence. Subjects in both studies were enrolled in a 24-week behavioral weight control program with three supervised exercise sessions per week. At completion, neither intervention produced significant improvements in weight loss or exercise adherence compared to control conditions. The authors suggest future studies should attempt to gain a better understanding of the barriers to exercise in obese women and to design interventions that address these barriers.

Perri and colleagues (158) examined the effects of two aerobic exercise regimens on exercise participation, fitness, eating patterns, treatment adherence, and weight change in 49 obese women participating in a year-long behavioral weight loss program. Study participants were randomly assigned to the weight loss program plus either group- or home-based exercise. Both groups were instructed to complete a moderate-intensity walking program (30 min/day, 5 days a week).

The group-based exercise program was conducted at a clinic facility equipped with seven motorized treadmills and was available for participants from 4:00 – 7:00 p.m. The weight-loss group leaders staffed the facility and were available for questions regarding exercise and weight loss. The group-exercise participants were told that exercising in small groups at regular times in the same location would provide an environment conducive to the adoption and maintenance of exercise. Participants were instructed to complete three group exercise sessions per week for the first 26 weeks and two sessions per week from weeks 27 – 52. Each participant was provided with an exercise prescription in which the intensity was gradually increased over the first eight weeks to a level between 60% and 70% of maximum heart rate (HR). Participants were instructed to supplement their group sessions with 2-3 additional individual session of brisk walking to reach a goal of 150 min/week.

The home-based exercise program included an exercise prescription similar to that of the group-based training program. However, participants in the home-based program were told that exercising in the home (or work) environment would help them achieve their exercise goals. Participants were directed to complete 30 minutes of aerobic exercise 5 days a week and the exercise must be done in their home or work environment. They were also given ongoing advice from health care professionals on ways to integrate the walking program into their typical home and work routines.

During the first six months of treatment, significant improvements occurred in both groups in exercise participation, functional capacity, eating patterns, and weight loss. However, from months 7 – 12, exercise participation in the home-based program was significantly higher than the group condition (78.2% vs. 48.2%, respectively). Less than half of the group-based participants attended the group sessions in the second six month period. Weight loss from baseline to 15 weeks was also significantly higher in the home-based program than the group-based program (11.65 kg and 7.01 kg, respectively). The authors conclude greater convenience and flexibility of home-based exercise may produce higher levels of exercise participation among obese women, especially if participants learn to integrate the exercise into normal daily routines.

Chapter Two

Materials and Methods

PROJECT OVERVIEW

The overall goal of this research study was to develop and evaluate a 24-week lifestyle physical activity intervention for obese sedentary women. This intervention would utilize psychological models for behavior change and promote the integration of lifestyle and/or intermittent physical activity into daily routines. A primary aim of this study was to determine the effectiveness of this intervention in promoting change in physical activity patterns and cardiorespiratory fitness levels in obese sedentary women and determining if changes are sustained for an additional 24 weeks post-intervention.

Secondary aims of this research study include assessing the effects of the Lifestyle intervention on CVD risk factors (blood pressure, blood lipids and lipoproteins, waist circumference, and BMI) and dietary practices (energy intake and diet composition) and determining if changes in psychological measures are predictive of changes in physical activity and cardiorespiratory fitness.

Research Hypotheses

The hypotheses for the final study in this research project include the following:

1. At the end of 24 weeks, levels of physical activity and cardiorespiratory fitness in participants of the Lifestyle intervention will be significantly higher than at baseline.

2. At the end of 48 weeks, (24 weeks of intervention and 24 weeks of follow-up), levels of physical activity and cardiorespiratory fitness in participants of the Lifestyle intervention will be significantly higher than at baseline and also significantly higher than levels of physical activity and fitness in subjects assigned to the "Usual Care" group.

3. At the end of 24 weeks, scores on the "Processes of Change," "Self-Efficacy," and "Decisional Balance" questionnaires will be significantly higher than at baseline in the Lifestyle group and significantly higher than those of the Usual Care group.

4. At the end of 24 weeks, increased scores on the questionnaires listed above will be predictive of improvements in cardiorespiratory fitness.

Study Procedures

The procedure for developing the Lifestyle intervention required developing and evaluating a 24-week curriculum for use in the intervention. Evaluation of this preliminary curriculum was conducted in a pilot study and involved both qualitative and quantitative assessments. Revisions were made to the curriculum based on information from the pilot study and the revised curriculum was then evaluated in a "final study."

CURRICULUM DEVELOPMENT

Curriculum development for the Lifestyle intervention program, called "On the Move," involved obtaining information from a variety of sources and incorporating this information into the curriculum. These sources included:

1. Focus groups with obese, sedentary women (described below);
2. Published guidelines for promoting physical activity in sedentary individuals from the National Institutes of Health Consensus Conference Statement on Physical Activity and Cardiovascular Health (149)(See Table 8).
3. Published recommendations from the Centers for Disease Control and Prevention and the American College of Sports Medicine for promoting physical activity and health (157). The CDC/ACSM recommendation that "every US adult should accumulate 30 minutes or more of moderate-intensity physical activity on most, preferably all, days of the week" (157) was the primary goal for participants of the Lifestyle intervention.
4. Published recommendations on promoting physical activity in obese individuals by Grilo et al (77) (See Table 9).
5. Psychological models for behavior change (see below).
6. Attendance at the 1997 Physical Activity Interventions Conference at the Cooper Institute of Aerobics Research in Dallas, Texas.

Focus Groups

Six focus groups consisting of 42 obese, sedentary women (mean age 40, mean BMI 33) were conducted by Jonsson and Anderson at Colorado State University, Dept. of Food Science and Human Nutrition (92). The primary aim of the focus groups was to ascertain factors that

Table 8. Application of the NIH Guidelines for Promoting Physical Activity[1] into The Lifestyle Curriculum.

NIH Guideline Physical activity is more likely to be initiated and maintained if the individual:	On the Move
• Perceives a net benefit	Presentation of the health benefits of regular physical activity and listing of personal benefits from a physically active lifestyle
• Chooses an enjoyable activity	Group discussion of the importance of finding activities that one enjoys. Field trips provided to allow participants the chance to try new activities and find one that is enjoyable to them.
• Feels competent doing the activity	Field trips and group activities involving various types of physical activity to promote feelings of competence. Weekly group discussion of participant's efforts at being physically active can also enhance feelings of competence
• Feels safe doing the activity	Presentation on techniques for injury prevention and proper clothing for exercise during cold or wet weather
• Can easily access the activity on a regular basis	Group discussion of integrating lifestyle activities into one's daily schedule and/or choosing activities that are convenient and easily accessible.
• Can fit the activity into the daily schedule	Time Study assignment in which participants evaluate their own daily routine and make a list of times in which they can fit in 8-10 minute bouts of physical activity 3 times a day. Group discussion of integrating lifestyle activities into daily routine.
• Feels that the activity does not generate financial or social costs that he/she is unwilling to bear	Group discussion of how lifestyle physical activity is a less expensive approach to physical activity than joining a health club. Techniques on asking for support from family and friends to reduce any negative social consequences from making a lifestyle change are presented.
• Experiences a minimum of negative consequences such as injury, loss of time, negative peer pressure, and problems with self-identity	Presentation on injury prevention techniques, proper shoes and clothing, time management, and asking for support from friends, family, and co-workers. The emphasis on integration of lifestyle activity into one's daily schedule vs. going to a gym to exercise addresses the issue of loss of time.
• Is able to successfully address issues of competing time demands	Group discussion of making physical activity a priority and using cognitive restructuring techniques to address a perceived lack of time for physical activity.
• Recognizes the need to balance the use of labor-saving devices and sedentary activities (e.g., watching television, use of computers) with activities that involve a higher level of physical exertion.	Time Study assignment to identify large blocks of time the participant is sedentary and discussion of ways participant can integrate physical activity into those blocks of time. Emphasis on importance of gardening, yard work, and/or house work in achieving physical activity goal.

[1]NIH Consensus Conference Statement on Physical Activity and Cardiovascular Health (125).

Table 9. Application of Recommendations for Promoting Physical Activity in Obese Individuals[1] into the Lifestyle Curriculum

Recommendation	On the Move
Decrease focus on exercise threshold	Participants taught to work toward accumulating 30 minutes of moderate-intensity activity on most days of the week, thereby placing emphasis on accumulated time spent being physically active, not on intensity threshold
Increase focus on enhanced self-efficacy	Curriculum based on self-efficacy theory. Group activities planned to enhance self-efficacy
Emphasis on consistency and enjoyment, not amount and type	In the beginning, participants were encouraged to make a list of the activities they most enjoyed and a plan for how they could integrate those activities into their daily routine or engage in them on a regular basis. In the beginning, they were also encouraged to think more about consistency with lifestyle activities and less about how much activity they were doing. When they felt they were making a habit of including more lifestyle activities, they were encouraged to keep track of how much activity they were doing, in terms of minutes per day.
Consider sociocultural issues and gender influences	Group discussions were generated on the cultural influences on body image in women, especially from the media. Video clips from a documentary on these topics was presented and discussed.
Provide clear information about importance of activity, including psychological benefits	The impact of regular physical activity on all aspects of health was presented and discussed. Emphasis was placed on the effects of physical activity on improving mood and/or depression and has the potential to increase self-confidence.
Identify important targets other than weight loss, including physical changes, increased mobility and reduces heart rate	A session called "Body Awareness" was added to the program to teach participants to pay attention to physical changes that occur with increased activity, e.g., increased endurance or lowered heart rate etc., and that these are important ways of monitoring progress (instead of weight loss)
Identify potential high risk situations for skipping exercise	Participants were taught cognitive restructuring techniques to handle situations in which they are likely to skip exercise, e.g., when they are tired or on vacation.
Maximize walking for doing errands	Participants were asked to record situations in which they could walk to complete an errand or task instead of driving or using the telephone/computer. They were asked to try these ideas over the next week and report to the class how easy or hard it was for them to do that.
Use flexible guidelines and goal-setting but avoid rigid rules	The CDC/ACSM criterion for physical activity was chosen as the main goal participants should work toward and they should progress at a pace that feels comfortable to them.
Evaluate social support network	A session on enlisting social support was added to the program to teach participants how to ask for support from friends, family members, and co-workers. Role playing techniques were employed to teach participants how to speak with their doctor about their desire to be more physically active even if they don't lose weight.

From Grilo et al (77).

both inhibit and enhance regular physical activity and eating a healthful diet in obese sedentary women. The focus groups also aimed to gather opinions on what information should be included in a curriculum for a "healthy lifestyle" program.

The focus groups were conducted according to the protocol developed by Krueger (108). A trained moderator led the discussions and an assistant moderator took notes and controlled the recording equipment. Audiotapes for each focus group were later transcribed verbatim. The transcript was reviewed and edited by the moderator and the assistant moderator using the audiotape and assistant moderator's notes in order to achieve a high degree of accuracy in the transcript.

Data from the focus groups were grouped into two main categories: primary findings or strong agreement and secondary findings or lesser agreement. Primary findings included: 1) lack of time is a major barrier to physical activity, 2) the term "physical activity" is preferred over the term "exercise", 3) "feeling better" is a motivator for eating a healthful diet 4) information on emotional food cravings should be included in a program for obese women, 5) program length should be 3-6 months with on-going follow-up, 6) the program should promote feeling better about one's body weight or size.

This information was incorporated into the preliminary curriculum for the Lifestyle intervention by including class sessions on time management, emotions and eating behavior, and self-acceptance in relation to body weight. In addition, the term "physical activity" was used in place of "exercise" throughout the curriculum.

Incorporation of Psychological Models for Behavior Change

The underlying psychological models for behavior change upon which the Lifestyle intervention was based were the Stages of Change model (164) and Self-Efficacy Theory (17), both of which are described in Chapter One. The cognitive and behavioral processes of change and the four techniques for improving self-efficacy, described in Chapter One, were incorporated into the Lifestyle curriculum using the methods described below.

Cognitive Strategies for Change

1. Consciousness Raising (CR). The primary aim of the CR technique is to encourage the individual to read and think about physical activity or to increase their awareness of the need for physical activity. The CR technique was utilized in several different sessions that include the following:

- Presentation of the health benefits of physical activity. Discussion questions aimed at increasing awareness of the physical and psychological benefits of a physically active lifestyle.
- Discussion of the CDC/ACSM recommendations for physical activity and how they differ from previous recommendations.
- Discussion of the concept of "lifestyle physical activity" and the value of frequent shorter bouts of physical activity.
- Two-minute walk in the hallway to demonstrate moderate-intensity physical activity. Discussion of light vs. moderate activity.
- A "Personal Time Study" assignment whereby participants keep a 24-hour diary in which they record the amount of time they spend being sedentary (see Appendix A).

2. Dramatic Relief (DR). DR is the process by which an individual is emotionally moved to change a behavior. Activities that employed the DR technique include:

- Asking participants to recall pleasant memories of a time when they were physically active and to share this memory with the class. They were encouraged to express how being active felt, both physically and psychologically. They were also encouraged to share memories of just one single event whereby they engaged in an activity that was fun and enjoyable and what it would mean to them to add that type of activity back into their current lives.
- Participants were asked to think of situations in which they were not able to participate in a family activity because they were not physically able to do so. Discussions were generated about how being physically fit would enable them to participate in more activities with their family and friends.
- Viewing of a video in which obese women are talking about how physical activity has helped them to feel better physically and psychologically.
- Discussion of readings from *Great Shape: The First Fitness Guide for Large Women* (124) and Radiance magazine.

3. Self-Reevaluation (SR). SR is a cognitive appraisal of a problem behavior, such as physical inactivity, and the personal benefits of changing that behavior. SR has been referred to as "taking stock" of one's situation and how one would benefit by changing that situation (163). Activities that employed the SR technique include:

- Findings from the Personal Time Study (described above) were discussed in class. Discussion questions were given to help participants determine how they could reduce the amount of time they spend being sedentary.
- Having participants make a list of their own personal barriers to physical activity and discussing ideas on how to overcome those barriers.
- Participants were asked to complete a Decisional Balance sheet (see Appendix) during class, in which they recorded the consequences of increasing their physical activity to themselves, the consequences to others, the reaction they would have toward themselves for increasing their activity level, and the reactions of others as a result of this change.

4. Environmental Reevaluation (ER). The primary aim of ER is to encourage an individual to recognize how their inactivity affects their social environment. ER is first addressed in the Decisional Balance Scale and examined in more detail in other activities, including:

- Having participants make a list of the people around them who would benefit from the participant becoming physically active, including a list of activities the participant could engage in with specific family

members and/or friends. An example could be "playing golf with spouse, walking kids to school, bicycling with friends".
- Discussion of how being physically active on a regular basis sets an example for others around them, particularly children and teenagers.

5. Social Liberation (SL). SL aims to provide the individual with supportive structures within one's environment for increasing physical activity, such as community programs, bike paths, walking trails, etc. This technique was employed in the following ways:

- Bringing city and county maps to class and having participants locate parks, bike paths, walking trails, health clubs, and community centers where exercise programs are offered.
- Asking participants to locate opportunities within their own neighborhoods for physical activity, such as community gardening plots, "walking school buses" (parents taking turns walking their kids to school), or meeting friends in a park for a "walk and talk" instead of meeting for lunch.
- Meeting as a group at a local park and taking a short bicycle ride on the bike path in Ft. Collins.
- Meeting as a group at the Senior Center in Ft. Collins for a water aerobics class and a tour of the facility (which offers various exercise programs).
- Meeting as a group on the Poudre River Trail in Windsor for a short walk and discussion of the opportunities for activity that exists on this trail.
- Discussion of opportunities within one's own household or yard for physical activity.

Behavioral Strategies for Change

6. Counterconditioning (CC). CC involves teaching individuals to engage in physical activity at times when it is likely to be most beneficial but when it is rarely done, e.g., when feeling stressed or tired. CC techniques were employed by teaching the concept of "cognitive restructuring," a process in which an individual replaces negative thoughts with positive thoughts. Cognitive restructuring helps to change the way one thinks about a situation and not the situation itself. OTM participants were asked to identify a negative thought that they might have about physical activity, such as "I'm too tired to be active right now." They were then asked to restructure that statement to reflect a more positive response to the situation, such as "I'll have more energy if I get up and do something physical." A list of negative thoughts and their restructured counterparts were generated from the group and made into a handout for each participant.

7. Stimulus Control (SC). SC aims to help individuals set up their immediate environment so that it is conducive for physical activity. SC also includes controlling stimuli for sedentary activities. SC was employed in the following ways:

- Participants were encouraged to keep walking shoes near the door (or any visible place) at home and another pair in their car.
- If possible, participants were encouraged to purchase comfortable, stylish work-out clothing and to keep this clothing in plain view in one's closet, as a reminder to be active.
- Participants were encouraged to find a friend or family member to be physically active with and to record the dates and times of planned activities on a calendar as a reminder.
- Ideas for controlling stimuli for sedentary activities were generated from the group, including putting a timer by the computer to go off every 30 minutes as a reminder to get up and do something physical before returning to the computer.

8. Reinforcement Management (RM). The primary aim of RM is to teach individuals to reward or praise themselves for being physically active. RM was utilized in the following ways:

- Participants were asked to write down ideas for personal rewards for being physically active, e.g., things that would enhance their desire to follow through on their physical activity plan. They were encouraged to use those rewards and to share their experiences with the group.
- Cognitive restructuring techniques were used to employ RM by having participants restructure self-defeating thoughts to rewarding thoughts.

For example, instead of saying,

"The only physical activity I did today was taking the stairs instead of the elevator – I should have done more"

participants were encouraged to say,

"Taking the stairs instead of the elevator is a big change from my previous way of living and is an important step toward a physically active lifestyle."

9. Helping Relationships (HR). HR is the strategy by which individuals are encouraged to find a friend or family member who will provide support for being active. The different types of support were discussed and how to identify key people within one's life who could provide support for behavior change. In addition, techniques on *how* to ask for support were discussed and participants role-played situations where they

would ask for support from the identified key people. Participants were encouraged to think of people outside the realm of family and friends as important sources of support, such as co-workers and physicians. Role-playing situations were provided in which a participant asked a co-worker for support for her decision to go for a walk during her 15-minute work break instead of sitting and talking during that time. Another role-playing situation involved asking one's physician to support a decision to be work solely on improving fitness levels instead of attempting weight loss by dieting, (at least for the time being).

10. Self-Liberation (SL). The primary aim of SL is to encourage the individual to make a commitment to themselves to be physically active. Because all of the participants in this study were in the Contemplation stage of change at baseline, participants were asked to make a commitment to work toward achieving the CDC/ACSM recommendation for physical activity over the course of 24 weeks, allowing for time to progress through the other stages. They were encouraged to make small changes that were realistic and feasible for them rather than trying to achieve this recommendation right away.

Self-Efficacy

The four identified techniques for improving self-efficacy in relation to exercise or physical activity (described in the literature review) were incorporated into the Lifestyle curriculum using the following methods:

- Performance accomplishments or mastery experiences. The primary aim of this technique is provide opportunities for participants to engage in various types of activity as a way of "mastering" that activity. Field trips to the local bike path, hiking trails, and swimming pool were an integral part of Lifestyle program. Participants were encouraged to ride, walk, hike, swim, or engage in water aerobics on these trips and to consider these activities for recreation. In addition, classes were held for participants to learn yoga, tai chi, line dancing, or aerobic dancing.

- Social Modeling. This technique involves looking to others with similar physical characteristics for motivation and information regarding our own prospects for success. A volunteer from the pilot study was allowed to attend classes in the main study to tell of her experiences with behavior change. In addition, each week participants were encouraged to share their own "success stories" with being physically active in order to motivate others. Video clips of large-sized women talking about positive experiences with physical activity and/or overcoming barriers to physical activity were shown and discussed. A local obese woman who initially was sedentary but who made a commitment to herself to change her lifestyle, and eventually walked the Portland marathon, spoke to the class about her experience as a large woman becoming fit and active. Various books and magazines with stories about obese women becoming active were brought to class for discussion.

- Social persuasion. The primary aim of social persuasion is to provide information to a participant that may bolster their belief in their capabilities. The class leader would provide positive feedback to participants regarding their efforts to integrate physical activity into their daily routines.

- Physiological states. This technique teaches participants to reinterpret their physical experiences with exercise to be positive experiences. Participants are encouraged to anticipate various "aches and pains" as they begin to move their bodies more often and exert themselves. They are told to monitor their progress by observing changes in the degree of those symptoms, such as an increased heart rate, as indicators of an improved fitness level.

Table 10 lists the preliminary curriculum content and the behavioral constructs utilized within each session. The curriculum was designed to be presented in 16 weekly sessions, followed by 8 sessions every other week, totaling 20 sessions in 24 weeks.

Table 10. Description of Preliminary Lifestyle Curriculum and Behavioral Constructs Used in Each Unit.

Unit Number and Title	Topics Covered	Behavioral Constructs
Unit 1: Physical Activity and Health	❑ Health benefits of physical activity/health risks of sedentary living ❑ CDC/ACSM recommendations for physical activity ❑ Concept of frequent shorter bouts of activity as effective as one longer bout ❑ Concept of lifestyle physical activity, making it a part of one's daily routine	❑ Consciousness Raising ❑ Self-Evaluation ❑ Dramatic Relief ❑ Self-Liberation
Unit 2: A Time for Change	❑ Behavior change can be difficult but worth the effort ❑ Stages of Change theory ❑ Making small changes each day may be easier than changing everything at once ❑ Participants making a list of small changes they could make in their daily routine to add more physical activity	❑ Consciousness Raising ❑ Self-Evaluation
Unit 3: Breaking Down Barriers	❑ Discussing barriers to being active and listing solutions to barriers ❑ Discussing benefits of overcoming barriers to physical activity ❑ Viewing video clip of Julie Molnar, a large woman who completed Ironman triathlon, speaking of how she overcame her barriers to complete her goal	❑ Self-Reevaluation ❑ Social Liberation ❑ Dramatic Relief ❑ Modeling
Unit 4: Setting Goals	❑ Examining thought processes re behavior change before setting goals ❑ Wishful thinking vs. having hope ❑ Making a decision to set a goal; completion of Decisional Balance Scale ❑ Listing 3 short-term and one long-term goal	❑ Consciousness Raising ❑ Self-Reevaluation ❑ Self-Liberation ❑ Environmental Reevaluation
Unit 5: Body Awareness	❑ Physiological responses to exercise ❑ Mindfulness and how it applies to physical activity (paying attention to how movement feels; increased breathing, muscles, etc.) ❑ Meditative walking as a form of relaxation ❑ Demonstration of exercise intensity	❑ Consciousness Raising ❑ Physiological States ❑ Counterconditioning
Unit 6: Know the Basics: Clothing, Shoes, and Safety	❑ Appropriate clothing for indoor and outdoor exercise (sweat-wicking fabric vs. cotton) and winter vs. summer attire (keeping warm vs. keeping cool) ❑ Discussion of retail stores, catalogs, websites that carry exercise clothing for large women ❑ Presentation by outside speaker on athletic shoes – what to look for, use of insoles, etc. ❑ Prevention of injury by proper walking technique – stride length, foot strike, pronation vs. supination, etc.	❑ Consciousness Raising ❑ Increasing self-efficacy

Unit Number and Title	Topics Covered	Behavioral Constructs
Unit 7: Bicycling Field Trip	❑ Participants met at Rolland Moore Park for a bicycle ride on the bike path. The instructor provided instructions on safety.	❑ Increasing self-efficacy ❑ Social Liberation
Unit 8: Enlisting Support	❑ Types and sources of social support for making a behavior change ❑ How to ask for support from family, friends, and/or co-workers	❑ Helping Relationships ❑ Self-Liberation ❑ Increasing self-efficacy
Unit 9: Body Size Acceptance	❑ Prevalence of body dissatisfaction among women and girls ❑ Cultural influences on body image in women ❑ Discussion of "size acceptance" and practical approaches toward achieving a higher level of acceptance ❑ Viewing and discussion of clips from Body Trust© video ❑ Listing of sources of information on size acceptance	❑ Consciousness Raising ❑ Self-Reevaluation ❑ Dramatic Relief ❑ Counterconditioning ❑ Social Persuasion
Unit 10: Food as Fuel	❑ Discussion of healthful eating vs. dieting ❑ Presentation of dietary guidelines and food guide pyramid ❑ Discussion of nutrition and chronic disease, e.g., CVD and cancer	❑ Consciousness Raising
Unit 11: Food and Emotions	❑ How emotions affect eating behavior ❑ Binge eating disorder ❑ Learning to identify emotions that trigger binge eating ❑ Learning techniques for managing binge eating	❑ Consciousness Raising ❑ Self-Reevaluation ❑ Dramatic Relief ❑ Increasing self-efficacy
Unit 12: PBS video "Fat"	❑ Discussion of topics presented in video: cultural influences on body weight (reduced physical activity and increased intake of high calorie, high fat foods), surgical treatment of obesity, eating disorders among young girls, size acceptance, fat people who are physically fit	❑ Consciousness Raising ❑ Dramatic Relief ❑ Environmental Reevaluation
Unit 13: Field Trip to Senior Center for an "Aquacize" class	❑ Participants met at the swimming pool in the Senior Center to participate in an Aquasize class. An instructor led the pool exercises, which lasted for about 40 minutes. Participation was optional.	❑ Increasing self-efficacy ❑ Social liberation
Unit 14: Finding the Time to Be Active	❑ Time management techniques ❑ Prioritizing daily activities to fit in physical activity ❑ Discussion of simplifying one's life to free up time for physical activity ❑ Integration of several short bouts of activity into one's daily routine	❑ Decision making ❑ Social Liberation ❑ Counterconditioning
Unit 15: Revisiting Barriers to Physical Activity	❑ Review of barriers to physical activity listing and discussion of how those barriers are or are not being overcome ❑ Cognitive restructuring ❑ Planning for a relapse	❑ Self-Reevaluation ❑ Counterconditioning ❑ Increasing self-efficacy

Unit Number and Title	Topics Covered	Behavioral Constructs
Unit 16: Use Your Noodle Cooking Class	❑ Review of dietary guidelines ❑ Recipe modification techniques ❑ Cooking demonstration and tasting of samples	❑ Consciousness Raising
Unit 17: Dress for Success	❑ Demonstration of workout and casual wear clothing for large women, provided by Lane Bryant employees ❑ Discussion of importance of comfortable clothing for physical activity ❑ Discussion of how attractive, comfortable clothing can affect one's self-confidence	
Unit 18: DANCE – Do A Nother Cool Exercise – Line Dancing	❑ Participants met at the Senior Center with spouses or significant others for a line dancing lesson	❑ Increasing self-efficacy ❑ Helping Relationships
Unit 19: Pitfalls and Detours – How to Stay Motivated	❑ Discussion of relapse prevention ❑ Review of cognitive restructuring techniques ❑ Rewarding one's self for achieving goals ❑ Review of importance of setting small, realistic goals	❑ Counterconditioning ❑ Stimulus Control ❑ Reinforcement Management ❑ Self-Liberation

PILOT STUDY OF THE LIFESTYLE CURRICULUM

There were two primary aims of the pilot study. The first was to obtain feedback on the content and the logistics of the Lifestyle curriculum, such as length of individual sessions and length of program, etc. The second was to confirm the feasibility and efficiency of protocols for selected assessments, in particular the assessment of cardiorespiratory fitness and energy expenditure.

Recruitment of Pilot Study Participants

Recruitment of participants for the pilot study targeted healthy women between the ages of 25 and 60, who were obese (BMI >30), and sedentary. Specific exclusionary criteria are given below.

Methods of recruitment included newspaper advertisements and electronic mail announcements. Respondents were scheduled for an orientation session during which time the details of the study purpose, time commitment, and eligibility criteria were explained. Subjects who expressed continued interest in participating in the study were asked to complete an eligibility questionnaire that included the following exclusionary criteria:

1. History of myocardial infarction, stroke, or diabetes (Type 1 or 2);
2. Currently engaging in physical activity at least 3 days/week for 20 minutes or more each time;
3. Currently participating in an organized weight management program, such as Weight Watchers;
4. Having a plan to move from the local area within time span of the study;
5. Pregnant or planning to be pregnant;

6. Taking medication that could alter exercise performance;
7. Taking medication that could alter metabolism or appetite (except for birth control pills);
8. Smoking or recent history of smoking (within 3 months of study).

During the orientation session, height and weight was measured on all subjects for calculation of Body Mass Index (BMI). Eligible subjects were then asked to review and sign a consent form. Written consent was obtained from all eligible participants in accordance with the policy statement regarding the use of human subjects for research studies at Colorado State University (see Appendix C).

Intervention Procedures

The intervention program for the pilot study began in June of 1998. Pilot study subjects met weekly for 16 weeks then every other week for 8 weeks (20 sessions in 24 weeks). Sessions were 60 minutes in length and were conducted in the Gifford Building on the campus of Colorado State University.

Weekly sessions included a brief review of the topic covered in the previous session, discussion of any homework assignments, and a presentation of a new topic for group discussion, based on the preliminary curriculum syllabus. Some sessions consisted of organized activity, such as hiking or walking, in an effort to enhance exercise self-efficacy. Other activities and assignments are listed in Table 10. Attendance was monitored each week by having participants sign an attendance sheet during the class session.

For the 24-week period, pilot study participants were advised to work toward the goal of achieving the CDC/ACSM recommendations for physical activity (accumulating 30 minutes of moderate-intensity physical activity on most days of the week). They were encouraged to work toward this goal by integrating "lifestyle" activity into their daily routine, such as gardening, walking short distances, using stairs instead of an elevator, etc. They were encouraged to look for ways of integrating short bouts of moderate-intensity activity into their daily schedule.

Curriculum content also focused on overcoming barriers to physical activity and using the processes for change, identified by Prochaska and Diclemente (162), to change sedentary behavior (described earlier). For example, "consciousness raising" was employed by asking participants to complete a "time study" in which they spent one day recording how much time they typically spend sitting, whether it is at work or at home watching television. They were then asked to make a list of ways to replace some of the time sitting with physical activity, starting with short bouts of 8 –10 minutes each. Participants were also asked to make a list of their own personal barriers to physical activity and, as a group, to generate a list of possible solutions for each person's primary barrier. Each week, participants discussed the progress they made during the week toward eliminating their own barriers to activity.

In addition to the weekly curriculum materials, participants also received a copy of the book *Great Shape: The First Fitness Guide for*

Large Women (124). This book served as part of the modeling technique described earlier for enhancing exercise self-efficacy.

Lastly, subjects were encouraged to keep an activity log in which they recorded the number of minutes they spent participating in physical activity each day and how this activity was integrated into their daily schedule. The instructor reviewed the logs each week and provided feedback when necessary.

Pilot Study Assessments

In addition to BMI, the following assessments were taken at baseline and at 24 weeks on pilot study participants:

Cardiorespiratory fitness - The YMCA protocol for cycle ergometry was used to assess cardiorespiratory fitness. This protocol calls for two to four, 3-minute stages of continuous cycling on a bicycle ergometer (75). Heart rate (HR) is taken during the last minute of the initial workload (150 kgm/min or 25 watts) and is used to determine the workloads for the remaining stages (see Figure 3). Once a HR of 110 bpm is reached, the subject is allowed to cycle for only one additional stage beyond that point. For example, if a HR of 125 bpm were achieved in the first stage, only one additional 3-minute stage should be performed. Pedal speed is set at 50 rpm.

The final heart rate is plotted against work rate on a prediction worksheet (see Appendix D). A line is then drawn through the plotted points and extrapolated to the age-predicted maximal heart rate (e.g., 220 – age) and a perpendicular line is dropped to the X-axis to estimate the work rate that the individual would have achieved if he or she had worked to the maximum. VO_2max can then be calculated using the formula in Appendix D.

	HR < 80	**HR 80 – 89**	**HR 90 – 100**	**HR > 100**
2nd Stage	750 kgm/min	600 kgm/min	450 kgm/min	300 kgm/min
3rd Stage	900 kgm/min	750 kgm/min	600 kgm/min	450 kgm/min
4th Stage	1050 kgm/min	900 kgm/min	750 kgm/min	600 kgm/min

Figure 3. YMCA cycle ergometry protocol*(75)

*First stage: 150 kgm/min (0.5 kg); pedal speed 50 rpm; see Appendix D for complete instructions.

<u>Energy expenditure in physical activity</u> - Energy expenditure in physical activity was measured using the 7-Day Physical Activity Recall (PAR) (26). The PAR is an interviewer-administered instrument that estimates energy expenditure in physical activity over a one-week period and has acceptable reliability and validity (26). The convergent validity of the PAR was determined by Dunn et al (52) with concurrent temporally matched data from the Tritrac R-3D activity monitor. Correlations between total energy expenditure estimated from the PAR and the Tritrac

R-3D regression equation were between r = 0.86 and r = 0.95 across the seven days.

The PAR estimates energy expenditure by querying subjects on the amount of time spent in sleep and in moderate, hard, and very hard activities during the previous week. Time spent in light activities is obtained by subtraction after total hours in sleep are determined. The data are converted to kcals/kg/day by multiplying the time spent in each intensity category by a MET value (1 MET is the metabolic equivalent at rest; moderate-intensity activities are 3-6 times greater, or 3-6 METs). PAR interviews were conducted by telephone using a script developed especially for this questionnaire for use in the Activity Counseling Trial (see Appendix E)(26). One trained interviewer conducted the majority of interviews (85%); individuals trained by this interviewer conducted the remaining PAR interviews.

Waist Circumference – Waist circumference was assessed using instructions described by the NIH and NHLBI in the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report* (148) (see Appendix F).

Psychological Measures - As the Transtheoretical Model for Behavior Change and theory of self-efficacy served as the underlying basis for the development of the Lifestyle intervention, several measures associated with these models were obtained during the pilot study. These questionnaires, described below, along with scoring algorithms, are in Appendix G.

- Stage of Change – The participant's level of motivational readiness for physical activity adoption was assessed by a 5-item scale developed by Marcus and colleagues (130). This scale categorizes subjects into one of five stages of change in relation to physical activity. The five stages are 1) *Precontemplation*: not intending to change (individuals who do not engage in physical activity and who do not intend to start; 2) *Contemplation*: intending to change (individuals who do not engage in physical activity but do intend to start; 3) *Preparation*: making small changes (those who do engage in physical activity but not for five times a week for 30 minutes or longer; 4) *Action*: meeting behavior change criteria (those who currently participate in regular physical activity but who have done so for less than six consecutive months); or *Maintenance*: sustaining change over time (individuals who currently participate in regular physical activity and who have done so for at least six months.

- Processes of Change – The processes of change described by Marcus et al (131) (described on pages 111-116) that were incorporated into the Lifestyle curriculum were assessed using a 40-item scale developed by Marcus and colleagues (131). This scale consists of 10 subscales, five for the cognitive processes (consciousness raising, dramatic relief, environmental reevaluation, self-reevaluation, and social liberation) and five for the behavioral processes (counterconditioning, helping relationships, reinforcement management, self-liberation, and stimulus control). Each of the 10 process subscales was quantified as the average of four questionnaire items, each scored on a 5-point Likert scale ranging from never (1) to repeatedly (5) (see Appendix G).

- Exercise Confidence - The subject's level of self-efficacy in relation to physical activity adoption was assessed with a 5-item scale developed by Marcus et al.(132). Subjects were asked to indicate their level of confidence in participating in regular physical activity during five different situations: 1) when tired; 2) when being in a "bad mood"; 3) when feeling there is not enough time; 4) when on vacation; and 5) when it is raining or snowing.

- Decisional Balance – This scale, sometimes referred to as the Benefits to Barriers Index (130), is a 16-item scale that assesses the participant's decision making processes in relation to physical activity adoption. This scale is composed of 10 positive (benefits) and six negative (barriers) items with the benefits-to-barriers index being calculated by subtracting the sum of the positive items from the sum of the negative items.

Qualitative Assessment

In addition to the assessments described above, participants were asked to complete an evaluation survey that included a variety of questions pertaining to the curriculum as well as the intervention in general, e.g., how they felt about individual session length, program length, which sessions were most and least helpful, etc. The findings from this survey are presented in Chapter 3.

Final Curriculum

Based on information obtained from the pilot study, the following changes were made to the preliminary Lifestyle curriculum:

- A session was added in the beginning of the Lifestyle program that allowed participants to get acquainted with other class participants.
- The session called "A Time For Change" was eliminated (to allow for the added session on getting acquainted) and the information originally covered in that session was incorporated into the session called "Physical Activity and You (Yes, You!)".
- The session called "DANCE – Do A Nother Cool Exercise" in which participants learned how to country line dance, was replaced with a Tai Chi demonstration (based on a vote by participants in the final study)
- Because the "Use Your Noodle Cooking Class" was offered on a different weeknight during the final study, another class session was added to the final curriculum in its place. This session, called "Personal Triumphs", was given by an invited guest speaker – a large woman who had bilateral knee replacement surgery but who was able to eventually walk a marathon.

- A session explaining the four components of fitness was added to the final curriculum with a demonstration of proper stretching techniques by a physical therapist.

- Session length was increased to 90 minutes, from 60 minutes.

The final curriculum contained 20 sessions; each designed to last 90 minutes. Session topics and application of the theoretical model are presented in Table 11.

FINAL STUDY OF THE LIFESTYLE CURRICULUM

Research Design

The design of the final part of this study is considered an "experimental comparison" (12). This design is similar to clinical trials in medicine where a new treatment is compared to a standard or "usual care" treatment. In this part of the research project, the newly developed Lifestyle physical activity program is compared with a usual care program for sedentary individuals in improving physical activity patterns and cardiorespiratory fitness levels. Subjects were randomly assigned to one of two treatment groups – the "Lifestyle" group or the "Usual Care" group. Both groups received 24 weeks of intensive intervention. Assessments were measured at baseline and 24 weeks to assess intervention effects and again at 48 weeks to assess maintenance of changes made during the intervention.

Table 11. Description of Final Lifestyle Curriculum and Behavioral Constructs Used in Each Unit.

Unit Number and Title	Topics Covered	Behavioral Constructs
Unit 1 **Let's Get Acquainted** Jan. 19, 20	❑ Introductions of instructor and class participants ❑ Discussion of the role of the instructor ❑ Overview of the course curriculum - review of meeting times and calendar ❑ Health benefits of physical activity ❑ CDC/ACSM new recommendation for physical activity and health ❑ Concept of "lifestyle physical activity" ❑ Demonstration of exercise intensity – 2 minute walk Homework Assignment: Personal Time Study (see Appendix X), read Chapter One in *Great Shape: The First Fitness Guide for Large Women*	❑ Consciousness Raising ❑ Decision Making
Unit 2 **Physical Activity and You (Yes, You!)** Jan. 26, 27	❑ Review of health benefits of physical activity/health risks of sedentary living ❑ Discussion of Personal Time Study assignment and making physical activity a part of one's daily routine ❑ Changing behavior and the Stages of Change theory ❑ Value of making small changes gradually vs. big ones all at once ❑ Decisional Balance Scale (completed in class as a group) Homework Assignment: Read "A Five Minute Walk" and attempt to fit in a five minute walk on at least 3 days over the next week	❑ Consciousness Raising ❑ Self-Evaluation ❑ Dramatic Relief ❑ Self-Liberation ❑ Decision Making
Unit 3 **Breaking Down Barriers** Feb. 1, 2	❑ Discussing barriers to being active and listing solutions to barriers ❑ Discussing benefits of overcoming barriers to physical activity ❑ Cognitive Restructuring ❑ Viewing video clip of Julie Molnar, a large woman who completed Ironman triathlon, speaking of how she overcame her barriers to complete her goal	❑ Self-Reevaluation ❑ Social Liberation ❑ Dramatic Relief ❑ Modeling
Unit 4 **Know the Basics: Clothing and Shoes** Feb. 9, 10	❑ Appropriate clothing for indoor and outdoor exercise (sweat-wicking fabric vs. cotton) and winter vs. summer attire (keeping warm vs. keeping cool) ❑ Discussion of retail stores, catalogs, websites that carry exercise clothing for large women ❑ Presentation by outside speaker on athletic shoes – what to look for, use of insoles, etc. ❑ Prevention of injury by proper walking technique – stride length, foot strike, pronation vs. supination, etc.	❑ Consciousness Raising ❑ Increasing self-efficacy

Unit Number and Title	Topics Covered	Behavioral Constructs
Unit 5 **Body Awareness** Feb. 16, 17	❑ Physiological responses to exercise ❑ Mindfulness and how it applies to physical activity ❑ Meditative walking as a form of relaxation ❑ Yoga demonstration (by invited guest speaker)	❑ Consciousness Raising ❑ Physiological States ❑ Counterconditioning
Unit 6 **Make it Happen** Feb. 23, 24	❑ Evaluating thought processes re behavior change before setting goals ❑ Value of goal setting ❑ Viewing of video clip from "Fat" (PBS special on obesity) showing a large-size man and woman who have achieved their goals despite being obese ❑ Completing a Physical Activity Planning worksheet (see Appendix)	❑ Consciousness Raising ❑ Self-Reevaluation ❑ Self-Liberation ❑ Environmental Reevaluation
Unit 7 **Get Real About Fitness** March 2, 3	❑ The four components of fitness: aerobic, muscular, flexibility, and body composition ❑ Stretching and injury prevention techniques demonstration by outside speaker (physical therapist from HealthSouth)	❑ Consciousness Raising ❑ Self-Liberation ❑ Increasing self-efficacy
Unit 8 **Finding the Time to Be Active** March 9, 10	❑ Time management techniques ❑ Prioritizing daily activities to fit in physical activity ❑ Discussion of simplifying one's life to free up time for physical activity ❑ Integration of several short bouts of activity into one's daily routine	❑ Decision making ❑ Social Liberation ❑ Counterconditioning
Unit 9 **Field Trip – Senior Center "Aquacize" Class** March 15, 16	❑ Participants met at the swimming pool in the Senior Center to participate in an Aquasize class. An instructor led the pool exercises, which lasted for about 40 minutes. Participation was optional.	❑ Increasing self-efficacy ❑ Social Liberation
Unit 10 **Tai Chi** March 23, 24	❑ Demonstration of tai chi by outside speaker	❑ Increasing self-efficacy
Unit 11 **Body Acceptance** March 30, 31	❑ Prevalence of body dissatisfaction among women and girls ❑ Cultural influences on body image in women ❑ Discussion of "size acceptance" and practical approaches toward achieving a higher level of acceptance ❑ Viewing and discussion of clips from Body Trust© video ❑ Listing of sources of information on size acceptance	❑ Consciousness Raising ❑ Self-Reevaluation ❑ Dramatic Relief ❑ Counterconditioning ❑ Social Persuasion
Unit 12 **Food and Emotions** April 6, 7	❑ How emotions affect eating behavior ❑ Binge eating disorder ❑ Learning to identify emotions that trigger binge eating ❑ Learning techniques for managing binge eating	❑ Consciousness Raising ❑ Self-Reevaluation ❑ Dramatic Relief ❑ Increasing self-efficacy

Unit Number and Title	Topics Covered	Behavioral Constructs
Unit 13 **PBS video "Fat"** April 13, 14	❑ Discussion of topics presented in video: cultural influences on body weight (reduced physical activity and increased intake of high calorie, high fat foods), surgical treatment of obesity, eating disorders among young girls, size acceptance, fat people who are physically fit	❑ Consciousness Raising ❑ Dramatic Relief ❑ Environmental Reevaluation
Unit 14 **Enlisting Support** April 20, 21	❑ Types and sources of social support for making a behavior change ❑ How to ask for support from family, friends, and/or co-workers	❑ Helping Relationships ❑ Self-Liberation ❑ Increasing self-efficacy
Unit 15 **Revisiting Barriers to Physical Activity** April 27, 28	❑ Review of barriers to physical activity listing and discussion of how those barriers are or are not being overcome ❑ Cognitive restructuring ❑ Planning for a relapse	❑ Self-Reevaluation ❑ Counterconditioning ❑ Increasing self-efficacy
Unit 16 **Food as Fuel**	❑ Discussion of healthful eating vs. dieting ❑ Presentation of dietary guidelines and food guide pyramid ❑ Discussion of nutrition and chronic disease, e.g., CVD and cancer	❑ Consciousness Raising
Unit 17 **Field Trip – Ft. Collins Bike Path** May 18, 19	❑ Participants met at Rolland Moore Park for a bicycle ride on the bike path. The instructor provided instructions on safety.	❑ Increasing self-efficacy ❑ Social Liberation
Unit 18 **Personal Triumphs** June 1, 2	❑ Guest speaker, Mary Ann Litzu, shared her experiences as a large woman overcoming her barriers to walk the Portland marathon.	❑ Increasing self-efficacy (modeling technique) ❑ Decision Making
Unit 19 **Pitfalls and Detours – How to Stay Motivated** June 15, 16	❑ Discussion of relapse prevention ❑ Review of cognitive restructuring techniques ❑ Rewarding one's self for achieving goals ❑ Review of importance of setting small, realistic goals	❑ Self- Liberation ❑ Decision Making ❑ Increasing Self-Efficacy
Unit 20 **Class Review** June 29, 30	❑ Review of basic principles of the program ❑ Discussion of how to maintain the changes made during the program	

Sample Size Estimation for Final Study Intervention Groups

The sample size for the final study was calculated to detect a 2-kcal/kg/day difference in energy expenditure from baseline to 48 weeks in the Lifestyle group, assessed by the 7-Day Physical Activity Recall (described on pages 124-125). An energy expenditure of 2 kcal/kg/day is 150 kcal/day for a 75-kg individual or about 1000 kcal/week. This is the amount of physical activity recommended in *Physical Activity and Health: A Report of the Surgeon General* (192) and the amount considered adequate for moving a sedentary, unfit individual from the highest CVD risk category into a lower risk or "moderately fit, moderately active" category (192). Based on an anticipated 33% dropout rate (during the intervention) and 80% power at a 5% level of significance, the recruitment goal was determined to be 15 subjects per group.

Subject Recruitment

Subject recruitment methods and eligibility criteria for the final study were identical to those used in the pilot study. While the sample size estimation called for only 15 participants per group (including an expected 33% dropout rate), recruitment strategies resulted in more than 100 respondents to the newspaper advertisements and approximately 60 who were considered eligible and able to participate.

Description of Interventions

After completion of baseline screening, eligible study participants were randomized into one of two intervention programs, the "Lifestyle" program or the "Usual Care" program. The intervention programs were delivered over a 24-week period followed by a 24-week follow-up phase. The goal of both interventions was to increase energy expenditure by 2 kcal/kg/day by the end of 24 weeks and/or increase cardiorespiratory fitness by 3 ml/kg/min and to maintain this increase over the final 24 weeks. Both treatments are described below.

Usual Care Program. The Usual Care program was designed to mimic an intervention experience that would be available upon joining a health club or recreational facility. The information provided to participants was based upon the American College of Sports Medicine (ACSM) guidelines for exercise (7); thus, it would be similar to what one would receive from an exercise professional in a recreational or clinical setting.

Specifically, participants in the Usual Care group received an exercise prescription that recommends an exercise intensity of 60-70% of maximum heart rate and a duration of 20 – 60 min, 3-5 days a week (7). Initial exercise levels and progression of exercise dose followed ACSM exercise prescription recommendations (7). Instruction on the exercise prescription was given by an exercise physiologist in a group setting and each participant received their own "Fitness Plan" based on the exercise prescription (see Appendix H for a copy of the Fitness Plan and other handouts given to participants).

Usual Care participants also received a six-month membership to Miramont Sport Center (MSC), a local fitness club, and a copy of *The ACSM Fitness Book* (6), a book written for the lay public on starting an exercise program. Participants were encouraged to use the fitness club to carry out their exercise prescription but were given the option to exercise at home. Fitness trainers employed by MSC provided individual instruction on the exercise equipment at MSC and were available for questions and guidance at all times. The trainers were aware of the research study and were instructed to treat the Usual Care participants as they would treat any new member of MSC.

Four instructional classes were offered to participants of the Usual Care Group, all of which were held at MSC. These classes were similar to what is offered to new members upon joining MSC and included the following topics:

- Goal setting
- Taking heart rate
- Stretching and injury prevention
- Health benefits of exercise and physical activity
- Importance of good nutrition and hydration - the Food Guide Pyramid was used to explain "good nutrition" with an emphasis on moderate fat restriction and increasing fiber and carbohydrates. (The nutrition information was the same in both treatment groups)

Usual Care participants were encouraged to engage in the aerobic activities they most enjoyed and to progress at a level that felt comfortable for them. The instructor encouraged participants to become self-directed, to consider finding a partner to exercise with, and to keep an exercise log to record their exercise participation. Subjects were encouraged to call or email the instructor at any time during the 48-week period with questions or concerns.

Participation in the Usual Care intervention was monitored by asking participants to sign attendance sheets at all four instructional meetings and to sign an attendance sheet at the front desk of MSC each time they engaged in exercise at MSC. They were also encouraged to keep an exercise log that included how much, how often, and how intensely they engaged in exercise on a weekly basis and to turn the logs into the instructor at the end of the 24-week intervention.

During March of 1999, approximately 10 weeks into the intervention, a healthy cooking class was offered for participants in both treatment groups as a way of observing National Nutrition Month. This was the only time in which participants of both groups interacted with each other. The instructors of both treatment groups, who are both Registered Dietitians, taught the class. The class included general nutrition guidelines based on the Food Guide Pyramid and cooking demonstrations of recipes that are high in fiber and low in fat content.

Toward the end of the 24 weeks, the instructor offered two low-impact aerobics classes to Usual Care participants with an opportunity for group discussion before the class began. During the discussion, the instructor reviewed the components of the exercise prescription (intensity, duration, and frequency of exercise) and reinforced the value of structured exercise. Information on other fitness facilities and recreation centers within the Fort Collins area was provided as well as community events that involve physical activity, such as 5-kilometer walking events. Participants were given the opportunity to join MSC at a discounted price as soon as the six-month membership provided for them was over.

Lifestyle Program. Participants randomized to the Lifestyle program met weekly for group discussions and activities using the newly developed Lifestyle curriculum described earlier. To allow for better group cohesion, participants were divided into two smaller groups, with each group meeting on a different weeknight. Participants were encouraged to stay in their assigned group throughout the 24 weeks but were allowed to attend the other group meeting if they had to miss their group meeting. Meetings took place at Miramont Sport Center from 7:00–8:30 p.m. on Tuesday and Wednesday evenings.

As in the pilot study, Lifestyle participants were advised to work toward the goal of achieving the CDC/ACSM recommendations for physical activity (a minimum of 30 minutes of moderate-intensity physical activity on most days of the week). They were encouraged to work toward this goal by integrating "lifestyle" activity, such as gardening, taking the stairs instead of an elevator, parking their car further from their destination and walking, etc., into their daily routine. They were also encouraged to incorporate any type of physical activity they enjoyed into their daily schedule. Curriculum content focused on overcoming barriers to physical activity and using the strategies for change within the Stages of Change model to change sedentary behavior.

The delivery of the final curriculum occurred as it did in the pilot study: weekly sessions included a brief review of the topic covered in the previous session, discussion of any homework assignments, and a presentation of a new topic for group discussion. To increase exercise self-efficacy, several sessions consisted of organized activity, such as hiking or bicycling. Some sessions also included 15 – 20 minutes of light stretching exercises led by the instructor.

As described in the pilot study, participants received curriculum materials consisting of 4-6 page handouts each week with occasional home assignments and related articles of interest. Participants also received a copy of the book *Great Shape: The First Fitness Guide for Large Women* (124). Subjects were encouraged to keep an activity log in which they recorded the number of minutes they spent participating in physical activity each day and how this activity was integrated into their daily schedule. The instructor reviewed the logs each week and provided feedback when necessary.

After the 24-week intervention was over, participants met once a month for the remainder of the 48-week study period. The purpose of these monthly meetings was to reinforce skills learned in the active intervention and to generate more discussion on topics of interest. In addition, the instructor sent out frequent group email messages with information related to physical activity, fitness and health.

Table 12. Summary Description of the Lifestyle and Usual Care Intervention Programs

Lifestyle	Usual Care
• 24-Week program with group meetings held once a week for 16 weeks, then once every two weeks for remaining 8 weeks (20 meetings in 24 weeks)	• 24-Week program with four consecutive instructional meetings at the beginning of the 24 weeks followed by two follow-up meetings
• Curriculum* for group meetings based on theoretical models for behavior change and cognitive and behavioral processes of change	• Provision of exercise prescription, specifying the frequency, intensity, and duration of exercise needed to improve one's fitness level
• Groups meetings provide discussion and support	• Six month membership to a local fitness club with individualized instruction on exercise equipment
• Curriculum aims to help participants overcome barriers to physical activity using problem-solving techniques.	• Program goal for participants is to work up to 30 minutes of continuous exercise on most days of the week using their exercise prescription
• Curriculum teaches participants how to integrate lifestyle and/or intermittent physical activity into one's daily routine	• Access via telephone or email to the instructor for questions or concerns
• Program goal for participants is to work toward accumulating 30	

minutes of moderate-intensity physical activity on most days of the week • Emphasis on being active and fit regardless of body weight or size • Curriculum includes group activities and field trips to allow participants to try new and different types of activity	• One free low impact aerobics class with instructor of program • Monthly email message reminding participants of program goals and the importance of exercise for good health

*Final curriculum outline in Table 11 on pages 129-131.

ASSESSMENT OF OUTCOME MEASURES

The following assessments for the final study were conducted at baseline (January 1999), at 24 weeks (July 1999), and at 48 weeks (December 1999).

Anthropometric Measurements

Standing height was measured using a calibrated height board and body weight was measured using a calibrated medical scale. Height was measured at baseline only; weight was measured at baseline, at 24 weeks, and at 48 weeks. Body Mass Index (BMI) was calculated from these measurements by dividing the weight in kilograms by the square of height in meters.

Blood pressure, waist circumference, and body weight were measured by a physician, physician assistant, or other health professional during a brief physical examination at General Care Medical Clinic in Ft. Collins. All study participants were required to have this examination completed before participating in the study. Blood pressure was measured with the subject in a seated position by standard auscultatory techniques using a mercury sphygmomanometer (9). Instructions for assessing waist circumference, described by the NIH and NHLBI in the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report* (148) (see Appendix F) were provided to clinic personnel and reviewed with the physician's assistant. Body weight was measured as described above.

The clinic physician and his staff were advised not to counsel the subjects on nutrition, exercise, or weight loss, or provide any written information on these topics. They were, however, allowed to make statements about the health benefits of regular physical activity.

Metabolic Measurements

Fasting blood samples were obtained from subjects by trained phlebotomists at Quest Diagnostics Laboratory in Fort Collins. Serum cholesterol, high-density lipoprotein cholesterol (HDL-C) concentrations, low-density lipoprotein cholesterol (LDL-C) concentrations, the ratio of total blood cholesterol to HDL-C, triglycerides, and blood glucose were measured from each blood sample. The physician or a physician-assistant reviewed the results of the blood tests with each subject during the physical examination described above.

Energy Expenditure

As in the pilot study, energy expenditure in physical activity was measured using the 7-Day Physical Activity Recall (PAR) (26), described on page 124-125 (see Appendix E). All interviews were conducted by telephone. One interviewer conducted 80% of the interviews; the remaining interviews were conducted by individuals who were either trained by this interviewer or by individuals who were already familiar with the 7-Day PAR. All interviewers were provided with written and verbal instructions on conducting the 7-Day PAR interview, including a telephone script developed specifically for the 7-Day PAR interview (26).

Cardiorespiratory Fitness

Cardiorespiratory fitness was assessed using the Astrand-Ryhming submaximal cycle ergometer protocol (13), using guidelines established by the American College of Sports Medicine (ACSM) (9) (see Appendix I). The Astrand-Ryhming protocol is a single stage test that lasts for six minutes. Work rate is based on gender and the subject's fitness status. Heart rates were measured using a Polar Heart Rate monitor. An average of two heart rate measurements taken during the fifth and sixth minute of the test were used to estimate VO_2max from the Modified Astrand-Ryhming nomogram (see Appendix I), as described in ACSM's guidelines for exercise testing and prescription (9). Submaximal exercise tests were conducted at Miramont Sport Center by a trained exercise technician.

Energy Intake and Diet Composition

Subjects were asked to record their food and beverage intake for three days, preferably on two weekdays and one weekend day. Both written and verbal instructions were provided during the orientation session with a question and answer period following instruction. Subjects were encouraged to weigh or measure their food whenever possible and to provide the investigator with any food labels or recipes that may be considered to be uncommon (for data entry). Food records were analyzed using Computrition Nutrient Software Analysis (41) for daily totals of calories and fiber and percentage of calories from fat and carbohydrate. Three-day averages for calories, fiber, percent of daily calories from fat, and percent of daily calories from carbohydrate are reported in the Results section. (See Appendix E for food recording forms and instructions).

Psychological Measurements

Subjects were asked to complete the questionnaires that were utilized in the pilot study, described on page X. These include the Stage of Motivational Readiness for Physical Activity (133), Processes of Change (131), Decision Making for Physical Activity (130), and Exercise Self-Efficacy/Confidence (132) (see Appendix G). These questionnaires were given to subjects during the orientation session at baseline, at 24 weeks, and again at 48 weeks. Participants were allowed two weeks to complete the questionnaires at all three time points.

Remuneration

To increase the likelihood that participants would return for testing at the 24 and 48 week time points, participants were given a \$30 refund if they completed all of the testing at 24 and 48 weeks. Participants were asked to pay \$99 to participate in the study, thus, the \$30 was considered as a partial reimbursement (see consent form, Appendix C).

Intervention Adherence and Attrition

Because participation requirements were different in the two interventions, adherence to intervention requirements was calculated differently. Adherence to the Lifestyle intervention was based on attendance at group meetings, not exercise participation. Attending at least 15 group meetings (75%) was considered a criterion for adherence. Methods for assessing adherence and attrition are similar to those used in Project Active (53)

For the Usual Care group, attendance at three of the four instructional meetings held at Miramont Sport Center and answering "yes" to the question, "did you follow your exercise prescription for more than half of the six month period since receiving your exercise prescription?" was considered an adherence criterion. Usual Care participants were asked this question during their second physical examination at General Care Medical Clinic at the end of the 24-week intervention period by the physician or physician-assistant. Those participants who did not return for testing were asked this question by telephone.

Attrition rates were determined by the number of participants who dropped out of either intervention. Lifestyle participants were considered as "dropouts" if they attended less than 75% of the class meetings and Usual Care participants were considered as dropouts if they failed to return for follow-up testing at 24 weeks.

Dropout Information

To determine why participants dropped out of either intervention, "dropouts" were called on the telephone and asked if they would complete a short questionnaire telling the investigator why they had dropped out, if the questionnaire were mailed to them. If so, they would receive the questionnaire in the mail along with a stamped envelope addressed to the investigator in which they could return the questionnaire anonymously. They would also receive a $5 gift certificate to the local shopping mall for taking the time to complete the questionnaire. Results of the questionnaires are presented in Chapter 3 and a sample questionnaire is in Appendix J.

Qualitative Assessment

A complete evaluation of a behavior change intervention includes a qualitative assessment. In this study, qualitative data was obtained by asking participants who attended at least 15 of the 20 sessions (75%) of the Lifestyle intervention to evaluate the program by completing a survey similar to the one used in the pilot study. This survey queried participants on three aspects of the Lifestyle program: 1) content; 2) format (length of meetings, etc.); and 3) opinions of the program in general, particularly as to whether the program helped them become more physically active. A sample questionnaire can be found in Appendix J.

STATISTICAL ANALYSIS

For the pilot study, paired t tests were done to assess change in physical and psychological measures from baseline to 24 weeks. Chi square analysis was used to compare the distribution of subjects among the stages of change for physical activity at baseline and 24 weeks.

For the final study, statistical comparisons between intervention groups were made using all available data, with participants grouped as originally randomized, regardless of the types of activities actually performed. A repeated measures analysis of variance (ANOVA) over three time points (baseline, 24 weeks, and 48 weeks) was used to determine if any significant differences exist between groups at each time point as well as within groups over time for all of the physical and psychological outcome measures. To increase the power of detecting significant differences that exist between and within groups over time, responses for the physical data were also analyzed with a repeated measures analysis of covariance (ANCOVA) over two time points (24 and 48 weeks) using the baseline measure as a covariate. According to Gliner and Morgan (74), ANCOVA is recommended in a pretest/posttest control group design because it allows the investigator to use the pretest (baseline) scores as covariates and to adjust the posttest scores based on a significant relationship between the covariates and variates. This procedure can provide a more sensitive significant test (74). Both unadjusted and adjusted summary means from the ANOVA and ANCOVA, respectively, are presented as least square means ± the standard error of the mean (SEM).

As in the pilot study, chi square analysis was used to compare the distribution of subjects among the stages of change for physical activity at baseline and 24 weeks for both intervention groups. Chi square analysis was also used to compare the percentage of participants who increased energy expenditure by 2 kcals/kg/day (based on 7-Day PAR interviews) in each group and the percentage of participants who increased cardiorespiratory fitness by at least 3 ml/kg/min in each group. Chi square analysis was also used to compare differences in adherence rates between groups.

Correlation analysis with Pearson product moment correlation coefficients was conducted to determine if significant correlations exist between changes in energy expenditure and cardiorespiratory fitness and changes on the Self-Efficacy questionnaire.

To determine if changes in any of the psychological assessments were predictive of changes in cardiorespiratory fitness (by at least 3 ml/kg/min), separate multiple logistic regression analyses were conducted on measures of each of the ten cognitive and behavioral strategies, self-efficacy, and decisional balance. This analysis was conducted by regressing the odds of increasing cardiorespiratory fitness by 3 ml/kg/min at 24 weeks against the change since baseline in each of the psychological measures. The results of the logistic analysis are reported as odds ratios, as suggested by Dunn et al (53) in a similar analysis for Project Active. For example, an odds ratio of 2.0 indicates that, on average, a participant who increases one unit on a particular strategy for change would double her odds for increasing fitness by 3 ml/kg/min. This information may be helpful to clinicians in knowing which of the cognitive and behavioral strategies are most likely to promote physical activity in obese sedentary women.

Qualitative data for evaluation purposes are summarized and presented for discussion.

Data entry was conducted by the author using Microsoft Excel (Version 5.0 for Windows). Statistical analysis was conducted at the Colorado State University Statistical Laboratory using SAS Version 6.11 software (88). All reported P values are 2-tailed.

Chapter Three

Results

PILOT STUDY RESULTS

The pilot study intervention program began in June of 1998. Twelve women (mean age 45 years, ± 5.9 SD) completed baseline testing and began the pilot intervention program. Two participants dropped out during the 24-week intervention, both for job-related reasons. Ten women completed the intervention program and the post-intervention testing.

Demographic Data

At baseline, 75% of pilot study participants were Caucasian and 25% were Mexican-American. Two thirds were employed outside of the home. Of the two dropouts, one was 59 years old and Caucasian, the other was 41 years old and Mexican-American.

Physical Data

Physical characteristics of pilot study participants before and after the 24-week intervention are presented in Table 13. Paired sample t-tests show a significant increase ($p<0.5$) in cardiorespiratory fitness and physical activity and a significant decrease ($p<.005$) in waist circumference occurred from baseline to 24 weeks.

TABLE 13. Physical Data on Pilot Study Subjects

Variable[a]	Baseline (N=12)	24 Weeks (N=10)
Estimated VO_2 max (ml/kg/min)	26.1 ± 2.17	29.09 ± 2.15[b]
Energy expenditure (kcal/kg/d)	32.65 ± 0.20	34.37 ± 0.37[b]
Weight (kg)	93.72 ± 2.4	94.05 ± 2.53
Waist circumference (inches)	39.45 ± 1.03	38.9 ± 0.97[c]

[a]Mean ± SEM.
[b] $P<.05$
[c] $P<.005$, based on paired t test analysis

Psychological Data

Table 14 shows the distribution of subjects according to their stage of change for physical activity at baseline and again at the end of the 24-week intervention. At baseline, 100% of pilot participants were in the Contemplation stage. At 24 weeks, 33% of subjects were in the Contemplation stage and 67% were in the Action stage ($\chi^2 = 9.0$, $p = 0.003$).

TABLE 14. Distribution of Pilot Study Subjects by Stage of Change for Physical Activity

Stage of Change[a]	Baseline	24 Weeks
Precontemplation	0	0
Contemplation	100 (9)	33 (3)[b]
Preparation	0	0
Action	0	67 (6)[b]
Maintenance	0	0

[a]Percent (frequency)
[b]Distribution of subjects into stages at 24 weeks significantly different ($p<.05$) than distribution at baseline, according to chi square analysis.

The mean change and percent change in scores on the psychological assessments (Processes of Change, Self-Efficacy, and Decisional Balance questionnaires) for pilot study subjects are presented in Table 15. Results of the paired t tests reveal significant improvements occurred in measures of two of the cognitive processes and all five of the behavioral processes. The cognitive processes that improved included Consciousness Raising (mean change of 0.96 ± 0.63, p=0.007) and Self-Reevaluation (mean change of 0.60 ± 0.60, p=0.039), and the behavioral processes Counterconditioning, Stimulus Control, Reinforcement Management, Helping Relationships, and Self-Liberation.

Significant improvements in self-efficacy were also observed in pilot study subjects (mean change, 0.77 ± 0.86; p=0.007) but no significant change was observed for Decisional Balance (p=.0.07).

TABLE 15. Psychological Measures in Pilot Study Subjects[a]

	Mean Change[b]	% Change	P value[c]
Cognitive Processes[d]			
Consciousness Raising	0.96 ± 0.63	75.0	0.007
Dramatic Relief	0.05 ± 0.9	2.2	0.89
Self-Reevaluation	0.60 ± 0.60	23.5	0.039
Environmental Reevaluation	0.21 ± 0.27	22.0	0.078
Social Liberation	0.32 ± 0.49	32.0	0.136
Behavioral Processes[d]			
Counterconditioning	1.00 ± 0.77	77.0	0.014
Stimulus Control	0.96 ± 0.65	144.7	0.008
Reinforcement Management	0.92 ± 0.97	56.7	0.045
Helping Relationships	0.71 ± 0.6	79.7	0.0202
Self-Liberation	0.78 ± 0.79	34.6	0.0401
Self-Efficacy[d]	0.77 ± 0.5	86.6	0.007
Decisional Balance[d]	0.71 ± 0.86	56.3	0.071

[a]Baseline to 24 weeks
[b]Mean ± SD, based on paired t-test analysis
[c]Significance for mean change
[d]Cognitive and behavioral processes are measured by subscales on the Processes of Change questionnaire; self-efficacy is measured by the Self-Efficacy/ Confidence questionnaire; decisional balance is measured by the Decisional Balance questionnaire. See Appendix G for questionnaires and scoring algorithms.

Qualitative Assessment of the Preliminary Curriculum

Qualitative assessment of the preliminary curriculum was obtained from surveys participants were asked to complete. This information is summarized and presented below.

When asked "what did you like most about the program," all but one participant stated that meeting with other women who were similar in body size was what they liked most. Most (7 out of 10) stated that having weekly meetings and discussions on topics related to physical activity were also very helpful. All of the participants stated that they liked the field trips and all of the participants answered "yes" to the question, "would you recommend this program to a friend?"

To evaluate the individual sessions, participants were asked to review a list of session titles and circle which sessions were helpful to them. The following sessions were chosen by almost all of the participants as being most helpful to them:

Physical Activity and Health
Body Awareness
Body Acceptance

"Body Acceptance" was the only session chosen by all ten participants as being very helpful to them. One participant stated, "this was mostly a foreign concept to me but it made the difference in my mental and physical health during this program."

Participants were asked to circle two of the following field trips and group activities that were most helpful to them:

Bike ride on bike path	Country Line Dancing
Water aerobics class	Yoga class
Hike in Lory State Park	Belly Dancing

All ten participants circled water aerobics as most helpful and more than half of the participants circled bicycling, hiking, and yoga as most helpful. Some of the written comments on the field trips include:

"Water aerobics – I tried an activity I thought I'd hate and discovered it was something I enjoyed!"

"Water aerobics was something I wanted to try and never had before. I enjoyed the bike riding, it was comfortable for me."

"I enjoyed them all – it really allowed me to see what I can do at any size!"

In terms of format, the majority of participants stated they felt one hour was not long enough, that each session should be one and one half hours long or two hours long. Several participants stated they felt the program should be longer than six months and one person suggested it should be one year in length. Suggestions for improvement include the following: 1) more stretching or physical activity within each class period, 2) more time is needed in the beginning of the program to get to know the other participants before "jumping into" the topic of discussion, and 3) include more information on heart disease and how to prevent it.

Another important finding from the pilot study pertained to the use of the YMCA protocol for measuring cardiorespiratory fitness. The investigator noted a wide variation in the heart rate measurements taken within the last 30 seconds of each stage, making estimation of VO_2max somewhat difficult. A decision was made to use the Astrand-Ryhming protocol for cycle ergometry (see Appendix H) (13) for determining cardiorespiratory fitness in the final study, based on a suggestion by a member of the author's advisory committee.

RESULTS OF THE FINAL STUDY

Participants in the final study were 58 obese sedentary women; 29 in the Lifestyle group, 29 in the Usual Care group. The mean (SD) age of study participants was 47 years (6.8) for Lifestyle participants and 46 years (9.8) for Usual Care participants. More than 95% of subjects in both groups were Caucasian; the remaining 5% were Mexican-American, Indian, and African-American.

Baseline Measures and Measurement Compliance

Baseline measures of physiological characteristics for the 58 participants are shown in Table 16. The percentage of participants in both treatment groups who completed the follow-up testing at 24 and 48 weeks are presented in Table 17.

Major Findings at 24 Weeks – Intervention Effects

Changes from baseline to 24 weeks (pre- to post-intervention) in physical activity, cardiorespiratory fitness, CVD risk factors (blood chemistry, blood pressure, waist circumference, and BMI), psychological measures, and diet composition in both treatment groups are presented below. Summary means for the ANOVA and ANCOVA analyses are reported as unadjusted and adjusted least square means, respectively, in Tables 18-19.

Physical activity. The repeated measures ANOVA revealed a significant increase in energy expenditure occurred from baseline to 24

TABLE 16. Baseline Physical Data by Intervention Group. Mean (s.e.m.)

Measure	*Lifestyle* (n=29)	*Usual Care* (n=29)
Age, years	47 ± 6.8	46 ± 9.7
Energy expenditure, kcal/kg/day	32.95 ± 0.35	33.47 ± 0.36
Cardiorespiratory fitness, mL/kg/min	23.27 ± 0.99[a]	28.10 ± 1.03
Cardiorespiratory fitness, L/min	2.41 ± 0.09	2.64 ± 0.1
Total cholesterol level, mg/dl	218.72 ± 7.38	202.96 ± 7.43
HDL-C level, mg/dl	54.17 ± 2.71	53.11 ± 2.75
LDL-C level, mg/dl	130.66 ± 5.69	119.47 ± 5.78
Ratio of cholesterol to HDL-C	4.16 ± 0.23	3.92 ± 0.24
Triglycerides, mg/dl	163.03 ± 17.75	143.99 ± 17.99
Glucose, mg/dl	91.48 ± 3.34	89.23 ± 3.36
Systolic blood pressure, mm Hg	133.75 ± 3.22	132.65 ± 3.25
Diastolic blood pressure, mm Hg	85.00 ± 1.76	81.00 ± 1.79
BMI, kg/m^2	38.24 ± 1.03[a]	34.00 ± 1.03
Weight (kg)	105.10 ± 3.1[a]	95.9 ± 3.10

[a]Significantly ($p<0.05$) different from Usual Care group according to repeated measures ANOVA.

TABLE 17. Measurement Compliance Data at 24 and 48 Weeks by Intervention Group[a]

	Lifestyle (n=29)	Usual Care (n=29)
Physical Assessments		
Energy expenditure (7-day PAR)		
24 Weeks	93% (27)	72% (21)
48 Weeks	79% (23)	59% (17)
Cardiorespiratory fitness (bicycle test)		
24 Weeks	86% (25)	52% (15)
48 Weeks	76% (22)	41% (12)
Body weight (for BMI calculation)		
24 Weeks	86% (25)	55% (16)
48 Weeks	76% (22)	41% (12)
Blood chemistry analysis[1]		
24 Weeks	86% (25)	59% (17)
48 Weeks	76% (22)	48% (14)
Blood pressure (systolic and diastolic)		
24 Weeks	86% (25)	59% (17)
48 Weeks	76% (22)	48% (14)
Psychological Assessments		
Stage of Change		
24 Weeks	66% (19)	48% (14)
48 Weeks	48% (14)	59% (17)
Process of Change		
24 Weeks	66% (19)	48% (14)
48 Weeks	48% (14)	59% (17)
Self-Efficacy		
24 Weeks	66% (19)	48% (14)
48 Weeks	48% (14)	59% (17)
Decision Making		
24 Weeks	66% (19)	48% (14)
48 Weeks	48% (14)	59% (17)
Dietary Assessments		
3-day food records		
24 Weeks	66% (19)	48% (14)
48 Weeks	48% (14)	59% (17)

[a]Percent (frequency)

[1]Total cholesterol, HDL-C, LDL-C, ratio of total cholesterol to HDL-C, triglycerides, and glucose.

weeks in the Lifestyle group (32.95 ± 0.35 SEM to 33.9 ± 0.37 SEM; (p=.0264) (see Table 18) but not in the Usual Care group (33.47 ± 0.35 to 32.9 ± 0.39; p=.2076). Although there were no significant differences between groups at baseline for physical activity, an ANCOVA was conducted to control for any unexplained variability, using the baseline measure as a covariate. The ANCOVA also found energy expenditure was significantly higher in the Lifestyle group at 24 weeks than in the Usual Care group (33.92 ± 0.37 vs. 32.73 ± 0.39, respectively; p=.03). (See Table 19 and Figures 4 and 5.)

Changes in physical activity were also determined by comparing the percentage of participants in both intervention groups who achieved the intervention goal of increasing energy expenditure by 2 kcal/kg/day (see Table 20). According to the 7-Day PAR analyses, five of the 26 (19%) Lifestyle participants who completed the 7-Day PAR interview at 24 weeks had increased their daily energy expenditure by 2 kcal/kg. In the Usual Care group, none of 21 Usual Care participants who completed the questionnaire increased their energy expenditure by 2 kcal/kg/day. The difference between the two groups was significant (χ^2=6.135; p<.05).

TABLE 20. Percentage of Subjects Who Increased Energy Expenditure by 2 Kcals/Kg/day or More[a]

	Lifestyle	Usual Care	P value of Chi Square
24 weeks	19% (5 of 26)	0% (0 of 21)	0.013
48 weeks	23% (6 of 23)	0% (0 of 17)	0.002

[a]Assessed by 7-Day Physical Activity Recall interview
[b]Percent (frequency). Frequency based on number of subjects completing 7-Day PAR interview

TABLE 18. Physical Data at Baseline and 24 Weeks by Intervention Group[a]

	Lifestyle			*Usual Care*		
	Baseline	24 Weeks	P value	Baseline	24 Weeks	P value
EE (kcal-kg/d)	32.9 ± 0.3	33.9 ± 0.4	0.026	33.4 ± 0.4	32.9 ± 0.4	0.20
CRF (mL/kg/min)	23.3 ± 0.9	26.3 ± 0.9	0.0003	28.1 ± 1.0	27.8 ± 1.2	0.72
CRF (L/min)	2.4 ± 2.7	2.7 ± 0.1	0.0005	2.6 ± 0.1	2.6 ± 0.1	0.63
Cholesterol (mg/dl)	218.7 ± 7.4	213.0 ± 7.6	0.29	202.9 ± 7.4	203.4 ± 8.3	0.95
HDL-C (mg/dl)	54.2 ± 2.7	50.4 ± 2.9	0.20	53.1 ± 2.8	55.7 ± 3.4	0.46
LDL-C (mg/dl)	130.6 ± 5.7	127.7 ± 5.9	0.50	119.5 ± 5.8	121.5 ± 6.5	0.70
TC:HDL-C (mg/dl)	4.2 ± 0.2	4.4 ± 0.2	0.21	3.9 ± 0.24	3.7 ± 0.3	0.39
Triglycerides (mg/dl)	163.0 ± 17.7	174.0 ± 18.8	0.56	143.9 ± 17.9	132.6 ± 22.7	0.61
Glucose (mg/dl)	91.5 ± 3.3	95.5 ± 3.4	0.08	89.2 ± 3.4	90.4 ± 3.8	0.82
SBP (mm Hg)	133.7 ± 3.2	133.9 ± 3.3	0.94	132.0 ± 7	135.3 ± 3.9	0.44
DBP (mm Hg)	85.0 ± 1.7	80.2 ± 1.9	0.04	81.0 ± 1.8	76.4 ± 2.3	0.08
BMI (kg/m^2)	38.2 ± 1.0[b]	37.6 ± 1.0[b]	0.003	34.0 ± 1.0	34.1 ± 1.0	0.70
Weight (kg)	105.1 ± 3.1[b]	104.2 ± 3.1	0.43	95.4 ± 3.1	95.9 ± 3.2	0.71

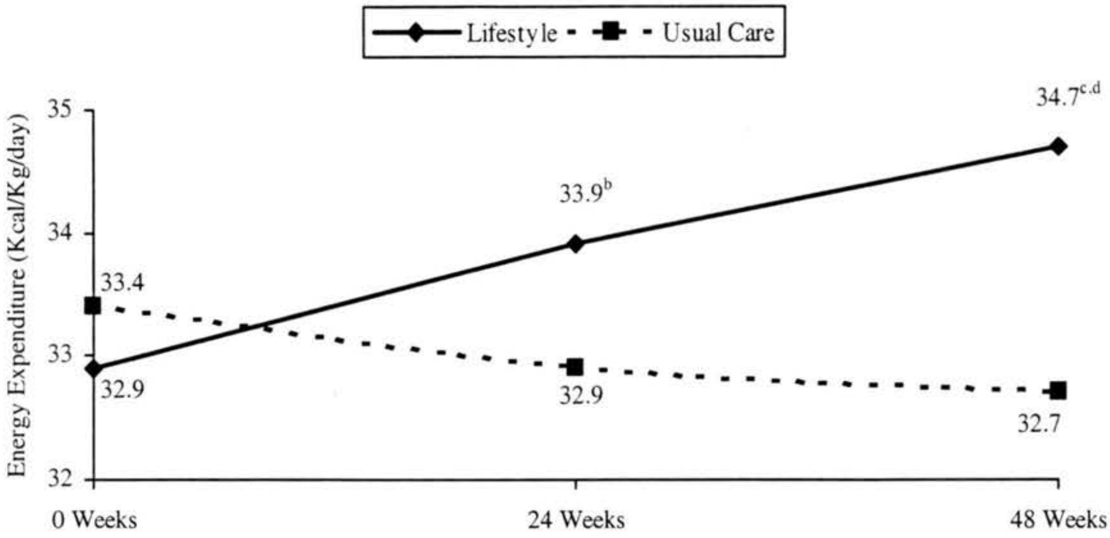
[a]Least square means ± SEM, based on ANOVA, [b]Significantly different ($p<0.05$) from Usual Care group

Abbreviations: EE, Energy Expenditure; CRF, Cardiorespiratory Fitness; HDL-C, High Density Lipoprotein; LDL-C, Low Density Lipoprotein; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; BMI, Body Mass Index

TABLE 19. Adjusted Least Square Means of Physical Data at 24 and 48 Weeks by Intervention Group[a]

	24 Weeks			*48 Weeks*		
	Lifestyle	Usual Care	Between Group Differences	Lifestyle	Usual Care	Between Group Differences
EE (kcal-kg/d)	33.92 ± 0.38	32.73 ± 0.39	0.03	34.75 ± 0.39	32.57 ± 0.46	0.0006
CRF (mL/kg/min)	27.4 ± 0.67	26.5 ± 0.9	0.47	27.0 ± 0.69	26.57 ± 0.98	0.72
Cholesterol (mg/dl)	204.8 ± 5.3	206.0 ± 6.6	0.89	203.9 ± 5.5	209.5 ± 7.0	0.54
LDL-C (mg/dl)	121.5 ± 4.1	123.3 ± 5.4	0.80	113.2 ± 4.5	119.5 ± 5.8	0.40
TC:HDL-C	4.3 ± 0.2	3.9 ± 0.2	0.12	3.9 ± 0.2	4.1 ± 0.26	0.53
Triglycerides (mg/dl)	167.5 ± 17.4	133.8 ± 21.8	0.23	188 ± 18.63	156.2 ± 23.5	0.29
Glucose (mg/dl)	93.1 ± 2.3	91.3 ± 2.9	0.62	92.7 ± 2.4	91.7 ± 3.0	0.79
SBP (mm Hg)	134.1 ± 2.9	136.0 ± 3.8	0.68	143.5 ± 3.0	132.9 ± 4.0	0.04
DBP (mm Hg)	79.8 ± 2.0	76.8 ± 2.3	0.37	86.2 ± 2.1[b]	79.7 ± 3.01	0.07
BMI (kg/m^2)	36.2 ± 0.24	36.9 ± 0.3	0.05	36.6 ± 0.25	37.5 ± 0.33[b]	0.04

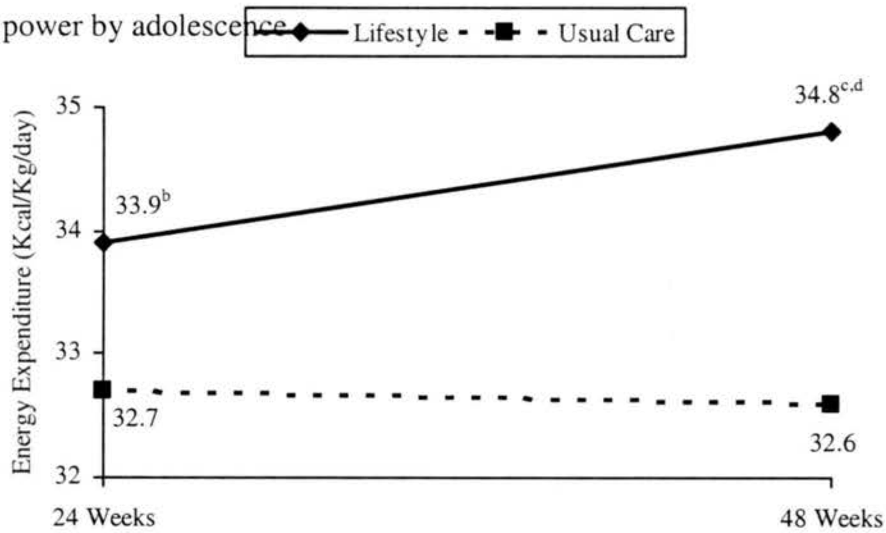
[a]Mean ± SEM, based on repeated measures ANCOVA with adjustments for the baseline measure of each variable. Cardiorespiratory fitness and BMI also adjusted for baseline between-group differences in fitness and BMI.
[b]Significantly different ($p < 0.05$) than at 24 weeks, same intervention group.
Abbreviations: EE, Energy Expenditure; CRF, Cardiorespiratory Fitness; HDL-C, High Density Lipoprotein; LDL-C, Low Density Lipoprotein; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; BMI, Body Mass Index



a. Based on repeated measures ANOVA
b. Significantly different (p = 0.026) than baseline
c. Significantly different (p = 0.0001) than baseline
d. Significantly different (p = 0.001) than Usual Care

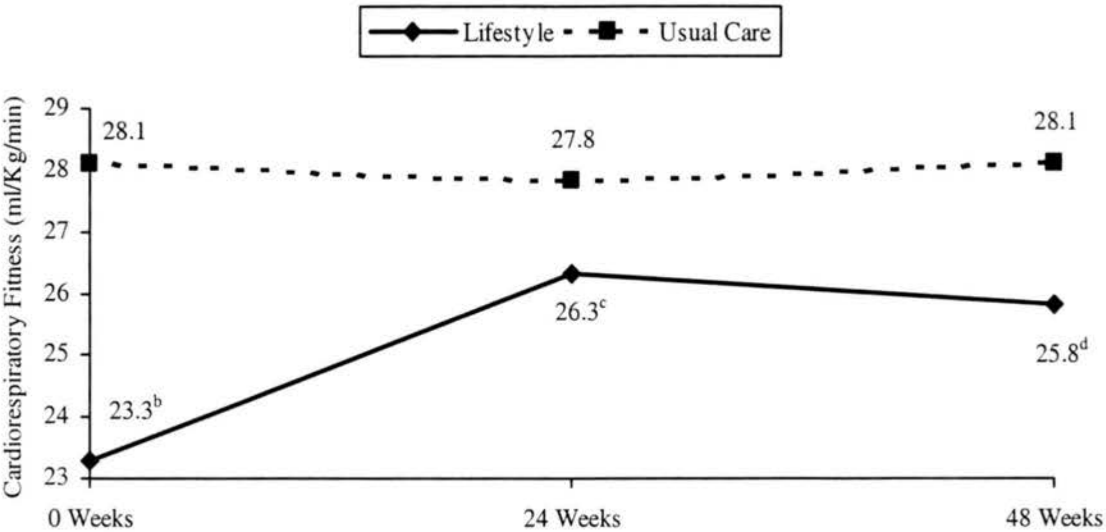
FIGURE 4. Unadjusted Mean Changes in Energy Expenditure by Intervention Group[a]

h and aerobic power by adolescence



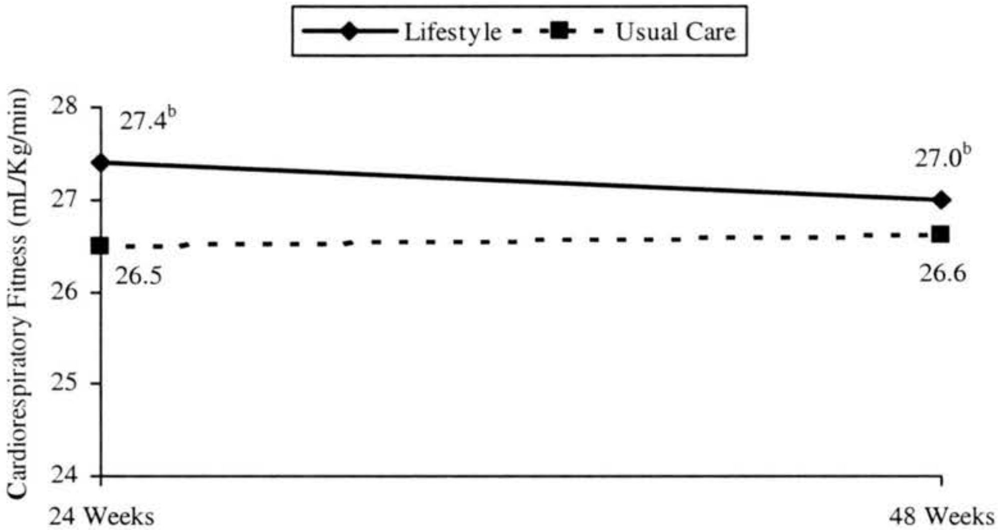
a. Based on repeated measures ANCOVA, adjusted for baseline measure
b. Significantly different (p = 0.033) than Usual Care group
c. Significantly different (p = 0.023) than 24 weeks, Lifestyle group
d. Significantly different (p = 0.0006) than Usual Care group

FIGURE 5. Adjusted Mean Changes in Energy Expenditure by Intervention Group[a]



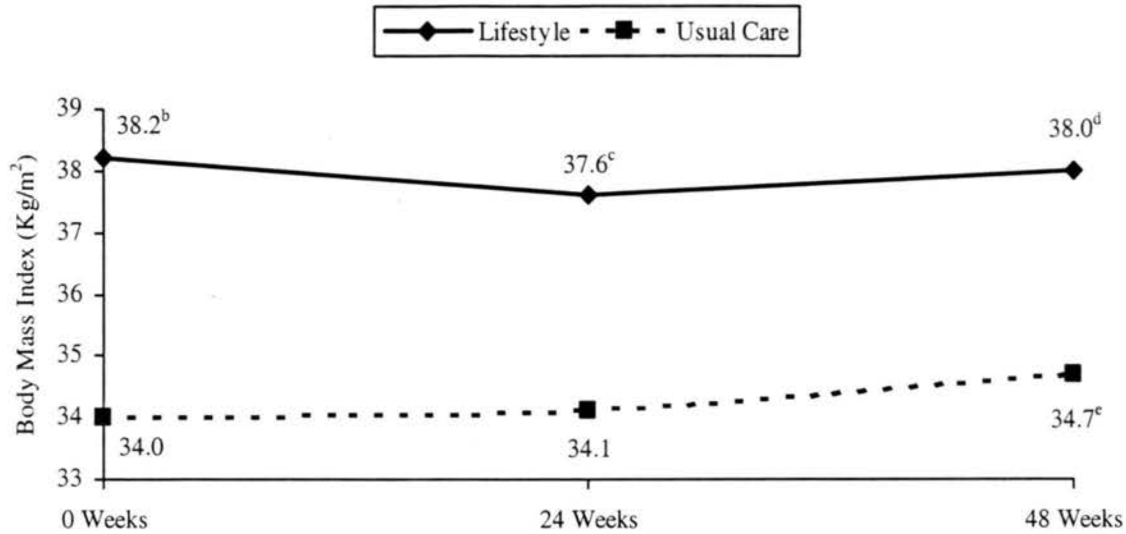
a. Based on repeated measures ANOVA
b. Significantly different ($p = 0.001$) than Usual Care group
c. Significantly different ($p = 0.0003$) than baseline
d. Significantly different ($p = 0.002$) than baseline

FIGURE 6. Unadjusted Mean Changes in Cardiorespiratory Fitness by Intervention Group[a]



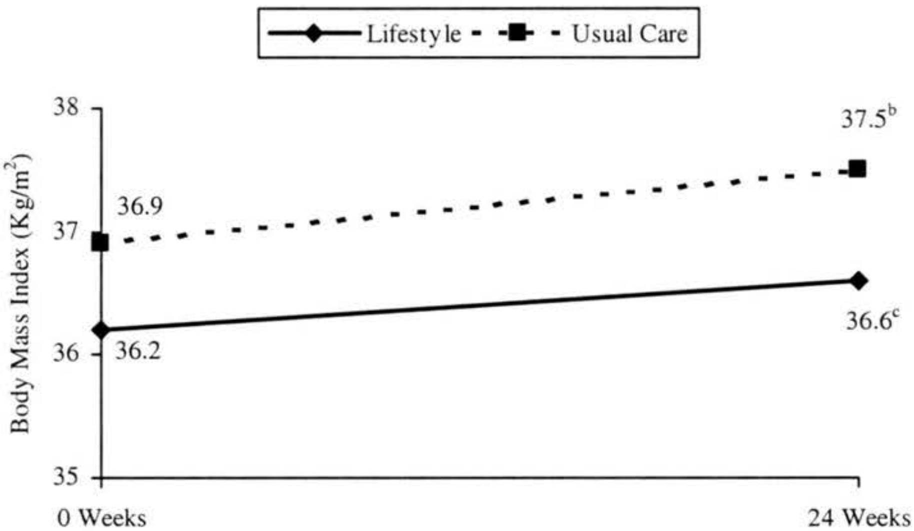
a. Based on repeated measures ANCOVA
b. No significant differences between or within groups

FIGURE 7. Adjusted Mean Changes in Cardiorespiratory Fitness by Intervention Group[a]



a. Based on repeated measures ANOVA
b. Significantly different ($p = 0.005$) than Usual Care group
c. Significantly different ($p = 0.02$) than Usual Care group and significantly different (0.003) than baseline, Lifestyle group
d. Significantly different ($p = 0.02$) than Usual Care group
e. Significantly different ($p = 0.03$) than baseline

FIGURE 8. Unadjusted Mean Changes in Body Mass Index by Intervention Group[a]



a. Based on repeated measures ANCOVA, adjusted for baseline differences in BMI
b. Significantly different ($p = 0.04$) than 24 weeks and significantly different ($p = 0.04$) than Lifestyle group
c. Significantly different ($p = 0.02$) than 24 weeks, Lifestyle group

FIGURE 9. Adjusted Mean Changes in Body Mass Index by Intervention Group[a]

Cardiorespiratory fitness (CRF). ANOVA revealed a significant increase in CRF occurred from baseline to 24 weeks in the Lifestyle group, from 23.27 ml/kg/min (± 0.99) to 26.25 ml/kg/min (± 1.02), an increase of 13% (p=.0003). In the Usual Care group, changes in CRF were not significant in ml/kg/min (28.1 ± 1.02 ml/kg/min to 27.8 ± 1.2 ml/kg/min; p=.7231). However, there were significant differences at baseline between treatment groups in CRF (in ml/kg/min, see Table 18) and after adjusting for these differences with ANCOVA, no significant differences were found at 24 weeks between groups (see Table 19 and Figures 6 and 7).

Intervention effects on CRF were also determined by comparing the percentage of participants in each group who increased their estimated VO_2max level by 3 ml/kg/min after 24 weeks. More than half (56%) of Lifestyle participants and approximately one-fourth (27%) of Usual Care participants achieved this goal (see Table 21).

TABLE 21. Percentage of Subjects Who Increased Cardiorespiratory Fitness by 3mL/kg/min or More[a]

	Lifestyle	Usual Care	P value of Chi Square
24 weeks	56% (14 of 25)	27% (4 of 15)	0.07
48 weeks	46% (10 of 22)	33% (4 of 12)	0.49

[a]Percent (frequency). Frequency based on number of subjects completing submaximal bicycle ergometer test at 24 and 48 weeks

Blood Chemistry. Baseline values for all blood chemistry indices (total cholesterol, HDL-C, LDL-C, ratio of cholesterol to HDL-C, triglycerides, and glucose) by intervention group are shown in Table 16.

There were no significant differences between groups on any of the blood chemistry indices at baseline or after 24 weeks of intervention.

Based on normal reference ranges used by Quest Diagnostics (Appendix K), mean values for HDL-C, the ratio of total cholesterol to HDL-C, LDL-C, triglycerides, and glucose were within normal limits in both groups at all three time points. Total cholesterol, however, was slightly elevated in both groups at all three time points.

Blood pressure. There were no significant differences between groups at baseline for either systolic or diastolic blood pressure. At 24 weeks, there were no significant differences between or within groups for systolic blood pressure, but a significant decrease in diastolic blood pressure occurred in the Lifestyle group (85 mmHg ±1.76 SEM to 80.2 ± 1.86 SEM; p=.0413).

Waist Circumference. Due to measurement error, the data on waist circumference was considered unusable. Baseline measures of waist circumference were obtained by a trained physician's assistant but measurements taken at 24 and 48 weeks were obtained by two different health professionals who were not properly trained in measuring waist circumference.

Body Mass Index. In the Lifestyle group, BMI was significantly lower at 24 weeks than at baseline (p=.0034) and also significantly lower than the Usual Care group (p=.0208). In the Usual Care group, no significant changes in BMI occurred during the 24-week intervention period (p=.7018). Because there were significant differences in BMI at baseline between intervention groups (p=.0049), the differences were adjusted by ANCOVA using the baseline measure as a covariate. ANCOVA showed the difference in BMI between groups at 24 weeks to be almost significant (p=.059). (See Table 19 and Figures 8 and 9.)

Diet Composition. As shown in Table 22, there were no differences at baseline between groups for total calories, percentage of calories from fat, percentage of calories from carbohydrate, or fiber intake. At 24 weeks, there was a significant increase in the percentage of calories from fat in the Usual Care group (32.47% to 38.27%; p=.017) but not in the Lifestyle group. Carbohydrate intake was reduced during the same time period in the Usual Care group: 51% (1.85 SEM) baseline and 45.68% (2.2 SEM) at 24 weeks (p=.043). No significant changes in diet composition or total calorie intake were observed in the Lifestyle group over the 24-week intervention period.

Psychological Measures. Table 23 shows the distribution of subjects according to their stage of change for physical activity at baseline and again at the end of the 24-week intervention period. In the Lifestyle group, almost 90% of subjects were in the Contemplation stage at baseline and after 24 weeks, more than half of the subjects who completed the questionnaire were in either the Action (15.79%) or Maintenance stage (47.37%). In the Usual Care group, 71.43% of subjects were in the Contemplation stage at baseline and 7.14% and 50% were in

TABLE 22. Dietary Data from Baseline to 24 Weeks by Intervention Group[a]

	Lifestyle			*Usual Care*		
	Baseline	24 Weeks	P value	Baseline	24 Weeks	P value
Total Calories	2081.2 ± 113.8	1990.3 ± 141.7	0.56	1885.9 ± 118.5	2143.4 ± 141.6	0.15
Composition						
% CHO	51.2 ± 1.8	46.8 ± 2.2	0.09	51.1 ± 1.9	45.7 ± 2.2	0.04
% Fat	34.7 ± 1.5	36.3 ± 1.9	0.47	32.5 ± 1.6	38.3 ± 1.9	0.01
Fiber, g	12.4 ± 1.2	13.4 ± 1.5	0.62	12.3 ± 1.24	10.9 ± 1.5	0.46

[a]Least square means ± SEM, based on repeated measures ANOVA.

the Action and Maintenance stage, respectively, at 24 weeks. However, only 48% of participants in the Usual Care group completed the Stage of Change questionnaire at 24 weeks, compared to 66% of Lifestyle participants.

TABLE 23. Distribution of Subjects by Stage of Change for Physical Activity

	Lifestyle		*Usual Care*	
Stage of Change[a]	Baseline (n=29)	24 Weeks (n=19)	Baseline (n=29)	24 Weeks (n=14)
Precontemplation	0%	0%	0%	0%
Contemplation	89% (26)	26% (5)	71% (21)	36% (5)
Preparation	11% (3)	11% (2)	29% (8)	7% (1)
Action	0%	16% (3)	0%	7% (1)
Maintenance	0%	47% (9)	0%	50% (7)

[a]Percent (Frequency).

Table 24 presents the least square means for all ten processes of change (five cognitive and five behavioral) at baseline and 24 weeks, by intervention group. In the Lifestyle group, significant changes occurred in measures of three cognitive processes and, as in the pilot study, all five behavioral processes. For the cognitive processes, significant increases were observed in Consciousness Raising, Environmental Reevaluation, and Social Liberation. For the behavioral processes, significant increases were observed in Counterconditioning, Stimulus Control, Reinforcement Management, Helping Relationships, and Self-Liberation. Although not significant, the only psychological measure that decreased in the Lifestyle group was Dramatic Relief (-0.09 ± 0.14; $p=0.60$).

TABLE 24. Psychological Data at Baseline and 24 Weeks by Intervention Group[a]

	Lifestyle			*Usual Care*		
	Baseline	24 Weeks	P value	Baseline	24 Weeks	P value
Cognitive Processes*						
Consciousness Raising	2.36 ± 0.13	2.80 ± 0.15	0.005	2.18 ± 0.12	2.48 ± 0.12	0.05
Dramatic Relief	2.39 ± 0.17	2.29 ± 0.19	0.60	2.03 ± 0.16	1.81 ± 0.19	0.22
Self-Reevaluation	3.10 ± 3.21	3.21 ± 0.14[b]	0.51	3.07 ± 0.12	2.79 ± 0.14	0.09
Environmental Reevaluation	2.31 ± 0.15	2.73 ± 0.17[b]	0.007	2.26 ± 0.14	2.20 ± 0.16	0.65
Social Liberation	1.92 ± 0.15	2.29 ± 0.17	0.009	1.83 ± 0.14	2.01 ± 0.16	0.19
Behavioral Processes*						
Counterconditioning	1.75 ± 0.15	2.48 ± 0.15	<0.0001	1.95 ± 0.12	2.45 ± 0.15	0.005
Stimulus Control	1.16 ± 0.13	1.96 ± 0.15	<0.0001	1.16 ± 0.12	1.66 ± 0.14	0.0014
Reinforcement Management	1.87 ± 0.12	2.29 ± 0.14	0.005	2.16 ± 0.12	2.37 ± 0.13	0.14
Helping Relationships	1.19 ± 0.16[b]	1.82 ± 0.19	0.004	1.68 ± 0.15	1.70 ± 0.18	0.92
Self-Liberation	2.90 ± 0.12	3.33 ± 0.14	0.009	2.73 ± 0.12	3.09 ± 0.14	0.06
Self-Efficacy*	1.22 ± 0.14[b]	1.67 ± 0.16	0.016	1.70 ± 0.13	1.80 ± 0.15	0.55
Decisional Balance*	1.37 ± 0.16	1.35 ± 0.19	0.89	1.44 ± 0.15	1.50 ± 0.21	0.80

[a]Mean ± SEM, based on repeated measures ANOVA
[b]Significantly different from Usual Care group ($p<0.05$)
*Cognitive and behavioral processes measured on separate subscales of the Processes of Change questionnaire; Self-Efficacy measures on the Self-Efficacy/ Confidence questionnaire; Decisional Balance is measured by the Decisional Balance questionnaire. See Appendix G for questionnaires and scoring algorithms.

In the Usual Care group, significant increases were observed in three of the behavioral processes, Counterconditioning, Stimulus Control, and Self-Liberation. The mean change in one of the cognitive processes, Consciousness Raising, could be considered as almost significant with a P value of 0.0523.

Table 24 also presents mean changes in measures of self-efficacy and decisional balance at 24 weeks. Self-efficacy scores in the Lifestyle group were significantly higher at 24 weeks than at baseline ($p = 0.016$) and significantly higher than self-efficacy scores in the Usual Care group at 24 weeks. No significant differences in decisional balance were found between or within groups at 24 weeks.

Correlational analyses revealed a significant and positive correlation between self-efficacy and energy expenditure in the Lifestyle group at 24 weeks ($r=0.56$; $p<0.05$) but not at 48 weeks ($r=-0.13$)(see Table 25). No significant correlations were observed among Usual Care participants at 24 or 48 weeks. Separate logistic regression analyses for each process of change showed revealed none of the odds ratios to be significantly greater than 1.0 (see Table 26).

Major Findings at 48 Weeks – Maintenance of Intervention Effects

Major findings at 48 weeks based on ANOVA and ANCOVA analyses are presented below and shown as unadjusted least square means

TABLE 25. Correlations[a] Between Self-Efficacy and Energy Expenditure and Cardiorespiratory Fitness.

	Lifestyle		*Usual Care*	
	24 Weeks	48 Weeks	24 Weeks	48 Weeks
Energy Expenditure	0.56[b]	-0.13	0.38	0.36
Cardiorespiratory Fitness	0.08	0.34	0.49	-0.01

[a]Pearson product moment correlation coefficients
[b]$p<0.05$

TABLE 26. Odds Ratios[a] for Cognitive and Behavioral Processes of Change[b]

	Odds Ratio	95% Confidence Intervals
Cognitive Processes		
Consciousness Raising	1.80	0.6 – 5.5
Dramatic Relief	0.45	0.17 – 1.2
Self-Reevaluation	1.07	0.39 – 2.9
Environmental Reevaluation	1.84	0.56 – 5.9
Social Liberation	1.16	0.32 – 4.2
Behavioral Processes		
Counterconditioning	0.91	0.27 – 3.0
Stimulus Control	0.96	0.33 – 2.8
Reinforcement Management	0.59	0.18 – 1.8
Helping Relationships	1.50	0.65 – 3.3
Self-Liberation	1.30	0.42 – 3.6
Self Efficacy	1.04	0.36 – 3.0
Decisional Balance	1.22	0.5 – 2.8

[a]Based on logistic regression analysis

bCognitive and behavioral processes measured on separate subscales of the Processes of Change questionnaire; Self-Efficacy measures on the Self-Efficacy/ Confidence questionnaire; Decisional Balance is measured by the Decisional Balance questionnaire. See Appendix G for questionnaires and scoring algorithms.

in Tables 27 and adjusted least square means one presented in Table 19 on page 159.

Physical activity. From baseline to 48 weeks, a significant increase in energy expenditure was observed in the Lifestyle group (32.9 ± 0.35 SEM to 34.7 ± 0.39 SEM; p=.0001) but not in the Usual Care group (33.4 ±0.36 SEM to 32.7 ± 0.44; p=0.1367) (See Table 27). There were no significant changes in energy expenditure for either group between 24 weeks and 48 weeks but the difference between groups at 48 weeks was significant (p=.001). The ANCOVA analysis also revealed significant group differences for physical activity at 24 and 48 weeks (p=.0328 and .0006, respectively) (See Table 19). Figures 4 and 5 demonstrates the changes in energy expenditure from baseline to 48 weeks in both intervention groups.

The percentage of participants achieving the intervention goal of increasing energy expenditure by 2 kcals/kg/day at 48 weeks from baseline was significantly higher among Lifestyle participants than among Usual Care participants (26% and 0%, respectively; χ^2=5.217; p<.05) (See Table 20).

Cardiorespiratory fitness. Estimated VO_2 max levels were significantly higher at 48 weeks than at baseline for Lifestyle participants (25.86 ml/kg/min ± 1.05 and 23.27 ± 0.98 SEM, respectively; p=.002) but no change occurred from 24 to 48 weeks (p=.63). In the Usual Care group, no significant changes in fitness occurred from baseline to 48

TABLE 27. Physical Data at 24 and 48 Weeks by Intervention Group[a]

	Lifestyle			*Usual Care*		
	24 Weeks	48 Weeks	P value	24 Weeks	48 Weeks	P value
EE (kcal/kg/d)	33.9 ± 0.4	34.7 ± 0.39[c,e]	0.047	32.9 ± 0.4	32.7 ± 0.44	0.73
CRF (mL/kg/min)	26.3 ± 0.9	25.8 ± 1.05[e]	0.63	27.8 ± 1.2	28.13 ± 1.3	0.74
CRF (L/min)	2.7 ± 0.1	2.7 ± 0.1[d]	0.86	2.6 ± 0.1	2.7 ± 0.1	0.21
Cholesterol (mg/dl)	213.0 ± 7.6	212.3 ± 7.7	0.86	203.4 ± 8.3	207.04 ± 8.7	0.59
HDL-C (mg/dl)	50.4 ± 2.9	55.6 ± 3.0	0.10	56.5 ± 3.0	58.9 ± 3.1	0.43
LDL-C (mg/dl)	127.7 ± 5.9	119.6 ± 6.1[e]	0.08	121.5 ± 6.5	116.9 ± 6.9	0.43
TC:HDL-C (mg/dl)	4.4 ± 0.2	4.07 ± 0.25	0.11	3.7 ± 0.3	4.02 ± 0.3	0.27
Triglycerides (mg/dl)	174.0 ± 18.8	195.2 ± 19.6	0.29	132.6 ± 22.7	149.8 ± 23.7	0.49
Glucose (mg/dl)	95.5 ± 3.4	93.7 ± 3.5	0.47	90.4 ± 3.8	91.0 ± 3.9	0.83
SBP (mm Hg)	133.9 ± 3.3	143.3 ± 3.4[b,d]	0.002	135.3 ± 3.9	132.0 ± 4.1	0.48
DBP (mm Hg)	80.2 ± 1.9	86.5 ± 1.9[b]	0.01	76.4 ± 2.3	79.2 ± 2.5	0.35
BMI (kg/m^2)	37.6 ± 1.0[b]	38.05 ± 1.03[b]	0.04	34.1 ± 1.0	34.7 ± 1.0[d]	0.06
Weight (kg)	104.2 ± 3.1	105.5 ± 3.1	0.29	95.5 ± 3.2	100.0 ± 3.3[d]	0.01

[a]Least square means ± SEM, based on ANOVA, [b]Significantly ($p<0.05$) different from Usual Care group,
[c]Significantly ($p<0.0001$) different from Usual Care group
[d]Significantly ($p<0.05$) different from baseline
[e]Significantly ($p<0.0001$) different from baseline
Abbreviations: EE, Energy Expenditure; CRF, Cardiorespiratory Fitness; HDL-C, High Density Lipoprotein; LDL-C, Low Density Lipoprotein; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; BMI, Body Mass Index

weeks or from 24 to 48 weeks. Because of the baseline differences between groups in VO_2 max, the ANCOVA revealed no significant differences between or within groups in VO_2 max levels at 48 weeks, as shown in Table 19.

Table 21 shows that the percentage of participants who increased cardiorespiratory fitness by at least 3 ml/kg/min at 48 weeks from baseline was higher among Lifestyle participants than Usual Care participants (46% and 33%, respectively) but the difference was not statistically significant ($\chi^2=0.471$, $p>.05$). However, only 41% of the Usual Care participants completed the cycle ergometer test at 48 weeks compared with 76% of the Lifestyle participants.

Blood Chemistry. In the Lifestyle group, ANOVA revealed a significant decrease in LDL-C was observed in the Lifestyle group from baseline to 48 weeks (130.6 ± 5.7 SEM to 119.6 ± 6.1 SEM; p=.0195) (See Table 27). No significant changes between or within groups were observed at 48 weeks for total cholesterol, HDL-C, ratio of total cholesterol to HDL-C, triglycerides, or glucose.

Body Mass Index. As shown in Table 27, the ANOVA revealed a significant increase in BMI occurred in the Lifestyle group from 24 to 48 weeks (37.6 ±1.03 SEM to 38.05 ± 1.03 SEM; p=.0423), but no change was observed from baseline to 48 weeks in the Lifestyle group (p= .4147). In the Usual Care group, a significant increase in BMI was observed from baseline to 48 weeks (34.0 ±1.03 SEM to 34.7 ±1.05 SEM; p=.0307) but the change from 24 to 48 weeks was not significant (p=.0662). The ANCOVA revealed a significant increase in BMI occurred in the Lifestyle group from 24 weeks to 48 weeks (36.1 ± 0.24 SEM to 36.7 ± 0..25 SEM; p=.0254) and a significant increase occurred in the Usual Care group (36.9 ± 0.3 SEM to 37.5 ± 0.3; p=.0431) during the same time period. At 48 weeks, BMI was significantly higher among Usual Care participants than Lifestyle participants (p=.0478)

Blood pressure. There was a significant increase in both systolic and diastolic blood pressure (p=0.0023 and p=.0121, respectively) in the Lifestyle group, from 24 to 48 weeks, but no significant changes occurred in the Usual Care group. The increase in systolic blood pressure in the Lifestyle group at 48 weeks was significantly different from baseline (p=.0017) and significantly different from the Usual Care group at 48 weeks (p=.0486). The increase in diastolic blood pressure in the Lifestyle group at 48 weeks was not significantly different from baseline (p=.5318) but was significantly different from the Usual Care group at 48 weeks (p=.0261).

Diet Composition. Usual Care participants increased the percentage of calories they consumed as fat from 32.5% at baseline (± 1.6% SEM) to 39% at 48 weeks (2.1% SEM; p=.0114) (See Table 28). From baseline to 48 weeks, the percentage of calories from carbohydrate reported by Usual Care participants dropped from 51.1% at baseline (±1.85% SEM) to 41.8% (± 2.4% SEM) at 48 weeks (p=.0015). At 48 weeks, the difference between the Lifestyle and Usual Care group was significant (49.26% and 41.86%, respectively; p=.0371).

Psychological Measures. Mean changes in psychological measures at 48 weeks (from baseline and from 24 weeks) in each intervention group are presented in Table 29. Repeated measures ANOVA revealed no significant improvements occurred in any of the psychological measures from 24 to 48 weeks in either intervention group. In fact, decreases in scores for the processes of change were observed in all but one of the ten processes of change in both intervention groups. In the Lifestyle group, the only process of change that increased from 24 to 48 weeks was Dramatic Relief. All of the decreases in scores from 24 to 48 weeks in the Lifestyle group were nonsignificant except for the decrease in Helping Relationships (-0.58 ± 0.23, $p=0.01$).

In the Usual Care group, the only process of change that increased from 24 to 48 weeks was Environmental Reevaluation and this increase was not statistically significant (0.04 ± 0.17, $p=0.79$). The decreases observed in all of the process change scores from 24 to 48 weeks were nonsignificant, except for the decrease in Consciousness Raising (-0.42 ± 0.16, $p=0.01$).

TABLE 28. Dietary Data From 24 to 48 Weeks by Intervention Group[a,b]

	Lifestyle			*Usual Care*		
	24 Weeks	48 Weeks	P value	24 Weeks	48 Weeks	P value
Total Calories	1990.3 ± 141.7	1787.7 ± 162.9	0.32	2143.4 ± 141.6	1781.8 ± 156.7	0.07
Composition						
% CHO	46.8 ± 2.2	49.2 ± 2.5[b]	0.43	45.7 ± 2.2	41.8 ± 2.4[c]	0.20
% Fat	36.3 ± 1.9	35.4 ± 2.2	0.73	38.3 ± 1.9	39.0 ± 2.12	0.77
Fiber, g	13.4 ± 1.5	11.1 ± 1.7	0.31	10.9 ± 1.5	11.4 ± 1.61	0.83

[a]Least square means ± SEM, based on repeated measures ANOVA.
[b]Significantly different (p<0.05) from Usual Care group
[c] Significantly different (p<0.05) from baseline

TABLE 29. Psychological Data at 24 and 48 Weeks by Intervention Group[a]

	Lifestyle			*Usual Care*		
	24 Weeks	48 Weeks	P value	24 Weeks	48 Weeks	P value
Cognitive Processes*						
Consciousness Raising	2.80 ± 0.15[b]	2.65 ± 0.15	0.35	2.48 ± 0.12	2.05 ± 0.15	0.01
Dramatic Relief	2.29 ± 0.19	2.34 ± 0.20	0.82	1.81 ± 0.19	1.80 ± 0.20	0.97
Self-Reevaluation	3.21 ± 0.14[b]	3.14 ± 0.15[d]	0.72	2.79 ± 0.14	2.61 ± 0.16[b]	0.33
Environmental Reevaluation	2.73 ± 0.17[b]	2.42 ± 0.17	0.07	2.20 ± 0.16	2.24 ± 0.17	0.79
Social Liberation	2.29 ± 0.16[b]	2.19 ± 0.17	0.52	2.01 ± 0.16	1.73 ± 0.17	0.08
Behavioral Processes*						
Counterconditioning	2.48 ± 0.15[b]	2.48 ± 0.16[b]	0.99	2.45 ± 0.15[b]	2.10 ± 0.17	0.08
Stimulus Control	1.96 ± 0.15[b]	1.86 ± 0.16[c]	0.54	1.66 ± 0.14[b]	1.52 ± 0.16[b]	0.43
Reinforcement Management	2.29 ± 0.14[b]	2.29 ± 0.15[c]	0.95	2.37 ± 0.13	2.07 ± 0.15	0.06
Helping Relationships	1.82 ± 0.19[b]	1.23 ± 0.20	0.01	1.70 ± 0.18	1.49 ± 0.20	0.36
Self-Liberation	3.33 ± 0.14[b]	3.25 ± 0.15[b]	0.65	3.09 ± 0.14	2.90 ± 0.15	0.30
Self-Efficacy*	1.67 ± 0.16[b]	1.91 ± 0.17[c]	0.22	1.80 ± 0.15	1.85 ± 0.17	0.80
Decisional Balance*	1.35 ± 0.19	1.66 ± 0.20	0.20	1.50 ± 0.21	1.40 ± 0.20	0.71

[a]Mean ± SEM, based on repeated measures ANOVA
[b]Significantly different from baseline ($p<0.05$)
[c]Significantly different from baseline ($p<0.0001$)
[d]Significantly different from Usual Care group ($p<0.05$)
*Cognitive and behavioral processes measured on separate subscales of the Processes of Change questionnaire; Self-Efficacy measures on the Self-Efficacy/Confidence questionnaire; Decisional Balance is measured by the Decisional Balance questionnaire. See Appendix G for questionnaires and scoring algorithms.

Mean changes in self-efficacy and decisional balance in both intervention groups were not statistically significant from 24 to 48 weeks. However, the change in self-efficacy from baseline to 48 weeks in the Lifestyle group was significant ($p<0.0001$).

Other significant changes from baseline to 48 weeks in psychological measures include the following: increases in Counterconditioning, Reinforcement Management, and Self-Liberation in the Lifestyle group and decreases in Stimulus Control and Self-Reevaluation in the Usual Care Group (see Table 29).

Intervention Adherence and Attrition

According to the adherence criterion determined for this study, 27 of the 29 Lifestyle participants (93%) and four of the 29 Usual Care participants (14%), adhered to intervention requirements and this difference was significant ($\chi^2=36.6$; $p<.001$). Seventeen Usual Care participants returned for follow-up testing, including the four adherents, and the remaining 12 were considered as dropouts. Thus, 93% of Lifestyle participants and 59% of Usual Care participants completed their respective intervention program and this difference was significant ($\chi^2=9.4$; $p<.005$).

Dropouts were surveyed as to why they dropped out (as described in Chapter Two). The two Lifestyle participants provided different reasons for dropping out of the intervention program. One stated she dropped out due to health problems of a close family member and the other dropped out because she was too busy to attend class on a regular basis.

In the Usual Care group, 10 out of the 12 dropout participants returned the questionnaire. Answers to the question "please tell us why you were unable to complete the program" are provided below:

- "I had no support from my spouse, he made it near impossible to find the time to do anything without a demanding 2 year old. Was made to feel selfish, neglectful as a mother."
- "Not much group support"
- "I ruptured a disc in my spine"
- "I had emergency gall bladder surgery."
- "I became very ill, unable to function well"
- "Shortly after I started the program I fell down the stairs damaging the ligaments in my ankle – it took time and energy to heal. Also I had a life-changing situation at home (my husband retired)"
- "I had no time"
- "I didn't have a steady partner"
- "I injured my knee, can hardly walk"
- "My father died before the program ended. I was unable to get the paperwork or testing done."

Answers to the question "what would have helped you to complete the program?" include the following responses:

- "It would've been nice to have a steady partner"
- "More frequent group activities, family oriented, possibly including small children"
- "More companionship – a buddy to motivate and keep you going. Someone to be accountable to. Also, a closer facility."

- "For me a buddy would have helped encourage me when I was overwhelmed with my life situation."
- "More convenient center"

Qualitative Evaluation of the Lifestyle Program

Those who did complete the Lifestyle program were asked to complete an evaluation questionnaire (as described in Methods, p. 127). Eighteen evaluation questionnaires were completed and returned. Answers to the selected questions regarding content, format, and overall opinions of the program are summarized below:

Content. The session topics picked as "most helpful" by more than 50% of respondents included Physical Activity and You (Yes, You!), Breaking Down Barriers, Body Acceptance, and Finding the Time to Be Active. Only one session topic was chosen by more than half of the participants as "least helpful" and that was Enlisting Support.

Eight respondents had suggestions for other topics to be added to the program, including:

- "Help for problems with feet or shin splints"
- "More on body acceptance"
- "How to dress for size on a budget"
- "Psychology of exercise – why it's hard to find the time"
- "More on dealing with the media image of beauty"
- "More on exercise despite having knee or foot pain"

- "Physical changes before, during, and after menopause – how it affects weight and muscle tone"
- "Self-esteem"

Comments regarding the existing content include:

- "Excellent resources were always available. The camaraderie was wonderful!"
- "Covered so many topics; many topics led to great discussion"
- "I really like what was covered"
- "It was a relief not to always talk about our weight or whether we lost weight that week, like in Weight Watchers. I liked the fact that we just talked about physical activity"

Format. Sixteen (88%) respondents felt that 90 minutes was "just right" for session length; two respondents felt it was "too short". The amount of teaching by the instructor was considered "just right" by 83% of respondents and "not enough" by 17%. The amount of discussion for each topic was considered "just right" by 72% of respondents and "not enough" by the remaining 28%.

As for program length, 55% liked the fact that the program was 24 weeks in length (16 weekly sessions, 8 sessions every other week) but others felt the program should either be longer ("every week for a year") or meet weekly for the entire 24 weeks.

Overall Program. All 18 respondents answered the question "what did you like most about the program". Answers were varied but more than half commented on "group support" or "camaraderie" as being the most liked component. Several respondents commented that they liked the focus of the program being on physical activity and not weight loss. Several respondents also stated that having the opportunity to explore new types of physical activity were what they liked most. Other comments include:

- "It stressed the importance of good nutrition and exercise over and over but in a gentle, non-judgmental way"
- "I learned that I can be active now, at my size, I don't have to wait until I lose weight. This class was a real life-saver for me"
- "It helped realize that what is on the scale is less important than being fit and healthy"
- "It was a well-rounded program giving us information, demonstrations, and also allowing us to support each other"
- "You are giving hope to lots of inactive people out there!"

Twelve respondents answered the question "what did you like least about the program". Three respondents stated there was not enough "movement" (e.g., stretching, light calisthenics) within the class period and several commented on the short time spent on certain topics. Other comments include the following:

- "I would like to learn more about the food and nutrition earlier on"
- "It's a long time commitment but something I need to keep me motivated – held accountable"
- "Not enough time to spend on certain topics"
- "I would have liked more discussion on many of the topics"

Twelve respondents (66%) stated that the program did help them to overcome their barriers to physical activity. Four respondents said the program was "somewhat" helpful in overcoming barriers and of those four, three commented that the program length was too short for them to completely overcome their barriers. Two respondents answered no to this question; one stating that "emotional barriers that I have are beyond the scope of this program" and the other stated "I don't like to sweat."

More than half (83%) answered the question "have you made any changes in your life as a result of this program and if so, what kind of changes?" by saying that they are more physically active. Other comments include:

- "I have become more deliberate with my daily activities to increase physical activity"
- "I have never walked a race before and now I have. I realize that 'every little bit counts' so I do more yard work and I don't search for the closest parking spot. I take the stairs rather than elevator, when possible"
- "I may not be more active but I think about it more"
- "Adding different types of exercise, not just the usual types"
- "More conscious about using 'odd moments' to move/exercise, more conscious of lifestyle activities as being exercise"
- "I signed up for a water aerobics class – something I never thought I'd be able to do."
- "For the first time in my life, I was able to hike with my family on our vacation."
- "I walked my first 5k race and went on to walk the Tucson Marathon in December – would never have happened without this class!"

All respondents (100%) stated that they would recommend this program to a friend.

In addition, a follow-up session was held in which participants of the Lifestyle program provided verbal assessment of the program. Most of the comments were recorded by the instructor. When asked the question, "what kept you in the program, i.e., what was it that made you want to complete the program?" participants answered with comments regarding the weekly group support, the fact that weight loss was not the main goal of the program, and that increased fitness was important to health regardless of changes in weight.

Chapter Four

Discussion

The principal finding from this study is that a behaviorally based lifestyle physical activity intervention, developed specifically for this study, was more effective at increasing and maintaining physical activity levels in obese sedentary women than a traditional exercise program. The novel finding in this study is that the lifestyle intervention produced greater program adherence and lower attrition rates than traditional exercise or obesity treatment programs. These and other findings from this study are discussed below.

DEVELOPMENT OF THE INTERVENTION

The primary reason for developing an intervention for obese sedentary women that promoted "lifestyle" physical activity was to provide an alternative to the traditional exercise prescription as a method for increasing physical activity in this population. Dunn et al (52) and Andersen et al (10) have recently demonstrated that the lifestyle approach is an effective means of improving physical activity and cardiorespiratory fitness levels in sedentary individuals. However, these two studies differed from the present study in two important ways. The study by Dunn and colleagues included nonobese men and women and the study by Andersen's research group included obese women participating in a behavioral weight loss program. Thus, the subjects in the study by Dunn et al were a different population than that of the present study and subjects in the study by Andersen et al were attempting to change two behaviors at once (diet and physical activity) to achieve the goal of weight loss. The unique aspect of the present study is that only one behavior was intervened upon (physical activity) with the implicit goal of reducing CVD risk.

One of the primary differences between the Lifestyle and Usual Care interventions was the use of theoretical models for behavior change in the Lifestyle intervention. These models provided a framework for the development of the Lifestyle curriculum and facilitated the understanding of the behavior change process. For instance, incorporating the ten "processes of change" identified by the Stages of Change model into the curriculum was viewed as a method for accelerating participants' progress through the stages of change continuum, thereby increasing the likelihood for exercise adoption and maintenance.

This method appears to have succeeded in moving the majority of Lifestyle participants to the Action or Maintenance stage at 24 weeks, which parallels the increased physical activity and fitness observed in this group. However, 57% of the Usual Care group also were in the Action or

Maintenance stage whereas no change occurred in energy expenditure or fitness in this group. These findings suggest that Usual Care group participants may have overestimated the amount of change they had made in physical activity behavior. Taylor et al (188) reported a similar situation in which participants' self-assessed stage of change for nutrition behavior did not correlate with knowledge gained in a nutrition program. In that study, participants who claimed they were in Action or Maintenance for high fiber intake could not identify foods that were high in fiber.

The ten cognitive and behavioral "processes of change" identified by the Stages of Change model were key components of the Lifestyle intervention. Each process was integrated into the Lifestyle curriculum, as described in Table 11, and the utilization of each process by participants was measured on a subscale of the Processes of Change questionnaire. Both pilot and final study participants improved significantly on almost all of the ten cognitive and behavioral processes whereas the Usual Care group improved their scores on only two of the change processes. These findings confirm those by Dunn et al (53) in Project Active in which subjects who increased their level of physical activity also increased their use of the change processes.

The improvements in the cognitive and behavioral change processes indicate that participants were thinking and behaving differently in relation to physical activity as a result of the intervention. For instance, both pilot and final study participants significantly improved their scores on Consciousness Raising. Statements on the Processes of Change questionnaire that assessed this process include, "I think about information from articles and advertisements on how to make exercise a regular part of my life" and "I look for information related to exercise or physical activity". Improvements in this measure indicate that participants were thinking and looking for information on physical activity more often than they did before the intervention.

An example of how Lifestyle participants were behaving differently as a result of the intervention is demonstrated by significant changes in Reinforcement Management, a behavioral change process included in the development of the Lifestyle intervention. Lifestyle participants were encouraged to reward themselves if they engaged in physical activity and to think of physical activity as a way of taking good care of one's health. Statements on the subscale of the Processes of Change questionnaire for Reinforcement Management include "when I am physically active, I tell myself that I am being good to myself by taking care of my body" and "I do something nice for myself for making efforts to be more physically active." Lifestyle participants significantly improved their scores on this change process whereas Usual Care participants did not.

Despite the significant improvements in scores of the change processes in the Lifestyle group, they were not predictive of improvements in cardiorespiratory fitness, according to the logistic regression analyses. This analysis attempted to determine if significantly increased scores on any of the 10 subscales of the Processes of Change questionnaire at 24 weeks predicted improvements in cardiorespiratory fitness by at least 3 ml/kg/min at 24 weeks. However, the odds ratios obtained from this analysis were not significantly different from 1.0, indicating that improved scores on the subscales did not predict change in fitness. Although this was an unexpected finding, there are several potential explanations.

First, participants who improved their scores on the subscales may have also improved their fitness level but the improvement was less than 3 ml/kg/min. Second, because of genetic influences on cardiorespiratory fitness, some individuals may have increased the amount of physical activity they engaged in but did not achieve a significant change in their fitness level. According to Leon (118), cardiorespiratory fitness is influenced as much by genetic factors as physical activity and should not be viewed as a surrogate measure of habitual physical activity. In the MRFIT trial, total quantity of leisure time physical activity (LTPA) and high intensity LTPA accounted for only 17% and 19%, respectively, of the variability in exercise test performance (121). Hence, the lack of predictive power of the process change scores does not necessarily mean that those individuals who utilized the change processes did not improve their activity levels.

The Lifestyle intervention was also designed to increase self-efficacy for physical activity. The significant improvement in self-efficacy in both pilot and final study participants suggest that the Lifestyle intervention was successful in changing their perceptions about being physically active, particularly in challenging situations, such as poor weather or when feeling tired. The questionnaire for measuring self-efficacy related to physical activity includes statements about being confident one can be physically active when one is tired, in a "bad mood", on vacation, etc. Improvements in scores of self-efficacy therefore indicate participants are more confident in their ability to be active during these situations. These findings also underscore the importance of discussing barriers to physical activity and problem-solving with participants on how to overcome these barriers as a method for increasing self-efficacy.

The positive correlation between self-efficacy and energy expenditure in the Lifestyle group but not between self-efficacy and cardiorespiratory fitness is similar to findings from other studies. McAuley et al (135) reported participation in a physical activity program was significantly associated with improvements in self-efficacy scores in older adults whereas improvements in fitness were not. Because self-efficacy did not increase in the Usual Care group, these findings support the contention by King (101) that self-efficacy is potentially mediated by other variables, such as group support.

The significant improvements in self-efficacy at 24 weeks but not at 48 weeks among Lifestyle participants is also similar to findings in other studies. Oman and King (152) reported self-efficacy was a significant predictor of exercise adoption but not of exercise maintenance. These findings underscore the importance of cognitive processes in the beginning stages of changing sedentary behavior and suggest that they may be less important when exercise becomes more habitual. Conversely, the role of self-efficacy in changing sedentary behavior is perhaps most important when the intervention is terminated and participants are left to rely heavily upon their own cognitive strategies to sustain a higher level of activity.

The environmental differences between the two interventions may have influenced the difference in self-efficacy outcomes between the two groups. In the Lifestyle group, participants met weekly in a room with no mirrors and sat around a table facing each other. During the stretching exercises, participants stood in a circle facing each other. During the field trips, participants had the opportunity of observing each other attempt new activities, such as water aerobics or bicycling. In the Usual Care group, participants attended educational classes in a room with chairs facing the instructor, as is customary in a health club setting, and exercise sessions were performed individually, in a room with mirrored walls amidst other gym members who were mostly smaller in body size and shape.

Several authors contend that these types of environmental factors can impact self-efficacy as well as other psychological variables that influence exercise adoption and this is particularly true in women (137, 139, 200). Katula et al (96) compared the effects of three exercise conditions on self-efficacy in men and women. The conditions included standard laboratory exercise, exercising in front of a full-length mirror, and exercising in a location of the participant's choice. Results revealed the women's self-efficacy was significantly lower than the men's only in the mirrored condition; no differences between the sexes were observed in the other conditions. Moreover, fitness level and "physique anxiety" were significant predictors of exercise self-efficacy in the mirrored condition but not in the laboratory or natural environment conditions.

Intervention Adherence and Attrition

As stated earlier, one of the principal findings of this study was the low attrition rate among Lifestyle participants. Dropout rates in traditional exercise and weight management programs are typically high and degree of overweight is one of the most consistent predictors of attrition from exercise programs (49). Gwinup (79) reported a 68% dropout rate in a year-long program for obese women that required only walking.

In the present study, it is likely that a combination of factors played a role in keeping participants from dropping out of the Lifestyle intervention. The qualitative data indicate that the weekly group interaction with participants of similar backgrounds and goals was important as well as having an opportunity to try new types of physical activity that otherwise might not have been attempted. As discussed earlier, environmental factors, such as non-mirrored rooms and sitting at a table facing one another, may have produced an atmosphere that was more comfortable and less intimidating than traditional exercise settings.

The problem-solving approach to overcoming barriers to physical activity versus an education-only approach may have also affected adherence. Participants were encouraged to discuss their barriers in class and to generate possible solutions to these barriers. Each week they would report on the success of those solutions and have the opportunity to get feedback from the instructor and hear the progress made by others as well. This type of format may have fostered a feeling of camaraderie, which was mentioned by several participants in the evaluation questionnaire completed at the end of the intervention.

It is also highly possible that this type of approach facilitated a change in attitude toward exercise. Several studies have shown that attitudes and beliefs about exercise and health are primary factors influencing exercise adherence (2, 181, 185). Moreover, interventions that are sensitive to the needs of the target population may facilitate a change in attitude toward exercise, thereby improving adherence. Kennedy et al (99) demonstrated that attitudes toward exercise in sedentary Mexican-American women were improved by designing an exercise program that addressed language and cultural barriers in this population. In that study, a nine-month, bi-weekly exercise program was held in a predominantly Hispanic church social center, using ethnic music and a Hispanic middle-aged, bilingual, certified exercise instructor. At completion, attitudes toward exercise were significantly improved in the experimental group and attendance was found to be 84%.

Based on the qualitative assessment, one of the primary reasons for the low attrition rate was the focus on physical activity and not weight loss. Many of the women spoke of their experiences in traditional weight management programs, such as Weight Watchers or Slim for Life, as being initially positive, then turning negative when the weight they had lost returned. Many participants also commented, both verbally and on paper, about their desire to be physically active but that they believed weight loss needed to happen first. The concept of being active at their current weight was, according to many of them, a new concept and one that helped them to increase their activity level.

INTERVENTION EFFECTS

Physical Activity and Cardiorespiratory Fitness

As hypothesized, levels of physical activity and cardiorespiratory fitness were significantly higher in the Lifestyle group at the end of the 24-week intervention period than at baseline. This finding is similar to the findings of Project Active, in which a behaviorally based lifestyle physical activity intervention produced significant increases in physical activity and cardiorespiratory fitness in previously sedentary adults (52). This finding is also similar to the study by Andersen and colleagues (10) in which a lifestyle physical activity program increased activity and fitness levels in obese women participating in a weight loss program.

However, unlike Project Active and the study by Andersen and colleagues, the Usual Care or "structured exercise" program in this study did not produce improvements in activity or fitness levels. This finding supports the concepts of King (101) and others (163, 164), that behaviorally based interventions are more likely to promote physical activity in sedentary individuals than traditional exercise programs.

There are several possible reasons for the increased physical activity among Lifestyle participants. As discussed earlier, the emphasis on behavioral skill building within the Lifestyle intervention is a plausible explanation. Participants learned to used cognitive and behavioral strategies to overcome their barriers to physical activity. Cognitive restructuring, asking for support, and improving time management were just a few of the strategies employed within the Lifestyle intervention that were not a part of the Usual Care program. Although the Usual Care program provided education on exercise, the lack of a behavioral focus may have contributed to the lack of behavior change.

There are several other potential reasons for the increased levels of physical activity in the Lifestyle group. The Lifestyle program promoted the integration of a wide variety of moderate-intensity activities into one's daily routine, such as that recommended by the CDC, ACSM, NIH, and the surgeon general (149, 157, 192). As stated earlier, this approach is likely to be more appealing to sedentary individuals whose barriers to physical activity may include lack of time or dislike of vigorous exercise (51). The exercise prescription and six-month health club membership provided to Usual Care participants might not have been as appealing or as convenient.

Another potential reason for the increased levels of physical activity among Lifestyle participants is the ongoing group support provided in the weekly meetings. Hayaki and Brownell (82) have proposed that the integration into a social network and having positive interactions with others facilitates the behavior change process. Group support can also increase self-efficacy, improve mood, and have other effects that would enhance adherence to a behavior change program (82). However, the significant improvements in measures of the cognitive and behavioral processes that occurred among Lifestyle participants suggest that it was not merely the group support that elicited improvements in activity levels.

Also as hypothesized, physical activity levels in Lifestyle participants were significantly higher six months post-intervention (48 weeks) than at baseline and significantly higher than the activity levels of the Usual Care group at 48 weeks. This is perhaps the most important finding of this study considering the reported difficulties in exercise adherence among the obese (48). It is possible that the cognitive and behavioral skills learned by Lifestyle participants during the intervention phase facilitated the maintenance of physical activity post-intervention. The fact that there was virtually no change in the behavioral and cognitive process change scores from 24 to 48 weeks parallels the changes in energy expenditure: both increased during the intervention and plateaued during the follow-up phase. To achieve further increases in physical activity, the Lifestyle intervention may need to be longer, or perhaps, ongoing.

It is important to note that the increases in physical activity among the Lifestyle participants during the intervention phase were small: the mean change in energy expenditure over the 24 weeks was 1 kcal/kg per day. However, cardiorespiratory fitness improved by at least 3 ml/kg/min in 56% of Lifestyle participants indicating that the majority of Lifestyle participants did increase their activity to a level sufficient to improve fitness. Secondly, the energy expenditure data includes only the activities engaged in over the previous week. Thus, it is possible that Lifestyle participants were not as active, on average, during the week the interviews were conducted and/or their activity levels were beginning to taper off after the initial increase from baseline. Lastly, this level of increase in energy expenditure is similar to the increase observed in Project Active's Lifestyle group (1.53 kcal/kg/day).

It might also appear that the number of Lifestyle participants who reached the intervention goal of increasing energy expenditure by 2 kcals/kg/day at 24 weeks and 48 weeks (5 out of 26 or 19%; 6 out of 23 or 23%, respectively) was too small for practical significance. However, if viewed within a public health context, approximately one-fifth of initially sedentary obese women in this study were meeting or exceeding public health recommendations for physical activity at 24 and 48 weeks. If this same rate of improvement were applied to the general public, the impact on public health could be quite significant. Moreover, these findings are similar to Project Active in which 20% of Lifestyle participants in that study increased energy expenditure by at least 2 kcal/kg/day at 24 weeks.

Cardiorespiratory fitness levels were also significantly higher at 24 and 48 weeks in the Lifestyle group than at baseline, measured as ml/kg/min or L/min. These results are comparable to those by King et al (103) in which individuals assigned to a home-based physical activity program significantly increased activity and fitness levels that remained significantly higher at 24 months compared with baseline.

However, because of baseline differences between the Lifestyle and Usual Care groups in fitness, the adjusted analysis revealed no significant differences in fitness between groups at 24 and 48 weeks. This finding suggests that if the two groups were similar in fitness levels at baseline, their fitness levels at 24 weeks would not be significantly different. It also presents the question of whether the Usual Care group may have also improved the same amount as the Lifestyle group had they both started at the same point, in terms of fitness level. Viewed separately, it is correct to say that the Lifestyle group did achieve significant improvements in cardiorespiratory fitness but when the results of both groups are viewed together, fitness levels were not significantly different between groups at 24 or 48 weeks. As discussed earlier, the lack of a change in fitness does not necessarily mean that activity levels did not increase as other factors affect cardiorespiratory fitness levels, but it does suggest that the fitness change in Lifestyle participants was relatively small.

Cardiorespiratory levels did not change in the Usual Care group after 24 weeks of intervention nor did they change during the post-intervention period. This finding validates the lack of change in energy expenditure also observed in Usual Care participants. As stated earlier, the lack of a behavioral component to the Usual Care program most likely played a major role in the lack of a change in fitness. It is also possible that the exercise prescription provided to Usual Care participants was not appealing or was perhaps perceived as too difficult. In addition, the lack of group support is likely to be a major contributing factor as several of the dropout participants mentioned this as a primary reason for dropping out.

Body Mass Index

In the Lifestyle group, there was a significant decrease from baseline to 24 weeks in BMI followed by a subsequent increase to pre-intervention levels at 48 weeks. The reduction in BMI at 24 weeks was small (- 0.6 kg/m^2) but comparable to that found in other studies of exercise alone (versus exercise with low energy diet) in the treatment of obesity. The NHLBI task force of the Obesity Education Initiative (OEI)(148), discussed in Chapter 1, reviewed 12 RCT articles that examined the effects of physical activity on weight loss (without diet restriction) compared to controls. In ten of the 12 RCTs reviewed, the mean reduction in BMI was 0.7 kg/m^2 (approximately 2.4 kg)(148).

As discussed above, BMI levels were significantly different between groups at baseline. However, after adjusting for these differences, the mean BMI in the Usual Care group was higher than that of Lifestyle participants at 24 weeks with the difference being almost statistically significant ($p=0.05$). BMI levels increased in both groups from 24 to 48 weeks but the increase in the Usual Care group was significantly greater than that of the Lifestyle group. These findings suggest that although the Lifestyle group regained some of the weight they had lost during the intervention, they did not gain as much as the Usual Care group.

A point of consideration is that, despite randomization, the two groups were not homogeneous for fitness or BMI at baseline. Baseline fitness levels in the Usual Care group (28.1 mL/kg/min ± 1.0 SEM) would be considered as "below average" for women aged 40 – 49 by ACSM standards (69) whereas baseline fitness levels in the Lifestyle participants (23.3 ml/kg/min ±0.9 SEM) would be considered as "well below average" by ACSM. Likewise, the mean BMI at baseline for Usual Care participants (34.0 ± 1.0 SEM) would be classified by the OEI task force as Class 1 obesity whereas the mean BMI at baseline for Lifestyle participants (38.1 kg/m² ± 1.0 SEM) would be considered as Class 2 obesity (148). Gliner and Morgan (74) note that randomization is unlikely to provide equivalent groups with small samples, thus, a larger sample size might have provided more homogeneity on these measures. Thus, although all participants were obese and sedentary at baseline, the changes in fitness and BMI might need to be reviewed with caution.

Another point of consideration is whether the small reduction in BMI among Lifestyle participants at 24 weeks is clinically relevant. The OEI report recommends a reduction in body weight of approximately 10 percent from baseline to improve health outcomes (148). However, it should be remembered that weight loss was not the primary goal of the Lifestyle intervention. Rather, the primary goal was to increase activity and fitness levels. The amount of activity required of Lifestyle participants (30 minutes of moderate-intensity activity on most days of the week), while enough to lower CVD risk, is probably not enough to produce a large weight loss.

Conversely, the fact that Lifestyle participants did not *gain* weight during the intervention is equally as relevant considering there was no caloric restriction in the Lifestyle intervention. Many physicians and/or health care professionals may be reluctant to recommend an intervention for obese women that does not aim for weight loss, fearing that weight gain may occur. The results of this study suggest that this may not be the case.

Blood Lipids and Blood Pressure

The lack of significant change in blood lipids (total cholesterol, HDL-C, LDL-C, ratio of total cholesterol to HDL-C, and triglycerides) during the intervention phase in either treatment group is not surprising. The ACSM expert panel review (32) concluded that increased physical activity rarely produces improvements in HDL-C or triglycerides in obese individuals without a weight loss of at least 4.5 kg. Moreover, the evidence for improvements in blood lipids or lipoproteins from exercise-induced weight loss has come from studies in obese men – the evidence for obese women is considered weak (183).

A significant reduction in LDL-C did occur in the Lifestyle group from baseline to 48 weeks ($p=0.0195$) and although the dietary analysis showed no differences in fat intake as a percentage of total calories, saturated fat intake may have decreased. These findings are similar to those of Blair and colleagues who noted a reduction in saturated fat intake among clients classified as "continuers" in their exercise regime.

Andersen and colleagues (10) reported significant reductions in serum triglycerides and total cholesterol levels at week 16 in obese women randomized to either diet plus aerobic exercise or diet plus lifestyle activity. The diet in both groups was similar to that recommended by the American Heart Association guidelines for healthy weight reduction (1200 calories and < 30% fat)(59). Not surprisingly, both groups lost weight (8.3 kg and 7.9 kg, respectively, week 16) and maximal oxygen consumption improved significantly in both groups as well.

At week 68, the aerobic group regained 1.6 kg and the lifestyle group regained 0.08 kg and VO_2max continued to improve over time in the lifestyle group (19.9 to 22.6 to 22.4 mL/kg/min, aerobic group;19.4 to 21.5 to 24.6 mL/kg/min, lifestyle group;). Yet, from weeks 16 to 68, total cholesterol returned to near pre-intervention levels in both groups (184 mg/dl to 202 mg/dl, aerobic group; 186 to 201 mg/dl, lifestyle group), suggesting that blood cholesterol levels are only initially affected by weight loss or that dietary compliance deteriorated without being reported.

In Project Active, significant reductions in cholesterol levels occurred in both lifestyle and structured exercise groups after 24 weeks of intervention (-7.7 and 11.7 mg/dl, respectively) but reductions were not significant at 24 months (52). Weight loss followed the same pattern: small but significant losses of 0.6 and 1.3 kg in lifestyle and structured group, respectively, at 24 weeks, with no significant differences from baseline to 24 months in either group. However, there were significant reductions in the percentage of body fat at 24 weeks and again at 24 months in both groups. LDL-C also decreased significantly at 24 months (p=0.001) in the Structured group, despite no direct intervention on diet. These findings suggest reductions in LDL-C and total cholesterol may be due to the change in body composition or that intake of saturated fat was reduced, or both. For the present study, without the waist circumference data in the final study subjects, we are unable to make the same conclusion.

As for blood pressure, the reduction in diastolic blood pressure that occurred in the Lifestyle group during the intervention phase (85.0 mm Hg to 80.2 mm Hg, p=0.0413) is presumably a result of increased levels of physical activity and fitness that occurred during the intervention period versus a result of the weight loss. Aerobic training reduces blood pressure in both men and women and according to the ACSM expert panel review, this reduction is independent of changes in weight (61, 78). By week 48, diastolic blood pressure had returned to baseline levels. A potential reason for this latter increase is that physical activity levels may have been declining during the post-intervention period, despite what was reported during the 7 Day PAR interviews, and body weight was increasing back to baseline levels. Thus, the combination of the two events drove diastolic blood pressure back to pre-intervention levels.

An unexpected finding, however, was the increase in systolic blood pressure (133.75 mm Hg to 143.33 mm Hg) from baseline to 48 weeks in the Lifestyle group. Measurement compliance had dropped to 76% at that point which may have effected the statistical mean for the group. Also, blood pressure readings were obtained by health care professionals in a clinical setting (General Care Medical Clinic in Ft. Collins) and although they were adequately trained to measure blood pressure, because of time constraints, they were not able to take three readings as is customary in a research setting.

It is also possible that dietary changes could have influenced the increased systolic blood pressure. Because the food diary analysis was limited to calories and percentage of calories from carbohydrate and fat, it is difficult to know if dietary changes, such as changes in sodium intake, may have occurred during this time. A review by Kelly and Goodpaster (98) found that diet has a more powerful effect on blood pressure than exercise.

A point of consideration is the time of year in which the 48-week assessments were taken: December. Blood pressure, blood lipids, and body weight were all measured within one week of Christmas (the week before and the week after). Physical activity levels are known to be lowest in December (37) and it is possible that the increase in blood pressure in the Lifestyle group is a reflection of lower activity levels in the weeks prior to these assessments. Blood pressure remained relatively constant in the Usual Care group from baseline to 48 weeks as did physical activity and fitness levels.

Energy Intake and Diet Composition

The lack of a change in energy intake and diet composition in Lifestyle participants (based on 3-day food record analysis) is not surprising considering diet was not intervened upon directly. However, the reduction BMI at 24 weeks suggests calorie intake may have been reduced during that period as well. Although there was no difference in percent of calories from fat among Lifestyle participants at 24 or 48 weeks, the reduction in LDL-C at 48 weeks suggests a reduction in saturated fat may have occurred (59).

The significant increase in the percentage of calories from fat and significant decrease in the percentage of calories from carbohydrate in the Usual Care group is of interest considering both groups were provided nutrition information based on the Food Guide Pyramid as well as general guidelines for fat reduction. In addition, the cooking class offered to both groups included "heart healthy" nutrition information, such as reducing saturated fat and increasing fiber.

It is possible that the extreme popularity of various fad diets that occurred during the 24 week intervention period, such as The Zone, Sugar

Busters and Dr. Atkins' New Diet Revolution, all of which advocate a low carbohydrate diet, may have influenced the dietary practices of Usual Care participants. Because of the frequent contact with the author of this study, Lifestyle participants had more opportunities to ask about the effectiveness of these diets. Indeed, several discussions did transpire in response to questions from Lifestyle participants about the efficacy of these diets in promoting weight loss. Lifestyle participants were discouraged from following any restrictive diet during the time frame of this study and were encouraged to refer to the nutritional guidelines given to them during this study.

Because the food records were only three days in length and because the data was self-reported, it is difficult to conclude what changes, if any, occurred in either group. Obese women have been shown to under-report food intake (122). Future studies should perhaps lengthen the diet record to four or seven days and possibly include a food frequency questionnaire to better assess changes in energy intake and/or diet composition.

LIMITATIONS

There are several limitations of this study. First, the lack of a "no contact" control group may limit the strength of the findings as we do not know if a change in any of the outcome measures, such as energy expenditure, may have occurred without the intervention. However, the abundance of data demonstrating the sedentary behavior among most adults, particularly obese adults, suggests that it is unlikely that any changes would have been made.

Second, the participants in this study may have been more motivated to change than others who did not volunteer for participation. To participate in this study, one had to answer a newspaper advertisement or email announcement, attend informational meetings, and make a 48-week time commitment to the study. To take those steps, one would have to be at least somewhat motivated to change behavior or they would not have initiated contact and volunteered to participate in the study. In addition, participants in the Lifestyle group may have been more motivated to change because of the frequent contact with the author of this study and because they knew that it was a doctoral research study.

The location of the fitness center was a limiting factor during recruitment. Potential participants were told at the information meetings that both groups were expected to attend classes at Miramont Sport Center (located in the southeast part of Ft. Collins) and that one group would receive a free six-month membership to this facility. Two women who attended the meetings informed the investigator that they would not volunteer for participation because of the distance between their homes and this facility.

Other limitations are related to data collection. For instance, blood pressure and waist circumference were measured in a clinical setting instead of a research setting. Although the health care professionals at the medical clinic where these measurements were taken are well-trained in the technique of measuring blood pressure, they could not afford the time of taking three separate measurements with 5-10 minutes between each measurement, as would be the case in a research setting. In addition, they were not experienced in the technique of measuring waist circumference and because of time-constraints of the physician-assistant, they were not trained on the proper technique of measuring waist circumference.

Other limitations include the small sample size and, as stated earlier, the self-report nature of some of the data collection (energy intake and expenditure). Subjects may not have been accurate in their recording of food intake and/or reporting of activity levels. Recall questionnaires are limited by their reliance on the subject's memory but this was lessened by reminding participants that they would be interviewed and asking them to have their personal calendar close by during the interview to help them recall their activities over the previous week.

Another limitation is not knowing how much activity the Lifestyle participants engaged in during the two 24 week periods. Although both groups were encouraged to keep physical activity diaries, they were not required to do so. The majority of subjects in the pilot study said that they dislike recording exercise information and probably would not be consistent in doing so. Nevertheless, activity diaries would have provided useful information as to the frequency, duration, and intensity of activity among participants in both intervention groups.

A limitation to all intervention studies also applies to this one: it is not possible to determine which elements of the intervention were the most influential on outcome measures. There were a number of factors that could have contributed to the changes in energy expenditure and BMI among Lifestyle participants and the design of this study does not allow the investigator to determine which of these factors were the most influential.

CONCLUSION

Cardiovascular disease continues to claim the lives of thousands of Americans each year. Mounting evidence has demonstrated a strong, inverse relation between all-cause or CVD mortality and physical activity and fitness in both lean and obese individuals. Evidence from several randomized clinical trials has indicated that increased physical activity and fitness in obese individuals attenuates the comorbidities associated with obesity. Yet the majority of obese individuals remain sedentary and it is this segment of the population that has the most to gain in disease prevention through even modest increases in physical activity.

To that end, the primary aim of the present study was to develop a theory-based intervention that produced significant increases in energy expenditure and cardiorespiratory fitness levels in obese sedentary women. Using theoretical models for behavior change, this intervention aimed to help obese women become more physically active through the integration of shorter, more frequent bouts of activity over the course of a day and a focus on small, but sustainable, changes in sedentary behavior.

The results of this study suggest that the intervention was successful in achieving this goal. The intervention also produced positive changes in self-efficacy and body mass index. Perhaps most importantly, the intervention maintained a low attrition rate and it is notable that the majority of Lifestyle participants are continuing to meet on a regular basis.

However, the results of this study also demonstrate the challenges of attempting to change a complex human behavior such as physical inactivity. Although activity and fitness levels increased in the Lifestyle group, the changes were small and without further intervention, it is questionable whether these changes can be sustained past one year. The current environment in which we live requires such small amounts of energy expenditure that one must seek and create opportunities for physical activity and have the motivation for doing so. For obese sedentary women, this may be particularly difficult and without ongoing support and education, is not likely to happen. It is hoped that the cognitive and behavioral strategies for behavior change that participants learned during the intervention will better prepare them for living in a sedentary society and enable them to self-direct their efforts toward a physically active lifestyle.

RECOMMENDATIONS FOR FUTURE RESEARCH

1. Long-term studies are needed to determine if lifestyle physical activity interventions are successful in helping sedentary individuals sustain higher levels of physical activity and fitness for five or more years after completion of the intervention.

2. Research is needed to determine if ongoing support will help obese women sustain increased activity and fitness levels past one year. If so, how should that support be delivered - by monthly meetings, newsletters, group activities, the Internet, etc.

3. A better understanding of the factors associated with physical inactivity in obese women is needed. What are the determinants and antecedents for changing sedentary behavior in this population and how are they best addressed in group intervention programs? How are they best addressed by health professionals in clinical settings?

4. The dose-response data on CVD risk reduction in obese individuals needs to be further defined, e.g., how much activity is needed for CVD risk reduction in obese individuals and how does BMI and fat distribution affect this relationship.

5. Traditional behavioral weight management programs are successful in producing modest amounts of weight loss but the long-term success rates of these programs is generally poor. A comparison study is needed to determine which type of intervention best improves health outcomes (such as blood pressure, blood lipids, glucose tolerance) in obese individuals over time: a weight management program that focuses on weight loss (exercise and diet are a means to an end) or a lifestyle physical activity program that focuses on increased activity and fitness levels and improvements in diet composition (exercise and diet change are the "end" goal).

6. Research is needed to examine the relationship between body image and physical activity in obese women. Studies have shown body image to play a significant role in self-esteem in women and self-esteem may be a mediator of self-efficacy. In the present study, embarrassment and shame about one's body size was mentioned by several women as a primary barrier to being physically active and "Body Acceptance" was

rated as one of the most liked sessions. Thus, studies are needed to examine this relationship and determine whether improvements in body image are associated with increases in physical activity.

7. For women with children, studies are needed to determine if a family-based lifestyle activity intervention is more effective at increasing physical activity in obese women than one that is designed for just women by themselves?

8. Are lifestyle physical activity interventions effective at increasing physical activity and fitness levels in minority populations, such as African-American and Hispanic populations? Should they also be designed for individuals or for families?

9. Better methods are needed for assessing moderate-intensity activities, especially in women. A validated interview script is needed that specifically addresses home- and child-care activities for activity recall interviews.

10. More research is needed about the processes of behavior change among obese women. Ten cognitive and behavioral processes have been identified that promote movement along the stage of change continuum but it is possible that there are other processes involved in behavior change among specific population groups, such as obese women.

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APPENDICES

Appendix A

Examples of Lifestyle Curriculum Handouts

Physical Activity and You
(Yes, You!)

Session Two

It's Your Turn to Play

What comes to mind when you hear the word "exercise"? Fun and pleasure? Sweat and pain? Chances are you have negative thoughts about exercise. This isn't too surprising given the rigidity of the old fitness rules: no pain, no gain. As we mentioned last week, experts used to tell people to get those heart rates up *and keep them up* or it won't do you any good. The fitness industry didn't help matters any by using only stick-thin muscle-bound women in their advertisements. It's no wonder less than half of American women are physically active on a regular basis!

The good news is that physical activity is for *everyone*, regardless of their weight, size, or shape. As discussed last week, being active on a regular basis does a lot of good things for your body and these things happen whether you weigh 90 pounds or 300 pounds. The important thing to remember is that you don't have to be thin to be active. *You can do this now.*

In the book *Great Shape: The First Fitness Guide for Large Women* (Bull Publishing, 1990), co-author Pat Lyons states,

"Physically active large women have found that we can be fat *and* fit. We don't have to wait for a size 7 body to have efficient hearts, capable and graceful bodies, and good feelings about our physical selves. Many of us have reversed our collective 'couch potato' self-images. We've discovered that our bodies, like all human bodies, hunger to move; our muscles, too, itch to be used; our spirits yearn to play."

Taking Stock

Before lacing up those aerobic shoes, it's important to do a little mental inventory. According to Drs. James Prochaska, John Norcrosse, & Carlo DiClemente, authors of *Changing For Good* (Avon Books, 1994), there are three tasks that need to be done before trying to make a significant change to your lifestyle:

1. Assess your way of thinking

2. Make a decision

3. Determine your barriers

❖ Assess Your Way of Thinking

The way you think about change will affect whether you will actually change or not. For instance, are you "waiting for the magic moment"? Some people have an almost mystical belief that someday, somehow, a magic moment will occur that will be absolutely perfect for change to happen. Some people believe they will change "when the time is right". But when will the time be right? "When things slow down", they often reply. But, as we all know, *things never slow down*.

Or, are you a "wishful thinker"? Wishful thinking means that you want to have your cake and eat it too, to go on living as you always have, but with different outcomes. A few examples of wishful thinking:

"I wish I could eat whatever I want and not gain weight."
"I wish I could have great muscle tone without having to exercise."
"I wish I could play tennis without taking a lesson."

Wishing for change is easier than working toward it. Wishful thinking is passive; it implies a magic wand will somehow make things happen. Hope, on the other hand, is *active and realistic*. Having hope means that you can envision your success and work toward achieving your goals.

Wishful thinkers also believe change will occur overnight. The reality is that change is a *process*; a process that contains several stages. These stages have been labeled:

Precontemplation – People in this stage don't believe they need to change and/or they have no desire to change.

Contemplation – Contemplators believe that they need to change but haven't thought too much about how they will make the change and have made no effort to change. They see themselves as *possibly* making a change, some time within the next six months.

Preparation – People in the Preparation stage have taken a few steps toward changing. For instance, they may buy a pair of walking shoes or sign up for a tennis lesson. They generally believe that they will make the change within the next thirty days.

Action – People in the Action stage have not only taken a few steps but have been consistent and regular at accumulating 30 minutes, or more, of moderate physical activity on most days of the week. Their charge is to find ways to *continue* being regularly active for more than just a few months – hopefully, for a lifetime.

Maintenance – "Maintainers" are those people who have been physically active on a regular basis for at least six months. These people have made physical activity an important part of their lives. This doesn't mean that they are obsessed with exercise, it just means that they consider physical activity to be a high priority and have found ways to incorporate physical activity into their daily or weekly schedule. The goal of On The Move! is to help you reach the Maintenance stage.

Studies show that most people cycle through the different stages of change several times before permanently changing the behavior they set out to change. It is important to realize that change is a process, not an "all or nothing" event.

Pat Lyons and Debby Burgard, authors of *Great Shape: The First Fitness Guide for Large Women,* also suggest casting out the idea that being physically active is an "either/or" situation and believing that "there are hundreds of baby steps involved in any lasting change." They suggest drawing a continuum for yourself, such as the one below, which lists specific *behaviors* that you could undertake to reach your goal of being physically active on a regular basis.

Mary Meditator — Martha Marathoner

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

1. Throwing away the TV remote control and getting up to change channels.
2. Walking around the house at each half-hour break between TV programs.
3. Walking across the street to visit a neighbor instead of calling on the telephone. Enlist her support in your effort to be more active.
4. Parking your car at the far end of the grocery store parking lot.
5. Getting off the bus three blocks from your stop and walking the extra distance.
6. Going for a 15 minute walk before or after supper twice a week.
7. Doing stretching exercises for your back 15 minutes a day.
8. Doing We Dance exercises once a week at home.
9. Expanding your walks to include a hike with a friend.
10. Joining a martial arts, belly dancing, or yoga class.
11. Alternating walking and jogging on your outings.
12. Entering a local walk-a-thon for a good cause.
13. Taking your daughter on weekend hikes.
14. Training for a 5- or 10-kilometer race months in advance.
15. Finishing the 5- or 10-kilometer race with a smile on your face.

❖Make a Decision

So, you know you want the benefits of exercise – looking and feeling fit – but you realize that these benefits won't "just happen" on their own. You will need to make a decision as to whether you want to put the effort into *making things happen*. The Decisional Balance Scale was developed to help you make this important decision. This scale helps you evaluate the pros and cons of making a behavior change and incorporates the following four basic categories:

- ❖ Consequences of change to self
- ❖ Consequences of change to others
- ❖ Reactions of self as a result of change
- ❖ Reactions of others as a result of change

Case Study

Betty is a successful real estate agent. She just turned 45 and is happy with her career. However, she is unhappy with her body; she feels "fat" and lethargic. She has gained 40 pounds in the last two years. Betty has tried several diets over the last few years, losing an average of 10 pounds each time she dieted, but subsequently gained all the weight back within three months of each dieting attempt. She just heard about a new diet that promises to keep weight off forever but the diet has to be followed very closely. Betty is considering going on this diet as a "last ditch effort" to lose weight.

Betty decides to try a Decisional Balance Scale to help her decide if she wants to try this new diet. She makes a list of all the pros and cons of dieting and then considers the consequences to herself and to others if she were to try this new diet.

Next, she thinks about what reaction she would have toward herself if she dieted or if she didn't diet, and what reactions others around her would have if she dieted or didn't diet. After reviewing her completed scale, she found that she had listed more cons than pros; trying this new diet may not be such a good idea afterall!

Betty would also like to be more physically fit so she decides to complete a scale using just increased exercise or activity as her goal. Again, she makes a list of the pros and cons of increased exercise and considers the consequences to herself and to others if she were to increase her physical activity level. This proved to be the better choice.

Betty's First Decisional Balance Scale

	Pros of Dieting	Cons of Dieting
Consequences to self	Vanity will be satisfied.	Losing and gaining weight endangers my health. New diet is costly. I can't last forever. I'll be hungry all of the time.
Consequences to others		Can't eat out with others. I will be crabby.
Reactions of self	I'll be in control	I'll be embarrassed if I fail. I'm not sure my weight is a health problem. I'll feel like a slave to the fashion media.
Reactions of others	Children won't be embarrassed	Family loves me the way I am. Husband isn't willing to diet with me.

Betty's Second Decisional Balance Scale

	Pros of Physical Activity	Cons of Physical Activity
Consequences to Self	More energy Better muscle tone Learn to play tennis Keep up with kids Make new friends See new places Prevent heart disease Prevent cancer Prevent osteoporosis Relieve stress More productive at work	Takes time Health club is costly Need new clothes and shoes Embarrassment Re-structure work schedule
Consequences to Others	Set good example for kids Be around for grand-kids More family activities to do More business for company	Change in family scheduling
Reactions of Self	Increased self-esteem Feeling of accomplishment	I'll be embarrassed if I fail
Reactions of Others	Family proud of me Family will see me as healthy Family happy to do more activities together Co-workers impressed	

Completing Your Own Decisional Balance Scale

To help you make the decision as to whether you want to change a behavior, try completing your own balance scale. By comparing the list of pros and cons, you can see whether the decision is the right one for you. Completing such a scale requires some time and considerable self-examination and honesty, but the result should be worth the effort.

	Pros of being physically active	Cons of being physically active
Consequences to Self		
Consequences to Others		
Reactions of Self		
Reactions of Others		

Appendix B

Nutrition Information Provided to Lifestyle and Usual Care Participants

Resetting the Table

Because we live in such a fast-paced world it is sometimes hard to find the time to fix a balanced meal for our families and ourselves. Compounding the problem is the fact that we are surrounded by plenty of not-so-nutritious foods that are easy to get and inexpensive (e.g., fast food). Most of us lead very busy lives that keep us going in all different directions on any given day. We have meetings to attend, kids to pick up, errands to run, and bills to pay. Why spend an hour fixing dinner when you can get dinner for four at McDonald's in less than 10 minutes and for less than 10 bucks?

You *can* eat a healthy diet without spending hours in the kitchen or hundreds of dollars at the grocery store *and* without feeling deprived of all your favorite foods. For starters, let's review what a "healthy diet" means. The American Heart Association, American Cancer Society, and American Diabetic Association all agree that a healthy diet contains:

- 50 – 60% of total calories from complex carbohydrates
- 30% or less of total calories from fat
- 10% or less of total calories from saturated fat
- 15 or more grams of fiber

This type of diet not only helps to prevent heart disease, cancer, and diabetes; it also helps to maintain a healthy weight and provides plenty of energy for an active lifestyle.

How do these recommendations compare to the typical American diet? Most people in this country get approximately 40 – 45% of their calories from carbohydrates, 30 – 35% of their calories from fat, 10 – 15% of their calories from saturated fat, and consume less than 12 grams of fiber a day. In other words, we need to eat more complex carbohydrates and eat less fat, especially saturated fat.

How does that translate into daily food choices? First, take a close look at what you typically eat and think about what foods you could *add* to your diet to get the nutrients you need. Consider trying new foods and new recipes to make healthy eating a *pleasurable* part of your life, not something you dread or despise. Use the following guide, based on the USDA's Food Pyramid, to help you get started:

Daily Food Guide

Bread, Cereal, Rice, and Pasta – 6 to 11 servings a day
Build your meals around these foods. For extra fiber, use whole wheat bread, brown rice, and cereals with 2 or more grams of fiber/serving. Bread products are excellent sources of the B vitamins (niacin, riboflavin, and thiamin) as well as iron, magnesium, and zinc.

One serving =	1 slice of bread or ½ bagel, bun, or English muffin
	½ to 1 cup ready-to-eat cereal
	½ cup cooked cereal, rice, or pasta

Vegetables – 3 to 5 servings a day
Choose green leafy or dark yellow and orange vegetables to get the most "bang-for-the-buck", in terms of vitamins and cancer-fighting ingredients. Vegetables are excellent sources of vitamins A and C as well as potassium.

One serving =	1 cup raw, leafy vegetables
	½ cup cooked or raw, chopped vegetables
	¾ cup vegetable juice

Fruit – 2 to 4 servings a day
Include fruit in your meals as well as snacks. You can "sneak" fruit in easily by adding to salads and desserts. Use fresh or frozen fruits most often (although canned fruit is better than no fruit) and make sure fruit juice is 100% juice. Fruits are also excellent sources of vitamins A and C as well as potassium.

One serving =	1 medium-sized whole fresh fruit
	1 cup berries or a medium slice of melon
	½ cup chopped, cooked, or canned fruit
	¾ cup fruit juice

Meat, Poultry, Fish, Beans, Eggs, and Nuts – 2 to 3 servings a day
Choose fish, dried beans, tofu, or poultry most often for your protein needs. When choosing red meat, look for lean cuts with little or no visible fat. Although higher in fat, red meat is an excellent source of iron and zinc.

One serving =	2 to 3 ounces cooked fish, poultry, or lean meat (about the size of the palm of your hand and the thickness of a deck of cards)
	½ cup cooked beans or ¼ cup tofu
	1 whole egg or 2 egg whites
	2 tablespoons peanut butter, nuts, or seeds (about the size of a Ping-Pong ball)

Milk, Yogurt, and Cheese – 2 to 3 servings a day
Milk and yogurt are two of the best sources of calcium, each containing about 300 milligrams per cup. Choose non-fat or low-fat milk, yogurt, or cottage cheese. Look for reduced-fat cheeses to use in recipes and sandwiches.

One serving =	1 cup (8 ounces) milk or yogurt
	1 cup calcium-fortified soy or rice milk
	½ cup cottage cheese
	1 ½ ounces natural or soy cheese
	2 ounces processed cheese (1 ounce is about the size of a pair of dice)

Fats and Oils – Use sparingly
Limit added fat to no more than 1 –2 tablespoons a day. Choose unsaturated fats, such as liquid vegetable oils or margarines made with vegetable oils. Although margarine contains substances called "trans fatty acids", which are similar to saturated fat in that they may increase blood cholesterol levels, the amount of these fatty acids in margarine is relatively small. Butter contains more cholesterol-raising fatty acids than margarine. However, if you must use butter, use it sparingly. Avoid

using lard, solid shortening, or bacon fat as these fats are highly saturated and frequent use is likely to raise your blood cholesterol level.

Stocking the Pantry

Keep the following foods on hand in order to "whip up" a fast and healthy meal. This list is by no means complete but will provide your pantry with the "basics" for many recipes, including the ones below.

Pantry	Refrigerator	Freezer
Pasta	Skim or 1% milk	Chicken, skinless
spaghetti	Low-fat cheese	Fish, unbreaded
tortellini	mozzarella	Lean ground beef
manicotti shells	cheddar (reduced fat)	Round steak
macaroni noodles	cottage cheese, 1%	Ground turkey
Spaghetti sauce	Parmesan cheese	Imitation crabmeat
Canned chopped tomatoes	Margarine, tub	Margarine, stick
Italian style	Yogurt, plain	Whole wheat bread
Mexican style	Low-fat mayonnaise	French bread
Plain	Low-fat salad dressing	Bagels
Tuna fish	Pickles and relish	Tortillas
Rice, brown and white	Low-fat sour cream	Pizza dough
Variety of spices	Mustard & catsup	Frozen vegetables
Peanut butter	Fruits & vegetables	Fruit juice
Cereal & oatmeal	Eggs	
Corn or soybean oil	All-fruit jelly	
Olive oil & sesame oil		
Canned fruits		
Soy sauce		
Rice vinegar		
Salsa & picante sauce		
Canned refried beans & garbanzo beans		
Canned corn		
Almonds & walnuts		
Dried legumes		
Lentils, pinto beans, kidney beans		
Fresh garlic		

Nutrition Glossary

CARBOHYDRATES

Sometimes referred to as sugars or "starches", carbohydrates are the body's primary source of energy. Peaches, pears, popcorn, and pasta are all good sources of carbohydrates. The body converts carbohydrates into one substance: glucose – a form of sugar that is carried by the bloodstream to our cells, which in turn, use it for energy. Any glucose that is not used for energy is sent to the liver and the muscles where it is stored as "glycogen" (and used later during exercise) *or* it is stored as body fat. Endurance exercise increases the amount of glucose we can store as glycogen, decreasing the amount we convert to body fat.

In addition, there are two kinds of carbohydrates: simple and complex. Simple carbohydrates are single or double "units" of carbohydrate molecules, such as sucrose (table sugar) or fructose (honey). Complex carbohydrates are long chains of similar molecules and are found in foods such as vegetables, potatoes, and beans. Simple carbohydrates are metabolized quickly and reach the bloodstream within 30 minutes of ingestion. Complex carbohydrates take longer for the body to break down; thus they take longer to get into the bloodstream. For this reason, people with diabetes are encouraged to eat more complex carbohydrates than simple carbohydrates.

A healthy diet will contain a mix of both simple and complex carbohydrates. Nutritionists often recommend eating mostly complex carbohydrates because foods high in complex carbohydrates are usually packed with other health-promoting nutrients, such as vitamins, minerals, and fiber whereas high-sugar foods usually have little else in the way of nutrition. Carbohydrates supply 4 calories per gram.

FIBER

Fiber is not one substance but rather a large group of compounds with different effects on the body. One thing these compounds have in common is that they cannot be digested by enzymes in the human gastrointestinal tract. This means that fiber helps to "move things along", preventing constipation. In fact, "insoluble" fiber (one type of fiber) acts like a sponge: it absorbs many times its weight in water, causing it to swell in the intestines, producing a larger, softer stool that we can pass quickly and easily.

Insoluble fiber also plays an important role in preventing diverticulosis and colon cancer. Diverticulosis, a condition in which small "pouches" form within the wall of the colon, affects one in three adult over the age of 50. If food becomes trapped in these pouches, they become painfully inflamed (diverticulitis). Because insoluble fiber prevents constipation, it reduces pressure in the colon, which keeps the pouches from forming in the first place.

It is not known exactly how insoluble fiber prevents colon cancer but one theory is that by moving food through faster, it lessens the exposure of colon walls to potential cancer-causing agents. Moreover, numerous studies have found insoluble fiber to inhibit the formation of precancerous polyps, thus preventing colon cancer from developing. As colon cancer is the second leading cause of cancer deaths in this country, eating foods high in insoluble fiber, such as wheat bran and most vegetables, is a smart thing to do.

"Soluble" fiber is another type of fiber and it also is beneficial to health. Research has found soluble fiber reduces blood cholesterol levels and LDL levels (the "bad" cholesterol), thus, reducing the chances for heart disease to occur. Soluble fiber also helps to control blood sugar in people with diabetes, which in turn reduces their insulin or medication needs. Oat bran, barley, and fruit pectin (found in most fruits) are good sources of insoluble fiber.

Most Americans consume between 10 and 12 grams of fiber per day. Cancer experts strongly recommend doubling that intake to 20 - 30 grams per day. To make sure you get enough fiber, eat a wide variety of foods and include plenty of whole grains, legumes, fruits, and vegetables. One word of caution: be sure to drink *plenty of water* as you increase your fiber intake as too much fiber all at once, without adequate fluids, can cause bloating and abdominal cramps.

PROTEIN

Protein is not a single substance either, but rather a multitude of biochemical compounds. All of these compounds are made up of "amino acids", better known as "building blocks" of protein. There are nine amino acids that the human body is not able to make on its own and these are referred to as "essential" amino acids, found in meat, poultry, fish, dairy products, and eggs. Any protein containing all nine essential amino acids in adequate amounts is referred to as a "complete protein". Incomplete protein is found in foods that contain all but one or two of the essential amino acids. Complete protein can be obtained by combining two incomplete protein foods, such as beans and rice. This is how most vegetarians meet their protein needs.

A common myth among body builders is that eating extra protein will build bigger muscles. This has been found to be false in numerous studies. Although muscle is made of protein and protein is vital to the muscle-making process, *excess* protein is either used for energy or stored as fat. And because the body prefers to use carbohydrate and fat for energy, extra protein is most often turned into body fat.

Most adults need between 45 and 65 grams of protein a day. However, the typical American diet contains approximately 100 grams of protein per day. Many high protein foods, such as meat and cheese, are also high in saturated fat, which, as discussed below, may raise blood cholesterol and LDL levels. For this reason, it's not a good idea to eat too many high protein foods. Like carbohydrate, protein supplies 4 calories per gram.

FAT

There is probably no other nutrient that has as bad a reputation as fat has. We've all heard that too much fat is not good for us: it contributes to the development of heart disease, diabetes, excess body fat, and possibly cancer.

However, fat *is* necessary for good health. We rely on certain fatty acids, called "essential fatty acids", to make hormone-like compounds called prostaglandins, which help control blood pressure, blood clotting, inflammation, and other important bodily functions. These fatty acids are also necessary for healthy skin and hair as well as in transporting fat-soluble vitamins (A, D, E, and K).

Basically, there are two types of fat: saturated and unsaturated. Saturated fat is solid at room temperature and primarily comes from animal sources, such as butter, meat, and dairy products. There are a few vegetable fats that are highly saturated as well: coconut and palm oil and cocoa butter. These latter fats are often found in baked desserts and/or chocolate candy products. Saturated fat is metabolized differently than unsaturated fat in that it causes the liver to produce more cholesterol. It also is very effective in raising LDL levels – the "bad" cholesterol. Although there is some question as to the role of unsaturated fats in the development of heart disease, experts agree that too much saturated fat is a likely cause of high cholesterol and high LDL levels.

Unsaturated fats are liquid at room temperature; hence vegetable oils are unsaturated. This type of fat does not cause the liver to make more cholesterol and, in fact, may play a role in reducing blood cholesterol levels. For this reason, the American Heart Association recommends replacing shortening, butter, or lard in recipes with vegetable oils or margarine. Margarine is made from "partially hydrogenated" vegetable oils, meaning it contains a mix of unsaturated and saturated fat. The amount of saturated fat in margarine, however, is still less than what is in butter or shortening.

Type of fat	Grams of saturated fat per tablespoon
Vegetable oil	0 – 2
Margarine	1 – 2
Shortening	3
Butter	7

High fat diets are also a strong contributor to "obesity" or excess body fat. Numerous studies have found that people with excess body fat consume more fat in their diets than people with average amounts of body fat. In fact, some studies suggest that the amount of fat in one's diet may be more important than the total calories, in terms of weight control. In other words, it may be easier to maintain a healthy weight on a diet low in fat but unlimited in carbohydrate than a traditional low-calorie diet. A recent study found that large women following a low-fat, unlimited-carbohydrate diet lost as much weight as women following a standard low-calorie diet *and* rated this diet as more palatable and satisfying than the low-calorie diet.

The easiest way to know how much fat is in your diet is to write down what you eat for several days and add up the calories and fat grams. Fat gram information is widely available these days; look for it on food labels, in magazine recipes, in cookbooks, or in nutrition reference books. Remember that you should aim to consume no more than 30% of your total daily calories from fat. Use the following guide to see how many grams of fat you can eat without exceeding 30% from fat:

Caloric Intake	Grams of fat
1200	40
1500	50
1800	60
2000	66
2500	83

Fat supplies 9 calories per gram.

VITAMINS & MINERALS

Vitamins and minerals are organic substances that the human body needs in order to function properly. We are not able to manufacture vitamins and minerals on our own so we must obtain them from our diet. Vitamins help promote good vision, formation of red blood cells, strong bones and teeth, and proper functioning of the heart and nervous system. Some vitamins, such as vitamin E and folate, may play an important role in preventing heart disease. Vitamins do not give us energy but do aid in the conversion of food to energy.

There are 13 vitamins needed by human beings: A, C, D, E, K, and the B vitamins – thiamin, riboflavin, niacin, pantothenic acid, B6, B12, folate, and biotin.

There are 13 vitamins needed by human beings: A, C, D, E, K, and the B vitamins – thiamin, riboflavin, niacin, pantothenic acid, B6, B12, folate, and biotin.

Minerals are inorganic substances that are found in the earth's crust. They are carried into the soil, groundwater, and sea by erosion, taken up by plants, and consumed by animals and humans. Minerals are indestructible; burning food to a cinder will not destroy it's mineral content. When food is boiled, however, some minerals dissolve into the water and are not consumed if the water is discarded.

The human body contains more than 60 minerals (making up about 4% of its weight) but only 22 are "essential", meaning we must obtain them from our diet. Seven of the 22 – calcium, chlorine, magnesium, phosphorous, potassium, sodium, and sulphur – are called "macro-minerals" because they are present in the body in relatively large amounts. The rest are called "trace" minerals because they are present in such small quantities.

One mineral is of particular concern for women – calcium. Adequate calcium intake is necessary to maintain strong bones and teeth and many women consume only half the calcium they need. The result is an increased risk of fractures of the hip, wrist, or spine, all of which can be extremely debilitating. These fractures occur because, without adequate calcium, "trabecular" bone is lost, making bones thin and brittle. This condition is called osteoporosis.

One way to prevent osteoporosis is to consume plenty of calcium. Adult women need at least 1000 mg of calcium a day, which can easily be obtained with dairy products and/or supplements. Milk and yogurt are the best sources of calcium with approximately 300 milligrams of calcium per cup (see attached reference sheet). Dark, green leafy vegetables have calcium but they also contain a substance called oxalic acid, which inhibits the absorption of calcium. The best way to get calcium is by consuming milk, yogurt, or a calcium supplement.

Speaking of supplements, look for calcium "carbonate" on the label – it may be absorbed better than other forms of calcium. However, keep in mind that calcium carbonate is 40% calcium; thus, a 1000 mg calcium carbonate supplement contains 400 mg of calcium.

The following is a list of substances you may not have heard of but will likely hear more about in the future. They are currently being studied as potentially disease-preventing substances, however, firm conclusions have not been made yet. The discovery of these substances, which are mostly found in fruits and vegetables, underscores the importance of relying on food for our nutrition versus relying on supplements.

ANTIOXIDANTS

Antioxidants have received a lot of attention in the last few years as possible cancer-fighting agents. These substances have the ability to neutralize "free radicals", which are unstable oxygen molecules created in the energy-generating process within each cell. Free radicals combine with other compounds, creating a chain reaction that ultimately damages the cell wall. Normal processes within the cell create free radicals but so do cigarette smoke, alcohol, and various other pollutants.

Fortunately, our cells do have systems in place that help fight free radicals and repair the damage they cause. The antioxidants found in our food supply also help control free radicals. Some vitamins, such as vitamins E and C, act as antioxidants but so do other substances, such as phytochemicals and lycopenes (see below).

PHYTOCHEMICALS

Produced naturally by plants, these substances may help protect both plants and humans from disease. Their exact role is still under investigation but it is known that many phytochemicals have antioxidant activity.

CAROTENOIDS

Carotenoids are plant pigments; they give tomatoes their rosy red color and carrots their vivid orange color. Carotenoids may also help prevent cancer. Two promising carotenoids are beta carotene and lycopenes. Beta carotene, found in carrots and other vegetables, is converted to vitamin A in the body and also acts as an antioxidant. Lycopenes are described below.

Appendix C

Consent Forms

COLORADO STATE UNIVERSITY
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

TITLE OF PROJECT: A Lifestyle Physical Activity Intervention For Large Women: Effect on Cardiovascular Disease Risk Factors and Food Intake

NAME OF PRINCIPAL INVESTIGATOR: Jennifer Anderson. Ph.D.

NAME OF CO-INVESTIGATOR: Cindy Byfield. M.S., R.D.; Ph.D candidate

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS/PROBLEMS: Cindy Byfield, (970) 491-6401; or by email: cbyfield@lamar.colostate.edu

SPONSOR OF PROJECT: Sports, Cardiovascular, and Wellness Nutritionists Dietetic Practice Group of the American Dietetic Association (SCAN/ADA) and the American College of Sports Medicine (ACSM) Foundation.

PURPOSE OF THE RESEARCH:

The goal of this research study is to compare a lifestyle-oriented physical activity program to a structured exercise program in improving risk factors for heart disease and to determine which program is more effective at helping sedentary women sustain a higher level of physical activity for at least six months after the program is completed. In addition, the investigators will study whether improving one's confidence and ability to make decisions when thinking about exercise increases the chances for that person to become more physically active and to sustain that level of activity.

PROCEDURES/METHODS TO BE USED:

As a study participant, you will be randomly assigned to one of three groups:

Group One - Lifestyle Physical Activity Intervention, called "On The Move!" In this group, you will meet for 90 minutes once a week for 16 weeks, then for 90 minutes every other week for the next 8 weeks (total of 24 weeks). After that, you will have the option of meeting once a month for informal get-togethers for the next 24 weeks. The 90 minute meetings will include a short presentation by the class leader on a particular topic related to physical activity or nutrition and discussion of that topic. Each class session will also include 5 - 15 minutes of light stretching movements, led by the class instructor.

One of the goals of this intervention is to help you increase the amount of physical activity that you engage in on a weekly basis. Therefore, you will be asked to accumulate 30 minutes of moderate physical activity on 4 or more days of the week (starting with 15 minutes and working up to 30 minutes). This physical activity can be any type of activity you enjoy and can be done in short bouts of 8-10 minutes each. You can count common activities, such as house or yard work, as part of the 30 minutes. The class leader will help you set goals and work towards those goals and will provide you with information on how to integrate physical activity into your current lifestyle.

You will be asked to record the activities or exercise that you engage in and will receive feedback on that record. In addition, there will be a few class outings, such as a short hike in Horsetooth Mountain Park, a water aerobics class (optional), and a country-line dancing lesson. The class may vote to choose other activities in place of those already planned.

Group Two - Structured Exercise Intervention. In this group, you will be given an exercise plan with instructions on how often, how hard, and how long to exercise, with a goal of increasing your fitness level. This exercise plan starts off slow and easy and gradually gets a little longer and harder but never reaches an overly strenuous level (you will be able to progress at your own pace).

You will also be given free access to Miramont Sport Center (901 Oakridge Drive, Ft. Collins) where you will have a choice of exercise equipment to use, such as a stationary bicycle, treadmill, stairmaster, etc. and will be expected to use this facility to complete your exercise plan. Walking outdoors or participating in other forms of exercise can be substituted for exercising at Miramont Sport Center but needs to be discussed with co-investigator to ensure exercise plan is followed. One initial and two follow-up group meetings will be scheduled to allow you the chance to meet other group members and to discuss progress and answer questions. You will receive written material on exercise and nutrition and you will be asked to keep a daily record of your exercise activities.

Exercise specialists employed by Miramont Sport Center will provide you with instructions on how to use the exercise equipment and will be available at all times for any questions you may have. You may also participate in the exercise classes offered by Miramont Sport Center if you prefer.

Group Three - Waiting-List group. If you are assigned to this group, your name and telephone number will be put on a list for the next Lifestyle or Structured class period which will begin approximately 24 weeks from the start of the study (July, 1999). At that time, the Lifestlyle program will be open to the public, who will be charged a higher fee. As a research participant, you will be able to participate in the Lifestyle or the Structured program for the reduced fee of $99.00 (see Renumeration below); $30.00 will be returned to you upon completion of the study.

Note: If we do not recruit enough women for all three groups, the Waiting-List group will be deleted and you will be randomly assigned to Group One or Group Two.

As a study participant, you will be asked to complete the following assessments before, immediately after, and six months after completing either the lifestyle physical activity intervention or the structured exercise intervention. If you are assigned to the waiting-list group, you will be asked to complete the following assessments at the same time as the other two groups:

- Questionnaires on your feelings about exercise and physical activity
- 4-day food records (all food and beverage intake recorded for 4 days)
- Height, weight, waist and arm circumference, blood pressure (all of which will be taken privately)
- Fasting blood sample, taken by a trained phlebotomist at Quest Diagnostics, Inc., located at 1301 Riverside. The phlebotomist will take 2-3 teaspoons of blood from a vein in your

arm and will send this blood sample to a laboratory for analysis. The analysis consists of total cholesterol, high density lipoproteins (HDLs), low density lipoproteins (LDLs), triglycerides and glucose, all of which are considered to be risk factors for heart disease. You will be given a copy of the results of this blood test with an explanation of the results by a physician (see below). You will have a choice as to which day you provide a blood sample but will be asked to fast for a minimum of 12 hours before the test (no food or drink, except water, is allowed).

- Cardiorespiratory fitness, assessed by a bicycle ergometer test. To complete this test, you will be asked to ride a stationary bicycle for 6 - 12 minutes. The speed will be slow at first, then will gradually be increased to a higher level. You may stop the test at any time if you are uncomfortable. The highest speed will be moderately fast and will be based on your heart rate, which will be taken 3 - 4 times during the test. A trained female technician will take your heart rate with the use of a heart-rate monitor. This monitor is inside a belt that will be fitted around your rib cage, under your breast; the belt transmits the heart rate to a computer where the number will be displayed for the technician to see. This test provides an accurate estimate of your maximum oxygen uptake, which is an indicator of cardiorespiratory fitness.
- Physical Examination. You will be asked to meet with a physician or physician assistant (P.A.) prior to the beginning of the 24 week study and at the end of the study for a limited physical examination. This examination will confirm your eligibility to participate in this study and will be conducted at HealthSouth Sports Medicine Center (located in the same building as Miramont Sport Center) by physicians and P.A.s from GeneralCare Medical Clinic. The examination will include a medical history questionnaire, blood pressure measurement, general examination of the ears, nose, throat, heart, lungs, and abdomen. The physician or P.A. will also check your shoulders, knees, ankles, and feet. The physician or P.A. will review your blood test results with you and answer any medical questions you have related to the study. The physician or P.A. will contact you during the 24 week study to ask how you are doing and see if you have any medical questions or concerns.

All of the above information will be kept confidential (see below).

REMUNERATION

As a study participant, you will be asked to pay $99.00, of which $30.00 will be refunded to you if you complete the entire 48 weeks. This fee will help cover the cost of the manual you will receive, the blood analysis, and other related materials.

RISKS INHERENT IN THE PROCEDURES:

Blood Draw - Slight risk of infection, bruising, local soreness, and fainting. Risks will be minimized by having trained phlebotomists employed by a medical clinic obtain the blood samples from your arm.

Bicycle ergometer test - Fatigue, muscle soreness, musculoskeletal injury. Risk will be minimized by having a trained exercise technician administer the test and by using a standardized protocol for bicycle ergometer test.

Light stretching movements - Fatigue, muscle soreness, musculoskeletal injury. Risks will be minimized by using appropriate techniques for warm-up and cool-down and keeping the movements slow and easy. You will be encouraged to tell the instructor, during the activity, if

the movements are too difficult for you and you may stop at any time. Chairs will be available for those who would like to do the stretching movements while seated.
Pool exercise - Fatigue, muscle soreness, anxiety. Risks will be minimized by keeping this activity short (15 - 20 min), by making this activity optional, and by conducting the exercises in water that is 4 feet deep or less.
Trail Hike - Fatigue, muscle soreness, and exposure to elements. Risks will be minimized by keeping the hike short (< 2 miles), having an experienced person lead the hike, making sure all subjects have appropriate apparel (jackets, comfortable shoes, etc.), watching the weather forecast before the hike and post-poning hike if forecast predicts bad weather, having first-aid equipment available. You will be required to bring a water bottle filled with water and a light snack.
Increased physical activity of various types - This study requires that you increase your current level of physical activity to include 30 minutes of moderate physical activity on at least 4 days of the week. Therefore, there is an increased risk for fatigue, muscle soreness, or musculoskeletal injury from the increased activity. You will be given information on minimizing the soreness and fatigue as well as on how to prevent an injury.
Increased aerobic exercise at a fitness center - If you are assigned to Group Two (see above), you will be utilizing aerobic exercise equipment at a fitness club, such as a treadmill, stationary bicycle, stairmaster, etc. Use of this equipment may cause fatigue, muscle soreness, or musculoskeletal injury. Risks will be minimized by providing you with an exercise "prescription" which tells you how hard, how long, and how often to use the equipment, by having a trained exercise technician demonstrate how to use the equipment, and by having an exercise technician available to answer questions and to ensure proper use of the equipment. You will also be given information on minimizing soreness and fatigue as well as on how to prevent an injury.

I understand that it is not possible to identify all potential risks in an experimental procedure, but I believe that reasonable safeguards have been taken to minimize both the known and the potential, but unknown, risks.

BENEFITS: As a study participant, you will receive the most recent information on physical activity and fitness, how it can improve your overall health, and how to get started on an exercise program or increase the amount of physical activity in your current lifestyle. You will also receive information on how to eat a healthful diet and techniques for improving your eating behavior. You will have the opportunity to make realistic lifestyle changes that have the potential to improve your overall health.

CONFIDENTIALITY: All of the information obtained from this study will be kept confidential. You will be assigned a study number and this number will be used for identification purposes through out the course of this study.

LIABILITY: The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 180 days of the injury.

Questions concerning treatment of subjects' rights may be directed to
Celia S. Walker at 970-491-1563.

 Subject initials ______ Date ______

PARTICIPATION:

Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you were otherwise entitled.

Your signature acknowledges that you have read the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing __5__ pages.

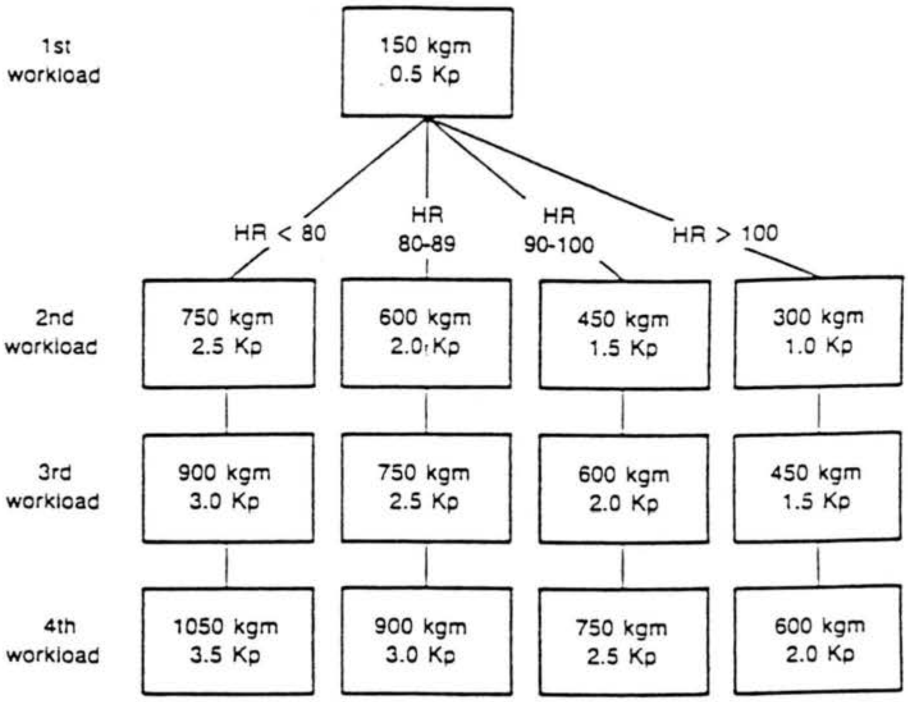
____
Subject name (printed)

______________________________ ________________
Subject signature Date

______________________________ ________________
Investigator or co-investigator signature Date

Appendix D

YMCA Protocol for Submaximal Cycle Ergometry



Directions:

1. Set the first workload at 150 kgm/min (0.5 Kp).
2. If the HR in the third min is
   - less than (<) 80, set the second load at 750 kgm (2.5 Kp);
   - 80 to 89, set the second load at 600 kgm (2.0 Kp);
   - 90 to 100, set the second load at 450 kgm (1.5 Kp);
   - greater than (>) 100, set the second load at 300 kgm (1.0 Kp).
3. Set the third and fourth (if required) loads according to the loads in the columns below the second loads.

Fig 8-1

YMCA Submaximal Cycle Ergometer Protocol

1. Record your name, age, and weight in Figure 8-3. Also calculate and record your predicted maximum heart rate (220 - age).
2. Use a calibrated cycle ergometer. Adjust the seat height so the knee is slightly bent when the pedal is in the down position. Record the seat height (Figure 8-3).
3. Have a partner administer the YMCA test protocol as outlined in Figure 8-1. The initial work rate should be set at 150 $kgm \cdot min^{-1}$) (25 Watts). Pedal speed should equal 50 rpm. Heart rates should be measured within the last minute of each stage. Adjust the work load according to each end-stage HR (see Figure 8-1). Note that the intent is to perform only one additional exercise stage beyond the point where a HR of at least 110 bpm is achieved. Thus, if a HR of 123 bpm were realized in the first stage only one additional 3-minute stage should be performed; likewise a HR of 118 bpm in the third stage would necessitate only one more 3-minute stage.

   The YMCA test is designed to require about 6-12 minutes of time (i.e., a minimum of two stages to a maximum of four stages).

4. Record your tests results in Figure 8-3. Plot the data (work rate versus heart rate) from 2-3 exercise stages. Use a straight edge to connect these points (i.e., line of best fit) and extrapolate to intersect the predicted maximum heart rate line (see Figure 8-2). Directly below this point of intersection, along the bottom of Figure 8-3, will be your corresponding VO_2max estimation score. See example in Figure 8-2.

5. Record your test results and normative rating in Table 8-9.

Computation Example: What would be the estimated VO_2max ($ml \cdot kg^{-1} \cdot min^{-1}$) of a 40 yr old male who weighs 80 kg and performed 3 stages of the YMCA protocol? Assume a HR (bpm) and work rate ($kgm \cdot min^{-1}$) of 105 and 150 (1st stage), 120 and 300 (2nd stage), and 145 and 450 (3rd stage). In addition, assume a predicted maximum heart rate of 180 bpm.

1. Refer to the example in Figure 8-2. Notice the three points were plotted according to the heart rate versus work rate data. Also note that an extrapolation line (dashed line) was drawn up to the maximum heart rate line.
2. Directly below this point of intersection, along the bottom of the graph, is the VO_{2max} estimation score which equals 1.6 $l \cdot min^{-1}$. Observe that an estimated maximum work rate of 650 $kgm \cdot min^{-1}$ is also recorded. Can you see how this value was determined?
3. Convert the estimated VO_2max score of 1.6 $l \cdot min^{-1}$ to $ml \cdot kg^{-1} \cdot min^{-1}$:

$$VO_2max = 1.6 \text{ l/min} \times 1000 \text{ ml/l} = 1600 \text{ ml} \cdot min^{-1}$$

$$1600 \text{ ml/min} \div 80 \text{ kg} = 20 \text{ ml} \cdot kg^{-1} \cdot min^{-1}$$

Fitness Level: Fair (See Table 4-1)

Sample Graph for the YMCA Cycle Ergometer Test

MAXIMUM PHYSICAL WORKING CAPACITY PREDICTION

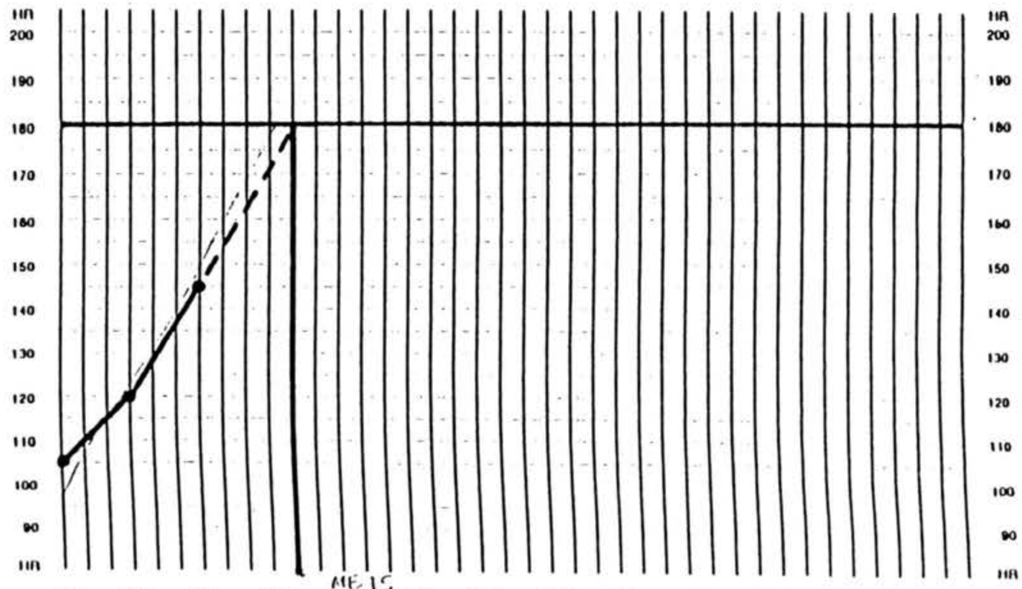
NAME Example Male AGE 40 WEIGHT 176 LB 80 KG SEAT HEIGHT 8

PREDICTED MAX HR

	DATE	1st WORKLOAD HR USED	2nd WORKLOAD HR USED	3rd WORKLOAD HR USED	MAX WORKLOAD	MAX O_2 (l/min)	MAX O_2 (ml/kg)
TEST 1	1-4-88	150/105	300/120	450/145	650	1.6	$\frac{1600}{80} = 20$
TEST 2							
TEST 3							

DIRECTIONS

1. Plot the HR of the 2 workloads versus the work (kgm/min)
2. Determine the subject's max HR line by subtracting subject's age from 220 and draw a line across the graph at this value
3. Draw a line through both points and extend to the max HR line for age.
4. Drop a line from this point to the baseline and read the predicted max workload and O_2 uptake



WORKLOAD (kgm/min)	150	300	450	600	750	900	1050	1200	1350	1500	1650	1800	1950	2100
MAX O_2 UPTAKE (l/m)	0 8	0 9	1 2	1 5	1 8	2 1	2 4	2 8	3 2	3 5	3 8	4 2	4 6	5 0
KCAL USED (kcal/m)	3 0	4 5	6 0	7 5	9 0	10 5	12 0	14 0	16 0	17 5	19 0	21 0	23 0	25 0
APPROX MET LEVEL (for 132 lb)	3 3	4 7	6 0	7 3	8 7	10 0	11 3	12 7	14 0	15 3	16 7	18 0	19 3	20 7
APPROX MET LEVEL (for 176 lb)	3 0	4 0	5 0	6 0	7 0	8 0	9 0	10 0	11 0	12 0	13 0	14 0	15 0	16 0

Source: The Y's Way to Physical Fitness (3rd Edition; 1989). YMCA of the USA, 101 N. Wacker Drive, Chicago, IL 60606.

DIRECTIONS FOR KEEPING YOUR FOOD DIARY

Please keep a food record for three consecutive days. These should include 2 workdays and 1 non-work day. Write down everything you eat or drink each day. This includes all meals, snacks, nibbling, sampling, sodas, cocktails, etc. Always record in your diary immediately after having a meal, snack, or drink.

ONLY RECORD ONE FOOD ITEM PER LINE

EXAMPLE: COFFEE 1 CUP
POLY RICH LIQUID CREAMER 1 TBSP
SUGAR 1 TSP

INDICATE AMOUNTS

USE MEASURING SPOONS FOR: jelly, sugar, syrup, gravy, salad dressing, butter, margarine and condiments

3 teaspoons (tsp) = 1 tablespoon (TBSP)

USE MEASURING CUPS FOR: Vegetables, rice, noodles, cereals, soups, stews, casseroles, ice cream, jello, and canned fruits

1 cup (c) = 8 ounces (oz)

USE OUNCES OR DIMENSIONS FOR: Meat, fish, poultry, cheese, pizza, cakes, pies, cookies, and brownies

USE NUMBER AND SIZE (SMALL, MEDIUM, LARGE) FOR: Breads, rolls, raw fruits, hot dogs, lunch meats, crackers, chips, and candy.

INDICATE HOW FOOD WAS PREPARED

EXAMPLE: baked or fried, trimmed or untrimmed, poultry skin removed or left on

INDICATE FATS USED IN COOKING

EXAMPLE: fried in corn oil or seasoned with Promise stick margarine

INDICATE WHETHER THE FOOD WAS EATEN AT HOME OR IN A RESTAURANT

If the food was eaten in a restaurant, indicate the price range of the restaurant using the following guide.

Inexpensive fast food restaurants = L (low)
Medium priced family style restaurants = M (medium)
Expensive restaurants = H (high)

REMEMBER TO ASK YOUR WAITER OR SERVER FOR PORTION SIZES. IF YOU RECORD A MENU WEIGHT, BE SURE YOU INDICATE MENU OR RAW WEIGHT ON YOUR RECORD. IF YOU DO NOT KNOW THE WEIGHT OF A FOOD, USE DIMENSIONS TO DESCRIBE THE FOOD. YOU CAN NOT USE DIMENSIONS FOR FOODS THAT ARE NOT SOLIDS (I.E. GREEN BEANS, SALADS, PEAS). USE CUPS TO DESCRIBE THESE FOODS. YOU CAN USE DIMENSIONS FOR SOLID FOODS (I.E. STEAK, BAKED POTATO, SUBMARINE ROLL, LUNCHEON MEATS, OR CHEESES). REFER TO THE INSTRUCTIONS ON THE NEXT PAGE IF YOU WISH TO USE DIMENSIONS.

FOOD DIARY

No.: ____________________

Date of diary: ____________________

Day of week: ____________________

	List Food or Drink here. Be specific. Give details. One food per line.	Amt. Specify oz., c., tsp., tb., etc.	Cooking method	H (home) R (restaurant) O (other)	Price range of restaurant L (low) M (med) H (high)	Specify brand names when possible
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						

Appendix E

7-Day Physical Activity Recall Interview
Instructions and Recording Forms

Three Day Food Record
Instructions and Recording Forms

ACT Physical Activity Recall

ID ☐☐☐☐☐☐	Acrostic ☐☐☐☐☐☐
Date Completed ☐☐ ☐☐ ☐☐ (Mon Day Year)	Visit Code ☐☐☐

Day of the week form completed : ____________________

1. Were you employed in the last seven days? ₁☐ Yes ₂☐ No

2. How many days of the last seven did you work? ☐ (round to nearest day)

3. How many total hours did you work in the last seven days? ☐☐ hours

4. What days of the week do you consider to be your weekend or non-work days? For most people this would be Saturday and Sunday but it may be different for you.
   ₁☐ Sunday ₂☐ Monday ₃☐ Tuesday ₄☐ Wednesday ₅☐ Thursday ₆☐ Friday ₇☐ Saturday

5. If you did not work your usual week, why did you work less than usual? ____________________

6. For the past seven days, and thinking only about activities that are *at least* of moderate intensity, how many days did you do activity or exercise that added up to at least 30 minutes each day?

   ☐ number of days (0 to 7)

7. Was this a typical week in terms of your usual pattern of activity or exercise?

- ₁☐ Yes
- ₂☐ No —— Were you more or less active in the past week than you usually are? ₁☐ More ₂☐ Less

Until now, we've just been talking about the last seven days. Now I would like you to think about your usual activities over the last three

8. During your work week, on average how many hours per day do you spend sitting quietly (e.g., watching TV, working at a desk or computer, eating, or reading)? ☐☐ average hours per

During your weekend, on average how many hours per day do you spend sitting quietly (e.g., watching TV, working at a desk or computer, eating, or reading)? ☐☐ average hours per

9. How many flights of stairs do you climb up each day? (1 flight = 10 steps) ☐☐ number of flights

10. If you had to add together the total minutes you spend walking during the day, how many minutes would that be? Remember, add up your actual walking time and don't add in the time spent just standing. Include your to and from walking and any fitness walking. Don't try to remember every step, just give a general idea of the time spent walking. ☐☐☐ total minutes p

11. What is your usual pace of walking? Mark ONE only.

- ₁☐ Casual or strolling (less than 2 miles per hour)
- ₂☐ Average or normal (2 to 3 miles per hour)
- ₃☐ Fairly brisk (3 to 4 miles per hour)
- ₄☐ Brisk or striding (4 miles per hour or faster)

12. Do you regularly do strength and flexibility exercises like sit-ups, push-ups, yoga, or stretching?

- ₁☐ Yes —— How many days per week do you do these exercises? ☐ number of days (0-7)
- ₂☐ No

13. On the days that you do strength and flexibility exercises, how many minutes do you spend doing them? ☐☐☐ total min

	Days of the Week	Yesterday						One Week Ago
		HRS MIN	HRS MIN	HRS MIN	HRS MIN	HRS MIN	HRS MIN	HRS MIN
	Sleep	:	:	:	:	:	:	:
MORNING	Moderate	:	:	:	:	:	:	:
	Hard	:	:	:	:	:	:	:
	Very Hard	:	:	:	:	:	:	:
AFTERNOON	Moderate	:	:	:	:	:	:	:
	Hard	:	:	:	:	:	:	:
	Very Hard	:	:	:	:	:	:	:
EVENING	Moderate	:	:	:	:	:	:	:
	Hard	:	:	:	:	:	:	:
	Very Hard	:	:	:	:	:	:	:

Calculated Energy Expenditure ☐☐.☐ Kcal/kg/day

7-Day Physical Activity Recall Interview

I. INTRODUCTION

The 7-Day Physical Activity Recall (PAR) interview technique is used to estimate an individual's average daily energy expenditure for the previous week. Based upon participant recalls, hours spent in ***moderate, hard,*** and ***very hard*** intensity activities are determined and total kilocalories can be estimated from the number of hours engaged at the various levels of intensity. The purpose, therefore, is not to single out specific physical activities but to identify participation in activities at various levels of intensity. With this interview technique, we will be looking at work-related activities, leisure-time activities, sitting patterns, and sleep patterns. By mathematical difference, these data will then be used to estimate activities classified as ***light*** intensity. The purpose of this manual is to standardize the interview process and to increase agreement among interviewers.

Your interview technique should limit bias (it should be objective), and you should try to keep the interview from becoming tedious. To achieve these goals, an interviewer script has been created and is included in the Appendix of this manual. Although the interviewer does not have to memorize this script it should be followed very closely to reduce variability between and within interviewers. A major effort should be made by the person conducting the interview not to be judgmental of participant responses. There are no right or wrong answers to the interview. It is important to set a positive, non-threatening tone and to put the participant at ease at the beginning of the interview. It is also important to remember not to let the study participant sidetrack you. It may be difficult for participants to remember their past week's activity. Some may not try very hard, and others get bogged down in details. You should strive to achieve a happy medium. You should control the pace of the interview; extraneous talk should be avoided. If participants are going into excessive detail, you should remind them that they need not account for every minute but that an average or estimate is expected. For example, you might ask, "How much time in general?" or "about how long?".

It is important to remember that most of the participants you see will spend a vast majority of their waking hours doing ***light*** activity. Many tiring and unpleasant household or occupational tasks do not have a very high energy cost. Clerks in a store, for example, may be on their feet all day and may feel fatigued, but the energy cost is in the ***light*** category. An exception to this example would be time spent in stocking shelves, which probably would be classified as ***moderate*** activity. Also, for most occupational tasks that require at least moderate energy expenditure, it is important to accurately determine the actual time spent doing the activity. In the stocking clerk example, even though a person might do that activity for an entire shift, it probably would not equal eight hours. You should try to subtract time spent on lunch, breaks, and the like.

II. INTERVIEWER PREPARATION GUIDELINES

A. THE FOLLOWING POINTS SHOULD BE EXPLAINED TO EACH PARTICIPANT BEFORE ACTUALLY BEGINNING THE PHYSICAL ACTIVITY INTERVIEW. REVIEWING THE INTERVIEWER SCRIPT PROVIDED IN THE APPENDIX WILL ASSIST IN COMMUNICATING THIS INFORMATION:

1. They are to think of their physical activities during the past seven days. It is important to stress that this is a recall of actual activities for the past week, <u>not a history of what they usually do</u>.
2. ***Light*** activities, such as desk work, standing, light housework, softball, archery, bowling, and the like (where there is little movement of large muscles) will be considered in a separate part of the physical activity interview. For the 7-day recall, we are interested in occupational, household, and sports activities that make you feel relative to how you feel when you are walking or make you feel like you are working as hard as when you are walking briskly (15-20 minutes per mile).
3. Explain to the participant that he or she will be asked to categorize the intensity of the activity into one of three groups, ***moderate, hard*** or ***very hard***. Explain that the ***moderate*** category is similar to how one might feel while walking at a 15-20 minute per mile pace and that the ***very hard*** category is similar to how one might feel when running. The ***hard*** category falls in between. In other words, if the activity in question seems harder

than walking but not as strenuous as running, place it in the ***hard*** category. Here (prior to the interview) it is a good idea to give examples and interact with the participant enough to allow feedback for a complete understanding of the types and intensities of activities that would fall into these categories. Laminated cards highlighting examples of each of the intensity categories are provided to each interviewer. Prior to conducting the interview, the interviewer should be familiar with the energy cost of many common activities (see Certification and Quality Control section later in this chapter). Study personnel are urged to consult the reprint of Ainsworth et al. (Compendium of Physical Activities, found in Appendix) for a listing of these energy costs.

4. Should any questions arise regarding administration of the PAR during the course of ACT, study personnel are requested to contact the Dallas Center (Laura Becker, [redacted]) for clarification and direction. All issues raised during the study will be recorded in a logging book for future reference.

III. INTERVIEW PROTOCOL AND GUIDELINES

Physical activity recall data for ACT will be collected on pre-printed forms and transferred to computerized form. Detailed information on participant interviewing can be found in the interviewer script (Appendix). Detailed information on completion of the pre-printed forms is found below.

A. Page 1 - Work Schedule and Physical Activity Accumulation Questions

1. Start the interview by asking the participant the employment question(s) on the 7-day PAR Questionnaire.
   a. "Were you employed in the last seven days (including paid work and volunteering)?"
      1. Yes
      2. No (Skip immediately to Question 6, page 1)

b. "How many days of the last seven did you work outside the home?"

1. Number of days

c. "How many total hours did you work in the last seven days?"

1. Hours last week

d. "What days of the week do you consider to be your weekend or non-work days?"

e. If the participant reports fewer than 7 days (reported weekdays + weekend days), "Why did you work fewer days this past week than usual?" If the participant's work days and weekend days total more than 7, note the reason for the increased work time.

f. "For the past seven days, and thinking only about activities that are at least of moderate intensity (show laminated cards), how many days did you do activity or exercise that added up to at least 30 minutes each day?"

g. Go to PAR Worksheet

B. Establishing the Days of the Week for the 7-day Recall and Use of Worksheet

1. **To aid the participant in recall you will ask about each day in turn starting with yesterday and working backwards.** "Okay, today is Tuesday, yesterday was Monday." Also make sure to **label the worksheet (see below) with the appropriate days of the week.** Do this by placing yesterday's day of the week in the blank below the column labeled "Yesterday." Then, working backwards with respect to day of the week, write each of the past 6 days of the week in the appropriate space above the columns, ending with the last day of the recall week below the column labeled "One Week Ago." This makes logging the participant's activities much easier. Also, connecting activities to specific days of the week helps the participant to remember more.

2. The PAR worksheet (a Xerox copy of page 2 of the PAR form) is used to help the interviewer summarize the physical activity recall reported by the

study participant. Minutes that the participant reports having spent in moderate, hard, and very hard activities (as well as sleep time) are recorded on the Worksheet. These data will then be transferred to the PAR form and used to calculate an estimate of energy expenditure to determine study eligibility (see Recruitment and Eligibility chapter of MOP) and as a primary outcome variable. Several key points about use of the Worksheet are listed below.

a. Make sure to **label the worksheet with the appropriate days of the week.** This makes logging the participant's activities much easier.

b. **Record time of sleep** in spaces provided on worksheet. Time segments should be recorded in 15 minute (:15), 30 minute (:30), 45 minute (:45), or hour (:00) time blocks. *Rounding to the nearest 15 minutes applies to sleep times only.*

c. **Record activity and time of activity** in spaces provided on worksheet for morning, afternoon, and evening at the various levels of intensity. For activity that is continuously performed, it must have been performed at least 10 minutes to be recorded. Round times spent in activities to the nearest minute. For example, jogging three miles in 27 minutes and 52 seconds would be recorded as follows:

Very Hard	3 mi. jog
	:28

Likewise, walking five miles in 1 hour, 15 minutes and 20 seconds would be recorded as follows:

Moderate	5 mi. walk
	1:15

d. **Draw a light, wavy line down the column of the individual's weekend day(s). Remember they may not necessarily be Saturday and Sunday.**

C. Sleep

1. The first item on the PAR Worksheet is an assessment of the participant's **sleep** times for the week. The goal in estimating the sleep pattern in the PAR is to get an estimate of an individual's hours spent in bed per night. Even if they claim not to have slept, if they were in a prone position, they used approximately the same number of kilocalories as sleep. The number would be rounded to the nearest 1/4 hour. For example, if the individual reported 20 minutes, round down to 15 minutes (:15). If they report 25 or 35 minutes this would be rounded to 30 minutes (:30), if they have 40 or 50 minutes, round to 45 minutes (:45), and if they report between 55 and 05, round to the nearest hour (:00). Many people will get in bed and get out of bed at consistent hours on the weekdays. This should be determined as an initial step by asking the following:

   a. For the past 5 weeknights, did you usually get in bed and get out of bed at the same time, or did it vary each night?

      1. If the times vary most nights, go day by day beginning with getting in bed last night and getting out of bed this morning (the day of the interview). Work your way back through the week asking for the specific times they got in bed and got out of bed each night and day. Going backwards helps people remember by starting with the most recent time frame.

      2. If the times of getting in bed and getting out of bed are fairly constant during the weekdays, ask what time they got in bed and what time they got out of bed and record these numbers on the worksheet. Ask the participant if there were any unusual weekdays when they might have gotten in bed or out of bed earlier or later.

Record any of these changes on the appropriate day. Next, ask the participant about the past Saturday night getting up on Sunday and the last Friday night (or equivalent weekend days) getting up on Saturday. Record these numbers on the worksheet.

For example, if the interview takes place on a Tuesday, the first night of recorded sleep (working backwards from Tuesday) would be going to sleep Monday night and getting up on Tuesday morning the day of the interview). The total number of hours slept in this time frame would be recorded for Monday night (labeled "yesterday" on the Worksheet). The next night of sleep assessed would be Sunday night, getting up on Monday. This number would be entered into the Sunday column. Therefore, keep in mind that although the labeled column refers to that *day's* activities, it also refers to that *night's* sleep times.

b. Keep in mind that some people may nap during the day or fall asleep while reclined in a chair. This time should be added to the pertinent night's sleep time. To capture this information the participant should be asked if they took any naps or laid down for any period during the last seven days. Interviewers should be particularly alert to this if there was a night of limited or no sleep time.

D. Overview Of The Interview

1. Starting with yesterday and working backward, ask about activities during each day.
2. Ask only about activities that are ***moderate***, (at least the intensity of brisk walking), ***hard*** (intensity between walking and running), and ***very hard*** (intensity of running).

3. Ask about activity during each segment of each day as a separate question. For example, "On Wednesday morning, from the time you got out of the bed until the time you had lunch, did you do anything you would consider moderate, hard, or very hard?" Morning is generally considered from the time they wake up in the morning to the time they have lunch, afternoon is from lunch to dinner and evening is from dinner until the time one goes to bed. The previous question would then be repeated for the remaining segments of the day.
4. It will help recall significantly to have the participant remember what he or she did during the day in question. If the participant is having trouble remembering their activities during each segment of the day, as the general question, "Do you remember what you did on (Tuesday)?" Once the participant starts remembering, switch back to the segments of the day as outlined above (i.e., morning, afternoon, evening).
5. The interview needs to be sensitive to walking. However, people walk many times during the day, and we will not count all of them. For example, we do not want them to add up each time they walk to the refrigerator. **The general rule is that they should do 10 minutes in a given intensity category in a given segment of the day (e.g., morning, afternoon, evening).** The specific rule for walking is that you only count walking that is continuous for at least 10 minutes or intermittent walking performed during a limited period of time (such as 1-2 hours) which would total 10 minutes or more. An example of intermittent walking that would qualify would be briskly walking through a shopping mall for 60 minutes with the walking time interspersed with stopping to window shop. If the total accumulation of walking was 45 minutes (of the 60) and 15 minutes was spent window shopping, the time to be recorded would be 45 minutes. This would be classified as ***moderate*** unless the participant walked very fast or race-walked.

6. Make sure to emphasize the intensity guidelines. For example, the participant should be asked, "When you are doing the activity, is it similar to how you feel when you are walking at a 15-20 minute per mile pace, or is it similar to how you feel when you are running, or is it somewhere in between?" If the activity is of an intensity less than a brisk walk, it is considered a ***light*** activity and is not included in the worksheet.

E. Activity

1. Frequency:

   a. Probe to determine if the amount of the activity the participant reports is per weekend, per week, or per day, etc. Someone may say, for example, "I did one hour of digging this past weekend " when what they meant is, "I did one hour of digging each of the two days this past weekend."

   b. Some people have trouble recalling or pinpointing the ***moderate*** to ***very hard*** activities they have engaged in over the past seven days. In such cases, **try to cue them** by asking them general questions. For example, "How about any housework that made you feel similar to brisk walking?", "Did you take any walks?", How do you get to and from work?", "Did you participate in any sports?", "Any vigorous family activities?", "Did you do any vigorous home repair or gardening?".

   c. Take a retrospective look back at each day by asking the respondent whether there is any activity they may have forgotten to mention.

2. Intensity:

   a. If you are unsure of the strenuousness of an activity that they may have participated in, **ask them to describe the physical effort involved.** For example, what does the activity entail? We have found that walking and running provide good frames of reference for classifying activities. Everyone should be familiar with the relative intensity of ***brisk*** walking, which is abou. the midpoint of the moderate activity category. Therefore, if some other activity that the participant reports seems to be about as strenuous to the individual as **walking briskly**, then the activity should be coded as ***moderate***. Most running or jogging at any speed falls into the ***very hard*** category. If some activity seems about as strenuous to the individual as running, classify the activity as ***very hard***. If the activity in question seems harder than walking but not as strenuous as running, place it in the ***hard*** category.

b. For most activities, the rate at which they are performed can make a huge difference in the energy cost. It is possible to play single tennis, for example, so as not to move around much and not expend much energy. **Try to get some indication of how hard they are working at a particular task.** Again, use comparisons to walking and running so they can rate how hard they did the activity.

3. Time:

a. Some people have trouble quantifying the amount of time they spent doing ***moderate***, ***hard***, or ***very hard*** activities. In such cases, **break down all of their activities into specific events and ask them how long they did each activity.** Then sum up the amount of time relevant to each category. If the individual is having difficulty quantifying the amount of time engaged in a particular activity, suggest to the individual possible time frames such as 15 minutes, 30 minutes, 45 minutes, or an hour. However, it is not necessary to round participant answers to anything but the nearest minute.

b. **The activity in question should be performed for a total of 10 minutes, intermittently or continuously, during one segment of the day; morning, afternoon, or evening.** For example, if their activities add up to at least 10 minutes in one intensity category (e.g., ***hard***) for one segment of the day (e.g., Wednesday afternoon), the total time of those activities should be counted. If 10 minutes of activity is spread out over two or more segments of the day, it is not counted. The purpose of this rule is to eliminate the need to recall and record each minute of activity.

c. **Be sure that the time reported for an activity was actually spent doing the activity.** Being at the pool for 2 hours but only swimming for 15 minutes, for example, should be recorded as 15 minutes, not 2 hours. Working in the garden all day Saturday (8 hours) should mean actually working for 8 hours. **Do not record the time spent on breaks, rest periods, meals, and the like.**

4. Special Cases:

a. **If the last week was totally atypical**—for example, in the hospital or in bed, or involving a family crisis, or a work crisis, or travel—**it is permissible to go to the previous week for the survey.** Do not take this action lightly; use it only **in unusual circumstances.**

b. If a person has weekdays instead of weekends off from work--for example, Tuesday and Wednesday instead of Saturday and Sunday--ask the participant if they consider the weekdays they have off as their weekend. If they do not consider the days off as their weekend days, ask them which days are most like weekends. Some participants may only consider one day as their weekend day. Others may have three day weekends. The point here is to determine the participant's non-work days as they are likely to have a different routine than the workdays. **Make sure to count the most appropriate days of the week, as indicated by the participant, as weekend days.**

c. Weekend days should be denoted on the worksheet by drawing a light, wavy line through the activities for the days which the participant counts as weekend days.

F. Strength and Flexibility Exercises

Any reported strength and flexibility exercises performed for at least 10 minutes should be recorded on the worksheet if they are performed at the moderate, hard, or very hard intensity level as are any other physical activities. Usually strength and flexibility exercises will be recorded as ***moderate*** physical activities, however the interviewer should be confident that these activities are performed at the same intensity as going on a brisk walk. The classification can be verified by determining the time spent in the activity and the total number of exercises (i.e., number of sit-ups, push-ups, etc.) performed during that time period.

G. Review

1. At the end of each day of recall, the interviewer should ask the participant to take a **retrospective look of the past week** as well as at the end of **each day** to determine any activities that may have been overlooked.
2. **Use cues as much as possible** to aid in the participant's recall of the past week. For example, "Did you want to add any other household, occupational, or sports activities that you participated in the past week and that we have not talked about?" "Did you take any walks we have not already covered?", "Are there any activities that you are unsure about?". However, it is important that the interviewer administer these questions consistently to all participants.

H. Other Physical Activity Questions.

1. Was this a typical week in terms of your usual pattern of activity or exercise? (YES/NO).
   a. If NO, were you more or less active in the past week than you usually are? (MORE/LESS).
2. Sitting Activities

   Sitting activities are not recorded as part of the PAR worksheet, but are of interest to ACT nonetheless. Therefore, two questions on such activities are included on page three of the Physical Activity Recall form. Such activities include sitting, watching television, working at a desk or computer, eating or reading, etc. We are interested in the participant's usual activity over the last three months.

a. Review the time period transition and the list of sitting activities with the participant and ask them to give an average of the hours spent sitting during their work week. Some participants will be able to do this quickly as their days usually follow a routine. Remember, we are looking for **a global** estimate of sitting time over the last three months, therefore, it is not appropriate to attempt to match this answer with the previous week's recall..

b. Repeat for average weekend or non-work time spent sitting for whichever days the participant considers to be weekend days.

2. Ask about the number of flights of stairs climbed up each day and record answer. Note that 10 steps equals a flight and that we are only interested in flights climbed, not flights up and down.
3. Participant should provide an estimate of the number of minutes walked during a day and the pace at which they walk. The participant does not need to count each step, rather a general estimate of the time they spend walking during a typical day.
4. Ask the participant the three questions regarding strength and flexibility exercises. Remember the time frame for these activities is over the last three months.
5. Thank the participant for their time and participation. The interview is concluded.

I. Summarizing The Worksheet

1. After the interview, data from the completed worksheet is entered into the ACT 7-day Energy Expenditure Calculation Software. The computer program calculates summaries of the intensity categories necessary to give a kilocalorie per day estimate of physical activity for each participant. Before entry into the computer, the interviewer must summarize the daily hours of

The following example refers to the responses for the 7 Day Recall Certification audio tape which was administered at each site. Very hard intensity activity has been added that was not part of the audio tape.

1. Sum the seven nights of sleep. Example:

6:00
5:30
7:15
5:30
9:45
7:00
5:30
46:30 = total hours of sleep

2. Sum the daily hours/minutes spent in moderate intensity activity for each line of the recall. Example:

Thurs. morning		:17	
Wed. morning	:17		
Tues. morning	:17		17 x 3 = 51 minutes
Sun. morning	:20		+ 20 minutes = 1 hour, 11 minutes
Sat. morning	:16		+ 16 minutes = 1 hour, 27 minutes
Fri. morning	:15		+ 15 minutes = 1 hour, 42 minutes
Thurs. afternoon		:15	
Mon. afternoon		1:15	afternoon totals = 1 hour, 30 minutes

Total moderate intensity activity = 3 hours, 12 minutes

3. Sum the daily hours/minutes spent in hard intensity activity for each line of the recall. Example:

Thurs. afternoon	:45
Wed. afternoon	:30
Fri. afternoon	:36

Total hard intensity activity = 1 hour, 51 minutes

4. Sum the daily hours/minutes spent in very hard intensity activity for each line of the recall. In this example there was no very hard intensity activity.

Tues. evening :42

Total very hard intensity activity = 0:42

5. Sum the totals for sleep, moderate, hard, and very hard. Example:

46:30
3:12
1:51
1:42
53:15 = total hours of sleep, moderate, hard, and very hard.

6. Subtract total obtained in step 5 from 168 to get time spent in light activity. Example:

168:00
- 53:15
114:45 = total hours of light activity.

7. Divide the minutes portion of each of the categories by 60 to obtain the fraction of each hour spent in activity. Example:

Sleep = 46:30 (30/60 = .5), total sleep = 46.5
Light = 114:45 (45/60 = .75), total light = 114.75
Moderate = 3:12 (12/60 = .20), total moderate = 3.20
Hard = 1:51 (51/60 = .85), total hard = 1.85
Very Hard = :42 (42/60 = .70), total very hard = .70

8. Use the following table to perform the next calculation:

Activity	Total Time	Multiply by:	Total
Sleep	46.5	1	46.5
Light	114.75	1.5	172.125
Moderate	3.20	4.0	12.8
Hard	1.85	6.0	11.1
Very Hard	1.70	10.0	17.0
	168.00	Grand Total	259.525

9. Divide grand total by 7 to obtain energy expenditure to determine eligibility. Example:

259.525/7 = 37.075

Because the energy expenditure is greater than 35 kcal/kg/wt, this person is ineligible.

3. Ask separately about each segment of the day. "What activities did you do in the morning; in the afternoon; in the evening?" Again, this helps the participant to remember more clearly.
4. Several times during the interview, remind the participant to think about all physical activities including work, household, and leisure/sport activities.
5. Count walking that is done for at least 10 minutes continuously. However, for the activity to be counted it must add up to at least 10 minutes in one intensity category during a limited time segment of the day.
6. At the end of the interview, ask the participant if he/she forgot any activities.
7. The interviewer should not guess what intensity an activity is. Have the participant classify all activities into intensity categories. They should use the rule: running is ***very hard***, brisk walking is ***moderate***, and ***hard*** is in between.
8. The purpose of the PAR is to estimate energy expenditure, so an activity does not have to be continuous to be coded. If their activities add up to at least 10 minutes in one intensity category (e.g., hard) for one segment of the day (e.g., Wednesday afternoon), then that activity or those activities should be counted. For example, consider 60 minutes of gardening which included both digging and planting. If the participant alternately dug and stopped to plant in five minute intervals, this activity would be recorded as 30 minutes of digging. and would qualify as ***hard*** activity. If 10 minutes of activity is spread out over two or more segments of the day, it is not counted. For example, 5 minutes of walking in the morning, 5 minutes in the afternoon and 5 minutes in the evening do not qualify. This rule allows the interviewer to code sporadic activities, but it does not force one to code every single minute of activity during the day, which would be too time consuming.
9. Weekend days should be marked with a "squiggly" line down the column.
10. If the participant offers information about sexual activities, the interviewer should offer his or her thanks, but the activity should not be recorded.

Appendix F

Instructions for Measuring Waist Circumference

Instructions for Measuring Waist Circumference

To define the level at which waist circumference is measured, a bony landmark is first located and marked. The subject stands and the examiner, positioned at the right of the subject, palpates the upper hip bone to locate the right iliac crest. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, then crossed with a vertical mark on the midaxillary line. The measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk. The plane of the tape is parallel to the floor and the tape is snug, but does not compress the skin. The measurement is made at a normal minimal respiration (148).

Appendix G

Psychological Questionnaires and Scoring Algorithms

Questionnaires, References, and Scoring for:

Stages of Change
Processes of Change
Self Efficacy/Confidence
Decision Making

Social Security Number: ______________________ 1

I. Stages of Change

For each question below, please mark **Yes** *or* **No.** *Physical activity or exercise means walking briskly, vacuuming, jogging, digging in the garden, climbing stairs or any other physical activity where the exertion is similar to these.*

Regular *physical activity or exercise means accumulating 30 minutes or more in the above activities most days of the week. For example, you could take one 30-minute walk, jog, bike, swim or three 10-minute walks or 5 minutes of vacuuming, 10 minutes of walking, 10 minutes of digging in the garden, and 5 minutes of climbing stairs.*

1. I am currently physically active.	**Yes**	**No**
2. I intend to become more physically active in the next 6 months.	**Yes**	**No**
3. I currently engage in **regular** physical activity.	**Yes**	**No**
4. I have been physically active regularly for the past 6 months.	**Yes**	**No**
5. I have been physically active regularly in the past for a period of at least 3 months.	**Yes**	**No**

II. Processes

The following experiences can affect the physical activity habits of some people. Think of any similar experiences you may be currently having or have had during the **past month.** *Then rate how frequently the event occurs.*

Please mark the number that best describes your answer for each experience.

How frequently does this occur?

1. Instead of remaining inactive I engage in some physical activity.	Never	Seldom	Occasionally	Often	Repeatedly
2. I tell myself I am able to be physically active if I want to.	Never	Seldom	Occasionally	Often	Repeatedly
3. I put things around my home to remind me to be physically active.	Never	Seldom	Occasionally	Often	Repeatedly
4. I tell myself that if I try hard enough I can be physically active.	Never	Seldom	Occasionally	Often	Repeatedly
5. I recall information people have personally given me on the benefits of physical activity.	Never	Seldom	Occasionally	Often	Repeatedly
6. I make commitments to be physically active.	Never	Seldom	Occasionally	Often	Repeatedly
7. I reward myself when I am physically active.	Never	Seldom	Occasionally	Often	Repeatedly
8. I think about information from articles and advertisements on how to make exercise a regular part of my life.	Never	Seldom	Occasionally	Often	Repeatedly
9. I keep things around my place of work that remind me to be physically active.	Never	Seldom	Occasionally	Often	Repeatedly
10. I find society changing in ways that make it easier to be physically active.	Never	Seldom	Occasionally	Often	Repeatedly
11. Warnings about health hazards of inactivity affect me emotionally	Never	Seldom	Occasionally	Often	Repeatedly
12. Dramatic portrayals of the evils of inactivity affect me emotionally					

13. I react emotionally to warnings about an inactive lifestyle. Never Seldom Occasionally Often Repeatedly

14. I worry that inactivity can be harmful to my body. Never Seldom Occasionally Often Repeatedly

'5. I am considering the idea that regular physical activity would make me a healthier, happier person to be around. Never Seldom Occasionally Often Repeatedly

16. I have someone on whom I can depend when I am having problems with being physically active. Never Seldom Occasionally Often Repeatedly

17. I read articles about exercise and physical activity in an attempt to learn more about it. Never Seldom Occasionally Often Repeatedly

18. I try to set realistic goals for myself rather than setting myself up for failure by expecting too much. Never Seldom Occasionally Often Repeatedly

19. I have a healthy friend that encourages me to be physically active when I don't feel up to it. Never Seldom Occasionally Often Repeatedly

20. When I am physically active, I tell myself that I am being good to myself by taking care of my body. Never Seldom Occasionally Often Repeatedly

21. The times I am physically active are my special times to relax and recover from the day's worries, not a task to get out of the way. Never Seldom Occasionally Often Repeatedly

22. I am aware of more and more people encouraging me to be more physically active. Never Seldom Occasionally Often Repeatedly

23. I do something nice for myself for making efforts to be more physically active. Never Seldom Occasionally Often Repeatedly

24. I have someone who points out my rationalizations for not being physically active. Never Seldom Occasionally Often Repeatedly

25. I have someone who provides feedback about my physical activity. Never Seldom Occasionally Often Repeatedly

26. I remove things that contribute to my inactivity. Never Seldom Occasionally Often Repeatedly

27. I am the only one responsible for my health, and only I can decide whether or not I will be physically active. Never Seldom Occasionally Often Repeatedly

28. I look for information related to exercise or physical activity. Never Seldom Occasionally Often Repeatedly

29. I avoid spending long periods of time in environments that promote inactivity. Never Seldom Occasionally Often Repeatedly

30. I feel I would be a better role model for others if I exercised regularly. Never Seldom Occasionally Often Repeatedly

31. I think about the type of person I will be if I am physically active. Never Seldom Occasionally Often Repeatedly

32. I notice that more businesses are encouraging their employees to be physically active by offering fitness courses and time off to work out. Never Seldom Occasionally Often Repeatedly

33. I wonder how my inactivity affects those people who are close to me. Never Seldom Occasionally Often Repeatedly

. I realize that I might be able to influence others to be healthier if I would be more physically active. Never Seldom Occasionally Often Repeatedly

35. I get frustrated with myself when I am not physically active. Never Seldom Occasionally Often Repeatedly

36. I am aware that many health clubs now provide free babysitting services to their members.

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37. Some of my close friends might be more physically active if I was. Never Seldom Occasionally Often Repeatedly

38. I consider the fact that I would feel more confident in myself if I was regularly physically active. Never Seldom Occasionally Often Repeatedly

39. When I feel tired I can make myself be physically active because I know I will feel better afterward. Never Seldom Occasionally Often Repeatedly

40. When I am feeling tense, I find that being physically active helps to relieve my worries. Never Seldom Occasionally Often Repeatedly

III. Confidence

Please mark a number to indicate how confident you are that you could be physically active in each of the following situations:

1. When I am tired. Not at all confident Slightly confident Moderately confident Very confident Extremely confident
2. When I am in a bad mood. Not at all confident Slightly confident Moderately confident Very confident Extremely confident
3. When I feel I don't have time. Not at all confident Slightly confident Moderately confident Very confident Extremely confident

When I am on vacation. Not at all confident Slightly confident Moderately confident Very confident Extremely confident

5. When it is raining or snowing. Not at all confident Slightly confident Moderately confident Very confident Extremely confident

IV. Decisional Balance

Please rate how important each of these statements is in your decision whether or not to be physically active. In each case, think about how you feel not how you have felt in the past or would like to feel.

1. I would have more energy for my family and friends if I was regularly physically active. Not at all important Slightly important Moderately important Very important Extremely important
2. Regular physical activity would help me relieve tension. Not at all important Slightly important Moderately important Very important Extremely important
3. I think I would be too tired to do my daily work after being physically active. Not at all important Slightly important Moderately important Very important Extremely important
4. I would feel more confident if I was regularly physically active. Not at all important Slightly important Moderately important Very important Extremely important

I would sleep more soundly if I was regularly physically active. Not at all important Slightly important Moderately important Very important Extremely important

6. I would feel good about myself if I kept my commitment to be more physically active. Not at all important Slightly important Moderately important Very important Extremely important

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. I would find it difficult to find a physical activity that I enjoy that is not affected in bad weather.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
8. I would like my body better if I was regularly physically active.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
9. It would be easier for me to perform routine physical tasks if I was regularly physically active.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
10. I would feel less stressed if I was regularly physically active.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
11. I feel uncomfortable when I engage in physical activity because I get out of breath and my heart beats very fast.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
12. I would feel more comfortable with my body if I was regularly physically active.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
13. Regular physical activity would take too much of my time.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
14. Regular physical activity would help me have a more positive outlook on life.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
15. I would have less time for my family and friends if I was regularly physically active.	Not at all important	Slightly important	Moderately important	Very important	Extremely important
16. At the end of the day, I am too exhausted to exercise.	Not at all important	Slightly important	Moderately important	Very important	Extremely important

Today's date

month 1 2 3 4 5 6 7 8 9 10 11 12

day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

year 93 94 95 96 97

Social Security Number:
(Fill in all columns)

0	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2	2
3	3	3	3	3	3	3	3	3
4	4	4	4	4	4	4	4	4
5	5	5	5	5	5	5	5	5
6	6	6	6	6	6	6	6	6
7	7	7	7	7	7	7	7	7
8	8	8	8	8	8	8	8	8
9	9	9	9	9	9	9	9	9

Scoring Algorithms

Stages of Change

Stage of Change	Responses to Questions				
	question 1	question 2	question 3	question 4	question 5
Precontemplation	No	No			
Contemplation	No	Yes			
Preparation	Yes		No		
Action	Yes		Yes	No	
Maintenance	Yes		Yes	Yes	

Processes of Change

Scores for the ten processes of change are created from the 40-item questionnaire by averaging the responses for the following questions. If three out of four questions for a process are answered, the score can be calculated.

Coding scale: never=0
seldom=1
occassionally=2
often=3
repeatedly=4

Cognitive Processes	To score calculate the average of the following questions
Consciousness Raising	5, 8, 17, 28
Dramatic Relief	11, 12, 13, 14
Self Reevaluation	15, 31, 35, 38
Environmental Reevaluation	30, 33, 34, 37
Social Liberation	10, 22, 32, 36

Behavioral Processes	To score calculate the average of the following questions
Helping Relationships	16, 19, 24, 25
Reinforcement Management	7, 18, 20, 23
Counter Conditioning	1, 21, 39, 40
Stimulus Control	3, 9, 26, 29
Self Liberation	2, 4, 6, 27

Self-Efficacy/Confidence

The confidence score is calculated by averaging the responses to the 5 questions. If four out of the five questions are answered, the score can still be calculated.

Coding scale: not at all confident=0
slightly confident=1
moderately confident=2
very confident=3
extremely confident=4

NOTE: For small samples in which the distribution of the scores does not follow the normal distribution, it is necessary to transform the scores to t-scores for each individual. First calculate the z-score for each subject, then convert it to a t-score.

a=average of five questions for the individual
b=mean of scores for the sample
c=standard deviation of the mean for the sample
z-score=(a - b)/c then t-score=(10*z-score)+50

Decision Making or Decisional Balance

Decisional Balance is calculated by calculating the average of the PRO questions and subtracting the average of the CON questions.

PRO questions are 1, 2, 4, 5, 6, 8, 9, 10, 12, and 14.
CON questions are 3, 7, 11, 13, 15, 16.
Decisional Balance=PRO average - CON average

If seven out of the ten PRO questions are answered and five out of the six CON questions are answered the score can still be calculated.

Coding scale: not at all important=0
slightly important=1
moderately important=2
very important=3
extremely important=4

NOTE: For small samples in which the distribution of the scores does not follow the normal distribution, it is necessary to transform both the PRO and CON averages to t-scores for each individual. First calculate the z-score for each subject, then convert it to a t-score.

a=average of PRO questions (or CON questions) for the individual
b=mean of PRO (or CON) scores for the sample
c=standard deviation of the mean for the sample
z-score=(a - b)/c then t-score=(10*z-score)+50

Appendix H

Instructions Provided to Usual Care Participants

Fitness Plan

Name:

Date:

Target Heart Rate Range:

Your fitness level has been assessed as:

Six Month Activity Plan

	One	Two	Three	Four	Five	Six
Frequency	3x/week	3-4x	3-5x	4-7x Most days	4-7x Most days	4-7x Most days
Intensity	n/a (optional)	40-60% THR	60-70% THR	60-90% THR	60-90% THR	60-90% THR
Time	10-15 min	15-20 min	15-20 min	20-30 min	20-30 min	30 min or more
Type	*Aerobic	Aerobic	Aerobic	Aerobic	Aerobic	Aerobic

*Walking, stationery bike, swimming, aerobics class....any aerobic exercise that you enjoy. Once you get into the habit of exercising every week, you can speak with your instructor or health club personnel about adding strength training.

The six month chart contains safe and minimum recommendations for participation in this program. You are welcome to set your goals higher. The general guideline for increasing either frequency, intensity, or time of exercise suggests that you increase only one at a time. The following table is an example of Jane Doe's actual first month of exercise, summarized:

	Week One	Week Two	Week Three	Week Four
Frequency	2x	2x	3x	3x
Intensity	n/a	n/a	n/a	60% THR
Time	10 min	20 min	20 min	20 min
Type	Walking	Walking	Walking	Walking

You can see that Jane surpassed the Month One goals by getting up to 60% of her Target Heart Rate Range. Congratulations!

Notes:

Components of an Exercise Program

AEROBIC EXERCISE PRINCIPLES

You will receive the following benefits from a regular aerobic exercise program...

- increase in cardiovascular system (i.e. its function in providing adequate amounts of oxygen to the working muscles);
- increase in HDL's the "good" cholesterol;
- increase in metabolism, decrease in appetite;
- increase in self esteem as you do something good for yourself;
- decrease in resting heart rate;
- decrease in blood pressure; and
- decrease in body fat, increase in muscle tone.

GUIDELINES FOR AEROBIC EXERCISE

These guidelines are based on the FIT principle.

(F)requency
frequency of exercise 3-5 days per week (for optimal weight loss 4-5 days per week)

(I)ntensity of Exercise
60-85% of your maximum heart rate (sedentary people and people trying to lose weight should work at 60-70% intensity)

(T)ime of Exercise
20-60 minutes of continuous exercise at your Target Heart Rate. Remember to take it slow and work up to this time if you have not exercised before or if it has been a while since you have worked out. However, for maximum weight loss, this time should be increased to a minimum of 40 minutes at the appropriate intensity.

(T)ype of Activity
Any activity that uses large muscle groups, rhythmic and continuous in nature (i.e. running/jogging, walking, cross country skiing, aerobic dance, cycling, etc.)

RATE OF PROGRESSION

The most significant conditioning effect may be observed during the first 6-8 weeks of the exercise program. You can increase the total work done by an increase in intensity, duration, or by some combination of the two.

TARGET HEART RATE (THR)

It is essential to your exercise program that you exercise within your training heart rate range. This is the most effective indicator of how much stress you are putting on your heart. Exercising within your THR will help you to improve your aerobic fitness by increasing your hearts capacity to pump blood. To improve the efficiency of weight loss, exercise at the lower range of your THR for a longer duration of time.

DETERMINING YOUR TARGET HEART RATE

To determine your Target Heart Rate, you must first know what your Resting Pulse is. To find your resting pulse, take your pulse at your wrist or your carotid artery in your neck. **Remember, do not press too hard.** Press gently with your index and second fingers, count your pulse for 10 seconds and multiply by 6. This will give you a number that is considered your resting pulse or your Resting Heart Rate (RHR). The ideal time to determine your RHR is in the morning before you get out of bed.

To figure your Target Heart Rate use the following formula:

	220	Heart Rate Constant
−	______	Your Age
−	______	Your Resting Heart Rate
x	______	Intensity Level (60-85%)
+	______	Your Resting Heart Rate
=	______	Your Target Heart Rate Range (60-85%)

It is very important to exercise at a comfortable pace. While you are exercising you should be able to keep up a conversation comfortably. When you stop exercising, if you do not feel "normal" again within 10-15 minutes of stopping your workout, you are pushing yourself too hard. Your workout should leave you feeling energized, not in distress!

PERCEIVED EXERTION

Perceived Exertion is your own perception about how hard you are working out. On a scale from 1-10, 1 being the easiest and 10 being the hardest, rate yourself on how hard you feel you are working out. You want to stay between 3-7 depending upon what your exercise goals are (i.e. exercise at a 3 for weight loss, 7 for a cardiovascular fitness).

STRENGTH TRAINING

You will receive the following benefits from a regular strength training program...

- better muscle to fat ratio, which will improve your body shape;
- increased muscle tone; and
- increased strength and flexibility.
- higher metabolism
- more energy
- better posture
- lower chance of osteoperosis

If you are interested in beginning a weight training program, we encourage you to make an additional appointment with a trainer to design a personalized program using weight equipment. Here are a few guidelines, if you would like to get started:

- Warm-up 5-7 minutes on a bike, treadmill, etc. (something that will raise muscle temperature) followed by stretching exercises.
- Start with 10-12 reps and 1-2 sets at a weight you can complete the sets. (Note: for endurance and toning 12-15 reps is recommended).
- Strength train a minimum of 2 days per week, 3 is preferred. Lift on non-consecutive days. The muscles need a chance to rest in between workouts.
- Do not "bang" the weights, lift in a smooth manner, counting 1-2 (up) and 1-2-3-4 (down). Again, these are general guidelines and we encourage you to make an appointment.
- Stretch 5-7 minutes after lifting.

It is recommended to strength train after aerobic exercise when muscles have the most blood flow and will recover quickest.

RATE OF PROGRESSION

- Your weight must be gradually and continually increased if you want your muscles to continue to develop strength and tone.

- If you reach 12 repetitions in a set, to progress you can do one of two things...
  - Add another set, up to 3 sets...or
  - Increase the weight by approximately 5% (or the smallest unit available).

- If you cannot do 10 repetitions in your ***first set***, the weight is too heavy.

- Follow these guidelines! You should see steady muscular improvement while reducing the risk of injury from doing too much too soon.

WARM UP, COOL DOWN, AND STRETCHING

Warm-Up Exercises

These exercises are designed to increase circulation to the muscles and joints that will be used during exercise. This increased circulation warms the muscles. Cold muscles tend to tear more easily. Simulate the cardiovascular activity you are about to take part in at a low intensity for about 5-7 minutes, then move into your higher intensity workout.

Cool Down

The cool-down period is designed to slowly bring your body processes (i.e. heart rate and blood pressure) back to pre-exercise rates. Cool down should be gradual, again simulating the cardiovascular activity you were performing only at a lower intensity (i.e. 40-50% Maximum Heart Rate).

Stretching

Stretching should only be done while the body is warm. For maximum results hold each stretch for 20-30 seconds. Stretching will increase your flexibility, help prevent muscle soreness, as well as help you *relax* and feel good!

Appendix I

Astrand Ryhming Protocol

Astrand-Ryhming Protocol for Submaximal Cycle

The Astrand-Ryhming cycle ergometer test (13) is used as a method for predicting maximal oxygen uptake (VO max). The protocol is described in the American College of Sports Medicine (ACSM) Guidelines for Exercise Testing and Prescription (69). It is a single-stage test lasting six minutes and the suggested work rate for unconditioned females is 300 or 450 kg/m/min (50 or 75 watts). Heart rate (HR) was measured using a Polar Heart Rate Monitor and measured twice every minute. The last two measurements taken during the fifth and sixth minute are averaged together and used to predict maximal oxygen uptake using the Astrand-Ryhming nomogram on the following pages. This value is then adjusted for age by multiplying by a age-correction factor (see below) (13, 69):

Age	Correction Factor
15	1.10
25	1.00
35	0.87
40	0.83
45	0.78
50	0.75
55	0.71
60	0.68
65	0.65

The following general procedures for submaximal testing from ACSM's guidelines for exercise testing were used (69):

1. Begin the exercise test with a 2- to 3-min warm-up to acquaint the client with the cycle ergometer.
2. The participant should be properly positioned on the cycle ergometer, i.e., upright posture, 5 degree bend in the knee at maximal leg extension, hands in proper position on handlebars.
3. Client appearance and symptoms should be monitored regularly.
4. The test should be terminated when the subject reaches 85% of age-predicted maximal heart rate (220 – age), fails to conform to the exercise test protocol, experiences adverse signs or symptoms, or requests to stop.
5. An appropriate cool-down/recovery period should be initiated consisting of either continued pedaling at a work rate equivalent to that of the first stage of the exercise test protocol or lower.

Table 5 a. Calculation of Maximum Oxygen Uptake - ml/kg×min.

Body Weight		Maximum Oxygen Uptake - litres/min.																								
pound	kg	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9
110	50	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58	60	62	64	66	68	70	72	74	76	78
112	51	29	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63	65	67	69	71	73	75	76
115	52	29	31	33	35	37	38	40	42	44	46	48	50	52	54	56	58	60	62	63	65	67	69	71	73	75
117	53	28	30	32	34	36	38	40	42	43	45	47	49	51	53	55	57	58	60	62	64	66	68	70	72	74
119	54	28	30	31	33	35	37	39	41	43	44	46	48	50	52	54	56	57	59	61	63	65	67	69	70	72
121	55	27	29	31	33	35	36	38	40	42	44	45	47	49	51	53	55	56	58	60	62	64	65	67	69	71
123	56	27	29	30	32	34	36	38	39	41	43	45	46	48	50	52	54	55	57	59	61	63	64	66	68	70
126	57	26	28	30	32	33	35	37	39	40	42	44	46	47	49	51	53	54	56	58	60	61	63	65	67	68
128	58	26	28	29	31	33	34	36	38	40	41	43	45	47	48	50	52	53	55	57	59	60	62	64	66	67
130	59	25	27	29	31	32	34	36	37	39	41	42	44	46	47	49	51	53	54	56	58	59	61	63	64	66
132	60	25	27	28	30	32	33	35	37	38	40	42	43	45	47	48	50	52	53	55	57	58	60	62	63	65
134	61	25	26	28	30	31	33	34	36	38	39	41	43	44	46	48	49	51	52	54	56	57	59	61	62	64
137	62	24	26	27	29	31	32	34	35	37	39	40	42	44	45	47	48	50	52	53	55	56	58	60	61	63
139	63	24	25	27	29	30	32	33	35	37	38	40	41	43	44	46	48	49	51	52	54	56	57	59	60	62
141	64	23	25	27	28	30	31	33	34	36	38	39	41	42	44	45	47	48	50	52	53	55	56	58	59	61
143	65	23	25	26	28	29	31	32	34	35	37	38	40	42	43	45	46	48	49	51	52	54	55	57	58	60
146	66	23	24	26	27	29	30	32	33	35	36	38	39	41	42	44	45	47	48	50	52	53	55	56	58	59
148	67	22	24	25	27	28	30	31	33	34	36	37	39	40	42	43	45	46	48	49	51	52	54	55	57	58
150	68	22	24	25	26	28	29	31	32	34	35	37	38	40	41	43	44	46	47	49	50	51	53	54	56	57
152	69	22	23	25	26	28	29	30	32	33	35	36	38	39	41	42	43	45	46	48	49	51	52	54	55	57
154	70	21	23	24	26	27	29	30	31	33	34	36	37	39	40	41	43	44	46	47	49	50	51	53	54	56
157	71	21	23	24	25	27	28	30	31	32	34	35	37	38	39	41	42	44	45	46	48	49	51	52	54	55
159	72	21	22	24	25	26	28	29	31	32	33	35	36	38	39	40	42	43	44	46	47	49	50	51	53	54
161	73	21	22	23	25	26	27	29	30	32	33	34	36	37	38	40	41	42	44	45	47	48	49	51	52	53
163	74	20	22	23	24	26	27	28	30	31	32	34	35	36	38	39	41	42	43	45	46	47	49	50	51	53
165	75	20	21	23	24	25	27	28	29	31	32	33	35	36	37	39	40	41	43	44	45	47	48	49	51	52
168	76	20	21	22	24	25	26	28	29	30	32	33	34	36	37	38	39	41	42	43	45	46	47	49	50	51
170	77	19	21	22	23	25	26	27	29	30	31	32	34	35	36	38	39	40	42	43	44	45	47	48	49	51
172	78	19	21	22	23	24	26	27	28	29	31	32	33	35	36	37	38	40	41	42	44	45	46	47	49	50
174	79	19	20	22	23	24	25	27	28	29	30	32	33	34	35	37	38	39	41	42	43	44	46	47	48	49
176	80	19	20	21	23	24	25	26	28	29	30	31	33	34	35	36	38	39	40	41	43	44	45	46	48	49
179	81	19	20	21	22	23	25	26	27	28	30	31	32	33	35	36	37	38	40	41	42	43	44	46	47	48
181	82	18	20	21	22	23	24	26	27	28	29	30	32	33	34	35	37	38	39	40	41	43	44	45	46	48
183	83	18	19	20	22	23	24	25	27	28	29	30	31	33	34	35	36	37	39	40	41	42	43	45	46	47
185	84	18	19	20	21	23	24	25	26	27	29	30	31	32	33	35	36	37	38	39	40	42	43	44	45	46
187	85	18	19	20	21	22	24	25	26	27	28	29	31	32	33	34	35	36	38	39	40	41	42	44	45	46
190	86	17	19	20	21	22	23	24	26	27	28	29	30	31	33	34	35	36	37	38	40	41	42	43	44	45
192	87	17	18	20	21	22	23	24	25	26	28	29	30	31	32	33	34	36	37	38	39	40	41	43	44	45
194	88	17	18	19	20	22	23	24	25	26	27	28	30	31	32	33	34	35	36	38	39	40	41	42	43	44
196	89	17	18	19	20	21	72	24	25	26	27	28	29	30	31	33	34	35	36	37	38	39	40	42	43	44
198	90	17	18	19	20	21	22	23	24	26	27	28	29	30	31	32	33	34	36	37	38	39	40	41	42	43
201	91	16	[illegible]	19	20	21	22	23	24	25	26	27	29	30	31	32	33	34	35	36	37	38	40	41	42	43
203	92	16	17	18	20	21	22	23	24	25	26	27	28	29	30	32	33	34	35	36	37	38	39	40	41	42
205	93	16	17	18	19	20	22	23	24	25	26	27	28	29	30	31	32	33	34	35	37	38	39	40	41	42
207	94	16	17	18	19	20	21	22	23	24	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
209	95	16	17	18	19	20	21	22	23	24	25	26	27	28	29	31	32	33	34	35	36	37	38	39	40	41
212	96	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	38	39	40	41
214	97	15	16	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
216	98	15	16	17	18	19	20	21	22	23	24	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
218	99	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
220	100	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39

Table 5 b. Calculation of Maximum Oxygen Uptake - ml/kg×min.

Body Weight		Maximum Oxygen Uptake - litres/min.																				
pound	kg	4.0	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	5.0	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	6.0
110	50	80	82	84	86	88	90	92	94	96	98	100	102	104	106	108	110	112	114	116	118	120
112	51	78	80	82	84	86	88	90	92	94	96	98	100	102	104	106	108	110	112	114	116	118
115	52	77	79	81	83	85	87	88	90	92	94	96	98	100	102	104	106	108	110	112	113	115
117	53	75	77	79	81	83	85	87	89	91	92	94	96	98	100	102	104	106	108	109	111	113
119	54	74	76	78	80	81	83	85	87	89	91	93	94	96	98	100	102	104	106	107	109	111
121	55	73	75	76	78	80	82	84	85	87	89	91	93	95	96	98	100	102	104	105	107	109
123	56	71	73	75	77	79	80	82	84	86	88	89	91	93	95	96	98	100	102	104	105	107
126	57	70	72	74	75	77	79	81	82	84	86	88	89	91	93	95	96	98	100	102	104	105
128	58	69	71	72	74	76	78	79	81	83	84	86	88	90	91	93	95	97	98	100	102	103
130	59	68	69	71	73	75	76	78	80	81	83	85	86	88	90	92	93	95	97	98	100	102
132	60	67	68	70	72	73	75	77	78	80	82	83	85	87	88	90	92	93	95	97	98	100
134	61	66	67	69	70	72	74	75	77	79	80	82	84	85	87	89	90	92	93	95	97	98
137	62	65	66	68	69	71	73	74	76	77	79	81	82	84	85	87	89	90	92	94	95	97
139	63	63	65	67	68	70	71	73	75	76	78	79	81	83	84	86	87	89	90	92	94	95
141	64	63	64	66	67	69	70	72	73	75	77	78	80	81	83	84	86	88	89	91	92	94
143	65	62	63	65	66	68	69	71	72	74	75	77	78	80	82	83	85	86	88	89	91	92
146	66	61	62	64	65	67	68	70	71	73	74	76	77	79	80	82	83	85	85	88	89	91
148	67	60	61	63	64	66	67	69	70	72	73	75	76	78	79	81	82	84	85	87	88	90
150	68	59	60	62	63	65	66	68	69	71	72	74	75	76	78	79	81	82	84	85	87	88
152	69	58	59	61	62	64	65	67	68	70	71	72	74	75	77	78	80	81	83	84	86	87
154	70	57	59	60	61	63	64	66	67	69	70	71	73	74	76	77	79	80	81	83	84	86
157	71	56	58	59	61	62	63	65	66	68	69	70	72	73	75	76	77	79	80	82	83	85
159	72	56	57	58	60	61	63	64	65	67	68	69	71	72	74	75	76	78	79	81	82	83
161	73	55	56	58	59	60	62	63	64	66	67	68	70	71	73	74	75	77	78	79	81	82
163	74	54	55	57	58	59	61	62	64	65	66	68	69	70	72	73	74	76	77	78	80	81
165	75	53	55	56	57	59	60	61	63	64	65	67	68	69	71	72	73	75	76	77	79	80
168	76	53	54	55	57	58	59	61	62	63	64	66	67	68	70	71	72	74	75	76	78	79
170	77	52	53	55	56	57	58	60	61	62	64	65	66	68	69	70	71	73	74	75	77	78
172	78	51	53	54	55	56	58	59	60	62	63	64	65	67	68	69	71	72	73	74	76	77
174	79	51	52	53	54	56	57	58	59	61	62	63	65	66	67	68	70	71	72	73	75	76
176	80	50	51	53	54	55	56	58	59	60	61	63	64	65	66	68	69	70	71	72	74	75
179	81	49	51	52	53	54	56	57	58	59	60	62	63	64	65	67	68	69	70	72	73	74
181	82	49	50	51	52	54	55	56	57	59	60	61	62	63	65	66	67	68	70	71	72	73
183	83	48	49	51	52	53	54	55	57	58	59	60	61	63	64	65	66	67	69	70	71	72
185	84	48	49	50	51	52	54	55	56	57	58	60	61	62	63	64	65	67	68	69	70	71
187	85	47	48	49	51	52	53	54	55	56	58	59	60	61	62	64	65	66	67	68	69	71
190	86	47	48	49	50	51	52	53	55	56	57	58	59	60	62	63	64	65	66	67	69	70
192	87	46	47	48	49	51	52	53	54	55	56	57	59	60	61	62	63	64	66	67	68	69
194	88	45	47	48	49	50	51	52	53	55	56	57	58	59	60	61	63	64	65	66	67	68
196	89	45	46	47	48	49	51	52	53	54	55	56	57	58	60	61	62	63	64	65	66	67
198	90	44	46	47	48	49	50	51	52	53	54	56	57	58	59	60	61	62	63	64	66	67
201	91	44	45	46	47	48	49	51	52	53	54	55	56	57	58	59	60	62	63	64	65	66
203	92	43	45	46	47	48	49	50	51	52	53	54	55	57	58	59	60	61	62	63	64	65
205	93	43	44	45	46	47	48	49	51	52	53	54	55	56	57	58	59	60	61	62	63	65
207	94	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	59	60	61	62	63	64
209	95	42	43	44	45	46	47	48	49	51	52	53	54	55	56	57	58	59	60	61	62	63
212	96	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	63
214	97	41	42	43	44	45	46	47	48	49	51	52	53	54	55	56	57	58	59	60	61	63
216	98	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61
218	99	40	41	42	43	44	45	46	47	48	49	51	52	53	54	55	56	57	58	59	60	61
220	100	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60

Appendix J

Program Evaluation Questionnaires

On The Move!

Evaluation

We want to know what you think about On The Move! Please take a few moments to answer the following questions.

What did you like most about this program?

____

____

____

____

What did you like least about this program?

____

____

____

____

Would you recommend this program to a friend? Yes No (please circle)

If not, why not?

____

____

____

____

What suggestions do you have to improve this program?

____

____

____

____

____

What parts of this program do you feel should stay the same?

Have you made any changes in your life as a result of this program? If so, what kind of changes?

Course Content

The following is a list of topics presented in On The Move! (This list does not include all topics presented). Which topics were the most useful to you and the least useful to you?

- Physical Activity & Health
- Clothing/Shoes
- Breaking Down Barriers
- Body Acceptance
- Enlisting Support
- Women & Food
- Non-Diet Method of Healthful Eating
- Finding the Time to Be Active
- Nutrition and Women's Health

The *most* useful topics:

The least useful topics and why?

Are there other topics you would like added to the program? Yes No

If yes, what topics?

Were there topics presented that you felt were not covered adequately enough?

Additional comments regarding the course content:

Was the book *Great Shape: The First Fitness Guide for Large Women* useful to you? Yes No (please circle)

What is your biggest barrier to physical activity?

Was On The Move! helpful to you in overcoming this barrier?

If not, why not?

Course Format (please circle best answer)

Each session was 90 minutes in length, do you feel that was:

Too short   Just right   Too long

The amount of actual teaching by the instructor was:

Not enough   Just right   Too much

The amount of discussion within each session was:

Not enough   Just right   Too much

Would you like more actual movement in this class (e.g., stretching, dancing)?

Yes   No

Would keeping a journal of your daily physical activity for this class help you to become more active?

Yes   No

On The Move! was scheduled to include 16 weekly sessions followed by 8 sessions held every other week for 8 weeks. Would you recommend the program continue this way? Yes   No (please circle)

If not, how you would recommend that it change?

____

____

Is 24 weeks (please circle):

Too short   Just right   Too long

Additional comments regarding On The Move!:

____

____

____

____

____

Appendix K

Normal Reference Range Values for Blood Lipid Analysis

Normal Reference Range Values for Blood Lipid Analysis*

Total Cholesterol
140 – 199 mg/dl

HDL – C
➢ 35 mg/dl

LDL – C
0 – 129 mg/dl

Cholesterol/HDL-C ratio
Avg. risk 3.71 – 4.76

Triglycerides
< 200

Fasting Glucose
65 – 109

*Quest Diagnostics Laboratory, Ft. Collins, CO, 80525